United States Environmental Protection Agency

Office of Water
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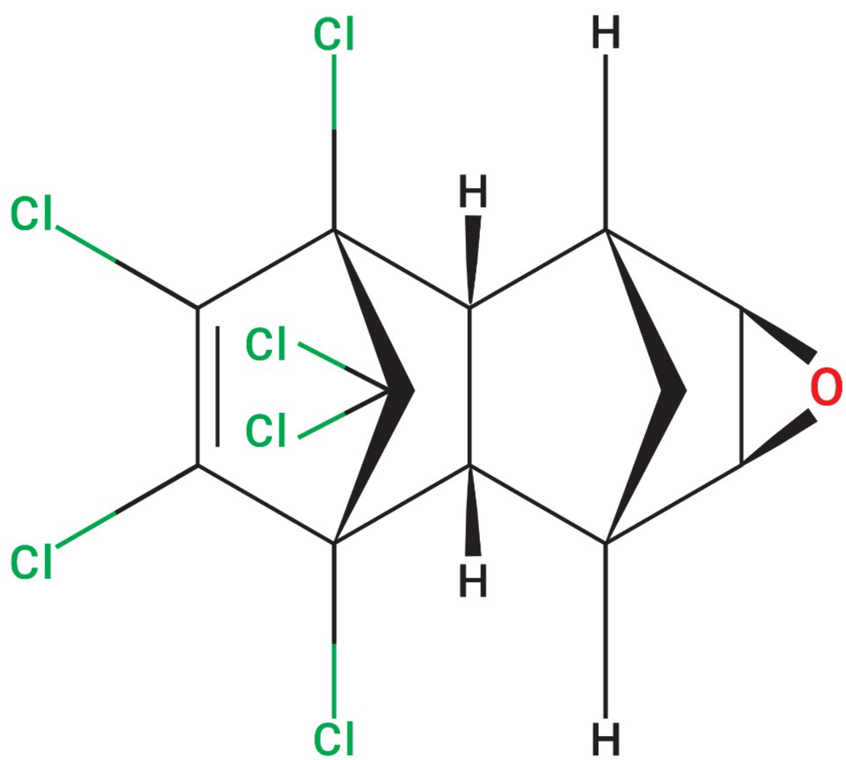
June 2015

Update of Human Health Ambient Water Quality Criteria:

Endrin
72-20-8



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1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for endrin to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 4,600 L/kg (TL2), 36,000 L/kg (TL3), and 46,000 L/kg (TL4) for endrin. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for endrin. Based on the characteristics of this chemical, EPA selected Procedure 1 for deriving a national BAF value. Endrin has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 5.47$ (ATSDR 1996)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 4,600 L/kg
TL3 = 36,000 L/kg
TL4 = 46,000 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for endrin. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (OPP) (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 3×10^{-4} mg/kg-d (0.0003 mg/kg-d) for endrin based on a 1988 EPA IRIS assessment (USEPA 1988a). EPA's IRIS program identified a study by the Velsicol Chemical Corporation (1969) as the critical study and mild histological lesions in the liver and occasional convulsions as the critical effects in dogs orally exposed to endrin (USEPA 1988a). The chronic study has a NOAEL of 0.025 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10) (USEPA 1988a).

In 2001, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the RfD for endrin and did not identify any critical new studies.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 1996 ATSDR assessment (ATSDR 1996) and a California EPA assessment (CalEPA 1999). Based on the selection process described in section 5, the 1988 EPA IRIS RfD is preferred for use in AWQC development at this time. Both of the other assessments were based on the same principal study and were numerically the same as the 1988 EPA IRIS RfD.

5.2.2 Cancer Slope Factor

Under EPA's 1986 *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), endrin is classified as Group D, "not classifiable as to carcinogenicity for humans" (USEPA 1988b).

In 2001, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the cancer assessment for endrin and did not identify any critical new studies.

EPA identified no CSF source through the search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Endrin is a pesticide that is no longer produced or used in the United States. All but one pesticidal use of endrin in the United States was voluntarily canceled with EPA OPP in 1985. The final pesticide registration cancellation occurred in 1991, and all U.S. tolerances were revoked (ATSDR 1996; USEPA 1998; USEPA 1993). Exposure of the general U.S. population could occur through ingestion of endrin residues on food items imported from countries where endrin is still used or from contact with contaminated soils and sediments (ATSDR 1996).

Endrin has a high octanol-water partition coefficient (K_{ow}); the log K_{ow} ranges from 5.3 to 5.6, with an average of 5.5 (ATSDR 1996). The national-level BAF estimates for endrin range from 4,600 L/kg (TL2) to 46,000 L/kg (TL4), which indicates endrin has a high-to-very high potential for bioaccumulation (USEPA 2011b). Before its cancellation as an approved pesticide, endrin was detected in fish samples collected from the Great Lakes region (ATSDR 1996). In the more recent EPA National Lake Fish Tissue Study (USEPA 2009c), endrin was detected in less than 1 percent (i.e., 3 of 486) of the predator fillets, and it was detected in 3.5 percent (i.e., 14 of 395) of bottom dweller whole-body fish samples (USEPA 2009c). Endrin has been detected in several ocean fish species in regional or state monitoring studies. From 1990 to 1993, endrin was found in 40 of 47 whole or fillet samples of red drum at two of four sites along the South Carolina coast. In that same study, endrin was found in 33 of 74 flounder samples and in 19 of 58 seatrout samples at one coastal site (ATSDR 1996). NOAA's Mussel Watch Survey recorded 3,355 data points available for aquatic organisms in the National Status and Trends Data Portal for endrin, focusing on clam, cockles, conch, coral, dreissenid mussel, fish filet, fish liver, fish muscle, flatfish, mussel, oyster, shrimp, and starfish samples. There were 824 detections reported; 267 were below the minimum detection limit (NOAA 2014). Thus, the available exposure information and its potential to bioaccumulate, ingestion of fish and shellfish is a potentially significant source of exposure to endrin despite the ban on its use in the United States.

Historically, endrin was detected in drinking water (ATSDR 1996). Endrin was detected in 5 of 67 raw water samples in 1966 and 1967, when it was still produced and used as a pesticide; and in 2 of 5,109 public drinking water sources sampled in California from 1984 to 1992 (maximum concentrations of 0.06 ppb and 0.10 ppb, respectively) (ATSDR 1996). Endrin is regulated under the Safe Drinking Water Act. EPA's drinking water standard (maximum contaminant level) for endrin is 2 µg/L (USEPA 2014c). Based on EPA's Six-Year Reviews of more than 28,000 surface water sources of drinking water, endrin was detected in 0.105 percent of samples (USEPA 2009a; USEPA 2009b). It was detected in 0.039 percent of samples from more than 105,000 ground water sources of drinking water (USEPA 2009a; USEPA 2009b). The Standard of Quality for bottled water is 2 µg/L (IBWA 2012). Therefore, based on its historic detection in drinking water, ingestion of drinking water is a possible source of exposure to endrin.

Endrin has been found to volatilize significantly (20–30 percent) from soils within days after application; the vapor pressure of endrin is 2.0×10^{-7} mm Hg at 25 °C (ATSDR 1996). Historically, the primary sources of endrin in the atmosphere were releases from production and processing facilities and agricultural application. There is a potential for atmospheric release from hazardous waste sites, although ATSDR did not find any instances documented (ATSDR 1996). EPA's Toxic Release Inventory did not report release data for endrin in 2013 (USEPA 2015g), and it is not listed as a hazardous air pollutant (USEPA 2013). Based on the fact that endrin is no longer produced or used in the United States, exposure to endrin from air is not considered likely.

Endrin can be taken up by plants from soils in which endrin remains (ATSDR 1996). Thus, exposure to the general U.S. population through ingestion of endrin residues on food items imported from countries where endrin is still used or has been used is possible (ATSDR 1996). However, endrin has been detected with declining frequency in U.S. total diet surveys (USFDA 2010; CDC 2013), and in recent biomonitoring studies, whole-weight serum levels of endrin in the U.S. population were below the limit of detection (CDC 2005; CDC 2009; CDC 2015). Endrin was detected above the detection limit in one of eight samples (i.e., 5.0 ppb in squash) in the FDA 2004–2005 Total Diet Study (USFDA 2005). In 2013, low levels of endrin residues were found in 1.1 percent of imported winter squash samples in the pesticide data program (USDA 2014). EPA does not set a 40 CFR part 180 pesticide tolerance for this chemical in food and feed commodities (USGPO 2015). Maximum residue limits were not found in the Global MRL Database (Bryant Christie Inc. 2015). Thus, based on the fact that endrin is no longer produced or used in the United States, exposure to endrin from ingestion of food is not considered likely.

In summary, based on the available exposure information for endrin, and given that the chemical is no longer produced or used in the United States, EPA does not anticipate that there will be significant sources and routes of exposure of endrin other than fish and shellfish from inland and nearshore waters. Based on EPA's 2000 Methodology, "If it can be demonstrated that other sources and routes of exposure are not anticipated for the pollutant in question (based on information about its known/anticipated uses and chemical/physical properties), then EPA would use the 80 percent ceiling" (see section 4.2.3 the 2000 Methodology) (USEPA 2000a). Therefore, EPA recommends an RSC of 80 percent (0.80) for endrin.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to endrin from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Endrin

Input Parameter		Value
RfD		0.0003 mg/kg-d
CSF		No data
RSC		0.80
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	4,600 L/kg
	TL3	36,000 L/kg
	TL4	46,000 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.0003 \text{ mg/kg-d} \times 0.80 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 4{,}600 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 36{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 46{,}000 \text{ L/kg}))}$$

$$= 0.0330\ \mu g/L$$

$$= 0.03\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.0003 \text{ mg/kg-d} \times 0.80 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 4{,}600 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 36{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 46{,}000 \text{ L/kg})}$$

$$= 0.0332\ \mu g/L$$

$$= 0.03\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for endrin using a noncarcinogenic toxicity endpoint. The updated human health AWQC for endrin are **0.03 µg/L** for consumption of water and organisms and **0.03 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2003b).

Table 2. Summary of EPA's Previously Recommended (2003) and Updated (2015) Human Health AWQC for Endrin

	2003 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.059 µg/L	**0.03 µg/L**
Organism Only	0.060 µg/L	**0.03 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to endrin from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for endrin take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

<u>Body Weight</u>

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

<u>Drinking Water Intake</u>

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 4,600, 36,000, and 46,000 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 3,970 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 17,280 L/kg
TL3 = 20,740 L/kg
TL4 = 30,820 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to

representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA retained an RfD of 0.0003 mg/kg-d for endrin based on a 1988 EPA IRIS assessment (USEPA 1988a; USEPA 2003b). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for endrin and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of endrin in its previous criteria update (USEPA 2003b).

Relative Source Contribution

An RSC of 80 percent is included in the AWQC calculation. This is higher than the 20 percent RSC used in the previous AWQC (USEPA 2003b). Assuming all other input parameters remain constant, a higher RSC in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

9 Chemical Name and Synonyms

- Endrin (CAS Number 72-20-8)
- Mendrin, 1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4(a)5,6,7,8,8a-octahydro-endo

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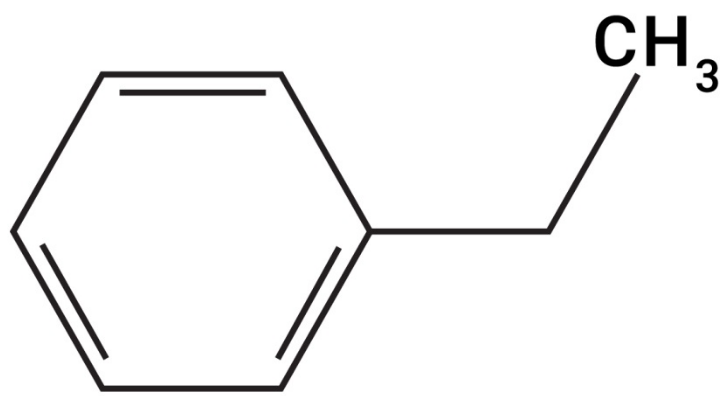
United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-042
June 2015

Update of Human Health Ambient Water Quality Criteria:

Ethylbenzene
100-41-4



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1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for ethylbenzene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level-(TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 100 L/kg (TL2), 140 L/kg (TL3), and 160 L/kg (TL4) for ethylbenzene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for ethylbenzene. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Ethylbenzene has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 3.74 (ATSDR 2010)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 100 L/kg
TL3 = 140 L/kg
TL4 = 160 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for ethylbenzene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015a)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD[g] of 2.2×10^{-2} mg/kg-d (0.022 mg/kg-d) for ethylbenzene based on a 2015 Health Canada assessment (HC 2015b). Health Canada identified a study by the National Toxicology Program (NTP 1996) as the critical study and the development of hyperplasia of the pituitary gland and liver cellular alterations as the critical effects in mice exposed to ethylbenzene in an inhalation study. The chronic study had a NOAEL of 75 ppm (326 mg/m^3). Health Canada used a physiologically based pharmacokinetic (PBPK) model to derive a human external dose of 0.54 mg/kg-d. In deriving the RfD, Health Canada applied a composite uncertainty factor of 25 to account for interspecies extrapolation (2.5) and intraspecies variation (10) (HC 2015b).

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[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

[g] Health Canada refers to this value as a Tolerable Daily Intake (HC 2015b).

EPA identified three other potential RfD sources: a 1985 EPA IRIS assessment (USEPA 1985), a 1997 CalEPA assessment (CalEPA 1997), and a 2010 ATSDR assessment (ATSDR 2010). Based on the selection process described in section 5, the Health Canada assessment is preferred for AWQC development at this time. The 2015 Health Canada assessment is the most current available RfD source, relies on a newer critical study (NTP 1996) compared to the IRIS assessment (Wolf et al. 1956), and applies PBPK modeling to derive an oral RfD.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), ethylbenzene is classified as Group D, “not classifiable as to human carcinogenicity” (USEPA 1987).

EPA identified no CSF source through the systematic search described in section 5. The most current available carcinogenicity assessment is from Health Canada (2015b). Health Canada used a nonlinear dose-response approach for characterizing the cancer risk from ethylbenzene because the mode of action for lung tumors suggests the existence of a threshold below which tumors are not expected to be observed. Health Canada identified a study by NTP (1996) as the critical study and lung tumor development as the critical effect for their nonlinear cancer assessment. Using PBPK modeling, Health Canada derived a human external dose of 10.17 mg/kg-d. In deriving the RfD, Health Canada applied a composite uncertainty factor of 25 to account for interspecies extrapolation (2.5) and intraspecies variation (10) (HC 2015b). Health Canada concluded that the RfD for noncancer effects of ethylbenzene described above (0.022 mg/kg-d) is also considered adequately protective of public health for cancer effects by the oral route (HC 2015b). EPA is not deriving AWQC for carcinogenic effects of ethylbenzene at this time.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD’s exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual’s total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the

chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Ethylbenzene is used in the production of styrene and is also a component of gasoline, paint, inks, varnishes, pesticides, carpet glue, tobacco products, and automotive products (ATSDR 2010). Air, drinking water, and food are potential sources of exposure of the general population to ethylbenzene.

The vapor pressure of ethylbenzene (7 mm Hg at 20 °C) indicates that volatilization is expected to be an important fate process (ATSDR 2010). Recent data from EPA's Toxic Release Inventory indicate that over 148,000 pounds of ethylbenzene were released to the air in 2013 (USEPA 2015g). Ethylbenzene is commonly detected in air near highways, in cities, and adjacent to industrial manufacturing facilities (ATSDR 2010). Inhalation exposure is also possible via showering, bathing, or cooking with contaminated water (ATSDR 2010). Ethylbenzene is listed as a hazardous air pollutant (USEPA 2013). Thus, based on the chemical's physical properties and widespread prevalence, air is a potentially significant source of exposure to it.

Ethylbenzene is regulated under the Safe Drinking Water Act, and EPA's drinking water standard (maximum contaminant level) is 700 µg/L (USEPA 2014c). Ethylbenzene has been detected in treated drinking water (ATSDR 2010). It was a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b) and was detected in drinking water, groundwater and surface water samples. The Standard of Quality for bottled water for ethylbenzene is 700 µg/L (IBWA 2012). Therefore, ingestion of surface and finished drinking water is a potentially significant source of exposure to ethylbenzene.

Ethylbenzene has been detected in food, such as split peas, lentils, and beans (ATSDR 2010). Thus, ingestion of food is a potentially significant source of exposure to ethylbenzene.

The log K_{ow} for ethylbenzene ranges from 3.13 to 4.34, with an average log K_{ow} of 3.74 (ATSDR 2010). The national-level BAF estimates for ethylbenzene range from 100 L/kg (TL2) to 160 L/kg (TL4), which indicates that the chemical has a moderate potential for bioaccumulation (USEPA 2011b). It was not measured in NOAA's Mussel Watch Survey (NOAA 2014) and was not a target analyte in EPA's National Lake Fish Tissue Study (USEPA 2009c). Recent exposure information regarding concentrations of ethylbenzene in fish and shellfish is lacking. Thus, the potential exposure to ethylbenzene is unknown.

In summary, based on the physical properties and available exposure information for ethylbenzene, air, surface and drinking water, and non-fish food are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for ethylbenzene.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to ethylbenzene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Ethylbenzene

Input Parameter		Value
RfD		0.022 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	100 L/kg
	TL3	140 L/kg
	TL4	160 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.022 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 100 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 140 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 160 \text{ L/kg}))}$$

$$= 67.95\ \mu g/L$$

$$= 68\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.022 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 100 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 140 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 160 \text{ L/kg})}$$

$$= 126.6\ \mu g/L$$

$$= 130\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for ethylbenzene using a noncarcinogenic toxicity endpoint. The updated human health AWQC for ethylbenzene are **68 µg/L** for consumption of water and organisms and **130 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2003b).

Table 2. Summary of EPA's Previously Recommended (2003) and Updated (2015) Human Health AWQC for Ethylbenzene

	2003 Human Health AWQC	2015 Human Health AWQC
Water and Organism	530 µg/L	**68 µg/L**
Organism Only	2,100 µg/L	**130 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to ethylbenzene from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for ethylbenzene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

<u>Body Weight</u>

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

<u>Drinking Water Intake</u>

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 100, 140, and 160 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 37.5 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 61.51 L/kg
TL3 = 65.33 L/kg
TL4 = 73.56 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to

representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.022 mg/kg-d for ethylbenzene based on a 2015 Health Canada assessment (HC 2015b). This RfD replaces the previous value of 0.1 mg/kg-d (USEPA 2003b). EPA used the RfD of 0.022 mg/kg-d to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, a decrease in the RfD in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

Cancer Slope Factor

EPA did not select a CSF for ethylbenzene and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of ethylbenzene in its previous criteria update (USEPA 2003b).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. This is the same RSC used in the previous AWQC (USEPA 2003b).

9 Chemical Name and Synonyms

- Ethylbenzene (CAS Number 100-41-4)
- Aethylbenzol
- Benzene, ethyl
- EB
- Ethylbenzeen
- Ethylbenzol
- Etilbenzene
- Etylobenzen
- NCI-C56393
- Phenylethane
- UN 1175

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-043
June 2015

Update of Human Health Ambient Water Quality Criteria:

Fluoranthene
206-44-0

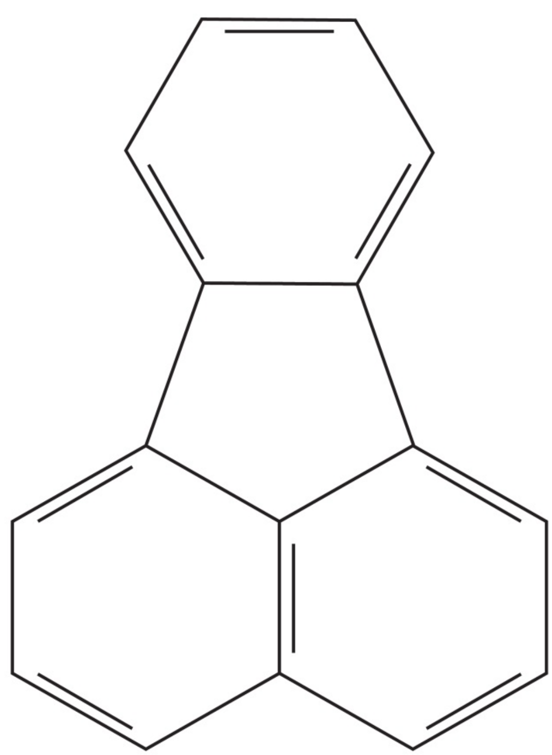

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for fluoranthene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 1,500 L/kg for fluoranthene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for fluoranthene. Based on the characteristics this chemical, EPA selected Procedure 2 for deriving a national BAF value. Fluoranthene has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 4.9$ (ATSDR 1995)
- High metabolism (NOAA n.d.)

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for all three TLs (2, 3, and 4). Therefore, EPA used the BCF method estimate with the TL2 BCF values available for fluoranthene (Arnot and Gobas 2006) to derive the national BAF value of 1,500 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for fluoranthene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both

noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 4×10^{-2} mg/kg-d (0.04 mg/kg-d) for fluoranthene based on a 1989 EPA IRIS assessment (USEPA 1989). EPA identified an EPA study (USEPA 1988) as the critical study and the development of nephropathy, increased liver weights, hematological alterations, and clinical effects as the critical effects in mice orally exposed to fluoranthene (USEPA 1989). The subchronic study had a NOAEL of 125 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 3000 to account for interspecies extrapolation (10), intraspecies variation (10), subchronic-to-chronic study extrapolation (10), and database deficiency (3) (USEPA 1989).

EPA identified two other potential RfD sources through the systematic search described in section 5: a 1995 ATSDR assessment (ATSDR 1995) and a 2012 EPA Office of Solid Waste and Emergency Response (OSWER) Provisional Peer Reviewed Toxicity Value (PPRTV) (USEPA 2012a). Based on the selection process described in section 5, the 1989 EPA IRIS RfD is preferred for use in AWQC development at this time. Neither of the other assessments include the relevant (chronic oral) toxicity value.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), fluoranthene is classified as Group D, “not classifiable as to human carcinogenicity” (USEPA 1990).

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD’s exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual’s total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR “Toxicological Profiles” (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine’s Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA’s Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Fluoranthene is a medium molecular weight polycyclic aromatic hydrocarbon (PAH) used as a lining material to protect the interior of some drinking water pipes and storage tanks (ATSDR 1995). Humans can be exposed to fluoranthene and other PAHs via several sources, including air, food, water, and fish and shellfish. Inhalation exposure to PAHs, including fluoranthene, may also occur from cigarette smoke and burning wood, and from working with substances that contain PAHs, such as roofing materials and asphalt (ATSDR 1995).

The vapor pressure of fluoranthene (5.0×10^{-6} mm Hg at 25 °C) indicates that if released to air, the chemical will exist in both the vapor and particulate phases in the atmosphere (ATSDR 1995). Fluoranthene is not listed as a hazardous air pollutant (USEPA 2013), and EPA's Toxic Release Inventory did not report release data for it in 2013 (USEPA 2015g). Given its physical properties, air is a potentially significant source of exposure to fluoranthene.

Food is also a significant source of PAHs such as fluoranthene. PAHs have been detected in unprocessed cereal, potatoes, grain, flour, bread, vegetables, fruit, and refined fats and oils, and are often associated with grilled or smoked food (ATSDR 1995). More specific information regarding concentrations of fluoranthene in food could not be identified. Thus, based on its detection in foods, ingestion of food is a potentially significant source of exposure to fluoranthene.

The log K_{ow} for fluoranthene is 4.90 (ATSDR 1995). The national-level BAF estimate for fluoranthene is 1,500 L/kg, which indicates that the chemical has a high potential for bioaccumulation (USEPA 2011b). NOAA's Mussel Watch Survey has detected fluoranthene in ocean fish and shellfish (NOAA 2014). Fluoranthene was a target analyte in EPA's National Lake Fish Tissue Study, but it was not detected (USEPA 2009c). Thus, based on available exposure information and its potential to bioaccumulate, ingestion of fish and shellfish is a potentially significant source of exposure to fluoranthene.

PAHs have been detected in finished drinking water (ATSDR 1995); however, recent information regarding concentrations of fluoranthene in drinking water could not be identified. Fluoranthene is not regulated under the Safe Drinking Water Act (USEPA 2014c), and it was not included in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). There is no Standard of Quality for bottled water for fluoranthene (IBWA 2012). Thus, exposure to fluoranthene from ingestion of drinking water is unknown.

In summary, based on the physical properties and available exposure information for fluoranthene, air, fish and shellfish, and food are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for fluoranthene.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to fluoranthene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Fluoranthene

Input Parameter	Value
RfD	0.04 mg/kg-d
CSF	No data
RSC	0.20
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	1,500 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.04\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + (0.022\ kg/d \times 1{,}500\ L/kg)}$$

$$= 18.1\ \mu g/L$$

$$= 20\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.04\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.022\ kg/d \times 1{,}500\ L/kg)}$$

$$= 19.4\ \mu g/L$$

$$= 20\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for fluoranthene using a noncarcinogenic toxicity endpoint. The updated human health AWQC for fluoranthene are **20 µg/L** for consumption of water and organisms and **20 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Fluoranthene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	130 µg/L	**20 µg/L**
Organism Only	140 µg/L	**20 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to fluoranthene from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for fluoranthene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 1,500 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 1,150 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012b) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 790.1 L/kg
TL3 = 563.4 L/kg
TL4 = 388.4 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA retained an RfD of 0.04 mg/kg-d for fluoranthene based on a 1989 EPA IRIS assessment (USEPA 1989; USEPA 2002c). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for fluoranthene and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of fluoranthene in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- Fluoranthene (CAS Number 206-44-0)
- 1,2-benzacenaphthene
- Benzene, 1,2-(1,8-naphthalenediyl)-
- Benzene, 1,2-(1,8-naphthylene)-
- Benzo(jk)fluorene
- HSDB 5486
- Idryl
- 1,2-(1,8-naphthylene)benzene
- NSC 6803
- RCRA waste number U120

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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June 2015

Update of Human Health Ambient Water Quality Criteria:

Fluorene
86-73-7

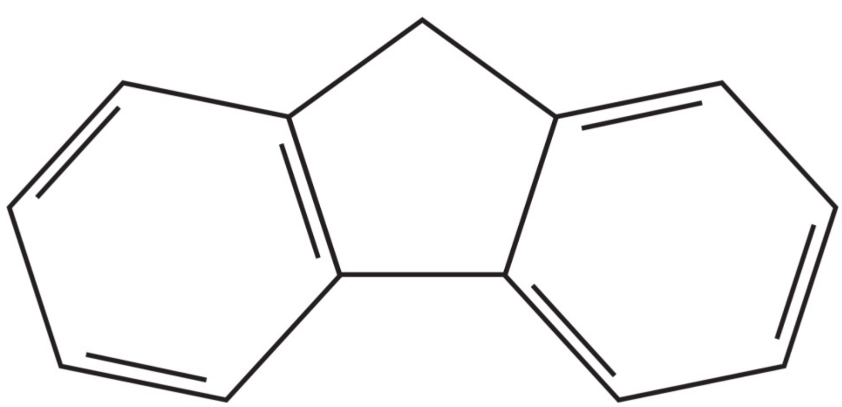

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for fluorene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 230 L/kg (TL2), 450 L/kg (TL3), and 710 L/kg (TL4) for fluorene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for fluorene. Based on the characteristics of this chemical, EPA selected Procedure 2 for deriving a national BAF value. Fluorene has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log K_{ow} = 4.18 (ATSDR 1995)
- High metabolism (NOAA n.d.)

EPA was not able to locate peer-reviewed, field-measured BAFs or BSAFs for all three TLs (2, 3, and 4). EPA did locate peer-reviewed, lab-measured BCFs for all three TLs for this chemical. Therefore, EPA used the Lab BCF method to derive the national BAF values for this chemical:

TL2 = 230 L/kg
TL3 = 450 L/kg
TL4 = 710 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for fluorene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 4×10^{-2} mg/kg-d (0.04 mg/kg-d) for fluorene based on a 1989 EPA IRIS assessment (USEPA 1989a). EPA identified an EPA study (USEPA 1989b) as the critical study and the development of decreased red blood cell counts, packed cell volume, and hemoglobin as the critical effects in mice orally exposed to fluorene. The subchronic study had a NOAEL of 125 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 3000 to account for interspecies extrapolation (10), intraspecies variation (10), subchronic-to-chronic study extrapolation (10), and database deficiency (3) (USEPA 1989a).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified one other potential RfD source through the systematic search described in section 5: a 1995 ATSDR assessment (ATSDR 1995). Based on the selection process described in section 5, the 1989 IRIS RfD is preferred for use in AWQC development at this time. The ATSDR assessment does not include the relevant (chronic oral) toxicity value.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), fluorene is classified as Group D, "not classifiable as to human carcinogenicity" (USEPA 1990).

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).

- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Fluorene is a low molecular weight polycyclic aromatic hydrocarbon (PAH) used in the manufacture of dyes, plastics, pesticides, explosives, and chemotherapeutic agents (ATSDR 1995). Fluorene is not a registered pesticide (USEPA 2015c). Humans can be exposed to fluorene and other PAHs via several sources, including air, food, water, and fish and shellfish.

The vapor pressure of fluorene (3.2×10^{-4} mm Hg at 20 °C) indicates that it will exist in the vapor phase in the atmosphere (ATSDR 1995). Inhalation exposure to PAHs, including fluorene, might also occur from cigarette smoke and burning wood, and from working with substances that contain PAHs, such as roofing materials and asphalt (ATSDR 1995). Recent air monitoring data for fluorene is limited (ATSDR 1995). Fluorene is not listed as a hazardous air pollutant (USFDA 2013). Recent data from EPA's Toxic Release Inventory are not available (USEPA 2015g). Given the anthropogenic sources of PAHs and their ability to exist in the atmosphere, air is a potentially significant source of exposure to fluorene.

Food is also a significant source of PAHs such as fluorene. PAHs in general have been detected in unprocessed cereal, potatoes, grain, flour, bread, vegetables, fruit, and refined fats and oils, and is often associated with grilled or smoked food (ATSDR 1995). More specific information regarding concentrations of fluorene in food could not be identified. Thus, based on its detection in foods, ingestion of food is a potentially significant source of exposure to fluorene.

The log K_{ow} for fluorene is 4.18 (ATSDR 1995). The national-level BAF estimates for fluorene range from 230 L/kg (TL2) to 710 L/kg (TL4), which indicates that fluorene has a moderate potential for bioaccumulation (USEPA 2011b). NOAA's Mussel Watch Survey has detected fluorene in fish and shellfish (NOAA 2014). Fish tissue samples collected in EPA's National Lake Fish Tissue Study were analyzed for fluorene, but it was not detected in any of them(USEPA 2009c). Based on its potential to bioaccumulate and available exposure information, ingestion of fish and shellfish is a potentially significant source of exposure to fluorene.

PAHs have been detected in finished drinking water (ATSDR 1995); however, recent information regarding concentrations of fluorene in drinking water could not be identified. Fluorene is not regulated under the Safe Drinking Water Act (USEPA 2014c). Fluorene was not included in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b), and there is no Standard of Quality for fluorene in bottled water (IBWA 2012). Therefore, the potential exposure to fluorene from ingestion of drinking water is unknown.

In summary, based on the physical properties and available exposure information for fluorene, air, fish and shellfish, and food are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources of exposure other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from these different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for fluorene.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to fluorene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Fluorene

Input Parameter		Value
RfD		0.04 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	230 L/kg
	TL3	450 L/kg
	TL4	710 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.04 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 230 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 450 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 710 \text{ L/kg}))}$$

$$= 54.99\ \mu g/L$$

$$= 50\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.04 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 230 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 450 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 710 \text{ L/kg})}$$

$$= 69.3\ \mu g/L$$

$$= 70\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for fluorene using a noncarcinogenic toxicity endpoint. The updated human health AWQC for fluorene are **50 µg/L** for consumption of water and organisms and **70 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Fluorene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	1,100 µg/L	**50 µg/L**
Organism Only	5,300 µg/L	**70 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to fluorene from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for fluorene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 230, 450, and 710 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 30 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 763 L/kg
TL3 = 789.7 L/kg
TL4 = 909.2 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to

representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA retained an RfD of 0.04 mg/kg-d for fluorene based on a 1989 EPA IRIS assessment (USEPA 1989a; USEPA 2002c). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for fluorene and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of fluorene in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- Fluorene (CAS Number 86-73-7)
- 9H-Fluorene
- Diphenylenemethane
- HSDB 2165
- Methane, diphenylene-
- NSC 6787
- o-BIPHENYLENEMETHANE
- 2,2'-METHYLENEBIPHENYL
- 9H-fluorene

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United States
Environmental Protection
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EPA 820-R-15-045
June 2015

Update of Human Health Ambient Water Quality Criteria:

gamma-Hexachlorocyclohexane (HCH)
58-89-9

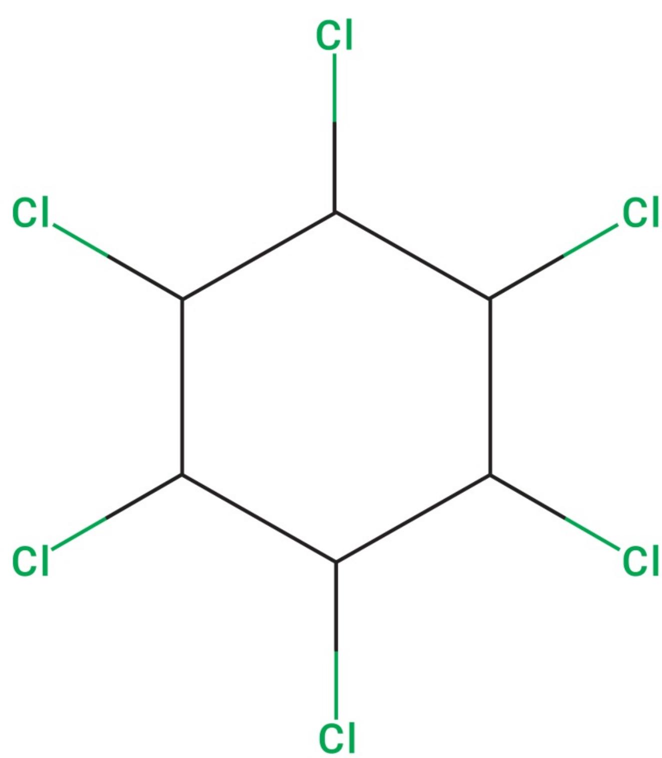

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for gamma-hexachlorocyclohexane (HCH) to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency’s goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC}\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC}\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level-(TL)-specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national trophic level-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and trophic level; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across trophic level to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three trophic levels (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three trophic levels and (b) the BCF method produced national-level BAF estimates for all three trophic levels.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three trophic levels.

In cases where the procedure called for the BAF method but there were fewer than three trophic level estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported trophic levels by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any trophic levels, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 1,200 L/kg (TL2), 2,400 L/kg (TL3), and 2,500 L/kg (TL4) for gamma-HCH. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for gamma-HCH. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Gamma-HCH has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 3.72$ (ATSDR 2005)
- Low/unknown metabolism

EPA was able to locate peer-reviewed, field-measured BAFs for TLs 2, 3, and 4 (Arnot and Gobas 2006; Environment Canada 2006). Therefore, EPA used the Field BAF method to derive the national BAF values for this chemical:

TL2 = 1,200 L/kg
TL3 = 2,400 L/kg
TL4 = 2,500 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for gamma-HCH. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 4.7×10^{-3} mg/kg-d (0.0047 mg/kg-d) for gamma-HCH based on a 2002 EPA Office of Pesticide Programs (OPP) Reregistration Eligibility Decision (RED) (USEPA 2002c). EPA OPP identified a study by Amyes (1989) as the critical study and periacinar hepatocyte hypertrophy, increased liver/spleen weight, and decreased platelets as the critical effects in rats orally exposed to gamma-HCH (USEPA 2002c). The study had a NOAEL of 0.47 mg/kg-d. In deriving the RfD, EPA OPP applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10) (USEPA 2002c).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified three other potential RfD sources through the systematic search described in section 5: a 1986 EPA IRIS assessment (USEPA 1986), a 1999 California EPA assessment (CalEPA 1999), and a 2005 ATSDR assessment (ATSDR 2005). Based on the selection process described in section 5, the 2002 OPP RfD is preferred for use in AWQC development at this time. The ATSDR assessment does not include the relevant (chronic oral) toxicity endpoint. The OPP RED is the most current available RfD source.

5.2.2 Cancer Slope Factor

Under the 1999 EPA Review Draft *Guidelines for Carcinogen Risk Assessment* (USEPA 1999), EPA OPP classified gamma-HCH as "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential" (USEPA 2001; USEPA 2002c). Citing a 2001 Cancer Assessment Review Committee report on the carcinogenicity of gamma-HCH (USEPA 2001), OPP did not quantify human cancer risk in its 2002 RED (USEPA 2002c). EPA's IRIS program has not developed a carcinogenicity assessment for gamma-HCH (USEPA 1986).

EPA identified one source of a CSF for gamma-HCH through the systematic search described in section 5: a 1999 California EPA assessment (CalEPA 1999). Based on the selection process described in section 5, EPA is not selecting this CSF for AWQC development at this time. Cancer risk was not quantified by EPA in its most recent assessment (USEPA 2001; USEPA 2002c). Thus, EPA will not derive AWQC for carcinogenic toxicological effects for gamma-HCH at this time.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology

Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Gamma-HCH is an insecticide that, until 2006, when its registration was voluntarily cancelled, was used on fruits, vegetables, grains, forest crops, and animals and in animal premises. Gamma-HCH is presently used as prescription medication for scabies and head lice (ATSDR 2005; USEPA 2006). Due to its pharmaceutical uses, dermal exposure could also be a source of gamma-HCH to those using it for a prescribed treatment. Because of its prior use on various crops and persistence, ingestion from food is a potential source of gamma-HCH exposure to the general population. In addition, surface water, finished drinking water, and ingestion of fish and shellfish are possible sources of gamma-HCH exposure.

Gamma-HCH is regulated under the Safe Drinking Water Act (SDWA), and EPA's drinking water standard (maximum contaminant level) is 0.2 µg/L (USEPA 2014c). Gamma-HCH has previously been detected in treated drinking water: with mean concentrations of 23 ng/L and 147 ng/L in 1978; a mean concentration of 0.01 ng/L in 1976; and a mean concentration of 0.2 ng/L in 1972 (ATSDR 2005). Prior to its cancellation as a pesticide, gamma-HCH was a target analyte in EPA's Six-Year Reviews (1996–2002) and was detected in some drinking water, groundwater, and surface water samples (USEPA 2009a; USEPA 2009b). There is a Standard of Quality for bottled water for gamma-HCH of 0.2 µg/L (IBWA 2012). Therefore, based on available information regarding detection, ingestion of surface water and finished drinking water is a potentially significant source of exposure to gamma-HCH.

The log K_{ow} for gamma-HCH is 3.72 (ATSDR 2005). The national-level BAF estimates for gamma-HCH range from 1,200 L/kg (TL2) to 2,500 L/kg (TL4), which indicates gamma-HCH has a high potential for bioaccumulation (USEPA 2011b). Gamma-HCH was not a target analyte in NOAA's Mussel Watch Survey (NOAA 2014). EPA's National Lake Fish Tissue Study included gamma-HCH as a target analyte, and it was detected in predator and bottom-dwelling fish (USEPA 2009c). More recent exposure information regarding concentrations of gamma-HCH in fish and shellfish from inland and nearshore waters and ocean fish and shellfish could not be identified. Thus, based on its potential to bioaccumulate, ingestion of fish and shellfish is a potentially significant source of exposure to gamma-HCH.

The 2004–2005 FDA Total Diet Study detected trace amounts of gamma-HCH in food samples including chocolate chip cookies, brownies, and candy bars (USFDA 2005). According to ATSDR (2005), gamma-HCH was also previously detected in ready-to-eat foods in an FDA study conducted between 1982 and 1991 (an average concentration of 0.0012 µg/L). Recent monitoring data indicate that food may no longer be a significant exposure source for the chemical. In 2013, gamma-HCH was *not* detected in fruit and vegetables, drinking water, or groundwater, as reported by the Pesticide Data Program (USDA 2014). EPA no longer sets a 40 CFR part 180 pesticide tolerance for this chemical in food and feed commodities (USGPO 2015). Based on its more recent information regarding detection of gamma-HCH, exposure to gamma-HCH from ingestion of food is not considered likely.

Air is a potential source of gamma-HCH exposure (ATSDR 2005). Recent data from EPA's Toxic Release Inventory indicate that 9,079 pounds of gamma-HCH were released in 2013; however, all sources appear to have been at disposal facilities (USEPA 2015g). Gamma-HCH has been previously detected in the air near highways, in cities, and adjacent to industrial manufacturing plants (ATSDR 2005). It also was detected in samples collected between 1979 and 1980, with a mean concentration of 0.23 ng/m^3; in troposphere air samples in 1985 with a mean concentration of 0.509 ng/m^3; and in 1988, with a mean concentration of 0.021 ng/m^3. Samples collected in 1996 and 1997 had a mean concentration of 0.050 ng/m^3, and samples collected between 1990 and 1997 had average concentrations of 0.024–0.062 ng/m^3 (ATSDR 2005).

Inhalation exposure is also possible via showering, bathing, or cooking with contaminated water (ATSDR 2005). The vapor pressure of gamma-HCH (4.2×10^{-5} mm Hg at 20 °C) indicates that volatilization is not an important fate process for this chemical (ATSDR 2005). EPA lists gamma-HCH as a hazardous air pollutant (USEPA 2013). Based on its limited use, exposure to gamma-HCH from air is possible but not considered likely.

In summary, based on the physical properties and available exposure information for gamma-HCH, drinking water and fish and shellfish from inland and nearshore waters are likely to be the most significant sources of gamma-HCH exposure. Although gamma-HCH has been detected in food and air in the past, its limited use as a pharmaceutical product is expected to limit exposure from these sources to the general population. Therefore, the most significant routes of exposure to the general population are expected to be from ingestion of fish and shellfish from inland and nearshore waters and drinking water. Limited exposure is also possible from inhalation and dermal contact. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), there is not likely to be significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion (Box 7 in the Decision Tree). Therefore, EPA recommends an RSC of 50 percent (0.50) for gamma-HCH.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to gamma-HCH from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for gamma-HCH

Input Parameter		Value
RfD		0.0047 mg/kg-d
CSF		No data
RSC		0.50
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	1,200 L/kg
	TL3	2,400 L/kg
	TL4	2,500 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{0.0047\ \text{mg/kg-d} \times 0.50 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{2.4\ \text{L/d} + ((0.0076\ \text{kg/d} \times 1{,}200\ \text{L/kg}) + (0.0086\ \text{kg/d} \times 2{,}400\ \text{L/kg}) + (0.0051\ \text{kg/d} \times 2{,}500\ \text{L/kg}))}$$

$$= 4.186\ \mu g/L$$

$$= 4.2\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{0.0047\ \text{mg/kg-d} \times 0.50 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{(0.0076\ \text{kg/d} \times 1{,}200\ \text{L/kg}) + (0.0086\ \text{kg/d} \times 2{,}400\ \text{L/kg}) + (0.0051\ \text{kg/d} \times 2{,}500\ \text{L/kg})}$$

$$= 4.422\ \mu g/L$$

$$= 4.4\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for gamma-HCH using a noncarcinogenic toxicity endpoint. The updated human health AWQC for gamma-HCH are **4.2 µg/L** for consumption of water and organisms and **4.4 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2003b).

Table 2. Summary of EPA's Previously Recommended (2003) and Updated (2015) Human Health AWQC for gamma-HCH

	2003 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.98 µg/L	**4.2 µg/L**
Organism Only	1.8 µg/L	**4.4 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to gamma-HCH from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for gamma-HCH take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) trophic level BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 1,200, 2,400, and 2,500 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national trophic level BAFs replace EPA's previously recommended BCF of 130 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 934.9 L/kg
TL3 = 1,118 L/kg
TL4 = 1,935 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three trophic levels of fish and shellfish consumed, as opposed to representing all trophic levels of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.0047 mg/kg-d for gamma-HCH based on a 2002 EPA OPP RED (USEPA 2002c). This RfD replaces the previous value of 0.0003 mg/kg-d (USEPA 2003b). EPA used the RfD of 0.0047 mg/kg-d to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, an increase in the RfD in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Cancer Slope Factor

EPA did not select a CSF for gamma-HCH and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of gamma-HCH in its previous criteria update (USEPA 2003b).

Relative Source Contribution

An RSC of 50 percent is included in the AWQC calculation. This is higher than the 20 percent RSC used in the previous AWQC (USEPA 2003b). Assuming all other input parameters remain constant, a higher RSC in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

9 Chemical Name and Synonyms

- Gamma-HCH (Lindane) (CAS Number 58-89-9)
- Aalindan
- Aficide
- Agrisol G-20
- Agronexit
- Ameisenatod
- Ameisenmittel Merck
- Aparasin
- Aphtiria
- Aplidal
- Arbitex
- BBH
- Ben-Hex
- Bentox 10
- Gamma-Benzene Hexachloride
- Benzene Hexachloride-Gamma-Isomer
- Bexol
- BHC
- Gamma-BHC
- Celanex
- Chloresene
- Codechine
- Cyclohexane, 1,2,3,4,5,6-Hexachloro-, Gamma-Isomer
- DBH
- Detmol-Extrakt
- Detox 25
- Devoran
- Dol Granule
- Drill Tox-Spezial Aglukon
- ENT 7,796
- Entomoxan
- Exagama
- Forlin
- Gallogama
- Gamacarbatox
- Gamacid
- Gamaphex
- Gamene
- Gamiso
- Gamma-Col

- Gammahexa
- Gammahexane
- Gammalin
- Gammalin 20
- Gammaterr
- Gammex
- Gammexane
- Gammopaz
- Gexane
- HCCH
- HCH
- Gamma-HCH
- Heclotox
- Hexa
- Hexachloran
- Hexachlorane
- Gamma-Hexachlorane
- Gamma-Hexachloran
- Gamma-Hexachlor
- Gamma-Hexachlorobenzene
- 1,2,3,4,5,6-Hexachlorocyclohexane
- 1-Alpha,2-Alpha,3-Beta,4-Alpha,5-Alpha,6-Beta-Hexachlorocyclohexane
- Hexachlorocyclohexane, Gamma-
- Gamma-1,2,3,4,5,6-Hexachlorocyclohexane
- 1,2,3,4,5,6-Hexachlorocyclohexane, Gamma-Isomer
- Hexachlorocyclohexane, Gamma-Isomer
- Hexatox
- Hexaverm
- Hexicide
- Hexyclan
- HGI
- Hortex
- Inexit
- Isotox
- Jacutin
- Kokotine
- Kwell
- Lendine
- Lentox
- Lidenal
- Lindafor
- Lindagam

- Lindagrain
- Lindagranox
- Lindane
- Gamma-Lindane
- Lindapoudre
- Lindatox
- Lindosep
- Lintox
- Lorexane
- Milbol 49
- Mszycol
- NA 2761
- NCI-C00204
- Neo-Scabicidol
- Nexen Fb
- Nexit
- Nexit-Stark
- Nexol-E
- Nicochloran
- Novigam
- Omnitox
- Owadziak
- Pedraczak
- Pflanzol
- Quellada
- RCRA Waste Number U129
- Sang Gamma
- Silvanol
- Spritz-Rapidin
- Spruehpflanzol
- Streunex
- TAP 85
- Tri-6
- Viton

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United States Environmental Protection Agency
Office of Water
Office of Science and Technology
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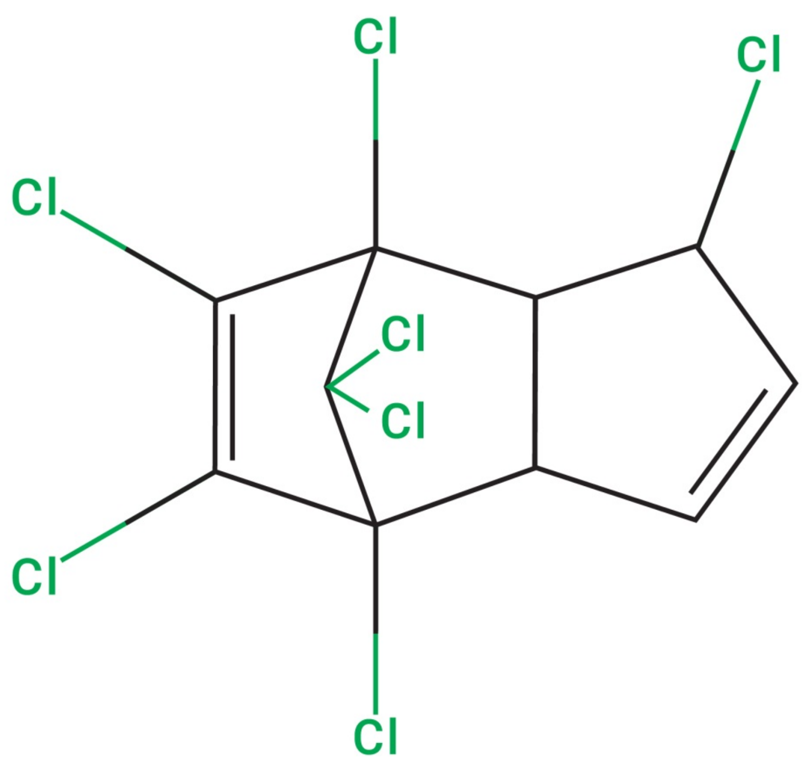
Update of Human Health Ambient Water Quality Criteria:

Heptachlor
76-44-8



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Office of Science and Technology
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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for heptachlor to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ \mu g/mg^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ \mu g/mg^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))} \qquad \text{(Eq. 2)}$$

Where:

AWQC = ambient water quality criteria

toxicity value = RfD x RSC (mg/kg-d) for noncarcinogenic effects
or
10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]

RSC = relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)

BW = body weight

DI = drinking water intake

$\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4

FCR_i = fish consumption rate for aquatic TLs 2, 3, and 4

BAF_i = bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 12,000 L/kg (TL2), 180,000 L/kg (TL3), and 330,000 L/kg (TL4) for heptachlor. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for heptachlor. Based on the characteristics of this chemical, EPA selected Procedure 1 for deriving a national BAF value. Heptachlor has the following characteristics:

- Nonionic organic chemical (USDHHS 2012)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 6.10$ (ATSDR 2007)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 12,000 L/kg
TL3 = 180,000 L/kg
TL4 = 330,000 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for heptachlor. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

In place of an RfD, EPA selected an intermediate-duration oral minimal risk level (MRL) of 1×10^{-4} mg/kg-d (0.0001 mg/kg-d) for heptachlor based on a 2007 ATSDR assessment (ATSDR 2007). An intermediate-duration MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure (15–364 days).

ATSDR identified studies by Smialowicz et al. (2001) and Moser et al. (2001) as the critical studies and the development of immunological and neurological effects in rats exposed to heptachlor in utero followed by postnatal exposure (until postnatal day 42) (ATSDR 2007). A LOAEL of 0.03 mg/kg-d and a composite uncertainty factor of 300 were used to derive the intermediate-duration MRL of 1×10^{-4} mg/kg-d (0.0001 mg/kg-d). In deriving the MRL, ATSDR

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

applied a composite uncertainty factor of 300 to account for interspecies extrapolation (10), intraspecies variation (10), and use of a LOAEL instead of a NOAEL (3) (ATSDR 2007). Consistent with EPA practice, an uncertainty factor was *not* used to account for extrapolation from less-than-chronic exposure because the critical effects were developmental (immunological and neurological) effects. The developmental period is recognized as a susceptible lifestage in which exposure during certain critical time windows are more relevant to the induction of developmental effects than lifetime exposure; repeated exposure is not necessary for the manifestation of developmental toxicity (USEPA 1991).

EPA identified three other potential RfD sources through the systematic search described in section 5: a 1987 EPA IRIS assessment (USEPA 1987a), a 1992 EPA Office of Pesticide Programs (OPP) Reregistration Eligibility Decision[g] (RED) (USEPA 1992), and a 1999 California EPA assessment (CalEPA 1999). Based on the selection process described in section 5, the 2007 ATSDR MRL is preferred for use in AWQC development at this time. The 2007 ATSDR MRL relies on newer principal studies (Smialowicz et al. 2001; Moser et al. 2001), which became available after publication of the other three assessments (USEPA 1987a; USEPA 1992; CalEPA 1999).

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), heptachlor is classified as Group B2, “probable human carcinogen” (USEPA 1987b).

EPA selected a CSF of 4.1 per mg/kg-d for heptachlor based on a 1999 California EPA assessment (CalEPA 1999). CalEPA derived the CSF using four data sets from two strains of mice from studies by the National Cancer Institute (NCI 1977) and Davis (1965) based on development of hepatocellular carcinoma in both sexes of mice orally exposed to heptachlor (CalEPA 1999).

EPA identified two other potential CSF sources through the systematic search described in section 5: a 1987 EPA IRIS assessment (USEPA 1987b) and a 1992 EPA OPP RED (USEPA 1992). Based on the selection process described in section 5, the 1999 CalEPA assessment is preferred for use in AWQC development at this time. The 1999 CalEPA assessment evaluated the same studies as the IRIS assessment (NCI 1977; Davis 1965) but applied more current guidance and modeling approaches. Specifically, the LED_{10} (the lower 95 percent confidence limit on the estimated dose associated with 10 percent extra risk) was selected by CalEPA as the point of departure for derivation of the slope factor in place of a linear multistage (LMS) slope factor. Additionally, the CalEPA CSF uses a cross-species scaling approach based on $BW^{3/4}$, which is consistent with current EPA practice (USEPA 2005). The 1992 OPP RED does not include the relevant oral CSF.

[g] Note: Heptachlor is no longer a current use pesticide in the United States.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.

- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to heptachlor from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Heptachlor

Input Parameter		Value
RfD		0.0001 mg/kg-d
CSF		4.1 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	12,000 L/kg
	TL3	180,000 L/kg
	TL4	330,000 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC }(\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{0.0001\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 12{,}000\ L/kg) + (0.0086\ kg/d \times 180{,}000\ L/kg) + (0.0051\ kg/d \times 330{,}000\ L/kg))}$$

$$= 0.000481\ \mu g/L$$

$$= 0.0005\ \mu g/L\ \text{(rounded)}$$

For consumption of organisms only:

$$\text{AWQC }(\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{0.0001\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 12{,}000\ L/kg) + (0.0086\ kg/d \times 180{,}000\ L/kg) + (0.0051\ kg/d \times 330{,}000\ L/kg)}$$

$$= 0.000482\ \mu g/L$$

$$= 0.0005\ \mu g/L\ \text{(rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC }(\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{(10^{-6} / 4.1)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 12{,}000\ L/kg) + (0.0086\ kg/d \times 180{,}000\ L/kg) + (0.0051\ kg/d \times 330{,}000\ L/kg))}$$

$$= 0.000005869\ \mu g/L$$

$$= 0.0000059\ \mu g/L\ \text{(rounded)}$$

For consumption of organisms only:

$$\text{AWQC }(\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{(10^{-6} / 4.1)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 12{,}000\ L/kg) + (0.0086\ kg/d \times 180{,}000\ L/kg) + (0.0051\ kg/d \times 330{,}000\ L/kg)}$$

$$= 0.000005873\ \mu g/L$$

$$= 0.0000059\ \mu g/L\ \text{(rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for heptachlor using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for heptachlor are **0.0005 µg/L** for consumption of water and organisms and **0.0005 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for heptachlor are **0.0000059 µg/L** for consumption of water and organisms and **0.0000059 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of heptachlor, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Heptachlor

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.000079 µg/L	**0.0000059 µg/L**
Organism Only	0.000079 µg/L	**0.0000059 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to heptachlor at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for heptachlor take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the

AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 12,000, 180,000, and 330,000 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 11,200 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 31,680 L/kg
TL3 = 33,940 L/kg
TL4 = 39,160 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

In place of an RfD, EPA selected an intermediate-duration oral MRL of 0.0001 mg/kg-d for heptachlor based on a 2007 ATSDR assessment (ATSDR 2007). EPA used the MRL of 0.0001 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of heptachlor in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 4.1 per mg/kg-d for heptachlor based on a 1999 California EPA assessment (CalEPA 1999). This CSF replaces the previous value of 4.5 per mg/kg-d (USEPA 2002c). EPA used the CSF of 4.1 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, a decrease in the CSF in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Heptachlor (CAS Number 76-44-8)
- Agroceres
- 3-chlorochlordene
- Dicyclopentadiene, 3,4,5,6,7,8,8a-heptachloro-
- Drinox
- Drinox H-34
- E 3314
- ENT 15,152
- Eptacloro
- 1,4,5,6,7,8,8-eptacloro-3a,4,7,7a-tetraidro-4,7-endo-metano-indene
- GPKH
- H
- H-34
- Heptachloor

- 1,4,5,6,7,8,8-heptachloor-3a,4,7,7a-tetrahydro-4,7-endo-methano-indeen
- Heptachlor
- Heptachlore
- 1(3a),4,5,6,7,8,8-heptachloro-3a(1),4,7,7a-tetrahydro-4,7-methanoindene
- 3,4,5,6,7,8,8-heptachlorodicyclopentadiene
- 3,4,5,6,7,8,8a-heptachlorodicyclopentadiene
- 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-endomethanoindene
- 1,4,5,6,7,10,10-heptachloro-4,7,8,9-tetrahydro-4,7-endomethyleneindene
- 1,4,5,6,7,8,8a-heptachloro-3a,4,7,7a-tetrahydro-4,7-methanoindane
- 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methanoindene
- 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methanol-1h-indene
- 1,4,5,6,7,10,10-heptachloro-4,7,8,9-tetrahydro-4,7-methyleneindene
- 1,4,5,6,7,8,8-heptachloro-3a,4,7,7,7a-tetrahydro-4,7-methylene indene
- 1,4,5,6,7,8,8-heptachlor-3a,4,7,7,7a-tetrahydro-4,7-endo-methano-inden
- Heptagran
- Heptamul
- 4,7-methanoindene, 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-
- NA 2761
- NCI-C00180
- RCRA waste number P059
- Rhodiachlor
- Velsicol 104

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-048
June 2015

Update of Human Health Ambient Water Quality Criteria:

Hexachlorobenzene
118-74-1

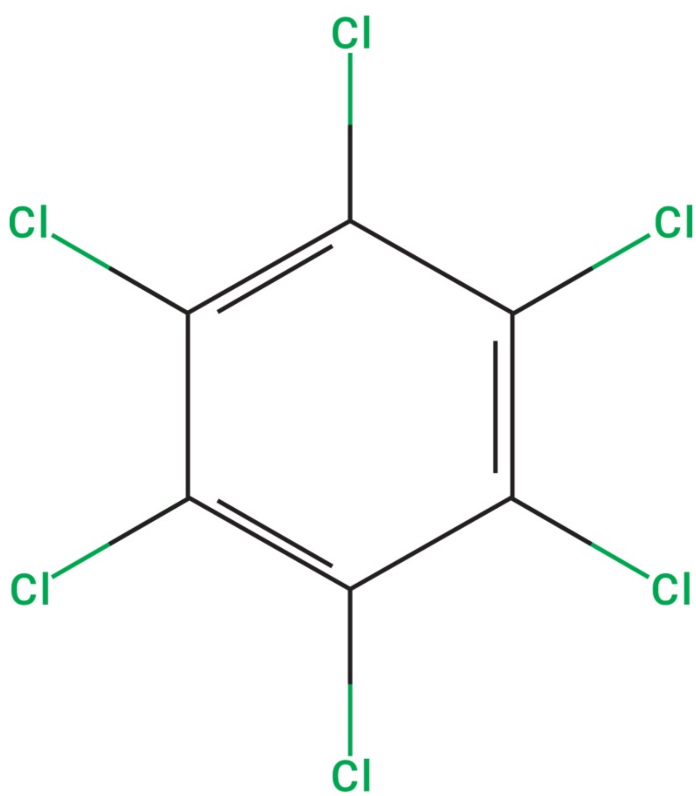

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for hexachlorobenzene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure-3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 18,000 L/kg (TL2), 46,000 L/kg (TL3), and 90,000 L/kg (TL4) for hexachlorobenzene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for hexachlorobenzene. Based on the characteristics of this chemical, EPA selected Procedure 1 for deriving a national BAF value. Hexachlorobenzene has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 5.73$ (ATSDR 2013)
- Low/unknown metabolism

EPA was able to locate peer-reviewed, field-measured BAFs for TLs 2, 3, and 4 (USEPA 2003a; Arnot and Gobas 2006; Environment Canada 2006). Therefore, EPA used the Field BAF method to derive the national BAF values for this chemical:

TL2 = 18,000 L/kg
TL3 = 46,000 L/kg
TL4 = 90,000 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for hexachlorobenzene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 8×10^{-4} mg/kg-d (0.0008 mg/kg-d) for hexachlorobenzene based on a 2008 Office of Pesticide Programs (OPP) Reregistration Eligibility Decision (RED) (USEPA 2008). Hexachlorobenzene is a contaminant formed during the manufacturing process of pentachlorophenol, a current-use pesticide, among other sources. EPA OPP identified a study by Arnold et al. (1985) as the critical study and hepatic centrilobular basophilic chromogenesis as the critical effect in rats orally exposed to hexachlorobenzene (USEPA 2008). The chronic study had a NOAEL of 0.08 mg/kg-d. In deriving the RfD, EPA OPP applied an uncertainty factor (margin of exposure) of 100 to account for interspecies extrapolation (10) and intraspecies variation (10) (USEPA 2008).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified three other potential RfD sources through the systematic search described in section 5: a 1988 EPA IRIS assessment (USEPA 1988), a draft 2013 ATSDR assessment (ATSDR 2013), and a 2003 California EPA assessment (CalEPA 2003). Based on the selection process described in section 5, the 2008 EPA OPP RfD is preferred for use in AWQC development at this time. Although not a current-use pesticide itself, hexachlorobenzene is a contaminant formed during the manufacturing process of a current-use pesticide. The chronic oral endpoint from the OPP assessment (0.0008 mg/kg-d) is identical to the 1988 EPA IRIS RfD (USEPA 1988). The 2013 ATSDR assessment is currently in draft form and is not yet final. Therefore, the OPP assessment is the most current available RfD source.

5.2.2 Cancer Slope Factor

Under the 1996 EPA *Proposed Guidelines for Carcinogen Risk Assessment* (USEPA 1996), hexachlorobenzene is classified as Group B2, "probable human carcinogen" (USEPA 2008).

EPA selected a CSF of 1.02 per mg/kg-d for hexachlorobenzene based on a 2008 EPA OPP RED (USEPA 2008). OPP derived the CSF by applying the Agency's currently recommended cross-species scaling factor based on $BW^{3/4}$ to a 1989 EPA IRIS CSF (USEPA 1989). EPA IRIS derived the 1989 CSF using a principal study by Erturk et al. (1986) based on development of hepatocellular carcinomas in rats orally exposed to hexachlorobenzene (USEPA 1989).

EPA identified one other CSF source through the systematic search described in section 5: a 2003 California EPA assessment (CalEPA 2003). Based on the selection process described in section 5, the 2008 EPA OPP CSF is preferred for use in AWQC development at this time. The OPP assessment is the most current available CSF source.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the

chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to hexachlorobenzene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Hexachlorobenzene

Input Parameter		Value
RfD		0.0008 mg/kg-d
CSF		1.02 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	18,000 L/kg
	TL3	46,000 L/kg
	TL4	90,000 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.0008 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 18{,}000 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 46{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 90{,}000 \text{ L/kg}))}$$

$$= 0.0129\ \mu g/L$$

$$= 0.01\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.0008\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 18{,}000\ L/kg) + (0.0086\ kg/d \times 46{,}000\ L/kg) + (0.0051\ kg/d \times 90{,}000\ L/kg)}$$

$$= 0.0129\ \mu g/L$$

$$= 0.01\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI } (L/d) + \sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 1.02)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 18{,}000\ L/kg) + (0.0086\ kg/d \times 46{,}000\ L/kg) + (0.0051\ kg/d \times 90{,}000\ L/kg))}$$

$$= 0.00007892\ \mu g/L$$

$$= 0.000079\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 1.02)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 18{,}000\ L/kg) + (0.0086\ kg/d \times 46{,}000\ L/kg) + (0.0051\ kg/d \times 90{,}000\ L/kg)}$$

$$= 0.00007911\ \mu g/L$$

$$= 0.000079\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for hexachlorobenzene using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for hexachlorobenzene are **0.01 µg/L** for consumption of water and organisms and **0.01 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for hexachlorobenzene are **0.000079 µg/L** for consumption of water and organisms and **0.000079 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of hexachlorobenzene, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Hexachlorobenzene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.00028 µg/L	**0.000079 µg/L**
Organism Only	0.00029 µg/L	**0.000079 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to hexachlorobenzene at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for hexachlorobenzene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

<u>Body Weight</u>

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

<u>Drinking Water Intake</u>

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

<u>Fish Consumption Rate</u>

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a

contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 18,000, 46,000, and 90,000 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 8,690 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 157,300 L/kg
TL3 = 294,000 L/kg
TL4 = 791,100 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.0008 mg/kg-d for hexachlorobenzene based on a 2008 EPA OPP RED (USEPA 2008). EPA used the RfD of 0.0008 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of hexachlorobenzene in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 1.02 per mg/kg-d for hexachlorobenzene based on a 2008 EPA OPP RED (USEPA 2008). This CSF replaces the previous value of 1.6 per mg/kg-d (USEPA 2002c). EPA used the CSF of 1.02 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, a decrease in the CSF in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Hexachlorobenzene (CAS Number 118-74-1)
- Granox
- Pentachlorophenyl chloride
- Perchlorobenzene

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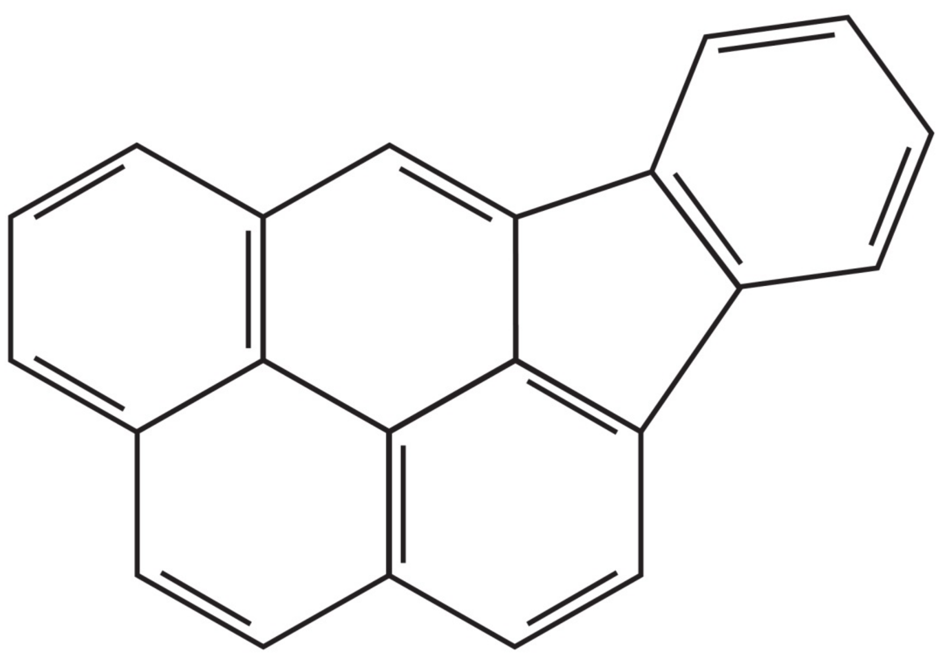
United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-053
June 2015

Update of Human Health Ambient Water Quality Criteria:

Indeno(1,2,3-cd)pyrene
193-39-5



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Office of Science and Technology
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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for indeno(1,2,3-cd)pyrene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency’s goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 3,900 L/kg for indeno(1,2,3-cd)pyrene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for indeno(1,2,3-cd)pyrene. Based on the characteristics of this chemical, EPA selected Procedure 2 for deriving a national BAF value. Indeno(1,2,3-cd)pyrene has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 6.58$ (ATSDR 1995)
- High metabolism (NOAA n.d.)

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for this polycyclic aromatic hydrocarbon (PAH) (Arnot and Gobas 2006; Environment Canada 2006). In the absence of chemical-specific information, EPA used the field-measured BAF for benzo(a)pyrene, an index PAH, as a surrogate for the estimation of BAFs for other PAHs. This approach is consistent with conclusions of Neff (2002) that benzo(a)pyrene is a good indicator of the presence of pyrogenic PAHs in the environment and that type of PAH is expected to concentrate in organisms such as fish and shellfish, as does benzo(a)pyrene. Therefore, EPA used the benzo(a)pyrene BCF method estimate for the reported TLs by calculating the geometric mean of the TL2 and TL3 BCF values available for benzo(a)pyrene (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 3,900 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for indeno(1,2,3-cd)pyrene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

EPA's IRIS program does not currently have an RfD or CSF for indeno(1,2,3-cd)pyrene (USEPA 1990). In the absence of chemical-specific information, EPA recommends use of the index PAH benzo(a)pyrene, an index PAH, as a surrogate for the determination of risk to other PAHs. In this approach, the potencies of other PAHs relative to benzo(a)pyrene are determined. EPA's IRIS program is currently reassessing benzo(a)pyrene, which may be used in the future to derive toxicity values for other PAHs, including indeno(1,2,3-cd)pyrene. In 2013 EPA's IRIS program published the draft Toxicological Review for benzo(a)pyrene for public review and comment, discussion at a public meeting, and subsequent expert peer review (USEPA 2013a; USEPA 2013b). The 2013 draft Toxicological Review included both a draft RfD and a draft CSF. In addition, in 2010, EPA's IRIS program published draft updated relative potency factors for PAH mixtures (USEPA 2010).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA anticipates updating the AWQC for PAHs following finalization of EPA's IRIS toxicological assessment for benzo(a)pyrene and relative potency factors for PAHs. In the meantime, based on the selection process described above, EPA will use IRIS's current toxicity values for benzo(a)pyrene (USEPA 1991) and IRIS's currently recommended relative potency factors (USEPA 1993) for the purpose of AWQC derivation for indeno(1,2,3-cd)pyrene.

5.2.1 Reference Dose

EPA has not selected an RfD for derivation of AWQC for indeno(1,2,3-cd)pyrene. EPA's IRIS program does not currently have an oral RfD for indeno(1,2,3-cd)pyrene or for benzo(a)pyrene, the index PAH (USEPA 1990; USEPA 1991).

EPA identified two RfD sources for indeno(1,2,3-cd)pyrene through the systematic search described in section 5: a 1995 ATSDR assessment (ATSDR 1995) and a 2005 California EPA assessment (CalEPA 2005). However, due to EPA's ongoing reassessments, the toxicity values from these assessments will not be used to derive AWQC at this time.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), indeno(1,2,3-cd)pyrene is classified as Group B2, "probable human carcinogen" (USEPA 1990).

EPA selected a CSF of 0.73 per mg/kg-d for indeno(1,2,3-cd)pyrene based on a 1991 EPA IRIS assessment for benzo(a)pyrene (USEPA 1991). EPA's IRIS program derived a CSF of 7.3 per mg/kg-d using a principal study by Neal and Rigdon (1967), which was based on development of fore-stomach and squamous cell papillomas in mice orally exposed to benzo(a)pyrene (USEPA 1991). EPA applied a relative potency factor of 0.1 to derive the CSF for indeno(1,2,3-cd)pyrene (USEPA 1993).

EPA identified one other CSF source for indeno(1,2,3-cd)pyrene through the systematic search described in section 5: a 2005 California EPA assessment (CalEPA 2005). However, due to EPA's ongoing reassessments, EPA will use the current IRIS CSF to derive AWQC at this time.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean

fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not

anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using only a carcinogenic toxicity endpoint (CSF) because no RfD sources were identified through the systematic search described in section 5 (Hazard Identification and Dose Response). Therefore, no RSC was applied in the AWQC derivation for this chemical.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to indeno(1,2,3-cd)pyrene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Indeno(1,2,3-cd)pyrene

Input Parameter	Value
RfD	No data
CSF	0.73 per mg/kg-d
RSC	–
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	3,900 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

EPA identified no RfD sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for noncarcinogenic toxicological effects.

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 0.73) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + (0.022 \text{ kg/d} \times 3{,}900 \text{ L/kg})}$$

$$= 0.001243\ \mu g/L$$

$$= 0.0012\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 0.73) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.022 \text{ kg/d} \times 3{,}900 \text{ L/kg})}$$

$$= 0.001277\ \mu g/L$$

$$= 0.0013\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for indeno(1,2,3-cd)pyrene using a carcinogenic toxicity endpoint. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for indeno(1,2,3-cd)pyrene are **0.0012 µg/L** for consumption of water and organisms and **0.0013 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Indeno(1,2,3-cd)pyrene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.0038 µg/L	**0.0012 µg/L**
Organism Only	0.018 µg/L	**0.0013 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to indeno(1,2,3-cd)pyrene at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for indeno(1,2,3-cd)pyrene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 3,900 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 30 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 5,370 L/kg
TL3 = 1,465 L/kg
TL4 = 316.6 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA did not select an RfD for indeno(1,2,3-cd)pyrene and therefore did not derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of indeno(1,2,3-cd)pyrene in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.73 per mg/kg-d for indeno(1,2,3-cd)pyrene based on a 1991 EPA IRIS assessment for benzo(a)pyrene (USEPA 1991). This CSF replaces the previous value of 7.3 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.73 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, a decrease in the CSF in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Relative Source Contribution

No RfD sources were identified for this chemical. Therefore, no RSC was applied in the AWQC derivation for this chemical.

9 Chemical Name and Synonyms

- Indeno(1,2,3-cd)pyrene (CAS Number 193-39-5)
- HSDB 5101
- indeno(1,2,3-cd)pyrene
- o-phenylenepyrene
- RCRA waste number U137
- 1,10-(o-phenylene)pyrene
- 1,10-(1,2-phenylene)pyrene
- 2,3-o-phenylenepyrene
- 2,3-phenylenepyrene

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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June 2015

Update of Human Health Ambient Water Quality Criteria:

Methoxychlor
72-43-5

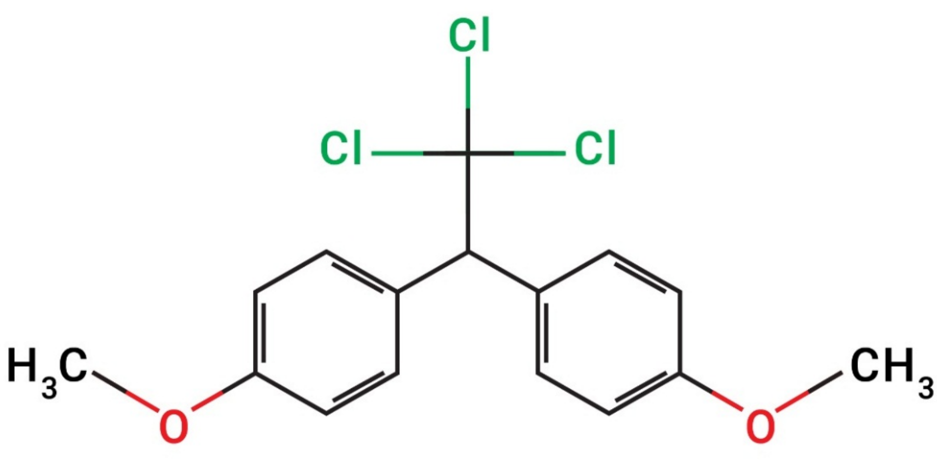

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for methoxychlor to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

<u>For consumption of organisms only:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC = ambient water quality criteria

toxicity value = RfD x RSC (mg/kg-d) for noncarcinogenic effects
or
10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]

RSC = relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)

BW = body weight

DI = drinking water intake

$\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4

FCR_i = fish consumption rate for aquatic TLs 2, 3, and 4

BAF_i = bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 1,400 L/kg (TL2), 4,800 L/kg (TL3), and 4,400 L/kg (TL4) for methoxychlor. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for methoxychlor. Based on the characteristics of this chemical, EPA selected Procedure 1 for deriving a national BAF value. Methoxychlor has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 4.88$ (ATSDR 2002)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 1,400 L/kg
TL3 = 4,800 L/kg
TL4 = 4,400 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for methoxychlor. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 2×10^{-5} mg/kg-d (0.00002 mg/kg-d) for methoxychlor based on a 2010 California EPA assessment (CalEPA 2010). CalEPA derived the RfD using a principal study by Judy et al. (1999) and increased prostate and seminal vesicle weights as the critical effects in mice orally exposed to methoxychlor (CalEPA 2010). The chronic study had a LOAEL of 2×10^{-2} mg/kg-d (0.02 mg/kg-d). In deriving the RfD, CalEPA applied an uncertainty factor of 1000 to account for interspecies extrapolation (10), intraspecies variation (10), and extrapolation from a LOAEL to a NOAEL (10) (CalEPA 2010).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 1990 EPA IRIS assessment (USEPA 1990) and a 2002 ATSDR assessment (ATSDR 2002). Based on the selection process described in section 5, the 2010 CalEPA RfD is preferred for use in AWQC development at this time. The 2010 CalEPA assessment relied on a more current principal study (Judy et al. 1999) to derive the RfD compared to the IRIS assessment (Kincaid Enterprises 1986). The ATSDR assessment did not include the relevant (chronic oral) toxicity value.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986a), methoxychlor is classified as Group D, "not classifiable as to human carcinogenicity" (USEPA 1987).

In 2003, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the cancer assessment for methoxychlor and did not identify any critical new studies.

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Methoxychlor is an insecticide that is no longer produced or used in the United States. It was used primarily in agriculture on crops and livestock and in animal feed, barns, and grain storage bins (ATSDR 2002). Methoxychlor was also used for controlling insects in gardens and on pets (ATSDR 2002). Methoxychlor might be released from hazardous waste sites where it has been disposed (ATSDR 2002). All registered sources of methoxychlor were canceled in 2002, and all tolerances have been revoked (USEPA 2002c; USEPA 2004). Prior to cancellation, the dominant possible exposure routes were dermal contact or through the ingestion of either contaminated water or food (ATSDR 2002).

Methoxychlor has a log K_{ow} that ranges from 4.68 to 5.08, with an average of 4.88 (ATSDR 2002). The national-level BAF estimates for methoxychlor range from 1,400 L/kg (TL2) to 4,800 L/kg (TL3), which indicates that methoxychlor has a high potential for bioaccumulation (USEPA 2011b). Prior to its cancellation as an approved pesticide, the chemical was detected in fish from the Great Lakes at levels ranging from 10 to 120 µg/kg wet weight (ATSDR 2002). It also was detected in several species of migratory fish in Great Lakes tributaries at concentrations up to 1.4 µg/kg (ATSDR 2002). In EPA's National Lake Fish Tissue Study (USEPA 2009c), the chemical was detected in 1–5 percent (i.e., 9 of 468) of the predator fillets (at a maximum concentration of 370 ppb) and 5.8 percent (i.e., 23 of 395) of the bottom dweller whole body fish samples (at a maximum concentration of 107 ppb) (USEPA 2009c). Methoxychlor was not included in NOAA's Mussel Watch Survey (NOAA 2014). Thus, based on available exposure information and its high potential to bioaccumulate, ingestion of fish and shellfish is a potentially significant source of exposure to methoxychlor.

The FDA 2004–2005 Total Diet Study indicated trace levels of methoxychlor in various foods (13 of 64 samples; maximum concentration of 0.2 ppb in pancakes) (USFDA 2005). In 2013, no methoxychlor residues were detected in tested fruits and vegetables (i.e., bananas, cauliflower, celery, and raspberries), infant formula, groundwater, or drinking water (USDA 2014). EPA does not set a 40 CFR part 180 pesticide tolerance for this chemical in food and feed commodities (USGPO 2015). It was not evaluated in the *Fourth National Report on Human Exposures to Environmental Chemicals* (CDC 2009; CDC 2015). Maximum residue limits were not found in the Global MRL Database (Bryant Christie Inc. 2015). Thus, based on the fact that methoxychlor is no longer produced or used in the United States, exposure to this chemical from ingestion of food is not considered likely.

Methoxychlor is not commonly detected in drinking water (ATSDR 2002). It is regulated under the Safe Drinking Water Act, and EPA's drinking water standard (maximum contaminant level) for methoxychlor is 40 µg/L (USEPA 2014c). Based on EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b) of more than 28,000 surface water sources of drinking water, methoxychlor was detected in less than 1 percent (0.128 percent) of samples (median value of 0.2 µg/L; maximum value of 1.1 µg/L). Of more than 108,000 groundwater sources of drinking water, methoxychlor was detected in 0.031 percent of the samples (median value of 0.04 µg/L; maximum value of 0.8 µg/L) (USEPA 2009a; USEPA 2009b). The Standard of Quality for methoxychlor in bottled water is 40 µg/L (IBWA 2012). More recent studies of methoxychlor in groundwater or drinking water were not available. Given this information, ingestion of drinking water might be a potential source of methoxychlor, but due to its cancellation as a pesticide, ingestion of drinking water is not expected to be a significant source of exposure to the general population.

Volatilization of methoxychlor from water might occur; it also has been observed to slowly volatilize from foliage (ATSDR 2002). This process was thought to contribute to the environmental cycling of methoxychlor (ATSDR 2002). Historically, the primary sources of methoxychlor to the atmosphere were from its use as a pesticide and from its production, formulation, and disposal (ATSDR 2002). Methoxychlor was detected in air samples collected in 1986–1988; mean outdoor concentrations were highest in winter months (0.1 ng/m^3) (ATSDR

2002). Recent data from EPA's Toxic Release Inventory indicate that 1,444 pounds of the chemical were released in 2013; however, all of the reported amounts were to disposal facilities (USEPA 2015g). Methoxychlor is listed as a hazardous air pollutant (USEPA 2013). Given this information, air might be a potential source of methoxychlor, but due to its cancellation as a pesticide, ambient air is not expected to be a significant source of exposure to the general population.

In summary, based on the available exposure information for methoxychlor, and given that the chemical is no longer produced or used in the United States, EPA does not anticipate that there will be significant sources and routes of exposure of methoxychlor other than fish and shellfish from inland and nearshore waters and water ingestion. Based on EPA's 2000 Methodology, "If it can be demonstrated that other sources and routes of exposure are not anticipated for the pollutant in question (based on information about its known/anticipated uses and chemical/physical properties), then EPA would use the 80 percent ceiling" (see section 4.2.3 the 2000 Methodology) (USEPA 2000a). Therefore, EPA recommends an RSC of 80 percent (0.80) for methoxychlor.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to methoxychlor from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Methoxychlor

Input Parameter		Value
RfD		0.00002 mg/kg-d
CSF		No data
RSC		0.80
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	1,400 L/kg
	TL3	4,800 L/kg
	TL4	4,400 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.00002 \text{ mg/kg-d} \times 0.80 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 1{,}400 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 4{,}800 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 4{,}400 \text{ L/kg}))}$$

$$= 0.0167\ \mu g/L$$

$$= 0.02\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.00002 \text{ mg/kg-d} \times 0.80 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 1{,}400 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 4{,}800 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 4{,}400 \text{ L/kg})}$$

$$= 0.0172\ \mu g/L$$

$$= 0.02\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for methoxychlor using a noncarcinogenic toxicity endpoint. The updated human health AWQC for methoxychlor are **0.02 µg/L** for consumption of water and organisms and **0.02 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 1986b; USEPA 2002d).

Table 2. Summary of EPA's Previously Recommended (1986) and Updated (2015) Human Health AWQC for Methoxychlor

	1986 Human Health AWQC	2015 Human Health AWQC
Water and Organism	100 µg/L	**0.02 µg/L**
Organism Only	---	**0.02 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to methoxychlor from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for methoxychlor take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 1,400, 4,800, and 4,400 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). The previous criterion for methoxychlor was derived prior to the current methodology and did not take bioaccumulation and fish consumption into consideration in its development (USEPA 1976; USEPA 2002b).

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 8,963 L/kg
TL3 = 8,860 L/kg
TL4 = 9,001 L/kg

Assuming all other input parameters remain constant, lower BAFs or BCFs result in higher AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish decreases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure increases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.00002 mg/kg-d for methoxychlor based on a 2010 California EPA assessment (CalEPA 2010). This RfD replaces the previous value of 0.005 mg/kg-d (USEPA 1986b; USEPA 2002d). EPA used the RfD of 0.00002 mg/kg-d to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, a decrease in the RfD in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

Cancer Slope Factor

EPA did not select a CSF for methoxychlor and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of methoxychlor in its previous criteria update (USEPA 1986b; USEPA 2002d).

Relative Source Contribution

An RSC of 80 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 1986b; USEPA 2002d). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- Methoxychlor (CAS Number 72-43-5)
- 2,2-di-p-anisyl-1,1,1-trichloroethane
- DMDT
- Marlate
- Methorcide
- Methoxy-DDT
- Moxie
- 1,1,1-trichloro-2,2-bis(p-methoxyphenyl)ethane

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Update of Human Health Ambient Water Quality Criteria:

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for methyl bromide to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 1.2 L/kg (TL2), 1.3 L/kg (TL3), and 1.4 L/kg (TL4) for methyl bromide. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for methyl bromide. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Methyl bromide has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 1.1$ (ATSDR 1992)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 1.2 L/kg
TL3 = 1.3 L/kg
TL4 = 1.4 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for methyl bromide. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 2×10^{-2} mg/kg-d (0.02 mg/kg-d) for methyl bromide, a current-use pesticide, based on a 2006 EPA Office of Pesticide Programs (OPP) human health risk assessment (USEPA 2006). EPA OPP identified a study by Danse et al. (1984) in which the authors found decreased BW, rate of BW gain, and food consumption as the critical effects in rats orally exposed to methyl bromide (USEPA 2006). The study had a NOAEL of 2.2 mg/kg-d. In deriving the RfD, EPA OPP applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10) (USEPA 2006).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 1988 EPA IRIS assessment (USEPA 1988) and a 1992 ATSDR assessment (ATSDR 1992). Based on the selection process described in section 5, the 2006 OPP RfD is preferred for use in AWQC development at this time. The OPP RfD was selected to derive the updated AWQC because this chemical is a current-use pesticide.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), methyl bromide is classified as Group D, "not classifiable as to human carcinogenicity" (USEPA 1989). Under the 1999 EPA Review Draft *Guidelines for Carcinogen Risk Assessment* (USEPA 1999), methyl bromide is classified as "not likely to be carcinogenic to humans" (USEPA 2006).

EPA identified no CSF source through the search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).

- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Methyl bromide is used as a soil fumigant and pesticide (ATSDR 1992). It is currently registered as a pesticide by EPA and is in the registration review process (USEPA 2015c). The use of methyl bromide as a pesticide was phased out in 2005, except for allowable exemptions (USEPA 2014c).The physical properties and uses of the chemical indicate that the general population might be exposed to methyl bromide via inhalation of ambient air and potentially through ingestion of food and water (ATSDR 1992).

The vapor pressure of methyl bromide (1,420 mm Hg at 20 °C) indicates that volatilization is an important fate process for the chemical (ATSDR 1992). Recent data from EPA’s Toxic Release Inventory indicate that nearly 190,000 pounds of methyl bromide were released to the atmosphere in 2013 (USEPA 2015g). Methyl bromide is listed as a hazardous air pollutant (USEPA 2013). Thus, based on its physical properties, air is a potentially significant source of exposure to methyl bromide.

Food might be a significant source of methyl bromide exposure (ATSDR 1992). EPA sets a 40 CFR part 180 pesticide tolerance for this chemical in food and feed commodities (USGPO 2015). The Global MRL Database reports maximum residual levels of methyl bromide in numerous food commodities (Bryant Christie Inc. 2015). Thus, based on available information, ingestion of food is a potentially significant source of exposure to methyl bromide.

Methyl bromide is not typically detected in drinking water or surface water due to its rapid volatilization (ATSDR 1992), although historically, it was detected in groundwater used as a drinking water source (ATSDR 1992). Methyl bromide is not regulated under the Safe Drinking Water Act (USEPA 2014d). It was not a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b), and a Standard of Quality for bottled water for methyl bromide has not been established (IBWA 2012). Thus, based on available information, the potential exposure to methyl bromide from ingestion of surface water and drinking water is possible.

The log K_{ow} for methyl bromide is 1.1 (ATSDR 1992). The national-level BAF estimates for methyl bromide range from 1.2 L/kg (TL2) to 1.4 L/kg (TL4), which indicates that it has a low potential for bioaccumulation (USEPA 2011b). No additional information on methyl bromide in ocean fish or shellfish was found by ATSDR (1992). The chemical was not included in NOAA's Mussel Watch Survey (NOAA 2014), and it was not a target analyte in EPA's National Lake Fish Tissue Study (USEPA 2009c). Recent exposure information regarding concentrations of methyl bromide in fish and shellfish is lacking. Thus, based on its low potential for bioaccumulation, exposure to this chemical from ingestion of fish and shellfish is not considered likely.

In summary, based on the physical properties and available exposure information for methyl bromide, air and non-fish food are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for methyl bromide.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to methyl bromide from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Methyl Bromide

Input Parameter		Value
RfD		0.02 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	1.2 L/kg
	TL3	1.3 L/kg
	TL4	1.4 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.02 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 1.2 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 1.3 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1.4 \text{ L/kg}))}$$

$$= 132\ \mu g/L$$

$$= 100\ \mu g/L \text{ (rounded)}$$

<u>For consumption of organisms only:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.02 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 1.2 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 1.3 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1.4 \text{ L/kg})}$$

$$= 11{,}662\ \mu g/L$$

$$= 10{,}000\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for methyl bromide using a noncarcinogenic toxicity endpoint. The updated human health AWQC for methyl bromide are **100 µg/L** for consumption of water and organisms and **10,000 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Methyl Bromide

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	47 µg/L	**100 µg/L**
Organism Only	1,500 µg/L	**10,000 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to methyl bromide from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for methyl bromide take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 1.2, 1.3, and 1.4 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 3.75 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 1.795 L/kg
TL3 = 1.891 L/kg
TL4 = 2.243 L/kg

Assuming all other input parameters remain constant, lower BAFs or BCFs result in higher AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish decreases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure increases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to

representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.02 mg/kg-d for methyl bromide based on a 2006 EPA OPP human health risk assessment (USEPA 2006). This RfD replaces the previous value of 0.0014 mg/kg-d (USEPA 2002c). EPA used the RfD of 0.02 mg/kg-d to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, an increase in the RfD in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Cancer Slope Factor

EPA did not select a CSF for methyl bromide and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of methyl bromide in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- Methyl bromide (CAS Number 74-83-9)
- Brom-o-gas
- Bromomethane
- Curafume
- Dowfume MC-2 Soil Fumigant
- Dowfume MC-33
- Edco
- Embafume
- Halon 1001
- Haltox
- Iscobrome
- Kayafume
- MB
- MBX
- MEBR
- Metafume
- Methane, Bromo-
- Methogas
- Monobromomethane

- Pestmaster
- Profume
- R40B1
- Rotox
- Terabol
- Terr-o-gas 100
- Zytox

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Office of Water
Office of Science and Technology
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Update of Human Health Ambient Water Quality Criteria:

Methylene Chloride
75-09-2

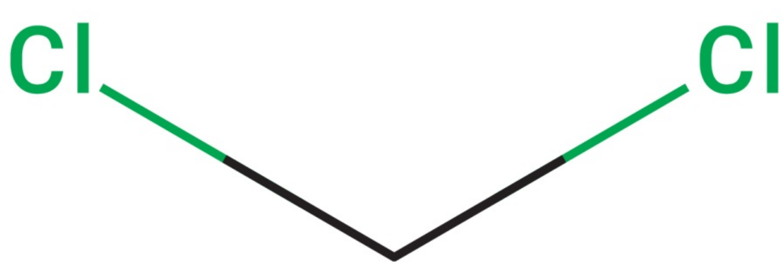

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for methylene chloride to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level-(TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 1.4 L/kg (TL2), 1.5 L/kg (TL3), and 1.6 L/kg (TL4) for methylene chloride. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for methylene chloride. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Methylene chloride has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 1.3$ (ATSDR 2000)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 1.4 L/kg
TL3 = 1.5 L/kg
TL4 = 1.6 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for methylene chloride. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 6×10^{-3} mg/kg-d (0.006 mg/kg-d) for methylene chloride[g] based on a 2011 EPA IRIS assessment (USEPA 2011b). EPA's IRIS program identified a study by Serota et al. (1986) as the critical study and hepatic effects (hepatic vacuolation, liver foci) as the critical effects in both sexes of rats orally exposed to methylene chloride (USEPA 2011b). A lower-bound confidence limit on the benchmark dose ($BMDL_1$) (1^{st} percentile human equivalent dose) of 0.19 mg/kg-d was used as the point of departure for the RfD. In deriving the RfD, EPA's IRIS applied a composite uncertainty factor of 30 to account for toxicodynamic uncertainty (3), intraspecies variation (3), and database deficiencies (3).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

[g] The IRIS file for methylene chloride is under its synonym dichloromethane.

EPA identified two other RfD sources through the systematic search described in section 5: a 2014 EPA Office of Pollution Prevention and Toxics (OPPT) assessment (USEPA 2014c) and a 2000 ATSDR assessment (ATSDR 2000). Based on the selection process described in section 5, the 2011 EPA IRIS RfD is preferred for use in AWQC development at this time. The OPPT assessment is based on the same principal study and is numerically the same as the 2011 EPA IRIS RfD. The EPA IRIS assessment is the most current available RfD source.

5.2.2 Cancer Slope Factor

Under the 2005 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 2005a), methylene chloride is “likely to be carcinogenic to humans” (USEPA 2011c). EPA concluded, by a weight of evidence evaluation, that methylene chloride is carcinogenic by a mutagenic mode of action (USEPA 2011c).

EPA selected a CSF of 2×10^{-3} per mg/kg-d (0.002 mg/kg-d) for methylene chloride based on a 2011 EPA IRIS assessment (USEPA 2011c). EPA’s IRIS program identified a study by Serota et al. (1986) as the critical study and the development of hepatocellular carcinomas or adenomas as the critical effect in male mice orally exposed to methylene chloride. The oral slope factor of 2×10^{-3} per mg/kg-d, calculated from data from adult exposure, does not reflect presumed early-life susceptibility[h] for this chemical (USEPA 2011c; USEPA 2005a; USEPA 2005b).

EPA identified one other CSF source through the systematic search described in section 5: a 2014 EPA OPPT assessment (USEPA 2014c). Based on the selection process described in section 5, the 2011 EPA IRIS CSF is preferred for use in AWQC development at this time. The OPPT assessment is based on the same principal study and is numerically the same as the 2011 IRIS CSF.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD’s exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual’s total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is

[h] The 2000 Methodology (USEPA 2000a) does not discuss application of age-dependent adjustment factors (ADAFs) because it was published prior to the 2005 EPA *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (“*Supplemental Guidance*”) (USEPA 2005b). Generally, the application of ADAFs is recommended when assessing cancer risks for a carcinogen with a mutagenic mode of action. The ADAF-adjusted total unit cancer risk for methylene chloride is 3.3×10^{-3} per mg/kg-d (0.0033 per mg/kg-d) (USEPA 2011d). For more information, see the IRIS toxicological review (USEPA 2011d) or EPA’s S*upplemental Guidance.*

not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not

anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to methylene chloride from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Methylene Chloride

Input Parameter		Value
RfD		0.006 mg/kg-d
CSF		0.002 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	1.4 L/kg
	TL3	1.5 L/kg
	TL4	1.6 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.006 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 1.4 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 1.5 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1.6 \text{ L/kg}))}$$

$$= 39.5\ \mu g/L$$

$$= 40\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.006\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 1.4\ L/kg) + (0.0086\ kg/d \times 1.5\ L/kg) + (0.0051\ kg/d \times 1.6\ L/kg)}$$

$= 3{,}028\ \mu g/L$

$= 3{,}000\ \mu g/L$ (rounded)

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI } (L/d) + \sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 0.002)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 1.4\ L/kg) + (0.0086\ kg/d \times 1.5\ L/kg) + (0.0051\ kg/d \times 1.6\ L/kg))}$$

$= 16.4\ \mu g/L$

$= 20\ \mu g/L$ (rounded)

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 0.002)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 1.4\ L/kg) + (0.0086\ kg/d \times 1.5\ L/kg) + (0.0051\ kg/d \times 1.6\ L/kg)}$$

$= 1{,}262\ \mu g/L$

$= 1{,}000\ \mu g/L$ (rounded)

7.3 AWQC Summary

EPA derived the AWQC for methylene chloride using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for methylene chloride are **40 µg/L** for consumption of water and organisms and **3,000 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for methylene chloride are **20 µg/L** for consumption of water and organisms and **1,000 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of methylene chloride, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Methylene Chloride

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	4.6 µg/L	**20 µg/L**
Organism Only	590 µg/L	**1,000 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to methylene chloride at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for methylene chloride take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a

contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 1.4, 1.5, and 1.6 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 0.9 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 1.968 L/kg
TL3 = 2.098 L/kg
TL4 = 2.63 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.006 mg/kg-d for methylene chloride based on a 2011 EPA IRIS assessment (USEPA 2011b). EPA used the RfD of 0.006 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of methylene chloride in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.002 mg/kg-d d for methylene chloride based on a 2011 EPA IRIS assessment (USEPA 2011c). This CSF replaces the previous value of 0.0075 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.002 mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, a decrease in the CSF in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Methylene chloride (CAS Number 75-09-2)
- Aerothene MM
- Chlorure de methylene
- DCM
- Dichlormethan, uvasol
- 1,1-Dichloromethane
- Freon 30
- Methane dichloride
- Methane, dichloro-
- Methylene bichloride
- Methylene dichloride
- Metylenu chlorek
- Narkotil
- NCI-C50102
- R 30
- Solaesthin
- Solmethine
- WLN: G1G

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-060
June 2015

Update of Human Health Ambient Water Quality Criteria:

Pentachlorophenol
87-86-5

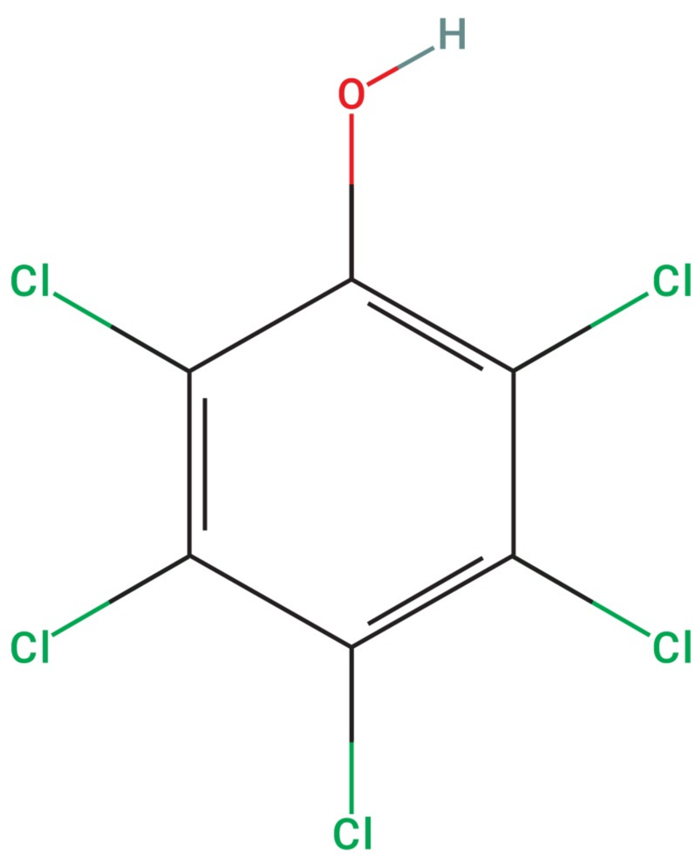

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for pentachlorophenol to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 44 L/kg (TL2), 290 L/kg (TL3), and 520 L/kg (TL4) for pentachlorophenol. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for pentachlorophenol. Based on the characteristics of this chemical, EPA selected Procedure 5 for deriving a national BAF value. Pentachlorophenol has the following characteristics:

- Ionic organic chemical, with ionization not negligible (USDHHS 2010)
- Biomagnification unlikely (ATSDR 2001)

EPA was able to locate peer-reviewed, lab-measured BCFs for TLs 2, 3, and 4 (Arnot and Gobas 2006; Environment Canada 2006). Therefore, EPA used the Lab BCF method (USEPA 2003a) to derive the national BAF values for this chemical:

TL2 = 44 L/kg
TL3 = 290 L/kg
TL4 = 520 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for pentachlorophenol. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 5×10^{-3} mg/kg-d (0.005 mg/kg-d) for pentachlorophenol, a current-use pesticide, based on a 2010 EPA IRIS assessment (USEPA 2010a). EPA's IRIS program identified a study by Mecler (1996) as the critical study and observed hepatotoxicity as the critical effect in Beagles after a 1-year oral exposure to pentachlorophenol in gelatin capsules (USEPA 2010a). The chronic study had a LOAEL of 1.5 mg/kg-d, the lowest dose tested (a NOAEL could not be established). In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 300 to account for intraspecies differences (10), interspecies extrapolation (10), and extrapolation from a LOAEL to a NOAEL (3).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified three other RfD sources through the systematic search described in section 5: a 2008 EPA Office of Pesticide Programs (OPP) Reregistration Eligibility Decision (RED) (USEPA 2008), a 2001 ATSDR assessment (ATSDR 2001), and a California EPA assessment (CalEPA 2009). Based on the selection process described in section 5, the IRIS RfD is preferred for use in AWQC development at this time. The IRIS RfD is the most current available RfD source. The same RfD (0.005 mg/kg-d) was included in the 2008 OPP RED for pentachlorophenol; however, as acknowledged by OPP (USEPA 2008), the 2008 RED was published prior to the peer review and finalization of the 2010 IRIS assessment.

5.2.2 Cancer Slope Factor

Under the 2005 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 2005), pentachlorophenol is “likely to be carcinogenic to humans” (USEPA 2010b).

EPA selected a CSF of 4×10^{-1} per mg/kg-d (0.4 per mg/kg-d) for pentachlorophenol based on a 2010 EPA IRIS assessment (USEPA 2010b). EPA’s IRIS program calculated the CSF using a principal study by the National Toxicology Program (NTP 1989) based on development of hepatocellular adenomas or carcinomas and adrenal benign or malignant pheochromocytomas in male mice with oral exposure to pentachlorophenol (USEPA 2010b).

EPA identified two other CSF sources through the systematic search described in section 5: a 2008 EPA OPP RED (USEPA 2008) and a 2009 California EPA assessment (CalEPA 2009). Based on the selection process described in section 5, the IRIS CSF is preferred for use in AWQC development at this time. The 2010 EPA IRIS assessment is the most current available CSF source. The OPP RED included a CSF of 0.07 per mg/kg-d based on the incidence of hepatocellular neoplasms, adrenal medullary neoplasms, and hemangiosarcomas in *female* mice in the same critical study as IRIS (USEPA 2008). The OPP RED, which was conducted using the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), acknowledged the not-yet-final IRIS reassessment of carcinogenic potential of pentachlorophenol and indicated that OPP would use the existing CSF (0.07 per mg/kg-d) until the ongoing IRIS assessment had been fully peer reviewed and finalized (USEPA 2008).

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD’s exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual’s total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR “Toxicological Profiles” (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine’s Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA’s Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to pentachlorophenol from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Pentachlorophenol

Input Parameter		Value
RfD		0.005 mg/kg-d
CSF		0.4 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	44 L/kg
	TL3	290 L/kg
	TL4	520 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.005 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 44 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 290 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 520 \text{ L/kg}))}$$

$$= 10.2\ \mu g/L$$

$$= 10\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.005\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 44\ L/kg) + (0.0086\ kg/d \times 290\ L/kg) + (0.0051\ kg/d \times 520\ L/kg)}$$

$$= 14.6\ \mu g/L$$

$$= 10\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI } (L/d) + \sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 0.4)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 44\ L/kg) + (0.0086\ kg/d \times 290\ L/kg) + (0.0051\ kg/d \times 520\ L/kg))}$$

$$= 0.0254\ \mu g/L$$

$$= 0.03\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 0.4)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 44\ L/kg) + (0.0086\ kg/d \times 290\ L/kg) + (0.0051\ kg/d \times 520\ L/kg)}$$

$$= 0.0365\ \mu g/L$$

$$= 0.04\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for pentachlorophenol using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for pentachlorophenol are **10 µg/L** for consumption of water and organisms and **10 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for pentachlorophenol are **0.03 µg/L** for consumption of water and organisms and **0.04 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of pentachlorophenol, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Pentachlorophenol

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.27 µg/L	**0.03 µg/L**
Organism Only	3.0 µg/L	**0.04 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to pentachlorophenol at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for pentachlorophenol take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a

contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 44, 290, and 520 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 11 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 486.1 L/kg
TL3 = 360.9 L/kg
TL4 = 254.7 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.005 mg/kg-d for pentachlorophenol based on a 2010 EPA IRIS assessment (USEPA 2010a). EPA used the RfD of 0.005 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of pentachlorophenol in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.4 per mg/kg-d for pentachlorophenol based on a 2010 EPA IRIS assessment (USEPA 2010b). This CSF replaces the previous value of 0.12 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.4 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, an increase in the CSF in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Pentachlorophenol (CAS Number 87-86-5)
- Chem-Tol
- Chlorophen
- Cryptogil OL
- Dowcide 7
- Dowicide EC-7
- DP-2, technical
- Durotox
- EP 30
- Fungifen
- Glazd penta
- Grundier arbezol
- 1-Hydroxy- 2,3,4,5,6-pentachlorobenzene
- Lauxtol
- Lauxtol A
- Liroprem
- NCI-C54933
- NCI-C55378
- NCI-C55389
- NCI-C56655
- PCP
- Penchlorol
- Penta
- Pentachloorfenol
- Pentachlorofenol

- Pentachlorofenolo
- Pentachlorophenate
- 2,3,4,5,6-Pentachlorophenol
- Pentachlorphenol
- Pentaclorofenolo
- Pentacon
- Penta-Kil
- Pentasol
- Penwar
- Peratox
- Permacide
- Permagard
- Permasan
- Permatox
- Permatox dp-2
- Permatox penta
- Permite
- Phenol, pentachloro-
- Preventol P
- Priltox
- Santobrite
- Santophen
- Santophen 20
- Sinituho
- Term-i-trol
- WLN: QR BG CG DG EG FG

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-061
June 2015

Update of Human Health Ambient Water Quality Criteria:

Phenol
108-95-2

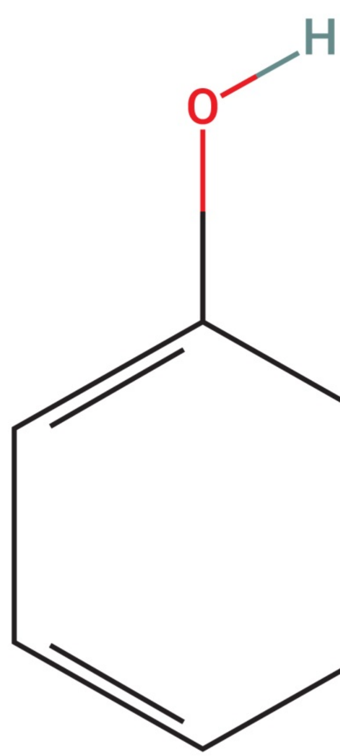

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for phenol to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency’s goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 1.5 L/kg (TL2), 1.7 L/kg (TL3), and 1.9 L/kg (TL4) for phenol. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for phenol. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Phenol has the following characteristics:

- Nonionic organic chemical (USDHHS 2013)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 1.46$ (ATSDR 2008)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 1.5 L/kg
TL3 = 1.7 L/kg
TL4 = 1.9 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for phenol. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 6×10^{-1} mg/kg-d (0.6 mg/kg-d) for phenol, a current-use pesticide, based on a 2009 EPA Office of Pesticide Programs (OPP) Reregistration Eligibility Decision (RED) (USEPA 2009a). EPA OPP identified a study by the Argus Research Laboratories (1997) as the critical study and decreased maternal weight gain as the critical effect in female rats orally exposed to phenol (USEPA 2009a). The developmental toxicity study had a NOAEL of 60 mg/kg-d. EPA OPP applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10) (USEPA 2009a).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified three other RfD sources through the systematic search described in section 5: a 2002 EPA IRIS assessment (USEPA 2002c), a 2008 ATSDR assessment (ATSDR 2008), and a 2000 Health Canada assessment (HC and EC 2000). Based on the selection process described in section 5, the 2009 OPP RfD is preferred for use in AWQC development at this time. The OPP RfD was selected to derive the updated AWQC because this chemical is a current-use pesticide.

5.2.2 Cancer Slope Factor

According to EPA OPP and IRIS programs, data regarding the carcinogenicity of phenol are inadequate for an assessment of human carcinogenic potential (USEPA 2002d; USEPA 2009a).

EPA identified no CSF source through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009b; USEPA 2009c).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009d).

- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Phenol is used to make plastics and as a disinfectant in household cleaning products and other consumer products (e.g., mouthwashes and throat sprays) (ATSDR 2008). Phenol is a registered pesticide and currently in the registration review process (USEPA 2015c). Air is the primary source of phenol exposure to the general population; however, food, fish and shellfish, and drinking water might also be sources of exposure.

Releases of phenol into the air occur from industries using or manufacturing phenol, automobile exhaust, cigarette smoke, and wood burning (ATSDR 2008). The vapor pressure of phenol (0.35 mm Hg at 25 °C) indicates that it is a semi-volatile compound (ATSDR 2008). Phenol is degraded rapidly in air, usually within 1 to 2 days (ATSDR 2008). Recent data from EPA's Toxic Release Inventory indicate that over 560,000 pounds of phenol were released to the air in 2013 (USEPA 2015g). It is listed as a hazardous air pollutant (USEPA 2013). Therefore, based on phenol's physical properties and its widespread use, air is a potentially significant source of exposure.

Food is a potential source of phenol exposure. The chemical has been detected in meat products (e.g., bacon, chicken), cheese, tea, honey, and soybean curds, as well as in medicinal preparations (e.g., throat lozenges, mouthwashes, gargles, and antiseptic lotions) (ATSDR 2008). In addition, phenol is listed in the Everything Added to Food in the United States database (USFDA 2013). EPA does not set a 40 CFR part 180 pesticide tolerance for this chemical in food and feed commodities (USGPO 2015). Thus, ingestion of food is a potentially significant source of exposure to phenol.

Phenol is highly soluble in water, but it has a half-life of less than 1 day (ATSDR 2008). Phenol primarily enters surface water from industrial effluent discharges and has been detected in drinking water, surface water, groundwater, and industrial and urban runoff (ATSDR 2008). It is not regulated under the Safe Drinking Water Act (USEPA 2014c), and it was not included in EPA's Six-Year Reviews of chemicals in treated drinking water (USEPA 2009b; USEPA 2009c). No Standard of Quality for bottled water for phenol has been established (IBWA 2012). Recent information on concentrations of phenol in drinking water could not be identified (ATSDR 2008). Therefore, based on phenol's chemical properties, ingestion of drinking and surface waters is a potentially significant source of exposure.

The log K_{ow} for phenol is 1.46 (ATSDR 2008). The national-level BAF estimates for phenol range from 1.5 L/kg (T2) to 1.9 L/kg (TL4), which indicates that it has a low potential for bioaccumulation (USEPA 2011b). However, phenol was detected in less than one percent of bottom-dwelling fish (e.g., carp or catfish) in EPA's National Lake Fish Tissue Study (USEPA 2009d). This chemical was not included as a target analyte in NOAA's Mussel Watch Survey (NOAA 2014). Concentrations in fish and shellfish were not reported in ATSDR (2008). Thus, because phenol has been detected in bottom-dwelling fish, ingestion of fish and shellfish is a potentially significant source of exposure.

In summary, based on the physical properties and available exposure information for phenol, air, non-fish food, drinking water, and fish and shellfish might be significant sources of exposure. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for phenol.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to phenol from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Phenol

Input Parameter		Value
RfD		0.6 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	1.5 L/kg
	TL3	1.7 L/kg
	TL4	1.9 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.6\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 1.5\ L/kg) + (0.0086\ kg/d \times 1.7\ L/kg) + (0.0051\ kg/d \times 1.9\ L/kg))}$$

$$= 3{,}941\ \mu g/L$$

$$= 4{,}000\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.6\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 1.5\ L/kg) + (0.0086\ kg/d \times 1.7\ L/kg) + (0.0051\ kg/d \times 1.9\ L/kg)}$$

$$= 268{,}832\ \mu g/L$$

$$= 300{,}000\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for phenol using a noncarcinogenic toxicity endpoint. The updated human health AWQC for phenol are **4,000 µg/L** for consumption of water and organisms and **300,000 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2009e).

Table 2. Summary of EPA's Previously Recommended (2009) and Updated (2015) Human Health AWQC for Phenol

	2009 Human Health AWQC	2015 Human Health AWQC
Water and Organism	10,000 µg/L	**4,000 µg/L**
Organism Only	860,000 µg/L	**300,000 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to phenol from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for phenol take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

<u>Body Weight</u>

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

<u>Drinking Water Intake</u>

The updated DI is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 1.5, 1.7, and 1.9 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 1.4 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 2.193 L/kg
TL3 = 2.27 L/kg
TL4 = 2.419 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to

representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.6 mg/kg-d for phenol based on a 2009 EPA OPP RED (USEPA 2009a). This RfD replaces the previous value of 0.30 mg/kg-d (USEPA 2009e). EPA used the RfD of 0.6 mg/kg-d to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, an increase in the RfD in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Cancer Slope Factor

EPA did not select a CSF for phenol and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of phenol in its previous criteria update (USEPA 2009e).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2009e). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- Phenol (CAS Number 108-95-2)
- Benzenol
- Carbolic Acid
- Hydroxybenzene
- Izal
- Monohydroxybenzene
- Monophenol
- NCI-C50124
- Oxybenzene
- Phenic Acid
- Phenyl Alcohol
- Phenyl Hydrate
- Phenyl Hydroxide
- Phenylic Acid
- Phenylic Alcohol

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United States Environmental Protection Agency
Office of Water
Office of Science and Technology
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June 2015

Update of Human Health Ambient Water Quality Criteria:

Pyrene
129-00-0

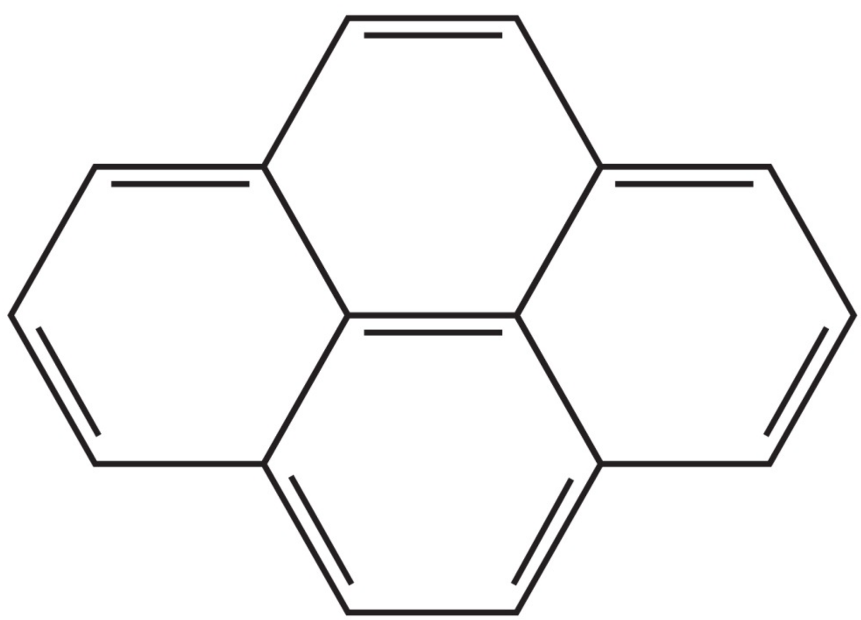

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for pyrene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC = ambient water quality criteria

toxicity value = RfD x RSC (mg/kg-d) for noncarcinogenic effects
or
10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]

RSC = relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)

BW = body weight

DI = drinking water intake

$\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4

FCR_i = fish consumption rate for aquatic TLs 2, 3, and 4

BAF_i = bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 860 L/kg for pyrene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for pyrene. Based on the characteristics this chemical, EPA selected Procedure 2 for deriving a national BAF value. Pyrene has the following characteristics:

- Nonionic organic chemical (USDHHS 2012)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log K_{ow} = 4.88 (ATSDR 1995)
- High metabolism (NOAA n.d.)

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for all three TLs (2, 3, and 4). Therefore, EPA used the BCF method estimate for the reported TLs by calculating the geometric mean of the TL2 and TL3 BAF values available for pyrene (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 860 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for pyrene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 3×10^{-2} mg/kg-d (0.03 mg/kg-d) for pyrene based on a 1989 EPA IRIS assessment (USEPA 1989a). EPA's IRIS program identified a study by EPA (USEPA 1989b) as the critical study and renal tubular pathology and decreased kidney weights as the critical effects in mice orally exposed to pyrene. The subchronic study has a NOAEL of 75 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 3000 to account for interspecies extrapolation (10), intraspecies variation (10), subchronic-to-chronic study extrapolation (10), and database deficiency (3) (USEPA 1989a).

EPA identified no other RfD sources through the systematic search described in section 5.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), pyrene is classified as Group D, "not classifiable as to human carcinogenicity" (USEPA 1990).

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Pyrene is a medium molecular weight polycyclic aromatic hydrocarbon (PAH) used to make dyes, plastics, and pesticides. It has also been used to make benzo(a)pyrene (ATSDR 1995; USDHHS 2012). Pyrene is not a registered pesticide (USEPA 2015c). Humans can be exposed to pyrene and other PAHs via several sources including air, food, and fish and shellfish (USDHHS 2012).

The most common route of exposure to pyrene is inhalation of exhaust from motor vehicles, especially in urban areas with heavy traffic, or near industrial sources (ATSDR 1995). Inhalation exposure is also likely from other products of incomplete combustion, such as emissions from cigarette smoke and coal-, oil-, and wood-burning stoves and furnaces (USDHHS 2012). If released to air, pyrene will exist in both the vapor and particulate phases in the atmosphere and, thus, could be maintained in the air for prolonged periods of time (USDHHS 2012). Pyrene is not listed as a hazardous air pollutant (USEPA 2013), and EPA's Toxic Release Inventory did not report release data for it in 2013 (USEPA 2015g). Given the anthropogenic sources of PAHs and pyrene's physical properties, air is a potentially significant source of exposure to pyrene.

Food is also a significant source of PAHs such as pyrene. Pyrene has been detected in unprocessed cereal, potatoes, grain, flour, bread, vegetables, fruits, and refined fats and oils and is often associated with grilled food (ATSDR 1995; USDHHS 2012). Additional information regarding concentrations of pyrene in food could not be identified. Thus, ingestion of food is a potentially significant source of exposure to pyrene.

The log K_{ow} for pyrene is 4.88 (ATSDR 1995). The national-level BAF estimate for pyrene is 860 L/kg, which indicates that it has a moderate potential for bioaccumulation (USEPA 2011b). NOAA's Mussel Watch Survey has detected pyrene in ocean fish and shellfish (NOAA 2014); it was detected in less than 1 percent of fish tissue samples collected in EPA's National Lake Fish Tissue Study (USEPA 2009c). Thus, available information as well as bioaccumulation potential of pyrene indicate that ingestion of fish and shellfish is a potentially significant source of exposure to it.

PAHs have been detected in finished drinking water (ATSDR 1995); however, recent information regarding concentrations of pyrene in drinking water could not be identified. Pyrene is not regulated under the Safe Drinking Water Act (USEPA 2014c), and it was not on EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). No Standard of Quality for bottled water for pyrene has been established (IBWA 2012). Therefore, the potential exposure to pyrene from ingestion of drinking water is unknown.

In summary, based on the physical properties and available exposure information for pyrene, air, non-fish food, and fish and shellfish are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for pyrene.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to pyrene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Pyrene

Input Parameter	Value
RfD	0.03 mg/kg-d
CSF	No data
RSC	0.20
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	860 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.03\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + (0.022\ kg/d \times 860\ L/kg)}$$

$$= 22.5\ \mu g/L$$

$$= 20\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.03\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.022\ kg/d \times 860\ L/kg)}$$

$$= 25.4\ \mu g/L$$

$$= 30\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for pyrene using a noncarcinogenic toxicity endpoint. The updated human health AWQC for pyrene are **20 µg/L** for consumption of water and organisms and **30 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Pyrene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	830 µg/L	**20 µg/L**
Organism Only	4,000 µg/L	**30 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to pyrene from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for pyrene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 860 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 30 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the

water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 1,322 L/kg
TL3 = 1,058 L/kg
TL4 = 784.9 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA retained an RfD of 0.03 mg/kg-d for pyrene based on a 1989 EPA IRIS assessment (USEPA 1989a; USEPA 2002c). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for pyrene and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of pyrene in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- Pyrene (CAS Number 129-00-0)
- Benzo(def)phenanthrene
- HSDB 4023
- NSC 17534
- Pyren [German]
- Beta-pyrene

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-063
June 2015

Update of Human Health Ambient Water Quality Criteria:

Tetrachloroethylene (Perchloroethylene) 127-18-4

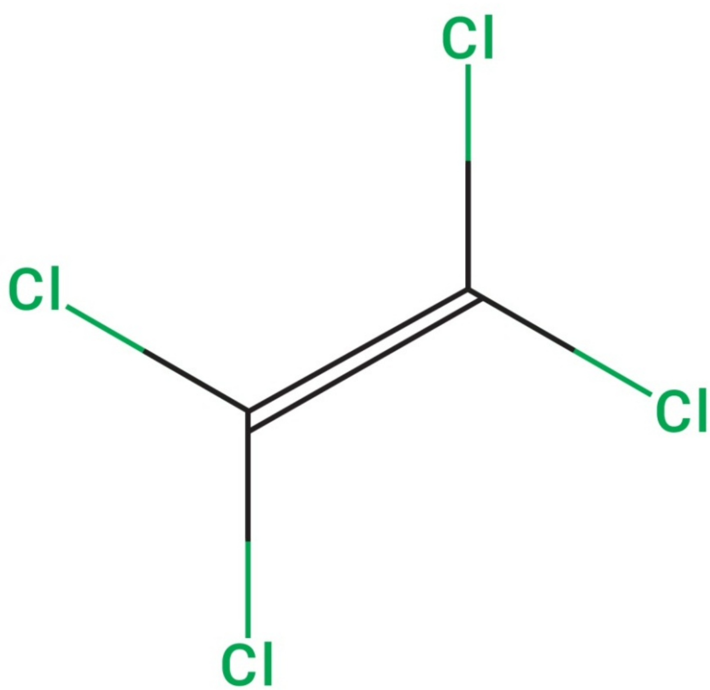

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for tetrachloroethylene (perchloroethylene) to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 49 L/kg (TL2), 66 L/kg (TL3), and 76 L/kg (TL4) for tetrachloroethylene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for tetrachloroethylene. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Tetrachloroethylene has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 3.40 (USDHHS 2014)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 49 L/kg
TL3 = 66 L/kg
TL4 = 76 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for tetrachloroethylene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 6×10^{-3} mg/kg-d (0.006 mg/kg-d) for tetrachloroethylene based on a 2012 EPA IRIS assessment (USEPA 2012a). EPA's IRIS program identified studies by Cavalleri et al. (1994) and Echeverria et al. (1995) as the critical studies and the development of neurological effects (i.e., color vision changes and cognitive and reaction time changes) as the critical effects in occupationally exposed humans (USEPA 2012a). The oral exposure point of departure (POD) equivalent to the continuous inhalation exposure NOAELs or LOAELs is estimated via physiologically based pharmacokinetic (PBPK) modeling. The resulting PODs are 2.6 mg/kg-d (Cavalleri et al. 1994) and 9.7 mg/kg-d (Echeverria et al. 1995). In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 1000 to account for intraspecies differences (10), LOAEL to NOAEL extrapolation (10), and database uncertainty (10) to each of the PODs. The candidate RfDs from these studies range from 2.6×10^{-3} to 9.7×10^{-3} mg/kg-d. The final RfD was selected as the midpoint of this range (0.006 mg/kg-d).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 2014 ATSDR draft assessment (ATSDR 2014) and a 2001 California EPA assessment (CalEPA 2001). Based on the selection process described in section 5, the IRIS RfD is preferred for use in AWQC development at this time. The ATSDR assessment (ATSDR 2014) is more current than EPA's 2012 IRIS assessment, but it is a draft version and undergoing public comment[g]. Thus, the 2012 EPA IRIS assessment is the most current RfD source.

5.2.2 Cancer Slope Factor

Under the 2005 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 2005), tetrachloroethylene is "likely to be carcinogenic to humans" by all routes of exposure (USEPA 2012b).

EPA selected a CSF of 2.1×10^{-3} per mg/kg-d (0.0021 per mg/kg-d) for tetrachloroethylene based on a 2012 EPA IRIS assessment (USEPA 2012b). EPA's IRIS program calculated the CSF using a principal study by the Japan Industrial Safety Association (JISA 1993) based on development of hepatocellular adenomas or carcinomas in male mice through inhalation exposure to tetrachloroethylene (USEPA 2012b). The oral CSF is developed from inhalation data because the only available oral bioassay had several limitations for extrapolating to lifetime risk in humans. Route-to-route extrapolation from the inhalation PODs developed from the JISA study was carried out using a harmonized PBPK model.

EPA identified one other CSF source through the systematic search described in section 5: a 2001 California EPA assessment (CalEPA 2001). Based on the selection process described in section 5, the 2012 IRIS CSF is preferred for use in AWQC development at this time. The 2012 EPA IRIS assessment is the most current CSF source.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

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[g] ATSDR's draft chronic-duration oral MRL for tetrachloroethylene is 0.008 mg/kg-d (ATSDR 2014).

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to tetrachloroethylene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Tetrachloroethylene

Input Parameter		Value
RfD		0.006 mg/kg-d
CSF		0.0021 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	49 L/kg
	TL3	66 L/kg
	TL4	76 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.006 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 49 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 66 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 76 \text{ L/kg}))}$$

$$= 25.8\ \mu g/L$$

$$= 30\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d] × RSC) × BW (kg) × 1,000 } (\mu g/mg)}{\sum_{i=2}^{4} (FCR_i \text{ (kg/d)} \times BAF_i \text{ (L/kg)})}$$

$$= \frac{0.006 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 49 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 66 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 76 \text{ L/kg})}$$

$$= 72.3\ \mu g/L$$

$$= 70\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d] × BW (kg) × 1,000 } (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (FCR_i \text{ (kg/d)} \times BAF_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.0021) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 49 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 66 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 76 \text{ L/kg}))}$$

$$= 10.22\ \mu g/L$$

$$= 10\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d] × BW (kg) × 1,000 } (\mu g/mg)}{\sum_{i=2}^{4} (FCR_i \text{ (kg/d)} \times BAF_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.0021) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 49 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 66 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 76 \text{ L/kg})}$$

$$= 28.69\ \mu g/L$$

$$= 29\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for tetrachloroethylene using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for tetrachloroethylene are **30 µg/L** for consumption of water and organisms and **70 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for tetrachloroethylene are **10 µg/L** for consumption of water and organisms and **29 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of tetrachloroethylene, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Tetrachloroethylene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.69 µg/L	**10 µg/L**
Organism Only	3.3 µg/L	**29 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to tetrachloroethylene at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for tetrachloroethylene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a

contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 49, 66, and 76 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 30.6 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012c) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 54.22 L/kg
TL3 = 52.97 L/kg
TL4 = 46.04 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.006 mg/kg-d for tetrachloroethylene based on a 2012 EPA IRIS assessment (USEPA 2012a). EPA used the RfD of 0.006 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of tetrachloroethylene in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.0021 per mg/kg-d for tetrachloroethylene based on a 2012 EPA IRIS assessment (USEPA 2012b). This CSF replaces the previous value of 0.0398 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.0021 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, a decrease in the CSF in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Tetrachloroethylene (CAS Number 127-18-4)
- Ankilostin
- Antisal 1
- Antisol 1
- Carbon bichloride
- Carbon dichloride
- Czterochloroetylen
- Dee-Solv
- Didakene
- Didokene
- Dowclene EC
- Dow-Per
- ENT 1,860
- Ethene, tetrachloro-
- Ethylene tetrachloride
- Ethylene, tetrachloro-
- Fedal-Un
- NCI-C04580
- Nema
- PCE
- PER
- Perawin
- PERC
- Perchloorethyleen, per
- Perchlor

- Perchloraethylen, per
- Perchlorethylene
- Perchlorethylene, per
- Perchloroethylene
- Perclene
- Percloroetilene
- Percosolv
- Percosolve
- PERK
- Perklone
- Persec
- Tetlen
- Tetracap
- Tetrachlooretheen
- Tetrachloraethen
- Tetrachloroethene
- Tetrachloroethylene
- 1,1,2,2-Tetrachloroethylene
- Tetracloroetene
- Tetraguer
- Tetraleno
- Tetralex
- Tetravec
- Tetroguer
- Tetropil

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Update of Human Health Ambient Water Quality Criteria:

Toluene
108-88-3

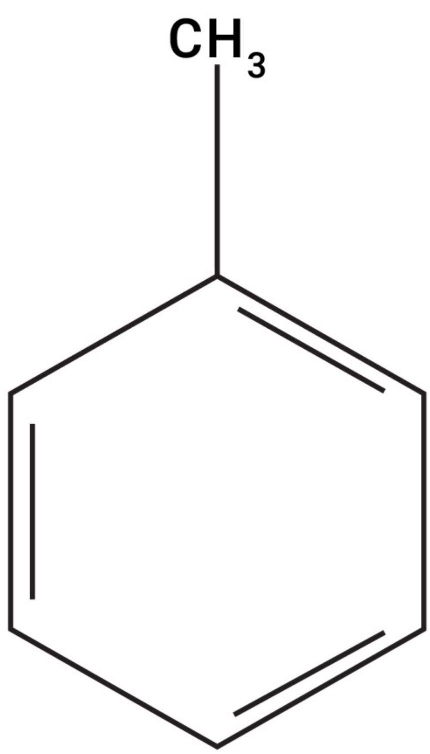

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for toluene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 11 L/kg (TL2), 15 L/kg (TL3), and 17 L/kg (TL4) for toluene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for toluene. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Toluene has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 2.72$ (ATSDR 2000)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 11 L/kg
TL3 = 15 L/kg
TL4 = 17 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for toluene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015a)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD[g] of 9.7×10^{-3} mg/kg-d (0.0097 mg/kg-d) for toluene based on a 2015 Health Canada assessment (HC 2015b). Health Canada identified studies by Seeber et al. (2004; 2005) as the critical studies and the development of various neurological symptoms as the critical effects in humans occupationally exposed to toluene (HC 2015b). The studies had NOAEL of 26 ppm (98 mg/m^3). Health Canada used a physiologically based pharmacokinetic (PBPK) model to derive the corresponding human external dose of 0.097 mg/kg-d. In deriving the RfD, Health Canada applied a composite uncertainty factor of 10 to account for intraspecies variation (10) (HC 2015b).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.
[g] Health Canada refers to this value as a Tolerable Daily Intake (HC 2015b).

EPA identified three other RfD sources through the systematic search described in section 5: a 2005 EPA IRIS assessment (USEPA 2005a), a 2000 ATSDR assessment (ATSDR 2000), and a 1999 California EPA assessment (CalEPA 1999). Based on the selection process described in section 5, the Health Canada RfD is preferred for use in AWQC development at this time. The 2015 Health Canada assessment is the most current available RfD source and is based on more recent critical studies (Seeber et al. 2004; Seeber et al. 2005) than is the IRIS assessment (NTP 1990).

5.2.2 Cancer Slope Factor

Under the 2005 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 2005b), there is "inadequate information to assess the carcinogenic potential" of toluene (USEPA 2005b).

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).

- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Toluene is an organic solvent used in the production of gasoline, paints, paint thinners, fingernail polish, lacquers, adhesives, and rubber, and in some printing and leather tanning processes. Toluene naturally occurs in crude oil and in the tolu tree (ATSDR 2000). ATSDR (2000) reports that inhalation might be the principal route of exposure to toluene.

The vapor pressure of toluene (28.4 mm Hg at 25 °C) indicates that volatilization is an important fate process for this chemical (ATSDR 2000). EPA lists it as a hazardous air pollutant (USEPA 2013). Recent data from EPA's Toxic Release Inventory indicate that over 920,000 pounds of toluene were released to the air in 2013 (USEPA 2015g). Thus, based on the physical properties and prevalence, air is a potentially significant source of exposure to toluene.

Toluene has also been detected in drinking water (ATSDR 2000). Toluene is regulated under the Safe Drinking Water Act and EPA's drinking water standard (maximum contaminant level) is 1,000 µg/L (USEPA 2014c). Toluene was not a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). The Standard of Quality for toluene in bottled water is 1,000 µg/L (IBWA 2012). Therefore, ingestion of drinking water is a potentially significant source of exposure to toluene.

Measurements of toluene in food are not generally reported, but it has been measured in eggs stored in polystyrene containers (ATSDR 2000). Additional comprehensive information regarding concentrations of toluene in food could not be identified. Thus, based on available information, exposure to toluene from ingestion of food is possible.

The log K_{ow} for toluene is 2.72 (ATSDR 2000). The national-level BAF estimates for toluene range from 11 L/kg (TL2) to 17 L/kg (TL4), which indicates toluene has a low potential for bioaccumulation (USEPA 2011b). Toluene was not a target chemical in EPA's National Lake Fish Tissue Study (USEPA 2009c) or in NOAA's Mussel Watch Survey (NOAA 2014). Recent exposure information regarding concentrations of toluene in fish and shellfish is lacking. Thus, based on its low potential for bioaccumulation, exposure to this chemical from ingestion of fish and shellfish is not considered likely.

In summary, based on the physical properties and available exposure information for toluene, air and drinking water are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for toluene.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to toluene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Toluene

Input Parameter		Value
RfD		0.0097 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	11 L/kg
	TL3	15 L/kg
	TL4	17 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.0097\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{2.4\ \text{L/d} + ((0.0076\ \text{kg/d} \times 11\ \text{L/kg}) + (0.0086\ \text{kg/d} \times 15\ \text{L/kg}) + (0.0051\ \text{kg/d} \times 17\ \text{L/kg}))}$$

= 57.496 µg/L

= 57 µg/L (rounded)

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.0097\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{(0.0076\ \text{kg/d} \times 11\ \text{L/kg}) + (0.0086\ \text{kg/d} \times 15\ \text{L/kg}) + (0.0051\ \text{kg/d} \times 17\ \text{L/kg})}$$

= 518.5 µg/L

= 520 µg/L (rounded)

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for toluene using a noncarcinogenic toxicity endpoint. The updated human health AWQC for toluene are **57 µg/L** for consumption of water and organisms and **520 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2003b).

Table 2. Summary of EPA's Previously Recommended (2003) and Updated (2015) Human Health AWQC for Toluene

	2003 Human Health AWQC	2015 Human Health AWQC
Water and Organism	1,300 µg/L	**57 µg/L**
Organism Only	15,000 µg/L	**520 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to toluene from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for toluene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 11, 15, and 17 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 10.7 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the

water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 27.6 L/kg
TL3 = 30.14 L/kg
TL4 = 37.79 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD (Tolerable Daily Intake) of 0.0097 mg/kg-d for toluene based on a 2015 Health Canada assessment (HC 2015b). This RfD replaces the previous value of 0.2 mg/kg-d (USEPA 2003b). EPA used the RfD of 0.0097 mg/kg-d to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, a decrease in the RfD in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

Cancer Slope Factor

EPA did not select a CSF for toluene and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of toluene in its previous criteria update (USEPA 2003b).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. This is the same RSC used in the previous AWQC (USEPA 2003b).

9 Chemical Name and Synonyms

- Toluene (CAS Number 108-88-3)
- Antisal 1a
- Benzene, Methyl
- Methacide
- Methylbenzene
- Methylbenzol
- Monomethylbenzene
- NCI-C07272
- Phenylmethane
- RCRA Waste Number U220
- Tolueen
- Toluen
- Toluol
- Toluolo
- Tolu-Sol
- UN 1294

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-065
June 2015

Update of Human Health Ambient Water Quality Criteria:

Toxaphene
8001-35-2

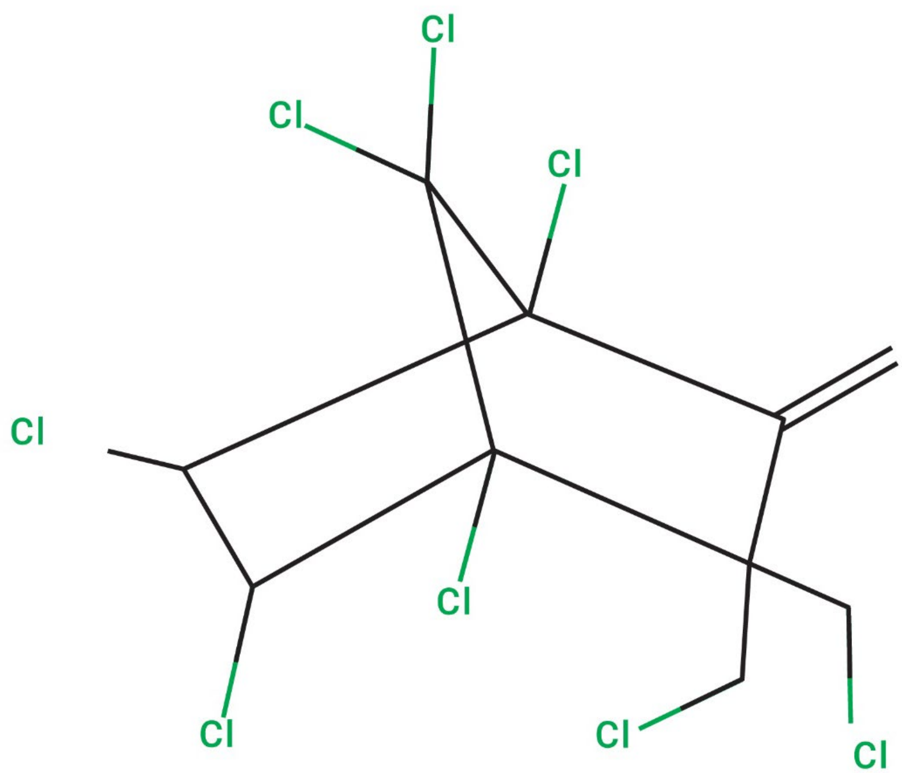

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for toxaphene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 1,700 L/kg (TL2), 6,600 L/kg (TL3), and 6,300 L/kg (TL4) for toxaphene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for toxaphene. Based on the characteristics of this chemical, EPA selected Procedure 1 for deriving a national BAF value. Toxaphene has the following characteristics:

- Nonionic organic chemical (USDHHS 2012)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log K_{ow} = 4.97 (ATSDR 2014)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 1,700 L/kg
TL3 = 6,600 L/kg
TL4 = 6,300 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for toxaphene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 3.5×10^{-4} mg/kg-d (0.00035 mg/kg-d) for toxaphene based on a 2003 California EPA assessment (CalEPA 2003). CalEPA identified a study by Chu et al. (1986) as the critical study and increased hepatic microsomal enzymatic activities as the critical effect in rats orally exposed to toxaphene (CalEPA 2003). The subchronic study had a NOAEL 0.35 mg/kg-d. In deriving the RfD, CalEPA applied a composite uncertainty factor of 1000 to account for interspecies extrapolation (10), intraspecies variation (10), and subchronic-to-chronic study extrapolation (10).

EPA identified two other RfD sources through the systematic search described in section 5: a 1996 EPA Office of Water (OW) assessment (USEPA 1996) and a 2014 ATSDR assessment (ATSDR 2014). Based on the selection process described in section 5, the 2003 CalEPA RfD is

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

preferred for use in AWQC development at this time. The CalEPA assessment is the most current available RfD source. The 2010 ATSDR assessment does not include the relevant (chronic oral) toxicity value. The OW RfD is based on the same principal study (Chu et al. 1986) and is numerically the same as the CalEPA RfD (USEPA 1996).

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), toxaphene is classified as Group B2, "probable human carcinogen" (USEPA 1987; USEPA 1996).

EPA selected a CSF of 1.1 per mg/kg-d for toxaphene based on a 1987 EPA IRIS assessment (USEPA 1987). EPA's IRIS program identified a study by Litton Bionetics (1978) as the critical study and development of hepatocellular carcinomas and neoplastic nodules as the critical effects in mice orally exposed to toxaphene (USEPA 1987).

In 2002, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the cancer assessment for toxaphene and identified one or more significant new studies; however, EPA's IRIS program has not reassessed this chemical.

EPA identified one other CSF source through the systematic search described in section 5: a 2003 California EPA assessment (CalEPA 2003). Based on the selection process described in section 5, the 1987 IRIS CSF is preferred for use in AWQC development at this time. The 2003 CalEPA assessment is based on the same principal study (Litton Bionetics 1978) and is numerically the same[g] as the EPA IRIS CSF.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical

[g] The CalEPA CSF is actually 1.2 per mg/kg-d; however, as the method to derive the CSF was the same between the two assessments, this slight difference from the IRIS CSF (1.1 per mg/kg-d) is likely due to rounding differences.

properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to toxaphene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Toxaphene

Input Parameter		Value
RfD		0.00035 mg/kg-d
CSF		1.1 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	1,700 L/kg
	TL3	6,600 L/kg
	TL4	6,300 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.00035\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 1{,}700\ L/kg) + (0.0086\ kg/d \times 6{,}600\ L/kg) + (0.0051\ kg/d \times 6{,}300\ L/kg))}$$

$$= 0.05374\ \mu g/L$$

$$= 0.054\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d] × RSC) × BW (kg) × 1,000 (µg/mg)}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.00035 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000 \text{ µg/mg}}{(0.0076 \text{ kg/d} \times 1{,}700 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 6{,}600 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 6{,}300 \text{ L/kg})}$$

= 0.05500 µg/L

= 0.055 µg/L (rounded)

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d] × BW (kg) × 1,000 (µg/mg)}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 1.1) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \text{ µg/mg}}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 1{,}700 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 6{,}600 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 6{,}300 \text{ L/kg}))}$$

= 0.0006979 µg/L

= 0.00070 µg/L (rounded)

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d] × BW (kg) × 1,000 (µg/mg)}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 1.1) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \text{ µg/mg}}{(0.0076 \text{ kg/d} \times 1{,}700 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 6{,}600 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 6{,}300 \text{ L/kg})}$$

= 0.0007143 µg/L

= 0.00071 µg/L (rounded)

7.3 AWQC Summary

EPA derived the AWQC for toxaphene using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for toxaphene are **0.054 µg/L** for consumption of water and organisms and **0.055 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for toxaphene are **0.00070 µg/L** for consumption of water and organisms and **0.00071 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of toxaphene, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Toxaphene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.00028 µg/L	**0.00070 µg/L**
Organism Only	0.00028 µg/L	**0.00071 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to toxaphene at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for toxaphene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a

contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 1,700, 6,600, and 6,300 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 13,100 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 117,800 L/kg
TL3 = 163,300 L/kg
TL4 = 278,100 L/kg

Assuming all other input parameters remain constant, lower BAFs or BCFs result in higher AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish decreases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure increases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.00035 mg/kg-d for toxaphene based on a 2003 California EPA assessment (CalEPA 2003). EPA used the RfD of 0.00035 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of toxaphene in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA retained a CSF of 1.1 per mg/kg-d for toxaphene based on a 1987 EPA IRIS assessment (USEPA 1987; USEPA 2002c). EPA used this CSF to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the CSF in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Toxaphene (CAS Number 8001-35-2)
- Alltox
- Chlorinated-camphene
- Geniphene
- Penphene
- Phenacide
- Toxadust
- Toxakil

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-066
June 2015

Update of Human Health Ambient Water Quality Criteria:

Trichloroethylene (TCE) 79-01-6

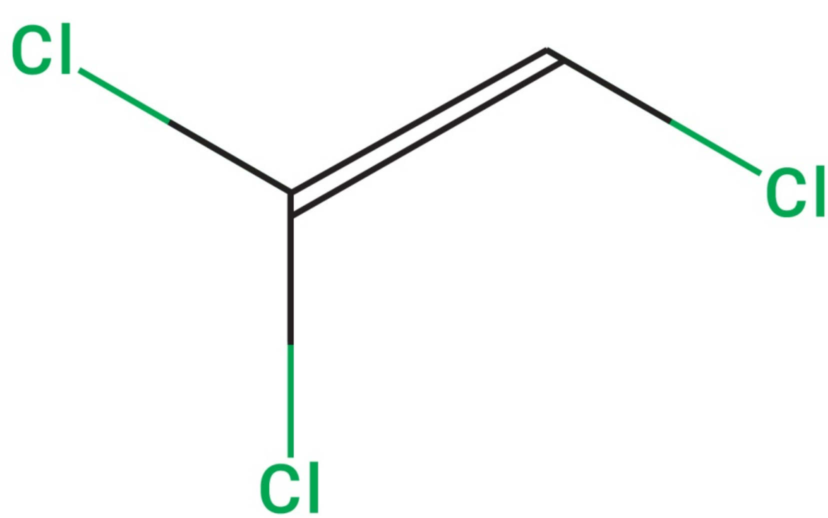

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for trichloroethylene (TCE) to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 8.7 L/kg (TL2), 12 L/kg (TL3), and 13 L/kg (TL4) for TCE. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for TCE. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. TCE has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 2.61$ (USDHHS 2014)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 8.7 L/kg
TL3 = 12 L/kg
TL4 = 13 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for TCE. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, ATSDR (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 5×10^{-4} mg/kg-d (0.0005 mg/kg-d) for TCE based on a 2011 EPA IRIS assessment (USEPA 2011b). EPA's IRIS program developed multiple candidate RfDs ranging 0.0003–0.0008 mg-kg/d based on three principal studies by Keil et al. (2009), Peden-Adams et al. (2006), and Johnson et al. (2003) and two supporting studies from Woolhiser et al. (2006) and the National Toxicology Program (NTP 1988). In deriving the RfDs, EPA's IRIS program applied uncertainty factors[g] as follows:

- Keil et al. (2009): Composite uncertainty factor 100; extrapolation from LOAEL rather than NOAEL (10), interspecies extrapolation (3), and intraspecies variation (3).
- Peden-Adams et al. (2006): Composite uncertainty factor 1000; extrapolation from LOAEL rather than NOAEL (10), interspecies extrapolation (10), and intraspecies variation (10).
- Johnson et al. (2003): Composite uncertainty factor 10; interspecies extrapolation (3) and intraspecies variation (3).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.
[g] Note: Uncertainty factors of 1 are not included in this summary.

- National Toxicology Program (NTP 1988): Composite uncertainty factor 10; interspecies extrapolation (3) and intraspecies variation (3).
- Woolhiser et al. (2006): Composite uncertainty factor 10; interspecies extrapolation (3) and intraspecies variation (3).

The RfD of 0.0005 mg/kg-d is based on the critical effects of heart malformations (rats), adult immunological effects (mice), and developmental immunotoxicity (mice), all from oral studies (USEPA 2011b). This RfD is further supported by results from an oral study for the effect of toxic nephropathy (rats) and route-to-route extrapolated results from an inhalation study for the effect of increased kidney weight (rats). The RfD (0.0005 mg/kg-d) reflects the midpoint among the candidate RfDs for the critical effects—0.0004 mg/kg-d for developmental immunotoxicity in mice and 0.0005 mg/kg-d for both heart malformations in rats and decreased thymus weights in mice, and is within 25 percent of each candidate RfD (USEPA 2011b).

EPA identified three other RfD sources through the systematic search described in section 5: a 2014 EPA Office of Pollution Prevention and Toxics (OPPT) assessment (USEPA 2014c), a 2014 draft ATSDR assessment (ATSDR 2014), and a 2009 California EPA assessment (CalEPA 2009). Based on the selection process described in section 5, the 2011 EPA IRIS RfD is preferred for use in AWQC development at this time. The assessments from OPPT and draft ATSDR assessments were published more recently; however, they are based on the same principal studies and are numerically the same as the 2011 EPA IRIS RfD.

5.2.2 Cancer Slope Factor

Under the 2005 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 2005a), TCE is characterized as “carcinogenic to humans” by all routes of exposure (USEPA 2011c). EPA’s IRIS program concluded, by a weight-of-evidence evaluation, that TCE is carcinogenic by a mutagenic mode of action for induction of kidney tumors (USEPA 2011c).

EPA selected a CSF of 5×10^{-2} per mg/kg-d (0.05 per mg/kg-d) for TCE based on a 2011 EPA IRIS assessment (USEPA 2011c). EPA’s IRIS program identified Charbotel et al. (2006) as the critical study and renal cell carcinoma as the critical effect (USEPA 2011c). The oral slope factor of 5×10^{-2} per mg/kg-d, calculated from data from adult exposure, does not reflect presumed increased early-life susceptibility[h] to kidney tumors for this chemical (USEPA 2011c).

[h] The 2000 Methodology (USEPA 2000a) does not discuss application of age-dependent adjustment factors (ADAFs) because it was published prior to the 2005 EPA *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (“*Supplemental Guidance*”) (USEPA 2005b). Generally, the application of ADAFs is recommended when assessing cancer risks for a carcinogen with a mutagenic mode of action. However, because the ADAF adjustment for trichloroethylene applies only to the kidney cancer component of the total cancer risk estimate, the impact of the adjustment on full lifetime risk is minimal and the adjustment might reasonably be omitted. Nonetheless, for exposure scenarios with increasing proportions of exposure during early life, the impact of the ADAF adjustment becomes more pronounced and the importance of applying the ADAFs increases (USEPA 2011b; USEPA 2011c). For more information, see the IRIS toxicological review (USEPA 2011b; USEPA 2011c) or EPA’s *Supplemental Guidance* (USEPA 2005b).

EPA identified two other CSF sources through the systematic search described in section 5: a 2014 EPA Office of Pollution Prevention and Toxics (OPPT) assessment (USEPA 2014c) and a 2009 California EPA assessment (CalEPA 2009). Based on the selection process described in section 5, the 2011 EPA IRIS RfD is preferred for use in AWQC development at this time. The assessment from OPPT was published more recently; however, it is based on the same principal studies and is numerically the same as the 2011 EPA IRIS CSF.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- Food and Drug Administration (FDA) Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- National Oceanic and Atmospheric Administration (NOAA) Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to TCE from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for TCE

Input Parameter		Value
RfD		0.0005 mg/kg-d
CSF		0.05 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	8.7 L/kg
	TL3	12 L/kg
	TL4	13 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.0005\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 8.7\ L/kg) + (0.0086\ kg/d \times 12\ L/kg) + (0.0051\ kg/d \times 13\ L/kg))}$$

$= 3.04\ \mu g/L$

$= 3\ \mu g/L$ (rounded)

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.0005\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 8.7\ L/kg) + (0.0086\ kg/d \times 12\ L/kg) + (0.0051\ kg/d \times 13\ L/kg)}$$

$= 34.0\ \mu g/L$

$= 30\ \mu g/L$ (rounded)

7.2 AWQC for Carcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.05) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 8.7 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 12 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 13 \text{ L/kg}))}$$

$$= 0.607\ \mu g/L$$

$$= 0.6\ \mu g/L \text{ (rounded)}$$

<u>For consumption of organisms only:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.05) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 8.7 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 12 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 13 \text{ L/kg})}$$

$$= 6.79\ \mu g/L$$

$$= 7\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for TCE using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for TCE are **3 µg/L** for consumption of water and organisms and **30 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for TCE are **0.6 µg/L** for consumption of water and organisms and **7 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of TCE, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for TCE

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	2.5 µg/L	**0.6 µg/L**
Organism Only	30 µg/L	**7 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to TCE at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for TCE take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 8.7, 12, and 13 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 10.6 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 15.43 L/kg
TL3 = 17.18 L/kg
TL4 = 23.7 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.0005 mg/kg-d for TCE based on a 2011 EPA IRIS assessment (USEPA 2011b). EPA used the RfD of 0.0005 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of TCE in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.05 per mg/kg-d for TCE based on a 2011 EPA IRIS assessment (USEPA 2011c). This CSF replaces the previous value of 0.0126 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.05 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, an increase in the CSF in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

<u>Relative Source Contribution</u>

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Trichloroethylene (CAS Number 79-01-6)
- Acetylene trichloride
- AI3-00052
- Algylen
- Anamenth
- Benzinol
- Caswell No 876
- Cecolene
- Chlorilen
- 1-Chloro-2,2-dichloroethylene
- Chlorylea, Chorylen, CirCosolv, Crawhaspol, Dow-Tri, Dukeron, Per-A-Clor, Triad, Trial, TRI-Plus M, Vitran
- Densinfluat
- 1,1-Dichloro-2-chloroethylene
- Pesticide Code: 081202
- EPA Pesticide Chemical Code 081202
- Ethene, trichloro-
- Ethinyl trichloride
- Ethylene trichloride
- Ethylene, trichloro-
- Fleck-Flip
- Flock Flip
- Fluate
- Germalgene
- Lanadin
- Lethurin
- Narcogen
- Narkosoid
- NCI-C04546
- NIALK
- NSC 389
- Perm-A-Chlor
- Petzinol
- Philex
- Threthylen

- Threthylene
- Trethylene
- TRI
- Triasol
- Trichloraethen (German)
- Trichloraethylen, tri (German)
- Trichloran
- Trichloren
- Trichlorethene (French)
- Trichlorethylene
- Trichlorethylene, tri (French)
- Trichloroethene
- 1,1,2-Trichloroethylene
- Triclene
- Tricloretene (Italian)
- Tricloroetilene (Italian)
- Trielin
- Trielina (Italian)
- Triklone
- Trilene
- Trimar
- Tri-Plus
- Vestro

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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June 2015

Update of Human Health Ambient Water Quality Criteria:

Vinyl Chloride
75-01-4

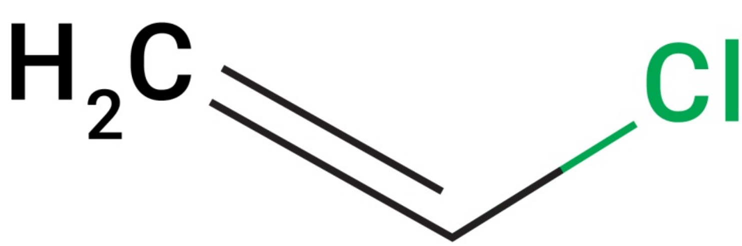

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for vinyl chloride to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC = ambient water quality criteria

toxicity value = RfD x RSC (mg/kg-d) for noncarcinogenic effects
or
10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]

RSC = relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)

BW = body weight

DI = drinking water intake

$\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4

FCR_i = fish consumption rate for aquatic TLs 2, 3, and 4

BAF_i = bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 1.4 L/kg (TL2), 1.6 L/kg (TL3), and 1.7 L/kg (TL4) for vinyl chloride. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for vinyl chloride. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Vinyl chloride has the following characteristics:

- Nonionic organic chemical (USDHHS 2013)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 1.36 (ATSDR 2006)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 1.4 L/kg
TL3 = 1.6 L/kg
TL4 = 1.7 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for vinyl chloride. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, ATSDR (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 3×10^{-3} mg/kg-d (0.003 mg/kg-d) for vinyl chloride based on a 2000 EPA IRIS assessment (USEPA 2000c). EPA identified studies by Til et al. (1983; 1991) as the critical studies and the development of liver cell polymorphism as the critical effect in rats orally exposed to vinyl chloride (USEPA 2000c). The chronic study had a NOAEL of 0.13 mg/kg-d. A physiologically based pharmacokinetic (PBPK) model was used to convert the administered animal dose to the human equivalent dose (HED); the NOAEL was 0.09 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 30 to account for intraspecies variation (10) and interspecies extrapolation (3) (USEPA 2000c).

In 2003, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the RfD for vinyl chloride and did not identify any critical new studies.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 2006 ATSDR assessment (ATSDR 2006) and a 2000 CalEPA assessment (CalEPA 2000). Based on the selection process described in section 5, the 2000 EPA IRIS RfD is preferred for use in AWQC development at this time. Both of the other assessments are based on the same principal studies as the IRIS assessment and use the same toxicity endpoint (NOAEL of 0.13 mg/kg-d) to derive an RfD.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), vinyl chloride is classified as group A, "known to be carcinogenic to humans" (USEPA 2000d). Under the 1996 EPA *Proposed Guidelines for Carcinogen Risk Assessment* (USEPA 1996), vinyl chloride is a "known human carcinogen by the inhalation route of exposure" and is also considered "highly likely to be carcinogenic by the dermal route" (USEPA 2000d).

EPA selected a CSF of 1.5 per mg/kg-d for vinyl chloride based on a 2000 EPA IRIS assessment (USEPA 2000d). The lower 95 percent confidence limit on the estimated dose associated with 10 percent extra risk (LED_{10}) was selected as the point of departure for derivation of the slope factor (USEPA 1996). EPA's IRIS program derived the CSF using a principal study by Feron et al. (1981) based on development of liver angiosarcomas, hepatocellular carcinomas, and neoplastic nodules in rats orally exposed to vinyl chloride (USEPA 2000d).

In 2003, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the cancer assessment for vinyl chloride and did not identify any critical new studies.

EPA identified one other potential CSF source through the systematic search described in section 5: a 2000 CalEPA assessment (CalEPA 2000). Based on the selection process described above, the EPA IRIS CSF is preferred for use in AWQC development at this time. The CalEPA assessment is an inhalation assessment and does not include an oral CSF.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- Food and Drug Administration (FDA) Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- National Oceanic and Atmospheric Administration (NOAA) Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to vinyl chloride from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Vinyl Chloride

Input Parameter		Value
RfD		0.003 mg/kg-d
CSF		1.5 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	1.4 L/kg
	TL3	1.6 L/kg
	TL4	1.7 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{0.003\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{2.4\ \text{L/d} + ((0.0076\ \text{kg/d} \times 1.4\ \text{L/kg}) + (0.0086\ \text{kg/d} \times 1.6\ \text{L/kg}) + (0.0051\ \text{kg/d} \times 1.7\ \text{L/kg}))}$$

$$= 19.7\ \mu g/L$$

$$= 20\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.003\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 1.4\ L/kg) + (0.0086\ kg/d \times 1.6\ L/kg) + (0.0051\ kg/d \times 1.7\ L/kg)}$$

$$= 1{,}451\ \mu g/L$$

$$= 1{,}000\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L)\ \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI } (L/d) + \sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 1.5)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 1.4\ L/kg) + (0.0086\ kg/d \times 1.6\ L/kg) + (0.0051\ kg/d \times 1.7\ L/kg))}$$

$$= 0.02192\ \mu g/L$$

$$= 0.022\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 1.5)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 1.4\ L/kg) + (0.0086\ kg/d \times 1.6\ L/kg) + (0.0051\ kg/d \times 1.7\ L/kg)}$$

$$= 1.613\ \mu g/L$$

$$= 1.6\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for vinyl chloride using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for vinyl chloride are **20 µg/L** for consumption of water and organisms and **1,000 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for vinyl chloride are **0.022 µg/L** for consumption of water and organisms and **1.6 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of vinyl chloride, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2003b).

Table 2. Summary of EPA's Previously Recommended (2003) and Updated (2015) Human Health AWQC for Vinyl Chloride

	2003 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.025 µg/L	**0.022 µg/L**
Organism Only	2.4 µg/L	**1.6 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to vinyl chloride at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for vinyl chloride take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a

contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 1.4, 1.6, and 1.7 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 1.17 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 3.343 L/kg
TL3 = 3.652 L/kg
TL4 = 4.892 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.003 mg/kg-d for vinyl chloride based on a 2000 EPA IRIS assessment (USEPA 2000c). EPA used the RfD of 0.003 mg/kg-d to derive AWQC for noncarcinogenic effects.

EPA did not derive AWQC for noncarcinogenic effects of vinyl chloride in its previous criteria update (USEPA 2003b).

Cancer Slope Factor

EPA selected a CSF of 1.5 per mg/kg-d for vinyl chloride based on a 2000 EPA IRIS assessment (USEPA 2000d). This CSF replaces the previous value of 1.4 per mg/kg-d (USEPA 2003b). EPA used the CSF of 1.5 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, an increase in the CSF in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Vinyl chloride (CAS Number 75-01-4)
- Vinyl chloride monomer
- Chloroethylene
- Chloroethene
- VC
- VCM

10 References

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-068
June 2015

Update of Human Health Ambient Water Quality Criteria:

1,1,1-Trichloroethane
71-55-6

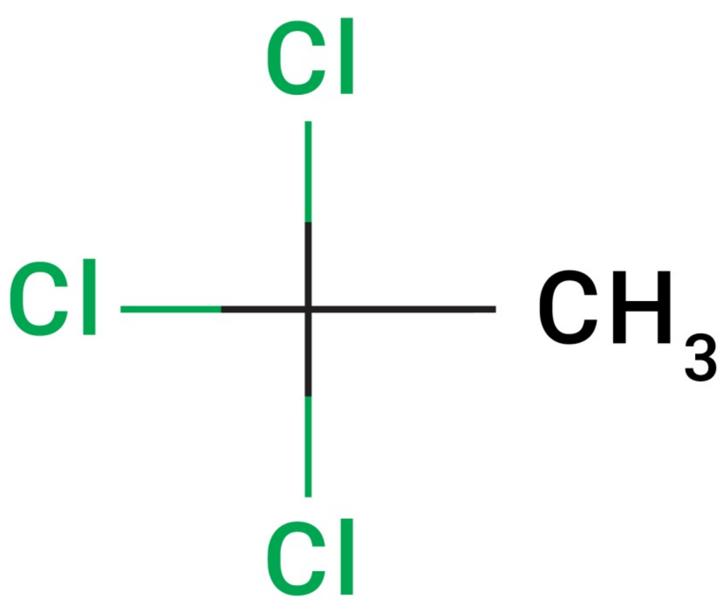

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 1,1,1-trichloroethane to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b, Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 6.9 L/kg (TL2), 9.0 L/kg (TL3), and 10 L/kg (TL4) for 1,1,1-trichloroethane. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 1,1,1-trichloroethane. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. 1,1,1-Trichloroethane has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 2.49 (ATSDR 2006)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 6.9 L/kg
TL3 = 9.0 L/kg
TL4 = 10 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 1,1,1-trichloroethane. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 2 mg/kg-d for 1,1,1-trichloroethane based on a 2007 EPA IRIS assessment (USEPA 2007a). EPA's IRIS program identified a study by the National Toxicology Program (NTP 2000) as the critical study and reduced BW as the critical effect in mice orally exposed to 1,1,1-trichloroethane (USEPA 2007a). The chronic study has a lower-bound confidence limit on the benchmark dose ($BMDL_{10}$) of 2,155 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 1000 to account for interspecies extrapolation (10), intraspecies variation (10), subchronic-to-chronic study extrapolation (3), and database deficiencies (3) (USEPA 2007a).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 2006 ATSDR assessment (ATSDR 2006) and a 2006 California EPA assessment (CalEPA 2006). Based on the selection process described in section 5, the IRIS RfD is preferred for use in AWQC development at this time. The 2007 EPA IRIS assessment is the most current RfD source.

5.2.2 Cancer Slope Factor

Under the 2005 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 2005), there is "inadequate information to assess the carcinogenic potential" of 1,1,1-trichloroethane (USEPA 2007b).

EPA identified no CSF source through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).

- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

1,1,1-Trichloroethane had many industrial and household uses prior to the phaseout of most of its uses in 2005. It was frequently used as a solvent to dissolve other substances, such as glues and paints, and it was widely used to remove oil or grease from manufactured parts. It also was an ingredient in household products, such as spot cleaners, glues, and aerosol sprays (ATSDR 2006). Domestic production and use of 1,1,1-trichloroethane were phased out in 2005, with some exemptions (e.g., use in medical devices and in aviation safety) (ATSDR 2006). Limited amounts of 1,1,1-trichlorethane (and other class I substances) may be produced domestically for potential essential-use exemptions in the United States and for export to developing countries, as specified in 42 U.S.C. section 7671c.[g] The dominant possible exposure route is inhalation, with other possible exposure routes being dermal contact and ingestion of contaminated water or food (ATSDR 2006).

[g] 42 U.S.C. section 7671c (Phase-out of production and consumption of class I substances). https://www.law.cornell.edu/uscode/text/42/7671c.

1,1,1-Trichloroethane is highly volatile and has a vapor pressure of 124 mm Hg at 20 °C (ATSDR 2006). During the time the chemical was used in many consumer products, indoor air concentrations in some instances were found to be higher than nearby outdoor air concentrations (ATSDR 2006). Recent data from EPA's Toxic Release Inventory indicate that 110,012 pounds of 1,1,1-trichlorethane were released for disposal in 2013 (USEPA 2015g). Today, 1,1,1-trichloroethane is regulated by EPA as a hazardous air pollutant. Based on its physical properties, air is a potentially significant source of exposure to 1,1,1-trichloroethane.

Surveys of U.S. drinking water indicate that there was potential for exposure to 1,1,1-trichloroethane from drinking water (ATSDR 2006; CDC 2009). 1,1,1-Trichloroethane is regulated under the Safe Drinking Water Act and EPA's drinking water standard (maximum contaminant level) is 200 µg/L (USEPA 2014c). 1,1,1-Trichloroethane has been found in surface water and groundwater drinking water sources (ATSDR 2006). The Standard of Quality for bottled water is 30 µg/L for 1,1,1-trichloroethane (IBWA 2012). Based on EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b), of more than 85,000 surface water sources of drinking water, 1,1,1-trichloroethane was detected in 0.95 percent of those sources. Of more than 289,000 ground water sources of drinking water, 1,1,1-trichloroethane was detected in 0.967 percent of those sources (USEPA 2009b). Therefore, ingestion of drinking water is a potentially significant source of exposure to 1,1,1-trichloroethane.

1,1,1-Trichloroethane has also been detected in multiple raw, processed, and prepared foods (ATSDR 2006). 1,1,1-Trichloroethane was not listed in the FDA Total Diet Study (USFDA 2005). Thus, based on detection in food, ingestion of food is a potentially significant source of exposure to 1,1,1-trichloroethane.

The log K_{ow} of 1,1,1-trichloroethane is 2.49 (ATSDR 2006). The national-level BAF estimates for 1,1,1-trichloroethane range from 6.9 L/kg (TL2) to 10 L/kg (TL4), which indicates 1,1,1-trichloroethane has a low potential for bioaccumulation (USEPA 2011b). 1,1,1-Trichloroethane was not a target chemical in EPA's National Lake Fish Tissue Study (USEPA 2009c), nor was it included in NOAA's Mussel Watch Survey (NOAA 2014). However, 1,1,1-trichloroethane has been detected in clams and oysters from Lake Pontchartrain, Louisiana, and in fish and shrimp from the Pacific Ocean (ATSDR 2006). Although historically detected in some fish and shellfish, its low potential to bioaccumulate suggests that ingestion of fish and shellfish is not a likely source of exposure to 1,1,1-trichloroethane.

In summary, based on the physical properties and available exposure information for 1,1,1-trichloroethane, air, non-fish food, and drinking water are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from these different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for 1,1,1-trichloroethane.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 1,1,1-trichloroethane from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 1,1,1-Trichloroethane

Input Parameter		Value
RfD		2 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	6.9 L/kg
	TL3	9.0 L/kg
	TL4	10 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg))}}$$

$$= \frac{2\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{2.4\ \text{L/d} + ((0.0076\ \text{kg/d} \times 6.9\ \text{L/kg}) + (0.0086\ \text{kg/d} \times 9.0\ \text{L/kg}) + (0.0051\ \text{kg/d} \times 10\ \text{L/kg}))}$$

$$= 12{,}399\ \mu g/L$$

$$= 10{,}000\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d] × RSC) × BW (kg) × 1,000 (µg/mg)}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{2 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000 \ \mu g/mg}{(0.0076 \text{ kg/d} \times 6.9 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 9.0 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 10 \text{ L/kg})}$$

$$= 176{,}952 \ \mu g/L$$

$$= 200{,}000 \ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for 1,1,1-trichloroethane using a noncarcinogenic toxicity endpoint. The updated human health AWQC for 1,1,1-trichloroethane are **10,000 µg/L** for consumption of water and organisms and **200,000 µg/L** for consumption of organisms only (Table 2).

Table 2. Summary of EPA's Previously Recommended and Updated (2015) Human Health AWQC for 1,1,1-Trichloroethane

	Previous Human Health AWQC*	2015 Human Health AWQC
Water and Organism	---	**10,000 µg/L**
Organism Only	---	**200,000 µg/L**

*AWQC for 1,1,1-trichloroethane were provided in USEPA 1986 but not in USEPA 2002c.

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to 1,1,1-trichloroethane from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for 1,1,1-trichloroethane take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 6.9, 9.0, and 10 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). For this chemical, there was no previous national recommended water quality criteria; EPA relied on a more stringent drinking water maximum contaminant level (USEPA 2002b).

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 10.55 L/kg
TL3 = 10.7 L/kg
TL4 = 10.32 L/kg

Assuming all other input parameters remain constant, lower BAFs or BCFs result in higher AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish decreases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure increases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 2 mg/kg-d for 1,1,1-trichloroethane based on a 2007 EPA IRIS assessment (USEPA 2007a). EPA used this RfD to derive AWQC for noncarcinogenic effects. The previous RfD of 0.09 mg/kg-d was withdrawn in 1991 (USEPA 2002c). EPA did not derive AWQC for noncarcinogenic effects of 1,1,1-trichloroethane in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA did not select a CSF for 1,1,1-trichloroethane and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of 1,1,1-trichloroethane in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- 1,1,1-trichloroethane (CAS Number 71-55-6)
- Aerothene MM
- Aerothene TT
- Algylen
- Baltana
- CF 2
- Chloroethane-NU
- Chloroethene
- Chloroethene NU
- Chloroform, Methyl-

- Chlorothane NU
- Chlorothene
- Chlorothene NU
- Chlorothene SM
- Chlorothene VG
- Chlortene
- Chlorten
- Chlorylen
- Dowclene LS
- Ethane, 1,1,1-Trichloro-
- Gemalgene
- Genklene LB
- ICI-CF 2
- Inhibisol
- Methylchloroform
- Methyltrichloromethane
- NCI C04626
- RCRA Hazardous Waste Number U226
- Solvent 111
- Alpha-T
- 1,1,1-TCE
- 1,1,1-TCA
- TCEA
- Trichloran
- Trichloroethane, 1,1,1-
- alpha-Trichloroethane
- Trichloromethylmethane
- Tri-ethane
- Trielene
- UN 2831

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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Update of Human Health Ambient Water Quality Criteria:

1,1,2,2-Tetrachloroethane 79-34-5

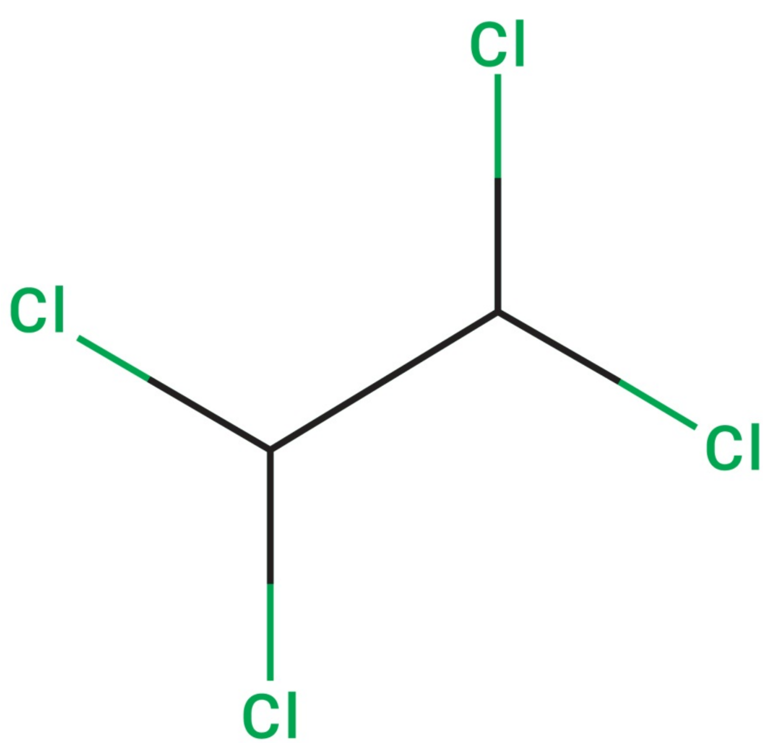

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 1,1,2,2-tetrachloroethane to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (FCR_i\ \text{(kg/d)} \times BAF_i\ \text{(L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (FCR_i\ \text{(kg/d)} \times BAF_i\ \text{(L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011), Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 5.7 L/kg (TL2), 7.4 L/kg (TL3), and 8.4 L/kg (TL4) for 1,1,2,2-tetrachloroethane. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 1,1,2,2-tetrachloroethane. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. 1,1,2,2-Tetrachloroethane has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 2.39 (ATSDR 2008)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 5.7 L/kg
TL3 = 7.4 L/kg
TL4 = 8.4 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 1,1,2,2-tetrachloroethane. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 2×10^{-2} mg/kg-d (0.02 mg/kg-d) for 1,1,2,2-tetrachloroethane based on a 2010 EPA IRIS assessment (USEPA 2010a). EPA's IRIS program identified a study by the National Toxicology Program (NTP 2004) as the critical study and an observed increase in relative liver weight as the critical effect in rats following a subchronic (14-week) gavage study (USEPA 2010a). The point of departure (POD) in this subchronic study is a lower-bound confidence limit on the benchmark dose ($BMDL_{1SD}$) of 15 mg/kg-d. EPA's IRIS program applied a composite uncertainty factor of 1000 to account for interspecies extrapolation (10), intraspecies variation (10), extrapolation from a subchronic exposure duration to a chronic exposure duration (3), and database deficiencies (3) (USEPA 2010a).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 2008 ATSDR assessment (ATSDR 2008) and a 2003 California EPA assessment (CalEPA 2003). Based on the selection process described in section 5, the IRIS RfD is preferred for use in AWQC development at this time. The 2010 EPA IRIS assessment is the most current RfD source.

5.2.2 Cancer Slope Factor

Under the 2005 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 2005), 1,1,2,2-tetrachloroethane is "likely to be carcinogenic to humans" (USEPA 2010b).

EPA selected a CSF of 2×10^{-1} per mg/kg-d (0.2 per mg/kg-d) for 1,1,2,2-tetrachloroethane based on a 2010 EPA IRIS assessment (USEPA 2010b). EPA's IRIS program calculated the CSF using a principal study by the National Cancer Institute (NCI 1978) based on development of hepatocellular carcinomas in female mice orally exposed to 1,1,2,2-tetrachloroethane (USEPA 2010b).

EPA identified one other CSF source through the systematic search described in section 5: a 2003 California EPA assessment (CalEPA 2003). Based on the selection process described in section 5, the IRIS CSF is preferred for use in AWQC development at this time. The 2010 EPA IRIS assessment is the most current CSF source.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 1,1,2,2-tetrachloroethane from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the

2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 1,1,2,2-Tetrachloroethane

Input Parameter		Value
RfD		0.02 mg/kg-d
CSF		0.2 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	5.7 L/kg
	TL3	7.4 L/kg
	TL4	8.4 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.02 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 5.7 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 7.4 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 8.4 \text{ L/kg}))}$$

$= 126\ \mu g/L$

$= 100\ \mu g/L$ (rounded)

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.02 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 5.7 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 7.4 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 8.4 \text{ L/kg})}$$

$= 2{,}136\ \mu g/L$

$= 2{,}000\ \mu g/L$ (rounded)

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.2) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 5.7 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 7.4 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 8.4 \text{ L/kg}))}$$

$$= 0.157\ \mu g/L$$

$$= 0.2\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.2) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 5.7 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 7.4 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 8.4 \text{ L/kg})}$$

$$= 2.67\ \mu g/L$$

$$= 3\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for 1,1,2,2-tetrachloroethane using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for 1,1,2,2-tetrachloroethane are **100 µg/L** for consumption of water and organisms and **2,000 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for 1,1,2,2-tetrachloroethane are **0.2 µg/L** for consumption of water and organisms and **3 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of 1,1,2,2-tetrachloroethane, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for 1,1,2,2-Tetrachloroethane

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.17 µg/L	**0.2 µg/L**
Organism Only	4.0 µg/L	**3 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to 1,1,2,2-tetrachloroethane at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular

pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for 1,1,2,2-tetrachloroethane take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 5.7, 7.4, and 8.4 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 5 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 13.72 L/kg
TL3 = 15.08 L/kg
TL4 = 19.6 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.02 mg/kg-d for 1,1,2,2-tetrachloroethane based on a 2010 EPA IRIS assessment (USEPA 2010a). EPA used the RfD of 0.02 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of 1,1,2,2-tetrachloroethane in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA retained a CSF of 0.2 per mg/kg-d for 1,1,2,2-tetrachloroethane based on a 2010 EPA IRIS assessment (USEPA 2002c; USEPA 2010b). EPA used this CSF to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the CSF in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- 1,1,2,2-Tetrachloroethane (CAS Number 79-34-5)
- Acetylene tetrachloride
- Bonoform
- Cellon
- 1,1,2,2-Czterochloroetan
- 1,1-Dichloro-2,2-dichloroethane
- Ethane, 1,1,2,2-Tetrachloro-
- NCI-C03554
- RCRA Waste Number U209
- TCE
- 1,1,2,2-Tetrachloorethaan
- 1,1,2,2-Tetrachloraethan
- Tetrachlorethane
- 1,1,2,2-Tetrachlorethane
- Tetrachloroethane, 1,1,2,2-
- sym-Tetrachloroethane
- Tetrachlorure d'acetylene
- 1,1,2,2-Tetrachloroetano
- UN 1702
- Westron

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-071
June 2015

Update of Human Health Ambient Water Quality Criteria:

1,1-Dichloroethylene
75-35-4

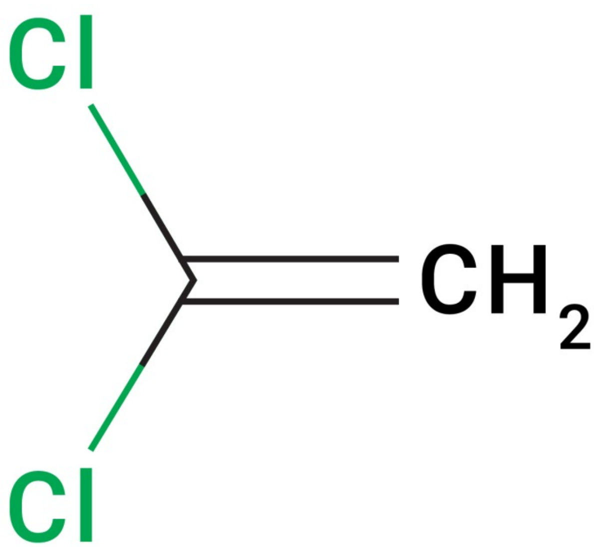

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 1,1-dichloroethylene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC = ambient water quality criteria

toxicity value = RfD x RSC (mg/kg-d) for noncarcinogenic effects
or
10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]

RSC = relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)

BW = body weight

DI = drinking water intake

$\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4

FCR_i = fish consumption rate for aquatic TLs 2, 3, and 4

BAF_i = bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 2.0 L/kg (TL2), 2.4 L/kg (TL3), and 2.6 L/kg (TL4) for 1,1-dichloroethylene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 1,1-dichloroethylene. Based on the characteristics this chemical, EPA selected Procedure 3 for deriving a national BAF value. 1,1-Dichloroethylene has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 1.73$ (ATSDR 1994)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 2.0 L/kg
TL3 = 2.4 L/kg
TL4 = 2.6 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 1,1-dichloroethylene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD for 1,1-dichloroethylene of 5×10^{-2} mg/kg-d (0.05 mg/kg-d) based on a 2002 EPA IRIS assessment (USEPA 2002c). EPA's IRIS program identified a study by Quast et al. (1983) as the critical study and the development of liver toxicity and fatty changes as the critical effect in rats orally exposed to 1,1-dichloroethylene. The chronic study had a lower-bound confidence limit on the benchmark dose ($BMDL_{10}$) of 4.6 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 100 to account for intraspecies variation (10) and interspecies extrapolation (10).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other potential RfD sources through the systematic search described in section 5: a 1999 California EPA assessment (CalEPA 1999) and a 1994 ATSDR assessment (ATSDR 1994). Based on the selection process described in section 5, the 2002 IRIS RfD is preferred for use in AWQC development at this time. The IRIS assessment is the most current RfD source.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), 1,1-dichloroethylene is classified as Group C, "possible human carcinogen" (USEPA 2002d). Under the 1999 EPA Review Draft *Guidelines for Carcinogen Risk Assessment* (USEPA 1999), 1,1-dichloroethylene exhibits "suggestive evidence" of carcinogenicity but not sufficient evidence to assess human carcinogenic potential (USEPA 2002d).

EPA identified no CSF source through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

1,1-Dichloroethylene is used to make certain plastics (e.g., packaging materials and flexible films like plastic wrap for food storage) and flame-retardant coatings for fiber and carpet backing (ATSDR 1994). Air is a potential source of exposure as it is a volatile compound and is released to air through fugitive and point source emissions.

The vapor pressure of 1,1-dichoroethylene (500 mm Hg at 20 °C) indicates that volatilization is expected to be an important fate process (ATSDR 1994). Historically, air releases served as the largest source to the environment. It is unlikely to be removed from the atmosphere by physical processes such as wet deposition or adsorption to atmospheric particulates (ATSDR 1994). Recent data from EPA's Toxic Release Inventory indicate that almost 33,000 pounds of

1,1-dichloroethylene were released to the air in 2013 (USEPA 2015g). 1,1-Dichoroethylene is listed as a hazardous air pollutant (USEPA 2013). Recent exposure information regarding concentrations of 1,1-dichloroethylene in air is lacking. Thus, based on its physical properties and prevalence, air is a potentially significant source of exposure to 1,1-dichoroethylene.

1,1-Dichloroethylene is regulated under the Safe Drinking Water Act and EPA's drinking water standard (maximum contaminant level) is 7 µg/L (USEPA 2014c). 1,1-Dichloroethylene has been detected in drinking water sources (ATSDR 1994). EPA's Six-Year Reviews also detected 1,1-dichloroethylene in surface water sources of drinking water (USEPA 2009a; USEPA 2009b). A Standard of Quality for bottled water of 2 µg/L for 1,1-dichloroethylene has been established (IBWA 2012). Therefore, based on historic detection and available information, ingestion of drinking water is a potentially significant source of exposure to 1,1-dichloroethylene.

Because 1,1-dichloroethylene is used in food packaging, food is a potential source of exposure. 1,1-Dichloroethylene has been detected as a residue in foods packaged in materials that contain this chemical (ATSDR 1994). More recent information regarding concentrations of 1,1-dichloroethylene in food could not be identified. Thus, based on exposure information, ingestion of food is a potentially significant source of exposure to 1,1-dichloroethylene.

The log K_{ow} of 1,1-dichloroethylene ranges from 1.32 to 2.13, with an average log K_{ow} of 1.73 (ATSDR 1994). The national-level BAFs for 1,1-dichloroethylene ranges from 2.0 L/kg (TL2) to 2.6 L/kg (TL4), which indicates 1,1-dichloroethylene has a low potential to bioaccumulate (USEPA 2011b). This chemical was not included in NOAA's Mussel Watch Survey (NOAA 2014) or in EPA's National Lake Fish Tissue Study (USEPA 2009c). Exposure information regarding concentrations of 1,1-dichloroethylene in fish and shellfish from inland and nearshore waters and ocean fish and shellfish is lacking. Thus, based on its low potential for bioaccumulation, exposure to this chemical from ingestion of fish and shellfish is not considered likely.

In summary, based on the physical properties and available exposure information for 1,1-dichloroethylene, air, drinking water, and non-fish food are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from these different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for 1,1-dichloroethylene.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 1,1-dichloroethylene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 1,1-Dichloroethylene

Input Parameter		Value
RfD		0.05 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	2.0 L/kg
	TL3	2.4 L/kg
	TL4	2.6 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{0.05\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{2.4\ \text{L/d} + ((0.0076\ \text{kg/d} \times 2.0\ \text{L/kg}) + (0.0086\ \text{kg/d} \times 2.4\ \text{L/kg}) + (0.0051\ \text{kg/d} \times 2.6\ \text{L/kg}))}$$

$$= 327\ \mu g/L$$

$$= 300\ \mu g/L \text{ (rounded)}$$

<u>For consumption of organisms only:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{0.05\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{(0.0076\ \text{kg/d} \times 2.0\ \text{L/kg}) + (0.0086\ \text{kg/d} \times 2.4\ \text{L/kg}) + (0.0051\ \text{kg/d} \times 2.6\ \text{L/kg})}$$

$$= 16{,}293\ \mu g/L$$

$$= 20{,}000\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for 1,1-dichloroethylene using a noncarcinogenic toxicity endpoint. The updated human health AWQC for 1,1-dichloroethylene are **300 µg/L** for consumption of water and organisms and **20,000 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2003b).

Table 2. Summary of EPA's Previously Recommended (2003) and Updated (2015) Human Health AWQC for 1,1-Dichloroethylene

	2003 Human Health AWQC	2015 Human Health AWQC
Water and Organism	330 µg/L	**300 µg/L**
Organism Only	7,100 µg/L	**20,000 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to 1,1-dichloroethylene from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for 1,1-dichloroethylene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

<u>Body Weight</u>

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

<u>Drinking Water Intake</u>

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 2.0, 2.4, and 2.6 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 5.6 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 8.186 L/kg
TL3 = 9.012 L/kg
TL4 = 11.93 L/kg

Assuming all other input parameters remain constant, lower BAFs or BCFs result in higher AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish decreases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure increases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to

representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA retained an RfD of 0.05 mg/kg-d for 1,1-dichloroethylene based on a 2002 EPA IRIS assessment (USEPA 2002c; USEPA 2003b). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for 1,1-dichloroethylene and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of 1,1-dichloroethylene in its previous criteria update (USEPA 2003b).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. This is the same RSC used in the previous AWQC (USEPA 2003b).

9 Chemical Name and Synonyms

- 1,1-dichloroethylene (CAS Number 75-35-4)
- 1,1-dichloroethene
- 1,1-DCE
- Dichloroethene, 1,1-
- Ethylene, 1,1-dichloro-
- NCI-C54262
- RCRA Waste Number U078
- Sconatex
- UN 1303
- Vinylidene chloride
- Vinylidene dichloride
- Vinylidine chloride
- Chlorure de vinylidene
- VDC

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United States Environmental Protection Agency
Office of Water
Office of Science and Technology
EPA 820-R-15-074
June 2015

Update of Human Health Ambient Water Quality Criteria:

1,2-Dichlorobenzene
95-50-1

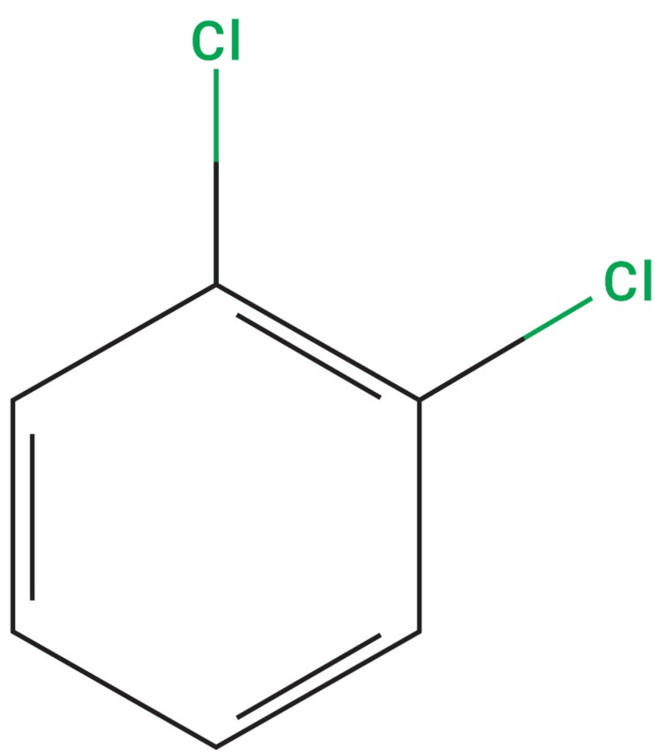

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 1,2-dichlorobenzene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC = ambient water quality criteria
toxicity value = RfD x RSC (mg/kg-d) for noncarcinogenic effects
or
10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC = relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW = body weight
DI = drinking water intake
$\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i = fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i = bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 52 L/kg (TL2), 71 L/kg (TL3), and 82 L/kg (TL4) for 1,2-dichlorobenzene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 1,2-dichlorobenzene. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. 1,2-Dichlorobenzene has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 3.43$ (ATSDR 2006)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 52 L/kg
TL3 = 71 L/kg
TL4 = 82 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 1,2-dichlorobenzene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

In place of an RfD, EPA selected a chronic oral minimal risk level (MRL) of 3×10^{-1} mg/kg-d (0.3 mg/kg-d) for 1,2-dichlorobenzene based on a 2006 ATSDR assessment for dichlorobenzenes (ATSDR 2006). A chronic oral MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects for a chronic duration (365 days and longer).

ATSDR identified a study by the National Toxicology Program (NTP 1985) as the critical study and the development of kidney lesions (renal tubular degeneration) as the critical effects in mice orally exposed to 1,2-dichlorobenzene for 103 weeks. The lower-bound confidence limit on the benchmark dose ($BMDL_{10}$) was 30.74 mg/kg-d. In deriving the chronic MRL, ATSDR applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10) (ATSDR 2006).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 1989 EPA IRIS assessment (USEPA 1989a) and a 1980 EPA Office of Water (OW) assessment (USEPA 1980). Based on the selection process described in section 5, the 2006 ATSDR chronic oral MRL is preferred for use in AWQC development at this time. The ATSDR assessment is the most current assessment. ATSDR relied on the same principal study as IRIS (NTP 1985), but used more current benchmark dose (BMD) modeling in order to identify the point of departure for the RfD derivation. According to EPA guidance, when data are amenable to modeling, the BMD approach is the preferred approach (USEPA 2012a).

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), 1,2-dichlorobenzene is classified as Group D, "not classifiable as to human carcinogenicity" (USEPA 1989b).

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the fish consumption rate), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

1,2-Dichlorobenzene was once registered as a pesticide and used in the production of herbicides. Currently, 1,2-dichlorobenzene is not registered as a pesticide (USEPA 2015c); however, it is a byproduct in the manufacture of 1,4-dichlorobenzene, which is a current-use pesticide (ATSDR 2006). The primary route of exposure of 1,2-dichlorobenzene for the general population is through inhalation (ATSDR 2006).

The vapor pressure of 1,2-dichlorobenzene (1.36 mm Hg at 25 °C) indicates that volatilization is expected to be an important fate process for this chemical (ATSDR 2006). 1,2-Dichlorobenzene has an atmospheric half-life of approximately 14–31 days. Therefore, 1,2-dichlorobenzene could become widely dispersed in the air (ATSDR 2006). Recent data from EPA's Toxic Release

Inventory (USEPA 2015g) indicate that over 37,000 pounds of 1,2-dichlorobenzene were released to the air in 2013. 1,2-Dichlorobenzene is not listed as a hazardous air pollutant (USEPA 2013). Thus, based on its physical properties and prevalence, air is a potentially significant source of exposure to 1,2-dichlorobenzene.

1,2-Dichlorobenzene is regulated under the Safe Drinking Water Act and EPA's drinking water standard (maximum contaminant level) is 600 µg/L (USEPA 2014c). 1,2-Dichlorobenzene has a half-life in water of approximately 4–120 hours (ATSDR 2006). Based on EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b), 1,2-dichlorobenzene was detected in surface water and groundwater sources of drinking water. A Standard of Quality for bottled water of 600 µg/L for 1,2-dichlorobenzene has been established (IBWA 2012). Therefore, ingestion of surface and drinking water is a potentially significant source of exposure to 1,2-dichlorobenzene.

The log K_{ow} of 1,2-dichlorobenzene is 3.43 (ATSDR 2006). The national-level BAF estimates for 1,2-dichlorobenzene range from 52 L/kg (TL2) to 82 L/kg (TL4), which indicates 1,2-dichlorobenzene has a low potential for bioaccumulation (USEPA 2011b). However, this chemical has been detected in fish and shellfish (ATSDR 2006). It was not, however, detected in EPA's National Lake Fish Tissue Study (USEPA 2009c), and it was not a target analyte in NOAA's Mussel Watch Survey (NOAA 2014). Recent exposure information regarding concentrations of 1,2-dichlorobenzene in fish and shellfish is lacking. Thus, given the previous detections, the potential exposure to 1,2-dichlorobenzene in fish and shellfish is possible.

ATSDR (2006) indicates that 1,2-dichlorobenzene has been detected in various food items. Recent information regarding concentrations of 1,2-dichlorobenzene in food could not be identified. Thus, the potential exposure to 1,2-dichlorobenzene in food is unknown.

In summary, based on the physical properties and available exposure information for 1,2-dichlorobenzene, air and drinking water are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from these different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for 1,2-dichlorobenzene.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 1,2-dichlorobenzene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 1,2-Dichlorobenzene

Input Parameter		Value
RfD		0.3 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	52 L/kg
	TL3	71 L/kg
	TL4	82 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.3\text{ mg/kg-d} \times 0.20 \times 80.0\text{ kg} \times 1{,}000\ \mu g/mg}{2.4\text{ L/d} + ((0.0076\text{ kg/d} \times 52\text{ L/kg}) + (0.0086\text{ kg/d} \times 71\text{ L/kg}) + (0.0051\text{ kg/d} \times 82\text{ L/kg}))}$$

$$= 1{,}255\ \mu g/L$$

$$= 1{,}000\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.3\text{ mg/kg-d} \times 0.20 \times 80.0\text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076\text{ kg/d} \times 52\text{ L/kg}) + (0.0086\text{ kg/d} \times 71\text{ L/kg}) + (0.0051\text{ kg/d} \times 82\text{ L/kg})}$$

$$= 3{,}371\ \mu g/L$$

$$= 3{,}000\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for 1,2-dichlorobenzene using a noncarcinogenic toxicity endpoint. The updated human health AWQC for 1,2-dichlorobenzene are **1,000 µg/L** for consumption of water and organisms and **3,000 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2003b).

Table 2. Summary of EPA's Previously Recommended (2003) and Updated (2015) Human Health AWQC for 1,2-Dichlorobenzene

	2003 Human Health AWQC	2015 Human Health AWQC
Water and Organism	420 µg/L	**1,000 µg/L**
Organism Only	1,300 µg/L	**3,000 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to 1,2-dichlorobenzene from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for 1,2-dichlorobenzene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

<u>Body Weight</u>

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

<u>Drinking Water Intake</u>

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 52, 71, and 82 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 55.6 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012b) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003) The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 151.5 L/kg
TL3 = 168.6 L/kg
TL4 = 235.6 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to

representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

In place of an RfD, EPA selected a chronic oral MRL of 0.3 mg/kg-d for 1,2-dichlorobenzene based on a 2006 ATSDR assessment for dichlorobenzenes (ATSDR 2006). This MRL replaces the previous RfD of 0.09 mg/kg-d (USEPA 2003b). EPA used the chronic oral MRL of 0.3 mg/kg-d to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, an increase in the chronic oral MRL in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Cancer Slope Factor

EPA did not select a CSF for 1,2-dichlorobenzene and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of 1,2-dichlorobenzene in its previous criteria update (USEPA 2003b).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. This is the same RSC used in the previous AWQC (USEPA 2003b).

9 Chemical Name and Synonyms

- 1,2-dichlorobenzene (CAS Number 95-50-1)
- Benzene, 1,2-dichloro-
- Benzene, o-dichloro-
- Chloroben
- Chloroden
- Cloroben
- DCB
- o-dichlorbenzene
- o-dichlor benzol
- o-dichlorobenzene
- o-dichlorobenzene
- Dichlorobenzene, ortho
- Dilantin DB
- Dilatin DB
- Dizene
- Dowtherm E
- NCI-C54944
- ODB
- ODCB
- Orthodichlorobenzene

- Orthodichlorobenzol
- Special termite fluid
- Termitkil
- UN 1591

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-075
June 2015

Update of Human Health Ambient Water Quality Criteria:

1,2-Dichloroethane
107-06-2

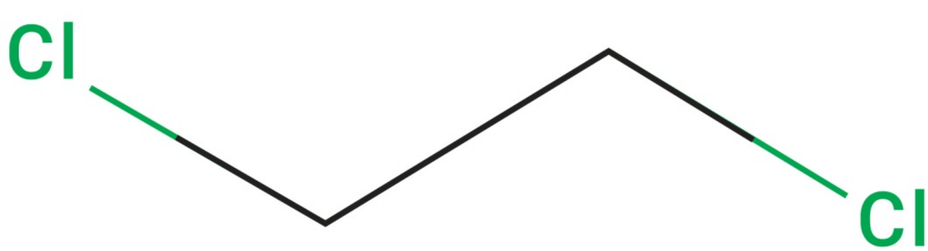

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 1,2-dichloroethane to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 1.6 L/kg (TL2), 1.8 L/kg (TL3), and 1.9 L/kg (TL4) for 1,2-dichloroethane. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 1,2-dichloroethane. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. 1,2-Dichloroethane has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 1.48$ (ATSDR 2001)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 1.6 L/kg
TL3 = 1.8 L/kg
TL4 = 1.9 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 1,2-dichloroethane. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015a)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 7.8×10^{-2} mg/kg-d (0.078 mg/kg-d) for 1,2-dichloroethane based on a 2015 Health Canada assessment (HC 2015b). Health Canada derived the RfD using a principal study by the National Toxicology Program (NTP 1991) based on renal tubular regeneration in female rats orally exposed to 1,2-dichloroethane in drinking water (HC 2015b). The lower-bound 95 percent confidence limit on the benchmark dose ($BMDL_{10}$) was 78 mg/kg-d. In deriving the RfD, Health Canada applied a composite uncertainty factor of 1000 to account for interspecies extrapolation (10), intraspecies variation (10), and subchronic-to-chronic extrapolation and database deficiencies (10) (HC 2015b).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 1999 California EPA assessment (CalEPA 1999) and a 2001 ATSDR assessment (ATSDR 2001). Based on the selection process described in section 5, the 2015 Health Canada RfD is preferred for use in AWQC development at this time. Health Canada evaluated the same principal study considered in the other two assessments (NTP 1991), but used more current benchmark dose (BMD) modeling in order to identify the point of departure for the RfD derivation. According to EPA guidance, when data are amenable to modeling, the BMD approach is the preferred approach (USEPA 2012a).

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986a), 1,2-dichloroethane is classified as Group B2, "probable human carcinogen" (USEPA 1986b).

EPA selected a CSF of 3.3×10^{-3} per mg/kg-d[g] (0.0033 per mg/kg-d) for 1,2-dichloroethane based on a 2015 Health Canada assessment (HC 2015b). Health Canada derived the CSF using a principal study by Nagano et al. (2006) based on development of mammary tumors in female rats orally exposed to 1,2-dichloroethane (HC 2015b).

EPA identified two other CSF sources through the systematic search described in section 5: a 1986 EPA IRIS assessment (USEPA 1986b) and a 1999 California EPA assessment (CalEPA 1999). Based on the selection process described in section 5, the 2015 Health Canada CSF is preferred for use in AWQC development at this time. The Health Canada assessment is based on a more recent critical study (Nagano et al. 2006) and applied more current guidance and modeling approaches. Specifically, the LED_{10} (the lower 95 percent confidence limit on the estimated dose associated with 10 percent extra risk) was selected by Health Canada as the point of departure for derivation of the slope factor in place of a linear multistage (LMS) slope factor. Additionally, the Health Canada CSF uses a cross-species scaling approach based on $BW^{3/4}$, which is consistent with current EPA practice (HC 2015b; USEPA 2005).

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is

[g] This CSF was calculated by dividing the cancer risk level (10^{-6}) by the human external dose (PBPK approach) (0.0003 mg/kg-d) (see Table 3 in HC 2015b).

not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 1,2-dichloroethane from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 1,2-Dichloroethane

Input Parameter		Value
RfD		0.078 mg/kg-d
CSF		0.0033 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	1.6 L/kg
	TL3	1.8 L/kg
	TL4	1.9 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{0.078 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 1.6 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 1.8 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1.9 \text{ L/kg}))}$$

$$= 512.0\ \mu g/L$$

$$= 510\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (FCR_i\ (kg/d) \times BAF_i\ (L/kg))}$$

$$= \frac{0.078\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 1.6\ L/kg) + (0.0086\ kg/d \times 1.8\ L/kg) + (0.0051\ kg/d \times 1.9\ L/kg)}$$

$$= 33{,}432\ \mu g/L$$

$$= 33{,}000\ \mu g/L\ \text{(rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / CSF)\ [mg/kg\text{-}d] \times BW\ (kg) \times 1{,}000\ (\mu g/mg)}{DI\ (L/d) + \sum_{i=2}^{4} (FCR_i\ (kg/d) \times BAF_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 0.0033)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 1.6\ L/kg) + (0.0086\ kg/d \times 1.8\ L/kg) + (0.0051\ kg/d \times 1.9\ L/kg))}$$

$$= 9.946\ \mu g/L$$

$$= 9.9\ \mu g/L\ \text{(rounded)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / CSF)\ [mg/kg\text{-}d] \times BW\ (kg) \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (FCR_i\ (kg/d) \times BAF_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 0.0033)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 1.6\ L/kg) + (0.0086\ kg/d \times 1.8\ L/kg) + (0.0051\ kg/d \times 1.9\ L/kg)}$$

$$= 649.4\ \mu g/L$$

$$= 650\ \mu g/L\ \text{(rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for 1,2-dichloroethane using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for 1,2-dichloroethane are **510 µg/L** for consumption of water and organisms and **33,000 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for 1,2-dichloroethane are **9.9 µg/L** for consumption of water and organisms and **650 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of 1,2-dichloroethane, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for 1,2-Dichloroethane

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.38 µg/L	**9.9 µg/L**
Organism Only	37 µg/L	**650 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to 1,2-dichloroethane at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for 1,2-dichloroethane take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a

contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 1.6, 1.8, and 1.9 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 1.2 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012b) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 2.67 L/kg
TL3 = 2.89 L/kg
TL4 = 3.777 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level bioaccumulation factor rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.078 mg/kg-d for 1,2-dichloroethane based on a 2015 Health Canada assessment (HC 2015b). EPA used the RfD of 0.078 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of 1,2-dichloroethane in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.0033 per mg/kg-d for 1,2-dichloroethane based on a 2015 Health Canada assessment (HC 2015b). This CSF replaces the previous value of 0.091 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.0033 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, a decrease in the CSF in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- 1,2-dichloroethane (CAS Number 107-06-2)
- Ethylene dichloride
- Dichloroethane, 1,2-
- Aethylenchlorid [German]
- AI3-01656
- Alpha,beta-dichloroethane
- Bichlorure d'ethylene [French]
- Borer sol
- Brocide
- Caswell no. 440
- CCRIS 225
- Chlorure d'ethylene [French]
- Cloruro di ethene [Italian]
- Destruxol borer-sol
- Di-chlor-mulsion
- Dichlor-mulsion
- Dichloremulsion
- Dichloro-1,2-ethane [French]
- Dichlorure d'ethylene [French]
- Dicloruro de etileno [Spanish]
- Dutch liquid
- Dutch oil
- EDC
- ENT 1,656
- EPA pesticide chemical code 042003

- Ethane dichloride
- Ethane, 1,2-dichloro-
- Ethyleendichloride [Dutch]
- Ethylene chloride
- Glycol dichloride
- HSDB 65
- NCI-C00511
- RCRA waste number U077
- Sym-dichloroethane
- 1,2-bichloroethane
- 1,2-DCA
- 1,2-dichloorethaan [Dutch]
- 1,2-dichlor-aethan [German]
- 1,2-dichlorethane
- 1,2-dicloroetano [Italian]
- 1,2-ethylene dichloride

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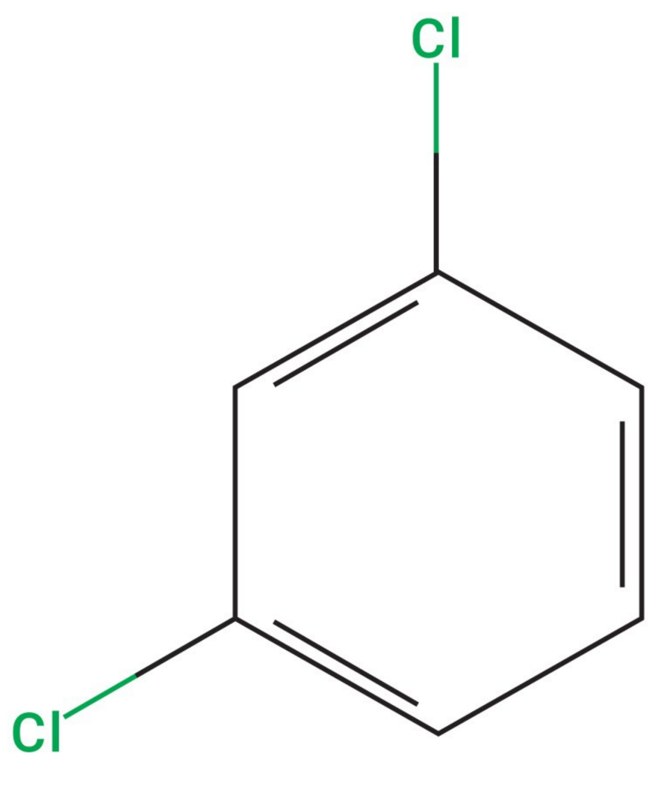
Update of Human Health Ambient Water Quality Criteria:

1,3-Dichlorobenzene
541-73-1



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Update of Human Health Ambient Water Quality Criteria:

1,3-Dichlorobenzene
541-73-1

Office of Science and Technology
Office of Water
U.S. Environmental Protection Agency
Washington, DC 20460

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1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 1,3-dichlorobenzene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 31 L/kg (TL2), 120 L/kg (TL3), and 190 L/kg (TL4) for 1,3-dichlorobenzene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 1,3-dichlorobenzene. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. 1,3-Dichlorobenzene has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 3.53 (ATSDR 2006)
- Low/unknown metabolism

EPA was able to locate peer-reviewed, lab-measured BCFs for TLs 2, 3, and 4 (Arnot and Gobas 2006; Environment Canada 2006). Therefore, EPA used the Lab BCF method (USEPA 2003a) to derive the national BAF values for this chemical:

TL2 = 31 L/kg
TL3 = 120 L/kg
TL4 = 190 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 1,3-dichlorobenzene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

In place of an RfD, EPA selected an intermediate-duration oral minimal risk level (MRL) of 2×10^{-2} mg/kg-d (0.02 mg/kg-d) for 1,3-dichlorobenzene from a 2006 ATSDR assessment (ATSDR 2006) and adjusted it to 2×10^{-3} mg/kg-d (0.002 mg/kg-d) for a chronic (lifetime) exposure (USEPA 2000a) . An intermediate-duration MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over an exposure period of 15–364 days.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

ATSDR derived an intermediate-duration oral MRL using a principal study by McCauley et al. (1995) based on the development of pituitary lesions, consisting of cytoplasmic vacuolation of the pars distalis in male rats orally exposed to 1,3-dichlorobenzene for 90 consecutive days (ATSDR 2006). A duration-adjusted, lower-bound confidence limit benchmark dose ($BMDL_{10}$) of 2.1 mg/kg-d was derived from this study. In deriving the MRL, ATSDR applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10), resulting in an intermediate-duration oral MRL of 0.02 mg/kg-day (ATSDR 2006). In this particular case, because there are no chronic oral toxicity values available for 1,3-dichlorobenze, EPA applied an additional uncertainty factor of 10 to account for intermediate-to-chronic duration to derive a chronic-duration oral MRL of 0.002 mg/kg-d for the purpose of AWQC development (USEPA 2000a).

EPA identified one other RfD source through the systematic search described in section 5: a 1980 EPA Office of Water (OW) assessment (USEPA 1980). The 1980 EPA OW RfD is based on toxicity studies for 1,2-dichlorobenzene and 1,4-dichlorobenzene—*not* for 1,3-dichlorobenzene. Hollingsworth et al. (1956; 1958) exposed several animal species over a period of 6–7 months in separate toxicity tests with 1,2-dichlorobenzene and 1,4-dichlorobenzene (i.e., no toxicity tests were performed with 1,3-dichlorobenzene) (USEPA 1980). OW derived the 1980 RfD based on the lowest NOAEL from those studies as a surrogate for 1,3-dichlorobenzene (USEPA 1980). Based on the selection process described in section 5, the 2006 ATSDR MRL is preferred for use in AWQC development at this time. The 2006 ATSDR assessment used a newer principal study specifically for 1,3-dichlorobenzene (McCauley et al. 1995) and applied more current benchmark dose (BMD) modeling in order to identify the point of departure for the MRL derivation (ATSDR 2006). According to EPA guidance, when data are amenable to modeling, the BMD approach is the preferred approach (USEPA 2012a). The ATSDR assessment represents the most current available human health assessment for 1,3-dichlorobenzene. In the event that a chronic toxicity value (RfD or chronic-duration MRL) for 1,3-dichlorobenzene becomes available in the future, EPA will update the AWQC to reflect the latest science.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), 1,3-dichlorobenzene is classified as Group D, “not classifiable as to human carcinogenicity” (USEPA 1989).

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD’s exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

1,3-Dichlorobenzene is used to make herbicides, insecticides, medicine, and dyes (ATSDR 2006). 1,3-Dichlorobenzene is not registered as a pesticide by EPA (USEPA 2015c). The principal route of exposure for dichlorobenzenes is inhalation (ATSDR 2006).

The vapor pressure of 1,3-dichlorobenzene (2.15 mm Hg at 25 °C) indicates that volatilization is an important fate process for this chemical (ATSDR 2006). 1,3-Dichlorobenzene is expected to be released into the air during use in herbicide production and from air emissions at hazardous waste sites and incinerator facilities. This chemical was detected from municipal solid waste composting facilities and hazardous waste sites (ATSDR 2006). Recent data from EPA's Toxic Release Inventory (USEPA 2015g) indicate that 18 pounds of 1,3-dichlorobenzene were released to the air in 2013. 1,3-Dichlorobenzene is not listed as a hazardous air pollutant (USEPA 2013). Thus, based on its physical properties, air is a potentially significant source of exposure to 1,3-dichlorobenzene.

Historically, 1,3-dichlorobenzene has been detected in food such as chocolate chip cookies, cake doughnuts, and sandwich cookies (ATSDR 2006). Recent information regarding concentrations of 1,3-dichlorobenzene in food could not be identified. Thus, given the previous detections, the potential exposure to 1,3-dichlorobenzene from ingestion of food is possible.

1,3-Dichlorobenzene has been detected in drinking water (ATSDR 2006). 1,3-Dichlorobenzene is not regulated under the Safe Drinking Water Act (USEPA 2014c) and was not a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). No Standard of Quality exists for this chemical in bottled water (IBWA 2012). Thus, given the previous detections, the potential exposure to 1,3-dichlorobenzene in drinking water is possible.

The log K_{ow} of 1,3-dichlorobenzene is 3.53 (ATSDR 2006). The national-level BAF estimates for 1,3-dichlorobenzene range from 31 L/kg (TL2) to 190 L/kg (TL4), which indicates 1,3-dichlorobenzene has a low-to-moderate potential for bioaccumulation (USEPA 2011b). 1,3-Dichlorobenzene was not detected in fish samples collected in EPA's National Lake Fish Tissue Study (USEPA 2009c), and it was not an analyte in the Mussel Watch Survey (NOAA 2014). Recent exposure information regarding concentrations of 1,3-dichlorobenzene in fish and shellfish is lacking. Thus, based on its low-to-moderate potential to bioaccumulate and available information regarding detection, exposure to this chemical from ingestion of fish and shellfish is not considered likely.

In summary, based on the chemical fate and available exposure information for 1,3-dichlorobenzene, air is a potentially significant source of this chemical. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), a significant potential source other than fish and shellfish from inland and nearshore waters and water ingestion exists (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from this source (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for 1,3-dichlorobenzene.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 1,3-dichlorobenzene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 1,3-Dichlorobenzene

Input Parameter		Value
RfD		0.002 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	31 L/kg
	TL3	120 L/kg
	TL4	190 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.002\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 31\ L/kg) + (0.0086\ kg/d \times 120\ L/kg) + (0.0051\ kg/d \times 190\ L/kg))}$$

$$= 6.90\ \mu g/L$$

$$= 7\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.002 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 31 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 120 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 190 \text{ L/kg})}$$

$$= 14.3\ \mu g/L$$

$$= 10\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for 1,3-dichlorobenzene using a noncarcinogenic toxicity endpoint. The updated human health AWQC for 1,3-dichlorobenzene are **7 µg/L** for consumption of water and organisms and **10 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for 1,3-Dichlorobenzene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	320 µg/L	**7 µg/L**
Organism Only	960 µg/L	**10 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to 1,3-dichlorobenzene from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for 1,3-dichlorobenzene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is

10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 31, 120, and 190 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 55.6 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012b) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 134.3 L/kg
TL3 = 140.1 L/kg
TL4 = 149.5 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

In place of an RfD, EPA selected an intermediate-duration oral MRL of 0.02 mg/kg-d for 1,3-dichlorobenzene from a 2006 ATSDR assessment (ATSDR 2006) and adjusted it to 0.002 mg/kg-d for a chronic (lifetime) exposure (USEPA 2000a). This MRL replaces the previous acceptable daily intake value of 0.0134 mg/kg-d (USEPA 2002c). EPA used the intermediate-duration oral MRL of 0.002 mg/kg-d to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, a decrease in the intermediate-duration oral MRL in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

Cancer Slope Factor

EPA did not select a CSF for 1,3-dichlorobenzene and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of 1,3-dichlorobenzene in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- 1,3-Dichlorobenzene (CAS Number 541-73-1)
- Benzene, 1,3-Dichloro-
- Benzene, M-Dichloro-
- M-Dichlorobenzene
- M-Dichlorobenzol
- HSDB 522
- M-Phenylene Dichloride
- NSC 8754

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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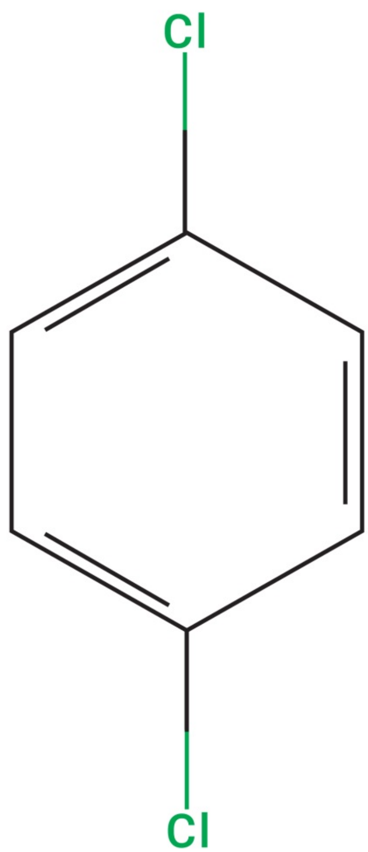
Update of Human Health Ambient Water Quality Criteria:

1,4-Dichlorobenzene
106-46-7



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Office of Science and Technology
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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 1,4-dichlorobenzene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 28 L/kg (TL2), 66 L/kg (TL3), and 84 L/kg (TL4) for 1,4-dichlorobenzene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 1,4-dichlorobenzene. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. 1,4-Dichlorobenzene has the following characteristics:

- Nonionic organic chemical (USDHHS 2012)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 3.44 (ATSDR 2006)
- Low/unknown metabolism

EPA was able to locate peer-reviewed, lab-measured BCFs for TLs 2, 3, and 4 (Arnot and Gobas 2006; Environment Canada 2006; Calamari et al. 1982). Therefore, EPA used the Lab BCF method (USEPA 2003a) to derive the national BAF values for this chemical:

TL2 = 28 L/kg
TL3 = 66 L/kg
TL4 = 84 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 1,4-dichlorobenzene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

In place of an RfD, EPA selected a chronic oral minimal risk level (MRL) of 7×10^{-2} mg/kg-d (0.07 mg/kg-d) for 1,4-dichlorobenzene based on a 2006 ATSDR assessment for dichlorobenzenes (ATSDR 2006). A chronic oral MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects for a chronic duration (365 days and longer).

ATSDR identified a study by Naylor and Stout (1996) as the critical study and increased serum alkaline phosphatase levels as the critical effect in female dogs orally exposed to 1,4-dichlorobenzene for 1 year. The duration-adjusted, lower-bound confidence limit on the benchmark dose ($BMDL_{10}$) was 7 mg/kg-d. In deriving the chronic MRL, ATSDR applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10) (ATSDR 2006).

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[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified three other RfD sources through the systematic search described in section 5: a 2008 EPA Office of Pesticide Programs (OPP) Reregistration Eligibility Decision (RED) (USEPA 2008), a 1980 EPA Office of Water (OW) assessment (USEPA 1980), and a 1997 California EPA assessment (CalEPA 1997). Based on the selection process described in section 5, the 2006 ATSDR chronic MRL is preferred for use in AWQC development at this time. 1,4-Dichlorobenzene is a current use pesticide; however, the EPA OPP assessment does not include a toxicity endpoint for chronic oral exposures (RfD) (USEPA 2008). The ATSDR assessment is the most current source of a chronic oral toxicity value and relies on a newer principal study (Naylor and Stout 1996) and more current benchmark dose modeling than was relied on in the 1980 OW assessment.

5.2.2 Cancer Slope Factor

Under the 2005 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 2005), 1,4-dichlorobenzene is classified as "not likely to be carcinogenic to humans" (USEPA 2008).

EPA OPP RED (USEPA 2008) includes a discussion of draft CSFs from a 2006 EPA IRIS draft Toxicological Review for 1,4-dichlorobenzene (USEPA 2006); however, this IRIS assessment has not been finalized.

EPA identified one other CSF source through the systematic search described in section 5: a 1997 California EPA assessment (CalEPA 1997). However, because this chemical is a current-use pesticide and EPA has not finalized a CSF, the CalEPA CSF will not be used for AWQC development at this time.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles"

(ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

1,4-Dichlorobenzene is used in the production of mothballs, deodorant blocks in garbage cans and rest rooms, and odor control devices in animal facilities. It is also used in the manufacture of resins and as a chemical intermediate for the manufacture of dyes, 2,5-dichloroaniline, pharmaceuticals, and agricultural products (ATSDR 2006). 1,4-Dichlorobenzene is registered as a pesticide and is currently in the reregistration process (USEPA 2015c). ATSDR (2006) reports that inhalation might be the principal route of exposure.

The vapor pressure of 1,4-dichlorobenzene (1.77 mm Hg at 25 °C) indicates that volatilization is an important fate process for this chemical (ATSDR 2006). Recent data from EPA's Toxic Release Inventory indicate that almost 25,000 pounds of 1,4-dichlorobenzene were released to the air in 2013 (USEPA 2015g). EPA lists this chemical as a hazardous air pollutant (USEPA 2013). Thus, based on its physical properties and prevalence, air is a potentially significant source of exposure to 1,4-dichlorobenzene.

1,4-Dichlorobenzene has been detected in various foods (i.e., beef, pork, chicken, eggs, baked goods, soft drinks, butter, peanut butter, fruits, vegetables, and fish) (ATSDR 2006). EPA has not set a 40 CFR part 180 pesticide tolerance level for this chemical in food and feed commodities (USGPO 2015). Thus, based on detection in food, ingestion of food is a potentially significant source of exposure to 1,4-dichlorobenzene.

1,4-Dichlorobenzene has also been detected in drinking water, based on EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). 1,4-Dichlorobenzene is regulated under the Safe Drinking Water Act and EPA's drinking water standard (maximum contaminant level) is 75 µg/L (USEPA 2014c). The Standard of Quality for bottled water is 75 µg/L (IBWA 2012). Therefore, ingestion of drinking water is a potentially significant source of exposure to 1,4-dichlorobenzene.

The log K_{ow} of 1,4-dichlorobenzene is 3.44. The national-level BAF estimates for 1,4-dichlorobenzene range from 28 L/kg (TL2) to 84 L/kg (TL4), which indicates 1,4-dichlorobenzene has a low potential for bioaccumulation (USEPA 2011b). 1,4-Dichlorobenzene has been detected in fish and shellfish such as Atlantic croaker, blue crabs, spotted seatrout, and blue catfish (USDHHS 2012). This chemical was not detected in fish tissue samples collected in EPA's National Lake Fish Tissue Study (USEPA 2009c) or identified as an analyte in the Mussel Watch Survey (NOAA 2014). Given that it has been historically detected in fish and shellfish, ingestion of fish and shellfish is a possible source of exposure to 1,4-dichlorobenzene.

In summary, based on the physical properties and available exposure information for 1,4-dichlorobenzene, air, drinking water, and non-fish food are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for 1,4-dichlorobenzene.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 1,4-dichlorobenzene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 1,4-Dichlorobenzene

Input Parameter		Value
RfD		0.07 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	28 L/kg
	TL3	66 L/kg
	TL4	84 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.07\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 28\ L/kg) + (0.0086\ kg/d \times 66\ L/kg) + (0.0051\ kg/d \times 84\ L/kg))}$$

$$= 310\ \mu g/L$$

$$= 300\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.07\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 28\ L/kg) + (0.0086\ kg/d \times 66\ L/kg) + (0.0051\ kg/d \times 84\ L/kg)}$$

$$= 927\ \mu g/L$$

$$= 900\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for 1,4-dichlorobenzene using a noncarcinogenic toxicity endpoint. The updated human health AWQC for 1,4-dichlorobenzene are **300 µg/L** for consumption of water and organisms and **900 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2003b).

Table 2. Summary of EPA's Previously Recommended (2003) and Updated (2015) Human Health AWQC for 1,4-Dichlorobenzene

	2003 Human Health AWQC	2015 Human Health AWQC
Water and Organism	63 µg/L	**300 µg/L**
Organism Only	190 µg/L	**900 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to 1,4-dichlorobenzene from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for 1,4-dichlorobenzene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

<u>Body Weight</u>

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

<u>Drinking Water Intake</u>

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 28, 66, and 84 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 55.6 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 165.7 L/kg
TL3 = 187.5 L/kg
TL4 = 281.3 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to

representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

In place of an RfD, EPA selected a chronic oral MRL of 0.07 mg/kg-d for 1,4-dichlorobenzene based on a 2006 ATSDR assessment for dichlorobenzenes (ATSDR 2006). This MRL replaces the previous acceptable daily intake value of 0.0134 mg/kg-d (USEPA 2003b). EPA used the chronic oral MRL of 0.07 mg/kg-d to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, an increase in the chronic oral MRL in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Cancer Slope Factor

EPA did not select a CSF for 1,4-dichlorobenzene and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of 1,4-dichlorobenzene in its previous criteria update (USEPA 2003b).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. This is the same RSC used in the previous AWQC (USEPA 2003b).

9 Chemical Name and Synonyms

- 1,4-Dichlorobenzene (CAS Number 106-46-7)
- 1,4-Dichloorbenzeen [Dutch]
- 1,4-Diclorobenzene [Italian]
- Benzene, 1,4-Dichloro-
- Benzene, P-Dichloro-
- Caswell No. 632
- Di-Chloricide
- Dichlorobenzene, Para
- EPA Pesticide Chemical Code 061501
- Evola
- HSDB 523
- NCI-C54955
- NSC 36935
- Paradi
- Paradichlorbenzol [German]
- Paradichlorobenzene
- Paradichlorobenzol
- Paradow
- Paramoth
- Parazene

- P-Chlorophenyl Chloride
- PDB
- P-Dichloorbenzeen [Dutch]
- P-Dichlorbenzol [German]
- P-Dichlorobenzene
- P-Dichlorobenzol
- P-Diclorobenceno [Spanish]
- P-Diclorobenzene [Italian]
- Persia-Perazol
- RCRA Waste Number U070
- RCRA Waste Number U072
- Santochlor
- UN 1592

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-083
June 2015

Update of Human Health Ambient Water Quality Criteria:

2,4,6-Trichlorophenol
88-06-2

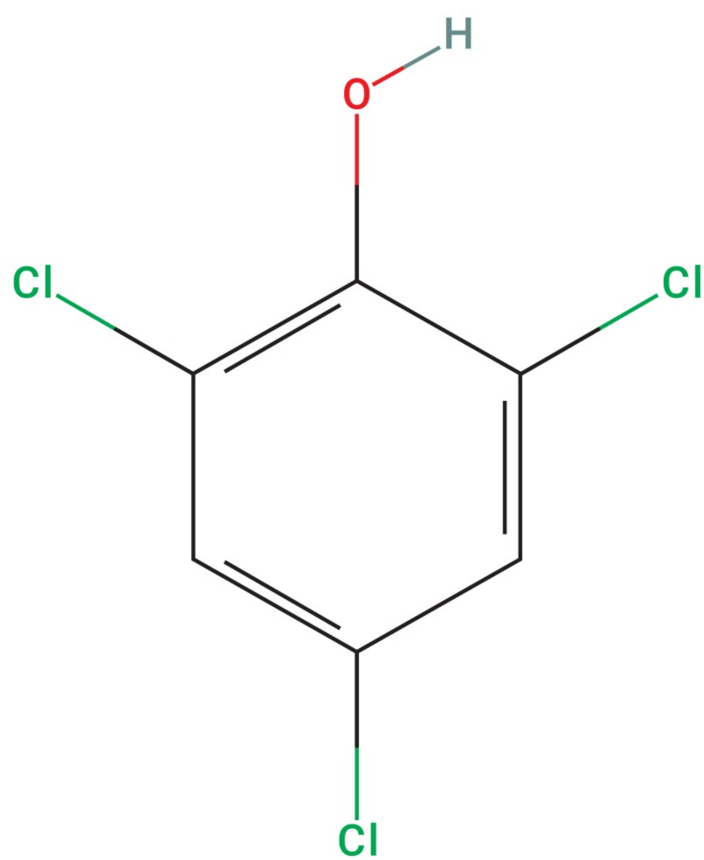

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 2,4,6-trichlorophenol to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC = ambient water quality criteria
toxicity value = RfD x RSC (mg/kg-d) for noncarcinogenic effects
or
10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC = relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW = body weight
DI = drinking water intake
$\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i = fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i = bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level-(TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 94 L/kg (TL2), 130 L/kg (TL3), and 150 L/kg (TL4) for 2,4,6-trichlorophenol. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 2,4,6-trichlorophenol. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. 2,4,6-Trichlorophenol has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 3.69 (ATSDR 1999)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 94 L/kg
TL3 = 130 L/kg
TL4 = 150 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 2,4,6-trichlorophenol. As described in the 2000 Methodology (USEPA 2000a), where data are available, EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, ATSDR (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 1×10^{-3} mg/kg-d (0.001 mg/kg-d) for 2,4,6-trichlorophenol based on a 2007 EPA Office of Solid Waste and Emergency Response (OSWER) Provisional Peer Reviewed Toxicity Value (PPRTV) (USEPA 2007). EPA identified a study by Exon and Koller (1985) as the critical study and a decrease in litter size as the critical effect in rats exposed to 2,4,6-trichlorophenol in drinking water for 10 weeks prior to mating and continuing throughout mating and gestation. The study had a NOAEL of 3 mg/kg-d. In deriving the RfD, EPA's OSWER applied a composite uncertainty factor of 3000 to account for intraspecies variation (10), interspecies extrapolation (10), subchronic-to-chronic extrapolation (10), and database deficiencies (3) (USEPA 2007).

EPA identified no other RfD sources through the systematic search described in section 5.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), 2,4,6-trichlorophenol is classified as Group B2, “ probable human carcinogen” (USEPA 1989).

EPA selected a CSF of 1.1×10^{-2} per mg/kg-d (0.011 per mg/kg-d) for 2,4,6-trichlorophenol based on a 1989 EPA IRIS assessment (USEPA 1989). EPA’s IRIS program derived the CSF using a principal study by the National Cancer Institute (NCI 1979) based on development of leukemia in rats orally exposed to 2,4,6-trichlorophenol (USEPA 1989).

In 2002, EPA’s IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the cancer assessment for 2,4,6-trichlorophenol and did not identify any critical new studies.

EPA identified no other CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD’s exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual’s total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR “Toxicological Profiles” (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine’s Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- Food and Drug Administration (FDA) Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- National Oceanic and Atmospheric Administration (NOAA) Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 2,4,6-trichlorophenol from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above.

(See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 2,4,6-Trichlorophenol

Input Parameter		Value
RfD		0.001 mg/kg-d
CSF		0.011 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	94 L/kg
	TL3	130 L/kg
	TL4	150 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.001 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 94 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 130 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 150 \text{ L/kg}))}$$

$$= 3.20\ \mu g/L$$

$$= 3\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.001 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 94 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 130 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 150 \text{ L/kg})}$$

$$= 6.16\ \mu g/L$$

$$= 6\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000 \ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.011) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 94 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 130 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 150 \text{ L/kg}))}$$

$$= 1.455 \ \mu g/L$$

$$= 1.5 \ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000 \ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.011) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \ \mu g/mg}{(0.0076 \text{ kg/d} \times 94 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 130 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 150 \text{ L/kg})}$$

$$= 2.800 \ \mu g/L$$

$$= 2.8 \ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for 2,4,6-trichlorophenol using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for 2,4,6-trichlorophenol are **3 µg/L** for consumption of water and organisms and **6 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for 2,4,6-trichlorophenol are **1.5 µg/L** for consumption of water and organisms and **2.8 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of 2,4,6-trichlorophenol, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for 2,4,6-Trichlorophenol

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	1.4 µg/L	**1.5 µg/L**
Organism Only	2.4 µg/L	**2.8 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to 2,4,6-trichlorophenol at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular

pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for 2,4,6-trichlorophenol take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 94, 130, and 150 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 150 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 109.6 L/kg
TL3 = 106.9 L/kg
TL4 = 93.59 L/kg

Assuming all other input parameters remain constant, lower BAFs or BCFs result in higher AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish decreases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure increases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.001 mg/kg-d for 2,4,6-trichlorophenol based on a 2007 EPA OSWER PPRTV (USEPA 2007). EPA used the RfD of 0.001 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of 2,4,6-trichlorophenol in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA retained a CSF of 0.011 per mg/kg-d for 2,4,6-trichlorophenol based on a 1989 EPA IRIS assessment (USEPA 1989; USEPA 2002c). EPA used this CSF to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the CSF in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- 2,4,6-trichlorophenol (CAS Number 88-06-2)
- Dowicide 2S
- NCI-C02904
- Omal
- Phenachlor
- Phenol, 2,4,6-trichloro-
- RCRA waste number U231
- Trichlorophenol, 2,4,6-

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-084
June 2015

Update of Human Health Ambient Water Quality Criteria:

2,4-Dichlorophenol
120-83-2

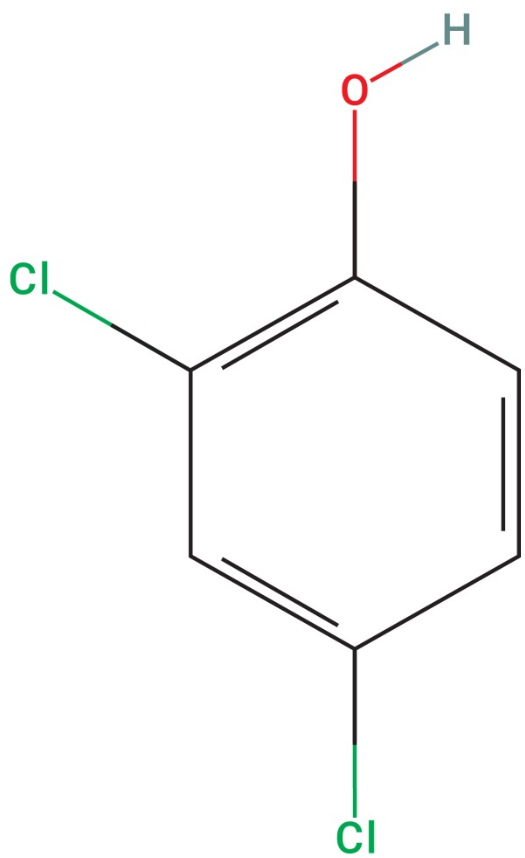

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 2,4-dichlorophenol to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level-(TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 31 L/kg (TL2), 42 L/kg (TL3), and 48 L/kg (TL4) for 2,4-dichlorophenol. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 2,4-dichlorophenol. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. 2,4-Dichlorophenol has the following characteristics:

- Nonionic organic chemical (USDHHS 2011)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 3.2$ (ATSDR 1999)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 31 L/kg
TL3 = 42 L/kg
TL4 = 48 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 2,4-dichlorophenol. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 3×10^{-3} mg/kg-d (0.003 mg/kg-d) for 2,4-dichlorophenol based on a 1986 EPA IRIS assessment (USEPA 1986). EPA's IRIS program identified a study by Exon and Koller (1985) as the critical study and decreased delayed hypersensitivity response as the critical effect in rats orally exposed to 2,4-dichlorophenol (USEPA 1986). The study has a NOAEL of 0.3 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10) (USEPA 1986).

In 2001, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the RfD for 2,4-dichlorophenol and did not identify any critical new studies.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 2007 EPA Office of Solid Waste and Emergency Response (OSWER) Provisional Peer Reviewed Toxicity Value (PPRTV) (USEPA 2007) and a 1999 ATSDR assessment (ATSDR 1999). Based on the selection process described in section 5, the 1986 EPA IRIS RfD is preferred for use in AWQC development at this time. Neither of the other assessments included the relevant (chronic oral) toxicity value.

5.2.2 Cancer Slope Factor

EPA identified no CSF source for 2,4-dichlorophenol through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).

- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

2,4-Dichlorophenol is used primarily as a component of pesticides (in particular, the herbicide 2,4-D) and antiseptics. 2,4-Dichlorophenol itself is not registered as a pesticide (USEPA 2015c). Sources of 2,4-dichlorophenol include water chlorination, wood pulp bleaching, pesticide manufacturing, and environmental degradation of 2,4-D (ATSDR 1999). Chlorophenols can be formed when water containing humic substances is treated with chlorine and has a pH ranging from 7 to 8 (Krijgsheld and van der Gen 1986). Dichlorophenols are difficult to produce in chlorinated waters without high levels of chlorine present for long contact times (ATSDR 1999). The general population could be exposed to chlorophenols through ingestion of water and food contaminated with 2,4-dichlorophenol well as inhalation of contaminated air (ATSDR 1999).

The majority of known environmental releases of 2,4-dichlorophenol are to surface water via degradation of 2,4-D in contaminated soil and water (ATSDR 1999). This chemical is highly soluble in water and has a half-life of 14.8 days (ATSDR 1999). 2,4-Dichlorophenol has been detected in some drinking water sources but data are very limited (ATSDR 1999). 2,4-Dichlorophenol is not regulated under the Safe Drinking Water Act (USEPA 2014c), and it was not a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). There is no Standard of Quality for 2,4-dichlorophenol in bottled water (IBWA 2012). Therefore, based on the chemical's physical and chemical properties, drinking water is a potentially significant source of exposure to it.

The vapor pressure of 2,4-dichlorophenol (0.14 mm Hg at 25 °C) indicates that volatilization is an important fate process for this chemical (ATSDR 1999). Recent data from EPA's Toxic Release Inventory (USEPA 2015g) indicate that 4,340 pounds of 2,4-dichlorophenol were released to the air in 2013. 2,4-Dichlorophenol is not listed as a hazardous air pollutant (USEPA 2013). Therefore, based on the chemical's physical properties, air is a potentially significant source of exposure to it.

Current information regarding concentrations of 2,4-dichlorophenol in food could not be identified. Thus, the potential exposure to the chemical from food is unknown.

The log K_{ow} for 2,4-dichlorophenol is 3.2 (ATSDR 1999). The national-level BAF estimates for 2,4-dichlorophenol range from 31 L/kg (TL2) to 48 L/kg (TL4), which indicates that it has a low potential for bioaccumulation (USEPA 2011b). 2,4-Dichlorophenol was not a target chemical either in NOAA's Mussel Watch Survey (NOAA 2014) or in EPA's National Lake Fish Tissue Study (USEPA 2009c). Recent exposure information regarding concentrations of 2,4-dichlorophenol in fish and shellfish is lacking. Based on its low potential for bioaccumulation, exposure to 2,4-dichlorophenol from ingestion of fish and shellfish is not considered likely.

Limited source information as well as physical properties of this chemical suggest that drinking water and air are potentially significant sources of 2,4-dichlorophenol. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for 2,4-dichlorophenol.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 2,4-dichlorophenol from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 2,4-Dichlorophenol

Input Parameter		Value
RfD		0.003 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	31 L/kg
	TL3	42 L/kg
	TL4	48 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.003 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 31 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 42 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 48 \text{ L/kg}))}$$

$$= 14.8\ \mu g/L$$

$$= 10\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.003 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 31 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 42 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 48 \text{ L/kg})}$$

$$= 57.0\ \mu g/L$$

$$= 60\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for 2,4-dichlorophenol using a noncarcinogenic toxicity endpoint. The updated human health AWQC for 2,4-dichlorophenol are **10 µg/L** for consumption of water and organisms and **60 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for 2,4-Dichlorophenol

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	77 µg/L	**10 µg/L**
Organism Only	290 µg/L	**60 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to 2,4-dichlorophenol from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for 2,4-dichlorophenol take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 31, 42, and 48 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 40.7 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 35.28 L/kg
TL3 = 35.65 L/kg
TL4 = 33.95 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to

representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA retained an RfD of 0.003 mg/kg-d for 2,4-dichlorophenol based on a 1986 EPA IRIS assessment (USEPA 1986; USEPA 2002c). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for 2,4-dichlorophenol and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of 2,4-dichlorophenol in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- 2,4-dichlorophenol (CAS Number 120-83-2)
- DCP
- 2,4-DCP
- Dichlorophenol, 2,4-
- NCI-C55345
- Phenol, 2,4-dichloro-
- RCRA waste number U081

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-085
June 2015

Update of Human Health Ambient Water Quality Criteria:

2,4-Dimethylphenol
105-67-9

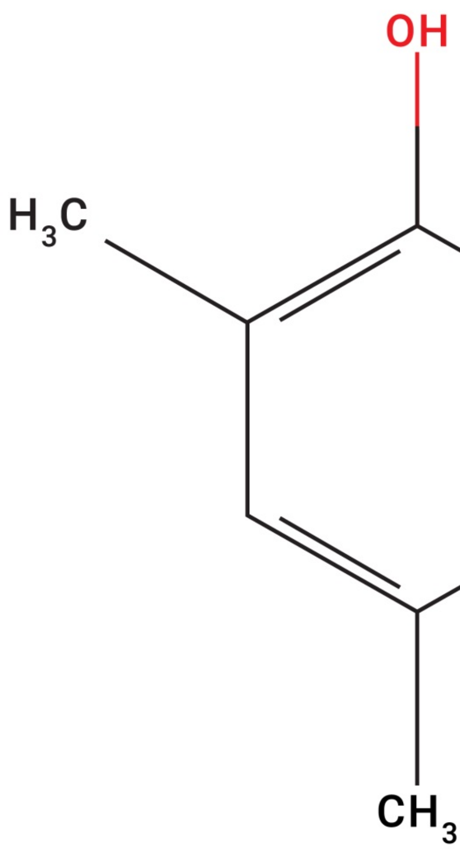

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 2,4-dimethylphenol to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a] and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 4.8 L/kg (TL2), 6.2 L/kg (TL3), and 7.0 L/kg (TL4) for 2,4-dimethylphenol. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 2,4-dimethylphenol. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. 2,4-Dimethylphenol has the following characteristics:

- Nonionic organic chemical (USDHHS 2003)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 2.3 (USDHHS 2003)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 4.8 L/kg
TL3 = 6.2 L/kg
TL4 = 7.0 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 2,4-dimethylphenol. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 2×10^{-2} mg/kg-d (0.02 mg/kg-d) for 2,4-dimethylphenol based on a 1990 EPA IRIS assessment (USEPA 1990). EPA's IRIS program identified a study by EPA (USEPA 1989) as the critical study and lethargy, prostration, ataxia, and hematological changes as the critical effects in mice orally exposed to 2,4-dimethylphenol. The subchronic study has a NOAEL of 50 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 3000 to account for interspecies extrapolation (10), intraspecies variation (10), subchronic-to-chronic study extrapolation (10), and database deficiencies (3) (USEPA 1990).

In 2002, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the RfD for 2,4-dimethylphenol and identified one or more significant new studies; however, EPA's IRIS program has not reassessed this chemical.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified no other RfD sources through the systematic search described in section 5.

5.2.2 Cancer Slope Factor

2,4-Dimethylphenol has not undergone a complete evaluation and determination under EPA's IRIS program for evidence of human carcinogenic potential (USEPA 1990).

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

2,4-Dimethylphenol is used in coal tar disinfectant, coal tar creosote, gasoline, and rubber production. It is also used in making pharmaceuticals, insecticides, fungicides, dye stuffs, and plastics (USDHHS 2003). Currently, 2,4-dimethylphenol is registered as an antimicrobial pesticide and listed by EPA as in the registration review process (USEPA 2015c). The general population might be exposed to 2,4-dimethylphenol primarily via inhalation of ambient air (i.e., tobacco smoke and automobile exhaust), and possibly via ingestion of fish and contact with other products containing 2,4-dimethylphenol (USDHHS 2003).

The vapor pressure of 2,4-dimethylphenol (0.102 mm Hg at 25 °C) indicates that volatilization is an important fate process for this chemical (USDHHS 2003). Recent data from EPA's Toxic Release Inventory (USEPA 2015g) indicate that over 9,800 pounds of 2,4-dimethylphenol were released to the air in 2013. It is not listed as a hazardous air pollutant (USEPA 2013). Thus, the physical properties and types of releases of 2,4-dimethylphenol indicate that air is a potentially significant source of exposure to the chemical.

2,4-Dimethylphenol has been detected in surface water, and it is expected to adsorb very little to suspended solids and sediment in the water column based on its organic carbon-referenced sorption coefficients (USDHHS 2003). It is very soluble in water and has an estimated half-life of 3–22 days (USDHHS 2003). This chemical has been detected in finished drinking water (USDHHS 2003); however, data are very limited. 2,4-Dimethylphenol is not regulated under the Safe Drinking Water Act (USEPA 2014c), and it was not a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). No Standard of Quality for bottled water for this chemical has been established (IBWA 2012). Thus, the physical and chemical properties of this chemical indicate that ingestion of surface and drinking water is a potentially significant source of exposure.

Current information regarding concentrations of 2,4-dimethylphenol in food could not be identified. EPA does not set a 40 CFR part 180 pesticide tolerance for this chemical in food and feed commodities (USGPO 2015). Thus, the potential exposure to 2,4-dimethylphenol from food is unknown.

The log K_{ow} for 2,4-dimethylphenol is 2.3 (USDHHS 2003). The national-level BAF estimates for 2,4-dimethylphenol range from 4.8 L/kg (TL2) to 7.0 L/kg (TL4), which indicates that it has a low potential for bioaccumulation (USEPA 2011b). Although one study reported a BCF for this chemical of 150 L/kg in bluegill sunfish (USDHHS 2003), it was not a target chemical in either NOAA's Mussel Watch Survey (NOAA 2014) or in EPA's National Lake Fish Tissue Study (USEPA 2009c). Thus, based on 2,4-dimethylphenol's low potential for bioaccumulation, exposure to it from ingestion of fish and shellfish is not considered likely.

In summary, limited source information as well as physical properties of this chemical suggest that air and surface and drinking water are potentially significant sources of 2,4-dimethylphenol. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to accurately characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for 2,4-dimethylphenol.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 2,4-dimethylphenol from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 2,4-Dimethylphenol

Input Parameter		Value
RfD		0.02 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	4.8 L/kg
	TL3	6.2 L/kg
	TL4	7.0 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{0.02\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{2.4\ \text{L/d} + ((0.0076\ \text{kg/d} \times 4.8\ \text{L/kg}) + (0.0086\ \text{kg/d} \times 6.2\ \text{L/kg}) + (0.0051\ \text{kg/d} \times 7.0\ \text{L/kg}))}$$

$$= 127\ \mu g/L$$

$$= 100\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{0.02\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{(0.0076\ \text{kg/d} \times 4.8\ \text{L/kg}) + (0.0086\ \text{kg/d} \times 6.2\ \text{L/kg}) + (0.0051\ \text{kg/d} \times 7.0\ \text{L/kg})}$$

$$= 2{,}550\ \mu g/L$$

$$= 3{,}000\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for 2,4-dimethylphenol using a noncarcinogenic toxicity endpoint. The updated human health AWQC for 2,4-dimethylphenol are **100 µg/L** for consumption of water and organisms and **3,000 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for 2,4-Dimethylphenol

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	380 µg/L	**100 µg/L**
Organism Only	850 µg/L	**3,000 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to 2,4-dimethylphenol from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for 2,4-dimethylphenol take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

<u>Body Weight</u>

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

<u>Drinking Water Intake</u>

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 4.8, 6.2, and 7.0 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 93.8 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 9.984 L/kg
TL3 = 10.67 L/kg
TL4 = 12.33 L/kg

Assuming all other input parameters remain constant, lower BAFs or BCFs result in higher AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish decreases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure increases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to

representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA retained an RfD of 0.02 mg/kg-d for 2,4-dimethylphenol based on a 1990 EPA IRIS assessment (USEPA 1990; USEPA 2002c). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for 2,4-dimethylphenol and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of 2,4-dimethylphenol in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- 2,4-dimethylphenol (CAS Number 105-67-9)
- Phenol, 2,4-dimethyl-
- Caswell No. 907A
- EPA Pesticide Chemical Code 086804
- HSDB 4253
- m-xylenol
- NSC 3829
- RCRA waste number U101
- 1-hydroxy-2,4-dimethylbenzene
- 2,4-xylenol
- 4-hydroxy-1,3-dimethylbenzene
- 4,6-dimethylphenol

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-086
June 2015

Update of Human Health Ambient Water Quality Criteria:

2,4-Dinitrophenol
51-28-5

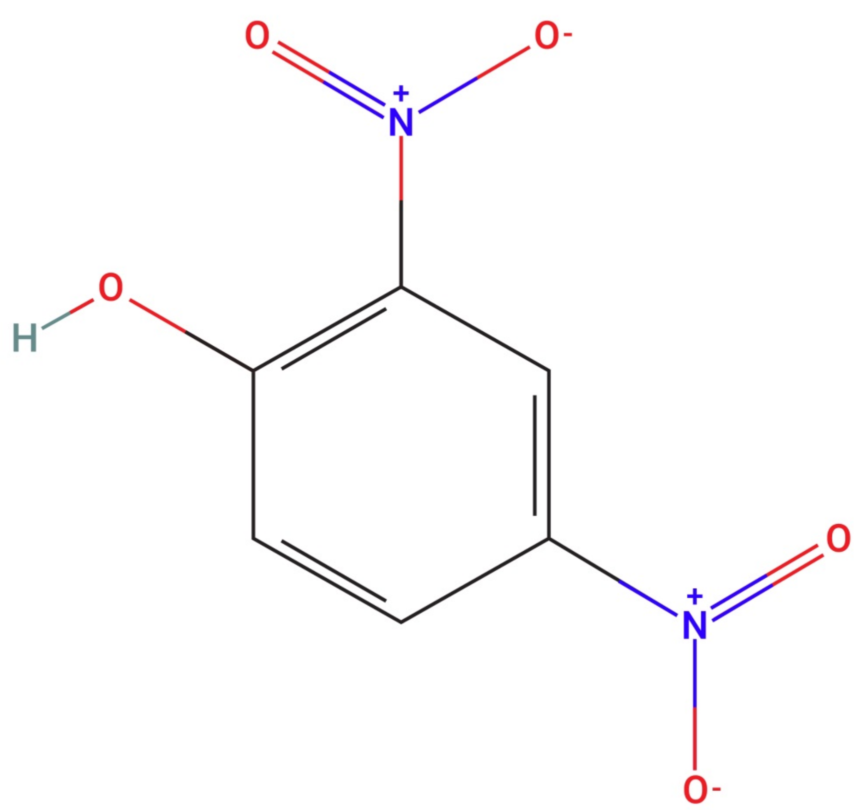

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 2,4-dinitrophenol to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 4.4 L/kg for 2,4-dinitrophenol. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 2,4-dinitrophenol. Based on the characteristics of this chemical, EPA selected Procedure 5 for deriving a national BAF value. 2,4-Dinitrophenol has the following characteristics:

- Ionic organic chemical, with ionization not negligible (USDHHS 2011)
- Biomagnification unlikely (ATSDR 1995)

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for all three TLs (2, 3, and 4). Therefore, EPA used the BCF method estimate for the reported TLs by calculating the geometric mean of the TL2 and TL3 BCF values available for 2,4-dinitrophenol (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 4.4 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 2,4-dinitrophenol. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both

noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 2×10^{-3} mg/kg-d (0.002 mg/kg-d) for 2,4-dinitrophenol based on a 1986 EPA IRIS assessment (USEPA 1986). EPA identified a study by Horner (1942) as the critical study and the development of cataracts as the critical effect in humans orally exposed to 2,4-dinitrophenol. The study had a LOAEL of 2 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 1000 to account for intraspecies variation (10), subchronic-to-chronic study extrapolation (10), and uncertainty in the estimation of a NOAEL from a LOAEL (10) (USEPA 1986).

In 2005, EPA's IRIS conducted a comprehensive review of toxicological studies and identified no new health effects data that would be directly useful in the revision of the existing RfD for 2,4-dinitrophenol.

EPA identified two other potential RfD sources through the systematic search described in section 5: a 2007 EPA Office of Solid Waste and Emergency Response (OSWER) Provisional Peer Reviewed Toxicity Value (PPRTV) (USEPA 2007) and a 1995 ATSDR assessment (ATSDR 1995). Based on the selection process described in section 5, the 1986 EPA IRIS RfD is preferred for use in AWQC development at this time. Neither of the other assessments include the relevant (chronic oral) toxicity value.

5.2.2 Cancer Slope Factor

2,4-Dinitrophenol has not undergone a complete evaluation and determination under EPA's IRIS program for evidence of human carcinogenic potential (USEPA 1986).

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

2,4-Dinitrophenol is primarily used for making dyes, other organic chemicals, and wood preservatives. It is also used to make photographic developer, explosives, and insect control substances (ATSDR 1995). 2,4-Dinitrophenol was once registered as a pesticide, but is not currently registered (USEPA 2015c). ATSDR (1995) reports inhalation could be a potential route of exposure.

Dinitrophenols are released during their manufacturing processes and can form in the air when benzene and nitrogen oxide (NO_x) react. The vapor pressure of 2,4-dinitrophenol (3.9×10^{-4} mm Hg at 20 °C) is expected to exist solely as a vapor in the atmosphere, and volatilization from water surfaces is not expected to be an important fate process based upon its anionic state (USDHHS 2011). Recent data from EPA's 2013 Toxic Release Inventory (USEPA 2015g) indicate that 2,403 pounds of 2,4-dinitrophenol were released to the air in 2013. 2,4-Dinitrophenol is listed as a hazardous air pollutant (USEPA 2013). Thus, based on the chemical's physical properties, air is a potentially significant source of exposure to it.

2,4-Dinitrophenol is very soluble in water and has a half-life of approximately 500 days (ATSDR 1995). Monitoring information regarding 2,4-dinitrophenol concentrations in surface water is not available. 2,4-Dinitrophenol is not regulated under the Safe Drinking Water Act (SDWA) (USEPA 2014c), and it was not a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). There is no Standard of Quality for this chemical in bottled water (IBWA 2012). Based on 2,4-dinitrophenol's solubility and half-life, drinking water ingestion is a potentially significant source of exposure to it.

The log K_{ow} for 2,4-dinitrophenol is 1.54 (ATSDR 1995). The national-level BAF estimate for 2,4-dinitrophenol is 4.4 L/kg, which indicates that the chemical has a low potential for bioaccumulation (USEPA 2011b). Despite its low potential for bioaccumulation, 2,4-dinitrophenol has been detected in fish from Lake Michigan tributaries and embayments (USDHHS 2011). 2,4-Dinitrophenol was not a target chemical in EPA's National Lake Fish Tissue Study (USEPA 2009c), and it was not included as an analyte in NOAA's Mussel Watch Survey (NOAA 2014). Therefore, based on available information, ingestion of fish and shellfish is potentially a significant source of exposure to 2,4-dinitrophenol.

Information regarding concentrations of 2,4-dinitrophenol in food could not be identified. Thus, the potential exposure to 2,4-dinitrophenol from food is unknown.

In summary, based on the chemical fate and available exposure information for 2,4-dinitrophenol, air, drinking water, and fish from inland and nearshore waters are potentially significant sources of this chemical. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree; however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for 2,4-dinitrophenol.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 2,4-dinitrophenol from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 2,4-Dinitrophenol

Input Parameter	Value
RfD	0.002 mg/kg-d
CSF	No data
RSC	0.20
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	4.4 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.002\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{2.4\ \text{L/d} + (0.022\ \text{kg/d} \times 4.4\ \text{L/kg})}$$

$$= 12.8\ \mu g/L$$

$$= 10\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.002\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{(0.022\ \text{kg/d} \times 4.4\ \text{L/kg})}$$

$$= 331\ \mu g/L$$

$$= 300\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for 2,4-dinitrophenol using a noncarcinogenic toxicity endpoint. The updated human health AWQC for 2,4-dinitrophenol are **10 µg/L** for consumption of water and organisms and **300 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for 2,4-Dinitrophenol

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	69 µg/L	**10 µg/L**
Organism Only	5,300 µg/L	**300 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to 2,4-dinitrophenol from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for 2,4-dinitrophenol take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 4.4 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 1.5 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the

water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 2.697 L/kg
TL3 = 2.765 L/kg
TL4 = 2.814 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA retained an RfD of 0.002 mg/kg-d for 2,4-dinitrophenol based on a 1986 EPA IRIS assessment (USEPA 1986; USEPA 2002c). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for 2,4-dinitrophenol and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of 2,4-dinitrophenol in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- 2,4-dinitrophenol (CAS Number 51-28-5)
- Aldifen
- Chemox PE
- 2,4-dinitrofenol
- Dinitrofenolo
- Dinitrophenol, 2,4-
- alpha-dinitrophenol
- 2,4-DNP
- Fenoxyl carbon N
- 1-hydroxy-2,4-dinitrobenzene
- Maroxol-50
- Nitro kleenup
- NSC 1532
- Phenol, 2,4-dinitro-
- Phenol, alpha-dinitro-
- RCRA waste number P048
- Solfo black 2B supra
- Solfo black B
- Solfo black BB
- Solfo black G
- Solfo black SB
- Tertrosulphur black PBb
- Tertrosulphur PBR

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-087
June 2015

Update of Human Health Ambient Water Quality Criteria:

2,4-Dinitrotoluene
121-14-2

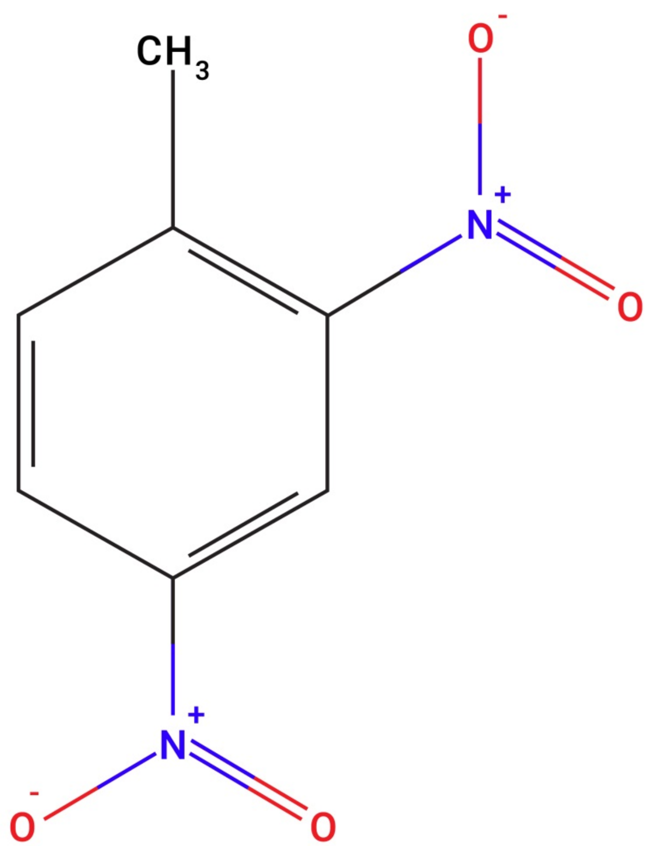

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 2,4-dinitrotoluene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level-(TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 2.8 L/kg (TL2), 3.5 L/kg (TL3), and 3.9 L/kg (TL4) for 2,4-dinitrotoluene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 2,4-dinitrotoluene. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. 2,4-Dinitrotoluene has the following characteristics:

- Nonionic organic chemical (USDHHS 2013)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 1.98 (USDHHS 2013)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 2.8 L/kg
TL3 = 3.5 L/kg
TL4 = 3.9 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 2,4-dinitrotoluene. As described in the 2000 Methodology (USEPA 2000a), where data are available, EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, ATSDR (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 2×10^{-3} mg/kg-d (0.002 mg/kg-d) for 2,4-dinitrotolulene based on a 1991 EPA IRIS assessment (USEPA 1991). EPA's IRIS program identified Ellis et al. (1985) as the critical study and the development of neurotoxicity, Heinz bodies, and biliary tract hyperplasia as the critical effects in Beagles fed 98 percent 2,4-dinitrotoluene and 2 percent 2,6-dinitrotoluene for up to 24 months. The chronic duration study has a NOAEL of 0.2 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10) (USEPA 1991).

In 2002, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the RfD for 2,4-dinitrotoluene and did not identify any critical new studies.

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[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 2008 EPA Office of Water assessment (USEPA 2008) and a draft 2013 ATSDR assessment (ATSDR 2013). Based on the selection process described in section 5, the 1991 EPA IRIS RfD is preferred for use in AWQC development at this time. Both assessments are based on the same critical study and are numerically the same as the IRIS RfD.

5.2.2 Cancer Slope Factor

Under the 1986 EPA's *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), 2,4-dinitrotoluene, in a mixture with 2,6-dinitrotoluene, is classified as Group B2, "probable human carcinogen" (USEPA 1986; USEPA 2008). Under the 2005 *Guidelines for Carcinogen Risk Assessment* (USEPA 2005), the 2,4-dinitrotoluene/2,6-dinitrotoluene mixture is characterized as "likely to be carcinogenic to humans" (USEPA 2008).

EPA selected a CSF of 6.67×10^{-1} per mg/kg-d (0.667 per mg/kg-d) for 2,4-dinitrotolulene based on a 2008 EPA Office of Water assessment (USEPA 2008). EPA Office of Water program identified a study by Ellis et al. (1979) as the critical study and development of mammary gland tumors as the critical effect in female rats orally exposed to a mixture of 98 percent 2,4-dinitrotoluene and 2 percent 2,6-dinitrotoluene (USEPA 2008). The benchmark dose (BMD) is estimated using the numbers of female rats with mammary gland tumors. For a benchmark risk (BMR) level of 0.10, the estimated BMD value is 0.25 mg/kg-d with a lower bound (95 percent) (BMDL) of 0.15 mg/kg-d using the multistage model. The BMDL is used as the point of departure selected for the quantification of cancer risk (USEPA 2008).

EPA identified one other CSF source through the systematic search described in section 5: a 1989 EPA IRIS assessment (USEPA 1989). Based on the selection process described in section 5, the 2008 Office of Water CSF is preferred for use in AWQC development at this time. The Office of Water assessment uses the same principal study (Ellis et al. 1979), but uses a more current BMD modeling approach than was used in the IRIS assessment.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- Food and Drug Administration (FDA) Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- National Oceanic and Atmospheric Administration (NOAA) Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 2,4-dinitrotoluene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 2,4-Dinitrotoluene

Input Parameter		Value
RfD		0.002 mg/kg-d
CSF		0.667 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	2.8 L/kg
	TL3	3.5 L/kg
	TL4	3.9 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.002 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 2.8 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 3.5 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 3.9 \text{ L/kg}))}$$

$$= 12.9\ \mu g/L$$

$$= 10\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d] × RSC) × BW (kg) × 1,000 (µg/mg)}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.002 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000 \ \mu g/mg}{(0.0076 \text{ kg/d} \times 2.8 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 3.5 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 3.9 \text{ L/kg})}$$

$$= 449 \ \mu g/L$$

$$= 400 \ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d] × BW (kg) × 1,000 (µg/mg)}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.667) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 2.8 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 3.5 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 3.9 \text{ L/kg}))}$$

$$= 0.04853 \ \mu g/L$$

$$= 0.049 \ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d] × BW (kg) × 1,000 (µg/mg)}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.667) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \ \mu g/mg}{(0.0076 \text{ kg/d} \times 2.8 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 3.5 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 3.9 \text{ L/kg})}$$

$$= 1.683 \ \mu g/L$$

$$= 1.7 \ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for 2,4-dinitrotoluene using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for 2,4-dinitrotoluene are **10 µg/L** for consumption of water and organisms and **400 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for 2,4-dinitrotoluene are **0.049 µg/L** for consumption of water and organisms and **1.7 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of 2,4-dinitrotoluene, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for 2,4-Dinitrotoluene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.11 µg/L	**0.049 µg/L**
Organism Only	3.4 µg/L	**1.7 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to 2,4-dinitrotoluene at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for 2,4-dinitrotoluene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a

contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 2.8, 3.5, and 3.9 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 3.8 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 6.485 L/kg
TL3 = 7.232 L/kg
TL4 = 10.33 L/kg

Assuming all other input parameters remain constant, lower BAFs or BCFs result in higher AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish decreases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure increases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.002 mg/kg-d for 2,4-dinitrotolulene based on a 1991 IRIS assessment (USEPA 1991). EPA used the RfD of 0.002 mg/kg-d to derive AWQC for noncarcinogenic effects.

EPA did not derive AWQC for noncarcinogenic effects of 2,4-dinitrotolulene in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.667 per mg/kg-d for 2,4-dinitrotolulene based on a 2008 EPA Office of Water assessment (USEPA 2008). This CSF replaces the previous value of 0.311 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.667 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, an increase in the CSF in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- 2,4-Dinitrotoluene (CAS Number 121-14-2)
- Benzene, 1-methyl-2,4-dinitro-
- 2,4-Dinitrotoluol
- 2,4-DNT
- 1-Methyl-2,4-dinitrobenzene
- Toluene, 2,4-dinitro-

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-088
June 2015

Update of Human Health Ambient Water Quality Criteria:

2-Chloronaphthalene
91-58-7

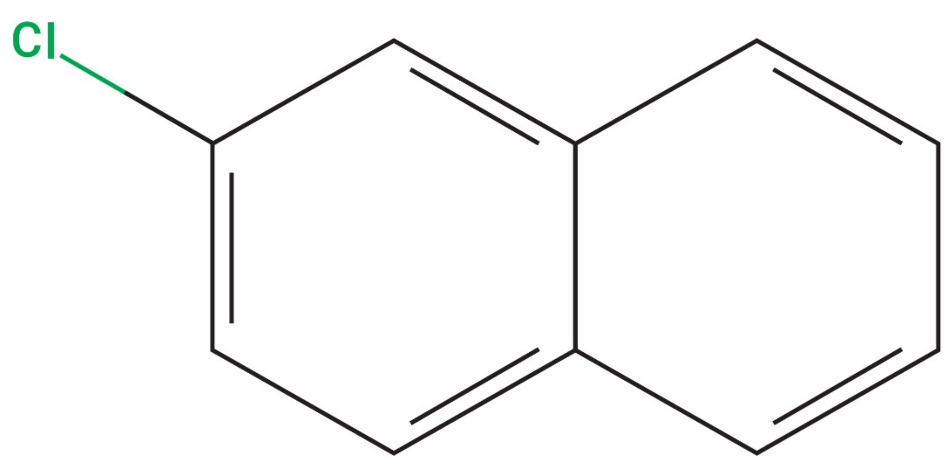

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 2-chloronaphthalene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC }(\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC }(\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 150 L/kg (TL2), 210 L/kg (TL3), and 240 L/kg (TL4) for 2-chloronaphthalene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 2-chloronaphthalene. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. 2-Chloronaphthalene has the following characteristics:

- Nonionic organic chemical (USDHHS 2004)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 3.9$ (USDHHS 2004)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 150 L/kg
TL3 = 210 L/kg
TL4 = 240 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 2-chloronaphthalene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 8×10^{-2} per mg/kg-d (0.08 mg/kg-d) for 2-chloronapthalene based on a 1990 EPA IRIS assessment (USEPA 1990). EPA's IRIS program identified a study by EPA (USEPA 1989) as the critical study and dyspnea, abnormal appearance, and liver enlargement as the critical effects in mice orally exposed to 2-chloronaphthalene. The subchronic study has a NOAEL of 250 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 3000 to account for interspecies extrapolation (10), intraspecies variation (10), subchronic-to-chronic study extrapolation (10), and database deficiencies (3) (USEPA 1990).

In 2005, EPA's IRIS program completed a comprehensive review of toxicological studies published through 2004 and identified no new health effects data that would be directly useful in revising the existing RfD for 2-chloronapthalene.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified no other RfD sources through the systematic search described in section 5.

5.2.2 Cancer Slope Factor

2-Chloronapthalene has not undergone a complete evaluation and determination under EPA's IRIS program for evidence of human carcinogenic potential (USEPA 1990).

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

2-Chloronaphthalene is no longer produced in the United States. In the past, it was used as a chemical-resistant gauge fluid, heat-exchange fluid, color dispersant, engine crankcase additive to dissolve sludge and gums, and ingredient in motor tune-up compounds. These uses might have resulted in its release to the environment through various waste streams. The only U.S. producer stopped manufacturing chloronaphthalene products in 1977 (CDC 2009). The major sources of release of chlorinated naphthalenes into the environment are likely waste incineration and disposal of items containing chlorinated naphthalenes in landfills (USDHHS 2004). Possible exposure routes for chlorinated naphthalenes are inhalation of ambient air and ingestion of food and drinking water (USDHHS 2004).

The log K_{ow} for 2-chloronaphthalene is 3.90 (USDHHS 2004). The national-level BAF estimates for 2-chloronaphthalene range from 150 L/kg (TL2) to 240 L/kg (TL4), which indicates 2-chloronaphthalene has a moderate potential for bioaccumulation (USEPA 2011b). 2-Chloronaphthalene was not included in NOAA's Mussel Watch Survey (NOAA 2014), and it was not a target chemical in EPA's National Lake Fish Tissue Study (USEPA 2009c). Prior to 2001, levels of 2-chloronaphthalene were measured in oysters and clams from Lake Pontchartrain, Louisiana: 34 µg/kg wet weight in oysters, and 140 and 970 µg/kg wet weight in clams (USDHHS 2004). A 1987 study reported detections of 2-chloronaphthalene in common carp, channel catfish, smallmouth and largemouth bass, rock bass, pumpkinseed, bowfin, lake trout, and northern pike from Lake Michigan (USDHHS 2004). Studies from 1985 reported detections of 2-chloronaphthlalene in fish collected from Great Lake harbors and tributary mouths (USDHHS 2004). Thus, based on its moderate potential to bioaccumulate and its historical detection in ocean fish, ingestion of fish and shellfish is a potentially significant source of exposure to 2-chloronaphthalene.

2-Chloronaphthalene is not regulated under the Safe Drinking Water Act (USEPA 2014c). For all samples taken from studies of 11 water utilities of the Ohio River Valley reported in the 1980s, 2-chloronaphthalene was detected in 4 of 150 raw water extracts and 30 of 120 finished drinking water extracts (USDHHS 2004). No Standard of Quality for Bottled Water is available for 2-chloronaphthalene (IBWA 2012), and it was not listed as a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). Therefore, based on its historical detection, ingestion of drinking water is a possible source of exposure to 2-chloronaphthalene.

Volatilization from moist soil surfaces and water surfaces is expected to be potentially important to fate processes based upon a Henry's Law constant of 3.2×10^{-4} atm-m^3/mole at 25 °C. However, adsorption to soil, suspended solids, and sediment are expected to attenuate volatilization (USDHHS 2004). 2-Chloronaphthalene (with a vapor pressure of 0.0122 mm Hg) is not expected to volatilize from dry soil surfaces. If released into the air, 2-chloronaphthalene is expected to exist solely as a vapor in the ambient atmosphere. Vapor-phase 2-chloronaphthalene will be degraded in the atmosphere by reacting with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 2.1 days (USDHHS 2004). EPA's 2013 Toxic Release Inventory did not report any releases of 2-chloronaphthalene (USEPA 2015g), and this chemical is not listed as a hazardous air pollutant (USEPA 2013). Thus, based on its physical properties, exposure to 2-chloronaphthalene from inhalation of air is not considered likely.

USDHHS (2004) notes that food is a potential exposure pathway for 2-chloronaphthalene; however, no reports of measured levels of 2-chloronaphthalene in food products (other than fish and shellfish) were found. 2-Chloronaphthalene was not listed in the FDA Total Diet Study (USFDA 2005). The few reported exposures of the general population primarily involve ingestion of cooking oil contaminated with several chemicals, including chlorinated naphthalene (WHO 2001). Thus, based on the available information, exposure to 2-chloronaphthalene from ingestion of food is possible but not considered likely.

In summary, based on the available exposure information for 2-chloronaphthalene and given that the chemical is no longer produced or used in the United States. EPA does not anticipate that there will be significant sources and routes of exposure to 2-chloronaphthalene other than fish and shellfish from inland and nearshore waters. Based on EPA's 2000 Methodology, "If it can be demonstrated that other sources and routes of exposure are not anticipated for the pollutant in question (based on information about its known/anticipated uses and chemical/physical properties), then EPA would use the 80 percent ceiling" (see section 4.2.3 the 2000 Methodology) (USEPA 2000a). Therefore, EPA recommends an RSC of 80 percent (0.80) for 2-chloronaphthalene.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 2-chloronaphthalene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 2-Chloronaphthalene

Input Parameter		Value
RfD		0.08 mg/kg-d
CSF		No data
RSC		0.80
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	150 L/kg
	TL3	210 L/kg
	TL4	240 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{0.08\ \text{mg/kg-d} \times 0.80 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{2.4\ \text{L/d} + ((0.0076\ \text{kg/d} \times 150\ \text{L/kg}) + (0.0086\ \text{kg/d} \times 210\ \text{L/kg}) + (0.0051\ \text{kg/d} \times 240\ \text{L/kg}))}$$

$$= 779\ \mu g/L$$

$$= 800\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.08\ mg/kg\text{-}d \times 0.80 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 150\ L/kg) + (0.0086\ kg/d \times 210\ L/kg) + (0.0051\ kg/d \times 240\ L/kg)}$$

$$= 1{,}228\ \mu g/L$$

$$= 1{,}000\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for 2-chloronaphthalene using a noncarcinogenic toxicity endpoint. The updated human health AWQC for 2-chloronaphthalene are **800 µg/L** for consumption of water and organisms and **1,000 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for 2-Chloronaphthalene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	1,000 µg/L	**800 µg/L**
Organism Only	1,600 µg/L	**1,000 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to 2-chloronaphthalene from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for 2-chloronaphthalene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is

10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 150, 210, and 240 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 202 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003) The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 440.4 L/kg
TL3 = 477.8 L/kg
TL4 = 626.2 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA retained an RfD of 0.08 mg/kg-d for 2-chloronapthalene based on a 1990 EPA IRIS assessment (USEPA 1990; USEPA 2002c). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for 2-chloronapthalene and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of 2-chloronapthalene in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 80 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- 2-chloronaphthalene (CAS Number 91-58-7)
- Naphthalene, 2-chloro-
- beta-chloronaphthalene
- HSDB 4014
- RCRA waste number U047
- 2-chlornaftalen [Czech]

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Office of Water
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Update of Human Health Ambient Water Quality Criteria:

2-Chlorophenol
95-57-8

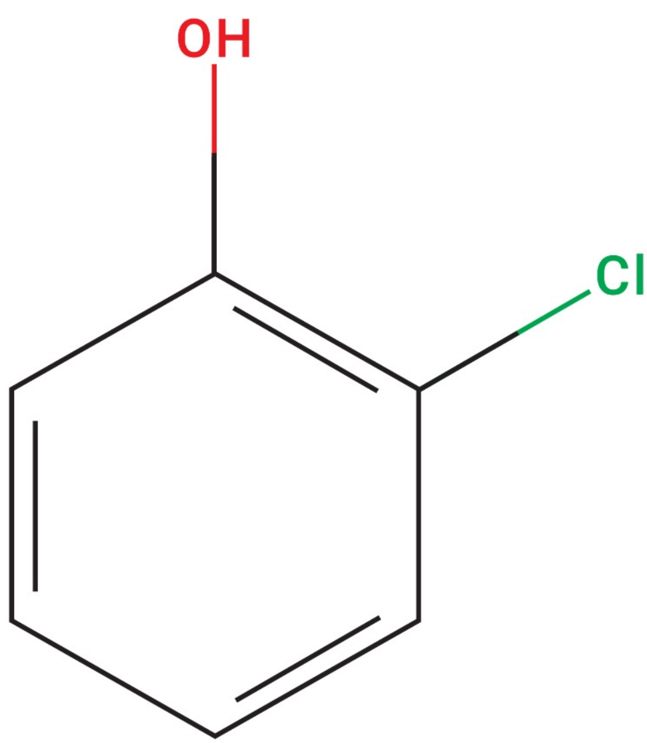

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 2-chlorophenol to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC = ambient water quality criteria

toxicity value = RfD x RSC (mg/kg-d) for noncarcinogenic effects
or
10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]

RSC = relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)

BW = body weight

DI = drinking water intake

$\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4

FCR_i = fish consumption rate for aquatic TLs 2, 3, and 4

BAF_i = bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level-(TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 3.8 L/kg (TL2), 4.8 L/kg (TL3), and 5.4 L/kg (TL4) for 2-chlorophenol. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 2-chlorophenol. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. 2-Chlorophenol has the following characteristics:

- Nonionic organic chemical (USDHHS 2009)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 2.17 (ATSDR 1999)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 3.8 L/kg
TL3 = 4.8 L/kg
TL4 = 5.4 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 2-chlorophenol. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 5×10^{-3} per mg/kg-d (0.005 mg/kg-d) for 2-chlorophenol based on a 1988 EPA IRIS assessment (USEPA 1988). EPA's IRIS program identified a study by Exon and Koller (1982) as the critical study and reproductive effects as the critical effects in female rats orally exposed to 2-chlorophenol in drinking water. The subchronic study has a NOAEL of 5 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 1000 to account for interspecies extrapolation (10), intraspecies variation (10), and subchronic-to-chronic study extrapolation (10) (USEPA 1988).

In 2002 EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the RfD for 2-chlorophenol and did not identify any critical new studies.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified no other RfD sources through the systematic search described in section 5.

5.2.2 Cancer Slope Factor

2-Chlorophenol has not undergone a complete evaluation and determination under EPA's IRIS program for evidence of human carcinogenic potential (USEPA 1988).

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

2-Chlorophenol was once registered for use as a pesticide, but is no longer registered (USEPA 2015c). It is also used in the organic synthesis of dyes (ATSDR 1999). Populations that could potentially have high exposure to 2-chlorophenol include those who work at facilities that manufacture or use the chemical and those who live near 2-chlorophenol-containing waste disposal sites and waste incinerators (ATSDR 1999). Chlorophenols can be formed when water containing humic substances are treated with chlorine and have a pH ranging from 7 to 8 (Krijgsheld and van der Gen 1986). Monochlorophenols are difficult to produce in chlorinated waters without high levels of chlorine present for long contact times (ATSDR 1999). The general population might be exposed to chlorophenols through ingestion of water and food contaminated with the compounds and inhalation of contaminated air (ATSDR 1999).

The vapor pressure of 2-chlorophenol (2.53 mm Hg at 25 °C) indicates that this chemical will exist solely as a vapor in the atmosphere (USDHHS 2009), and that volatilization is an important fate process (ATSDR 1999). 2-Chlorophenol tends to volatilize to the atmosphere during chlorophenol production and the manufacture of the various products in which it is used (ATSDR 1999). Recent data from EPA’s Toxic Release Inventory indicate that 347 pounds of chlorophenols were released to the air in 2013 (USEPA 2015g). 2-Chlorophenol is not listed as a hazardous air pollutant (USEPA 2013). Thus, based on its physical properties, air is a potentially significant source of exposure to 2-chlorophenol.

2-Chlorophenol released into surface water is expected to adsorb to suspended solids and sediment based on the measured organic carbon-referenced sorption coefficients (ATSDR 1999). 2-Chlorophenol is not regulated under the Safe Drinking Water Act (USEPA 2014c), and it was not a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). There is also no Standard of Quality for this chemical in bottled water (IBWA 2012). It has been reported that the chlorination of polluted and natural waters can produce chlorophenols (USDHHS 2009). Thus, the potential exposure to 2-chlorophenol from ingestion of surface and drinking water is unknown.

Sources of recent information to quantitatively assess food ingestion exposure are not available at this time. Thus, the potential exposure to 2-chlorophenol from food is unknown.

The log K_{ow} for 2-chlorophenol is 2.17 (USDHHS 2009). The national-level BAF estimates for 2-chlorophenol range from 3.8 L/kg (TL2) to 5.4 L/kg (TL4), which indicates 2-chlorophenol has a low potential for bioaccumulation (USEPA 2011b). 2-Chlorophenol was detected in fish samples collected from Great Lakes harbors and tributaries between 1980 and 1981 (USDHHS 2009); however, recent exposure information regarding concentrations of 2-chlorophenol in fish and shellfish from inland and nearshore waters and in ocean fish and shellfish could not be located. 2-Chlorophenol was analyzed for but not detected in fish tissue in the National Lake Fish Tissue Study (USEPA 2009c) or in NOAA's Mussel Watch Survey (NOAA 2014). Thus, exposure to 2-chlorophenol from ingestion of fish and shellfish is not considered likely.

In summary, based on the physical properties and available exposure information for 2-chlorophenol, air is a potentially significant source. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), a significant potential source other than fish and shellfish from inland and nearshore waters and water ingestion exists (Box 8A in the Decision Tree); however, information is not available to accurately characterize exposure from this source (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for 2-chlorophenol.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 2-chlorophenol from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 2-Chlorophenol

Input Parameter		Value
RfD		0.005 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	3.8 L/kg
	TL3	4.8 L/kg
	TL4	5.4 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.005 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 3.8 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 4.8 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 5.4 \text{ L/kg}))}$$

$$= 32.0\ \mu g/L$$

$$= 30\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.005 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 3.8 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 4.8 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 5.4 \text{ L/kg})}$$

$$= 819\ \mu g/L$$

$$= 800\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for 2-chlorophenol using a noncarcinogenic toxicity endpoint. The updated human health AWQC for 2-chlorophenol are **30 µg/L** for consumption of water and organisms and **800 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for 2-Chlorophenol

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	81 µg/L	**30 µg/L**
Organism Only	150 µg/L	**800 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to 2-chlorophenol from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for 2-chlorophenol take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 3.8, 4.8, and 5.4 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 134 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 8.957 L/kg
TL3 = 9.989 L/kg
TL4 = 14.07 L/kg

Assuming all other input parameters remain constant, lower BAFs or BCFs result in higher AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish decreases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure increases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to

representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA retained an RfD of 0.005 mg/kg-d for 2-chlorophenol based on a 1988 EPA IRIS assessment (USEPA 1988; USEPA 2002c). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for 2-chlorophenol and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of 2-chlorophenol in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- 2-chlorophenol (CAS Number 95-57-8)
- Chlorophenol, 2-
- o-chlorophenol, liquid
- o-chlorophenol
- o-chlorophenol, solid
- o-chlorphenol
- Phenol, 2-chloro-
- Phenol, o-chloro-
- RCRA Waste Number U048
- UN 2020
- UN 2021

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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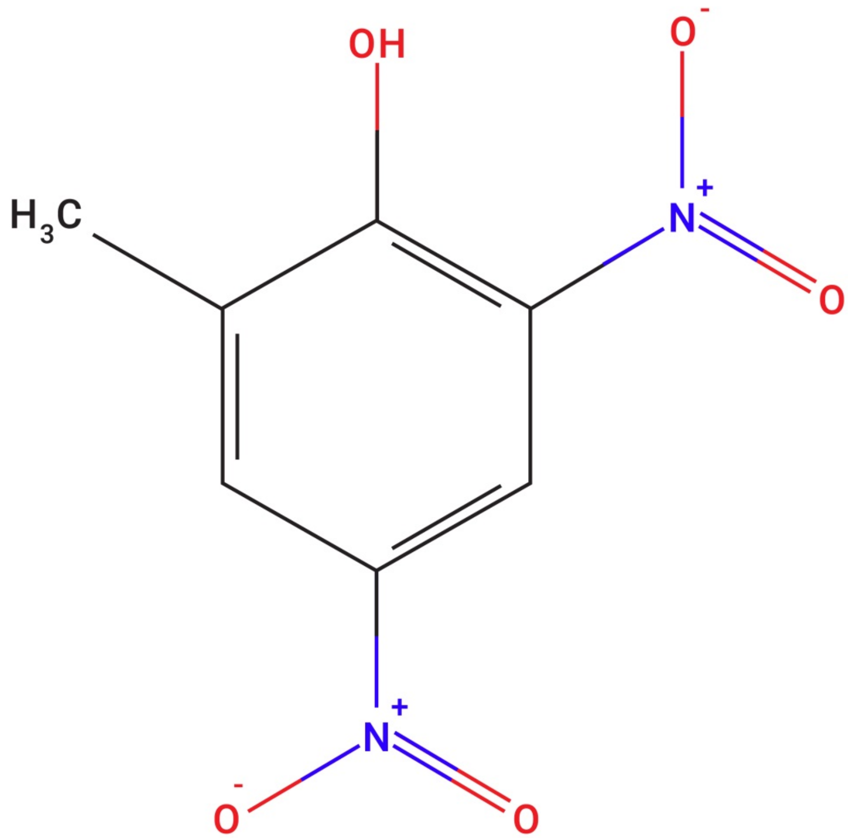
June 2015

Update of Human Health Ambient Water Quality Criteria:

2-Methyl-4,6-dinitrophenol
534-52-1



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Office of Science and Technology
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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for 2-methyl-4,6-dinitrophenol to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC = ambient water quality criteria

toxicity value = RfD x RSC (mg/kg-d) for noncarcinogenic effects
or
10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]

RSC = relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)

BW = body weight

DI = drinking water intake

$\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4

FCR_i = fish consumption rate for aquatic TLs 2, 3, and 4

BAF_i = bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a] and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 6.8 L/kg (TL2), 8.9 L/kg (TL3), and 10 L/kg (TL4) for 2-methyl-4,6-dinitrophenol. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for 2-methyl-4,6-dinitrophenol. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. 2-Methyl-4,6-dinitrophenol has the following characteristics:

- Nonionic organic chemical (USDHHS 2013)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 2.49 (ATSDR 1995a)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 6.8 L/kg
TL3 = 8.9 L/kg
TL4 = 10 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for 2-methyl-4,6-dinitrophenol. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 3×10^{-4} mg/kg-d (0.0003 mg/kg-d) for 2-methyl-4,6-dinitrophenol based on a 2010 EPA Office of Solid Waste and Emergency Response (OSWER) Provisional Peer Reviewed Toxicity Value (PPRTV) (USEPA 2010). EPA OSWER identified Ibrahim et al. (1934) as the critical study and reduced BW, excessive perspiration and fatigue, elevated basal metabolic rate (BMR) and body temperature, and the development of greenish-yellow coloration of the conjunctivae as the critical effects in humans orally taking 2-methyl-4,6-dinitrophenol. The 5.5-week human study has a LOAEL of 0.8 mg/kg-d.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

Based on this human oral toxicity endpoint for 2-methyl-4,6-dinitrophenol, EPA OSWER developed a subchronic provisional RfD (subchronic p-RfD) and an oral *screening chronic value* (screening chronic p-RfD) (USEPA 2010). To derive the subchronic p-RfD, EPA OSWER applied a composite uncertainty factor of 1000 to account for intraspecies variation (10), use of a LOAEL instead of a NOAEL (10), and database deficiencies (10), resulting in a subchronic p-RfD of 8×10^{-4} mg/kg-d. EPA OSWER applied an additional uncertainty factor of 10 (i.e., composite uncertainty factor of 10,000) to account for subchronic-to-chronic extrapolation in deriving the *screening* chronic p-RfD of 8×10^{-5} mg/kg-d (0.00008 mg/kg-d) (USEPA 2010). Based on current EPA OSWER guidelines and standard operating procedures, composite uncertainty factors greater than 3000 cannot be considered for provisional reference value derivation.

For the purpose of updating the AWQC for 2-methyl-4,6-dinitrophenol, EPA Office of Water (OW) selected the OSWER subchronic p-RfD (8×10^{-4} mg/kg-d) and applied an additional uncertainty factor of 3 to account for subchronic-to-chronic extrapolation [i.e., composite uncertainty factor of 3000, consistent with EPA guidance (USEPA 2000a)]. The resulting chronic RfD for the purpose of AWQC development is 3×10^{-4} mg/kg-d (0.0003 mg/kg-d).

Due to low confidence in the database—particularly the lack of chronic toxicity studies—confidence in the subchronic p-RfD for 2-methyl-4,6-dinitrophenol is low (USEPA 2010). However, other available RfD sources report values that are similar to the RfD of 3×10^{-4} mg/kg-d. EPA identified two other RfD sources through the systematic search described in section 5: a 1980 EPA OW assessment (USEPA 1980) and a 1995 ATSDR assessment (ATSDR 1995b). The EPA OW assessment—which was based on a National Institute for Occupational Safety and Health (NIOSH) occupational exposure standard for inhalation of 2-methyl-4,6-dinitrophenol (NIOSH 1978)—has an RfD of 3.9×10^{-4} mg/kg-d. (ATSDR 1995b) published an intermediate-duration MRL of 4×10^{-3} mg/kg-d based on a human study with a LOAEL of 0.35 (Plotz 1936) and a composite uncertainty factor of 100; if an additional uncertainty factor of 10 was applied for subchronic-to-chronic duration, the chronic value would be 4×10^{-4} mg/kg-d. In the event that more current toxicity data or assessments become available for 2-methyl-4,6-dinitrophenol in the future, as with all chemicals, EPA will work to update the AWQC to reflect the latest information.

5.2.2 Cancer Slope Factor

EPA identified no CSF sources for 2-methyl-4,6-dinitrophenol through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

2-Methyl-4,6-dinitrophenol is produced for industrial chemical manufacturing and was formerly used to develop dinitrocresol pesticides. 2-Methyl-4,6-dinitrophenol is not currently registered as a pesticide (USEPA 2015c). ATSDR (1995b) reports that inhalation might be a principal route of exposure.

The vapor pressure of 2-methyl-4,6-dinitrophenol (0.00012 mm Hg at 25 °C) indicates that the chemical will exist solely in the vapor phase in the ambient atmosphere (USDHHS 2013). Recent data from EPA's Toxic Release Inventory (USEPA 2015g) indicate that 1 pound of 2-methyl-4,6-dinitrophenol was released to the air in 2013. 2-Methyl-4,6-dinitrophenol is listed as a hazardous air pollutant (USEPA 2013). Thus, based on the chemical's physical properties, air is a potentially significant source of exposure to it.

2-Methyl-4,6-dinitrophenol was not reported as being detected in food (ATSDR 1995b). More recent information regarding concentrations of 2-methyl-4,6-dinitrophenol in food could not be identified. Thus, the potential exposure to this chemical from food is unknown.

Monitoring data regarding 2-methyl-4,6-dinitrophenol in surface water or drinking water could not be identified. 2-Methyl-4,6-dinitrophenol is not regulated under the Safe Drinking Water Act (USEPA 2014c), and it was not a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). There is no Standard of Quality for this chemical in bottled water (IBWA 2012). Therefore, the potential exposure to 2-methyl-4,6-dinitrophenol from drinking water ingestion is unknown.

The log K_{ow} for 2-methyl-4,6-dinitrophenol ranges from 2.12 to 2.85, with an average log K_{ow} of 2.49 (ATSDR 1995b). The national-level BAF estimates for 2-methyl-4,6-dinitrophenol range from 6.8 L/kg (TL2) to 10 L/kg (TL4), which indicates that 2-methyl-4,6-dinitrophenol has a low potential for bioaccumulation (USEPA 2011b). 2-Methyl-4,6-dinitrophenol was not a target chemical in EPA's National Lake Fish Tissue Study (USEPA 2009c), and it was not included as an analyte in NOAA's Mussel Watch Survey (NOAA 2014). Recent exposure information regarding concentrations of 2-methyl-4,6-dinitrophenol in fish and shellfish is lacking. Therefore, based on the chemical's low potential for bioaccumulation and available information, exposure to it from ingestion of fish and shellfish is not considered likely.

In summary, there is very limited exposure information for 2-methyl-4,6-dinitrophenol in all media, although the physical properties of the chemical indicate air might be a potentially significant source. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), a significant potential source other than fish and shellfish from inland and nearshore waters and water ingestion might exists (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from this source (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for 2-methyl-4,6-dinitrophenol.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to 2-methyl-4,6-dinitrophenol from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for 2-Methyl-4,6-dinitrophenol

Input Parameter		Value
RfD		0.0003 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	6.8 L/kg
	TL3	8.9 L/kg
	TL4	10 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.0003 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 6.8 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 8.9 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 10 \text{ L/kg}))}$$

$$= 1.86\ \mu g/L$$

$$= 2\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.0003\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 6.8\ L/kg) + (0.0086\ kg/d \times 8.9\ L/kg) + (0.0051\ kg/d \times 10\ L/kg)}$$

$$= 26.8\ \mu g/L$$

$$= 30\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for 2-methyl-4,6-dinitrophenol using a noncarcinogenic toxicity endpoint. The updated human health AWQC for 2-methyl-4,6-dinitrophenol are **2 µg/L** for consumption of water and organisms and **30 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for 2-Methyl-4,6-dinitrophenol

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	13 µg/L	**2 µg/L**
Organism Only	280 µg/L	**30 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to 2-methyl-4,6-dinitrophenol from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for 2-methyl-4,6-dinitrophenol take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is

10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 6.8, 8.9, and 10 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 5.5 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 4.757 L/kg
TL3 = 4.771 L/kg
TL4 = 4.485 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.0003 mg/kg-d for 2-methyl-4,6-dinitrophenol based on a 2010 EPA OSWER PPRTV (USEPA 2010). This RfD replaces the previous value of 0.00039 mg/kg-d (USEPA 1980; USEPA 2002c). EPA used the RfD of 0.0003 mg/kg-d to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, a decrease in the RfD in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

Cancer Slope Factor

EPA did not select a CSF for 2-methyl-4,6-dinitrophenol and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of 2-methyl-4,6-dinitrophenol in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- 2-Methyl-4,6-dinitrophenol (CAS Number 534-52-1)
- o-Cresol,4,6-dinitro-
- Antinonin
- Antinonnin
- Arborol
- Degrassan
- Dekrysil
- Detal
- Dillex
- Dinitro

- Dinitro-o-cresol
- Dinitrocresol
- Dinitrodendtroxal
- Dinitrol
- Dinoc
- Dinurania
- Ditrosol
- Dn
- Dnoc
- Effusan
- Effusan 3436
- Elgetol
- Elgetol 30
- Elipol
- Extrar
- Hedolit
- Hedolite
- K III
- K IV
- Kresamone
- Krezotol 50
- Lipan
- Nitrofan
- Prokarbol
- Rafex
- Rafex 35
- Raphatox
- Sandolin
- Sandolin A
- Selinon
- Sinox
- Winterwash
- 2,4-Dinitro-6-methylphenol
- 3,5-Dinitro-2-h

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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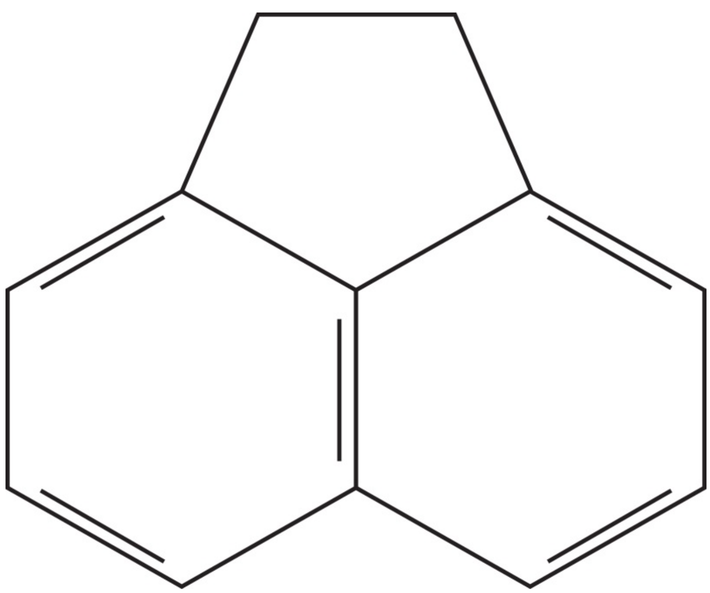
June 2015

Update of Human Health Ambient Water Quality Criteria:

Acenaphthene
83-32-9



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Washington, DC 20460

Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for acenaphthene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 510 L/kg for acenaphthene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for acenaphthene. Based on the characteristics of this chemical, EPA selected Procedure 4 for deriving a national BAF value. Acenaphthene has the following characteristics:

- Nonionic organic chemical (USDHHS 2001)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 3.98 (ATSDR 1995)
- High metabolism (NOAA n.d.)

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for all three TLs (2, 3, and 4). Therefore, EPA used the BCF method estimate for the TL3 BCF values available for acenaphthene (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 510 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for acenaphthene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both

noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 6×10^{-2} mg/kg-d (0.06 mg/kg-d) for acenaphthene based on a 1989 EPA IRIS assessment (USEPA 1989a). EPA's IRIS program identified a study by EPA (USEPA 1989b) as the critical study and hepatotoxicity as a critical effect in mice orally exposed to acenaphthene (USEPA 1989a). The subchronic study has a NOAEL of 175 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 3000 to account for interspecies extrapolation (10), intraspecies variation (10), subchronic-to-chronic study extrapolation (10), and database deficiency (3) (USEPA 1989a).

EPA identified two other RfD sources through the systematic search described in section 5: a 2011 EPA Office of Solid Waste and Emergency Response (OSWER) Provisional Peer Reviewed Toxicity Value (PPRTV) (USEPA 2011b) and a 1995 ATSDR assessment (ATSDR 1995). Based on the selection process described in section 5, the 1989 EPA IRIS RfD is preferred for use in AWQC development at this time. Neither of the other assessments included the relevant (chronic oral) toxicity value.

5.2.2 Cancer Slope Factor

EPA identified no CSF source for acenaphthene through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.

- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Acenaphthene is a low-molecular weight polyaromatic hydrocarbon (PAH) used to make plastics, pesticides, explosives, and chemotherapeutic agents (ATSDR 1995). It has not been registered as a pesticide (USEPA 2015c). Humans can be exposed to acenaphthene and other PAHs via several sources, including air, food, and fish and shellfish. The most common route of exposure to acenaphthene is inhalation of exhaust from motor vehicles, especially in urban areas with heavy traffic or near industrial sources (USDHHS 2001).

The vapor pressure of acenaphthene (0.00447 mm Hg) indicates that volatilization is a possible fate process for this chemical (ATSDR 1995; USDHHS 2001). Inhalation exposure is likely from other products of incomplete combustion, such as emissions from cigarette smoke and coal-, oil-, and wood-burning stoves and furnaces. Acenaphthene is a not listed as a hazardous air pollutant (USEPA 2013), and EPA’s Toxic Release Inventory did not report release data for it in 2013 (USEPA 2015g). Given the anthropogenic sources of PAHs and their physical properties, air is a potentially significant source of exposure to acenaphthene.

Food is also a significant source of exposure to PAHs such as acenaphthene. It has been detected in nuts, beans, grain, flour, bread, vegetables, fruits, and refined fats and oils and is often associated with grilled food (ATSDR 1995; USDHHS 2001). Thus, ingestion of food is a potentially significant source of exposure to acenaphthene.

The log K_{ow} for acenaphthene is 3.98 (ATSDR 1995). The national-level BAF estimate for acenaphthene is 510 L/kg, which indicates that it has a moderate potential for bioaccumulation (USEPA 2011c). NOAA’s Mussel Watch Survey has detected acenaphthene in fish and shellfish (NOAA 2014), but the chemical was not detected in fish tissue samples collected in EPA’s National Lake Fish Tissue Study (USEPA 2009c). Thus, based on its potential to bioaccumulate and available exposure information, ingestion of fish and shellfish is a potentially significant source of exposure to acenaphthene.

PAHs have been detected in finished drinking water (ATSDR 1995); however, recent information regarding concentrations of acenaphthene in drinking water could not be identified. Acenaphthene is not regulated under the Safe Drinking Water Act (USEPA 2014c), and it was not included in EPA's Six-Year Review (USEPA 2009a; USEPA 2009b). There is no Standard of Quality for bottled water for acenaphthene (IBWA 2012). Therefore, the potential exposure to acenaphthene from drinking water ingestion is unknown.

In summary, based on the physical properties and available exposure information regarding acenaphthene, air, non-fish food, and fish and shellfish are potentially significant sources. Following the EPA's Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from these different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for acenaphthene.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to acenaphthene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Acenaphthene

Input Parameter	Value
RfD	0.06 mg/kg-d
CSF	No data
RSC	0.20
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	510 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.06\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{2.4\ \text{L/d} + (0.022\ \text{kg/d} \times 510\ \text{L/kg})}$$

$$= 70.5\ \mu g/L$$

$$= 70\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.06\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{(0.022\ \text{kg/d} \times 510\ \text{L/kg})}$$

$$= 85.6\ \mu g/L$$

$$= 90\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for acenaphthene using a noncarcinogenic toxicity endpoint. The updated human health AWQC for acenaphthene are **70 µg/L** for consumption of water and organisms and **90 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Acenaphthene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	670 µg/L	**70 µg/L**
Organism Only	990 µg/L	**90 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to acenaphthene from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for acenaphthene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 510 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 242 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the

water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 123.1 L/kg
TL3 = 116.4 L/kg
TL4 = 94.95 L/kg

Assuming all other input parameters remain constant, higher bioaccumulation or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA retained an RfD of 0.06 mg/kg-d for acenaphthene based on a 1989 EPA IRIS assessment (USEPA 1989a; USEPA 2002c). Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for acenaphthene and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of acenaphthene in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- Acenaphthene (CAS Number 83-32-9)
- Acenaphthylene, 1,2-dihydro-
- HSDB 2659
- Naphthyleneethylene
- NSC 7657
- Peri-ethylenenaphthalene
- 1,2-dihydroacenaphthylene
- 1,8-ethylenenaphthalene

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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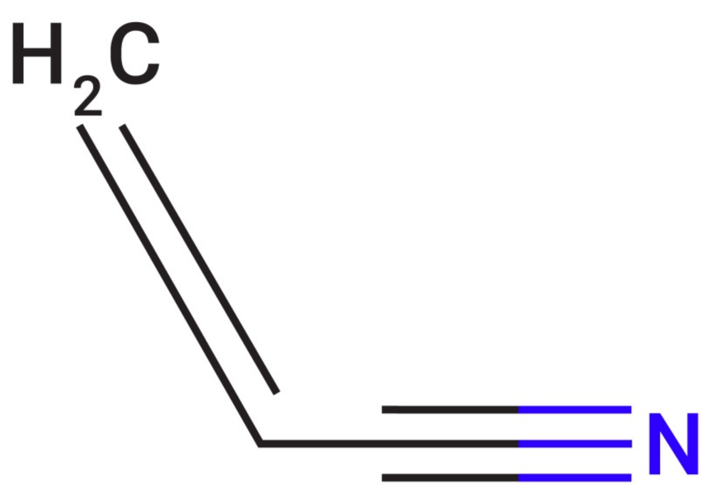
June 2015

Update of Human Health Ambient Water Quality Criteria:

Acrylonitrile
107-13-1



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Office of Science and Technology
Office of Water
U.S. Environmental Protection Agency
Washington, DC 20460

Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for acrylonitrile to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 1.0 L/kg (TL2), 1.0 L/kg (TL3), and 1.0 L/kg (TL4) for acrylonitrile. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for acrylonitrile. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Acrylonitrile has the following characteristics:

- Nonionic organic chemical (USDHHS 2013)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = -0.92 (ATSDR 1990)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 1.0 L/kg
TL3 = 1.0 L/kg
TL4 = 1.0 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for acrylonitrile. As described in the 2000 Methodology (USEPA 2000a), where data are available, EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, ATSDR (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA identified two potential RfD sources through the systematic search described in section 5: a 1990 ATSDR assessment (ATSDR 1990) and a 1999 Health Canada assessment (HC and EC 2000). The ATSDR assessment includes a chronic oral minimum risk level (MRL); however, it is based on a study by Biodynamics Inc. (1980a) that the IRIS program considered during development of a CSF (see section 5.2) but did not use quantitatively to derive an RfD (USEPA 1987). The 1999 Health Canada assessment is an inhalation assessment and does not include the relevant (chronic oral) toxicity value. Therefore, no RfD is available for AWQC development.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), acrylonitrile is classified as Group B1, "probable human carcinogen" (USEPA 1987).

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[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA selected a CSF of 5.4×10^{-1} per mg/kg-d (0.54 per mg/kg-d) for acrylonitrile based on a 1987 EPA IRIS assessment (USEPA 1987). EPA's IRIS program identified Biodynamics Inc. (1980a; 1980b) and Quast et al. (1980) as the critical studies and development of brain and spinal cord astrocytomas, Zymbal gland carcinomas, and stomach papillomas and carcinomas as the critical effects in rats orally exposed to acrylonitrile (USEPA 1987).

In 2002, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the cancer assessment for acrylonitrile and identified one or more significant new studies; however, EPA's IRIS program has not reassessed this chemical.

EPA identified one other CSF source through the systematic search described in section 5: a 1999 Health Canada assessment (HC and EC 2000). Based on the selection process described in section 5, the 1987 EPA IRIS CSF is preferred for use in AWQC development at this time. The Health Canada assessment is an inhalation assessment and does not include an oral CSF.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- Food and Drug Administration (FDA) Total Diet Study (USFDA 2015).

- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- National Oceanic and Atmospheric Administration (NOAA) Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using only a carcinogenic toxicity endpoint (CSF) because no RfD sources were identified through the systematic search described in section 5 (Hazard Identification and Dose Response). Therefore, no RSC was applied in the AWQC derivation for this chemical.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to acrylonitrile from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Acrylonitrile

Input Parameter		Value
RfD		No data
CSF		0.54 per mg/kg-d
RSC		–
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	1.0 L/kg
	TL3	1.0 L/kg
	TL4	1.0 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

EPA identified no RfD sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for noncarcinogenic toxicological effects.

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000 \ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.54) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 1.0 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 1.0 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1.0 \text{ L/kg}))}$$

$$= 0.06119 \ \mu g/L$$

$$= 0.061 \ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000 \ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.54) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \ \mu g/mg}{(0.0076 \text{ kg/d} \times 1.0 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 1.0 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1.0 \text{ L/kg})}$$

$$= 6.955 \ \mu g/L$$

$$= 7.0 \ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for acrylonitrile using a carcinogenic toxicity endpoint. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for acrylonitrile are **0.061 µg/L** for consumption of water and organisms and **7.0 µg/L** for consumption of organisms only[g] (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Acrylonitrile

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.051 µg/L	**0.061 µg/L**
Organism Only	0.25 µg/L	**7.0 µg/L***

*See footnote g.

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to acrylonitrile at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for acrylonitrile take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

[g] If a water body is not designated as a drinking water supply source, a state can adopt AWQC for consumption of organisms only instead of AWQC for consumption of water and organisms. EPA recommends, however, that the state evaluate whether organism-only AWQC for non-bioaccumulative chemicals pose a risk to swimmers in those water bodies. Because acrylonitrile has no bioaccumulation potential (BAF = 1 L/kg), EPA performed a screening analysis to determine whether the updated AWQC for organisms only is protective of incidental water ingestion from recreational uses (see section 4.1.1.3 in USEPA 2000a). EPA assumed an incidental water ingestion rate of 0.090 L/swimming event, which represents the upper (97^{th}) percentile for children (Table 3-5 in USEPA 2011) and a body weight of 31.8 kg, which represents the mean body weight of children ages 6 to <11 years (Table 8-1 in USEPA 2011). EPA relied on an acute duration (≤ 14 days) MRL for acrylonitrile of 3 mg/kg-d (ATSDR 1990). The resulting incidental water ingestion value (for screening purposes only) is 1,060,000 µg/L [(3 mg/kg-d × 31.8 kg × 1,000 µg/mg) / 0.090 L/d]. Therefore, the updated AWQC for consumption of organisms only of 7.0 µg/L for acrylonitrile is protective of incidental water ingestion from recreational uses. Where a water body is designated as a drinking water supply source EPA recommends the AWQC for consumption of water and organisms for acrylonitrile (0.061 µg/L) (USEPA 2000a).

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 1.0, 1.0, and 1.0 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 30 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 1.034 L/kg
TL3 = 1.036 L/kg
TL4 = 1.033 L/kg

Assuming all other input parameters remain constant, lower BAFs or BCFs result in higher AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish decreases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure increases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA did not select an RfD for acrylonitrile and therefore did not derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of acrylonitrile in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA retained a CSF of 0.54 per mg/kg-d for acrylonitrile based on a 1987 EPA IRIS assessment (USEPA 1987; USEPA 2002c). EPA used this CSF to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the CSF in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Relative Source Contribution

No RfD sources were identified for this chemical. Therefore, no RSC was applied in the AWQC derivation for this chemical.

9 Chemical Name and Synonyms

- Acrylonitrile (CAS Number 107-13-1)
- Acritet
- Acrylnitril
- Acrylon
- Acrylonitrile monomer
- Akrylonitryl

- Carbacryl
- Cianuro di vinile
- Cyanoethylene
- Cyanure de vinyle
- ENT 54
- Fumigrain
- Miller's fumigrain
- Nitrile acrilico
- Nitrile acrylique
- Propenenitrile
- 2-propenenitrile
- RCRA waste number u009
- TL 314
- UN 1093
- VCN
- Ventox
- Vinyl cyanide

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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June 2015

Update of Human Health Ambient Water Quality Criteria:

Aldrin
309-00-2

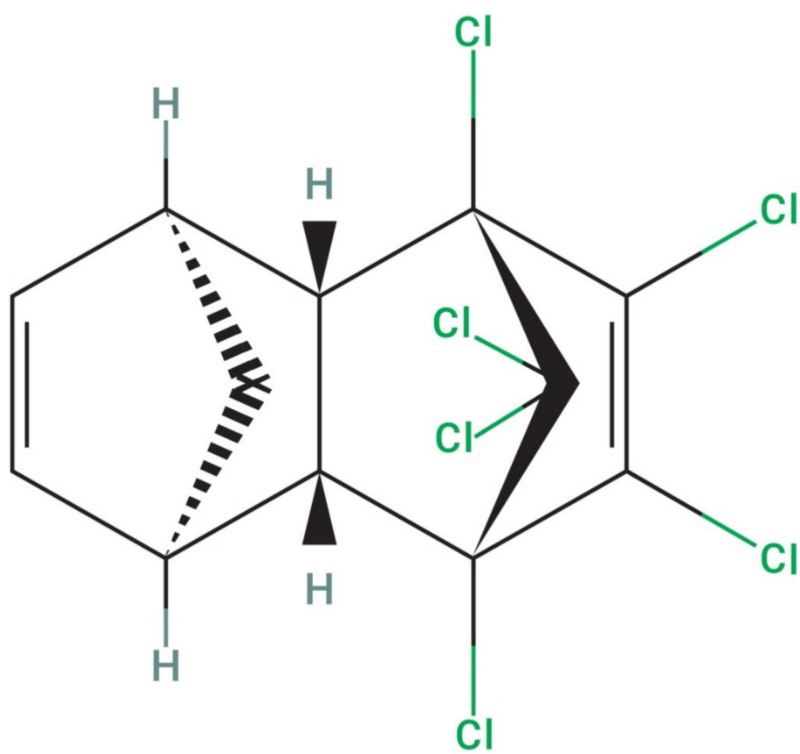

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for aldrin to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times BW\ (kg) \times 1{,}000\ (\mu g/mg)^{b}}{DI\ (L/d) + \sum_{i=2}^{4} (FCR_i\ (kg/d) \times BAF_i\ (L/kg))} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times BW\ (kg) \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (FCR_i\ (kg/d) \times BAF_i\ (L/kg))} \qquad \text{(Eq. 2)}$$

Where:

AWQC = ambient water quality criteria
toxicity value = RfD x RSC (mg/kg-d) for noncarcinogenic effects
or
10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC = relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW = body weight
DI = drinking water intake
$\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i = fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i = bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

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[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA using the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 18,000 L/kg (TL2), 310,000 L/kg (TL3), and 650,000 L/kg (TL4) for aldrin. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for aldrin. Based on the characteristics of this chemical, EPA selected Procedure 1 for deriving a national BAF value. Aldrin has the following characteristics:

- Nonionic organic chemical (USDHHS 2012)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log K_{ow} = 6.50 (ATSDR 2002)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 18,000 L/kg
TL3 = 310,000 L/kg
TL4 = 650,000 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for aldrin. As described in the 2000 Methodology (USEPA 2000a), where data are available, EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, ATSDR (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 3×10^{-5} mg/kg-d (0.00003 mg/kg-d) for aldrin based on a 1985 EPA IRIS assessment (USEPA 1985). EPA's IRIS program identified a study by Fitzhugh et al. (1964) as the critical study and liver toxicity as the critical effect in male rats orally exposed to aldrin in a chronic feeding study (USEPA 1985). The study has a LOAEL of 0.025 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 1000 to account for intraspecies variation (10), interspecies extrapolation (10), and extrapolation from a LOAEL to a NOAEL (10).

In 2002, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the RfD for aldrin and did not identify any critical new studies.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified three other RfD sources through the systematic search described in section 5: a 2005 EPA Office of Solid Waste and Emergency Response (OSWER) Provisional Peer Reviewed Toxicity Value (PPRTV) (USEPA 2005), a 2003 EPA Office of Water assessment (USEPA 2003c), and a 2002 ATSDR assessment (ATSDR 2002). Based on the selection process described in section 5, the 1985 EPA IRIS RfD is preferred for use in AWQC development at this time. The EPA OSWER assessment did not include the relevant (chronic oral) toxicity value (USEPA 2005). The ATSDR and EPA Office of Water assessments were based on the same principal study (Fitzhugh et al. 1964) and were numerically the same as the 1985 EPA IRIS RfD.

5.2.2 Cancer Slope Factor

Under EPA's 1986 *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), aldrin is classified as Group B2, "probable human carcinogen" (USEPA 1987; USEPA 2003c).

EPA selected a CSF of 17 per mg/kg-d for aldrin based on a 1987 EPA IRIS assessment (USEPA 1987). EPA IRIS's program calculated the CSF using principal studies by Davis (1965) and National Cancer Institute (NCI 1978) based on development of liver carcinomas in mice orally exposed to aldrin (USEPA 1987).

In 2002, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the cancer assessment for aldrin and identified one or more significant new studies; however, EPA's IRIS program has not reassessed this chemical.

EPA identified one other CSF source through the systematic search described in section 5: a 2003 EPA Office of Water assessment (USEPA 2003c). Based on the selection process described in section 5, the 1987 EPA IRIS CSF is preferred for use in AWQC development at this time. The EPA Office of Water assessment is based on the same principal studies (Davis 1965; NCI 1978) and is numerically the same as the 1987 EPA IRIS CSF.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- Food and Drug Administration (FDA) Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- National Oceanic and Atmospheric Administration (NOAA) Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to aldrin from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Aldrin

Input Parameter		Value
RfD		0.00003 mg/kg-d
CSF		17 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	18,000 L/kg
	TL3	310,000 L/kg
	TL4	650,000 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.00003 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 18{,}000 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 310{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 650{,}000 \text{ L/kg}))}$$

$$= 0.0000784\ \mu g/L$$

$$= 0.00008\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.00003 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 18{,}000 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 310{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 650{,}000 \text{ L/kg})}$$

$$= 0.0000785\ \mu g/L$$

$$= 0.00008\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 17) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 18{,}000 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 310{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 650{,}000 \text{ L/kg}))}$$

$$= 0.0000007689\ \mu g/L$$

$$= 0.00000077\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 17) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 18{,}000 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 310{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 650{,}000 \text{ L/kg})}$$

$$= 0.0000007692\ \mu g/L$$

$$= 0.00000077\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for aldrin using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for aldrin are **0.00008 µg/L** for consumption of water and organisms and **0.00008 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for aldrin are **0.00000077 µg/L** for consumption of water and organisms and **0.00000077 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of aldrin, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Aldrin

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.000049 µg/L	**0.00000077 µg/L**
Organism Only	0.000050 µg/L	**0.00000077 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to aldrin at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for aldrin take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a

contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 18,000, 310,000, and 650,000 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 4,670 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 222,600 L/kg
TL3 = 207,700 L/kg
TL4 = 184,000 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.00003 mg/kg-d for aldrin based on a 1985 EPA IRIS assessment (USEPA 1985). EPA used the RfD of 0.00003 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of aldrin in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA retained a CSF of 17 per mg/kg-d for aldrin based on a 1987 EPA IRIS assessment (USEPA 1987; USEPA 2002c). EPA used this CSF to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the CSF in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Aldrin (CAS Number 309-00-2)
- Aldrex
- Aldrite
- Aldrosol
- 1,4:5,8-Dimethanonaphthalene, 1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-Hexahydro-, (1 alpha, 4 alpha, 4a beta, 5 alpha, 8 alpha, 8a beta)-
- 1,4:5,8-Dimethanonaphthalene, 1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-Hexahydro-
- Drinox
- ENT 15,949
- 1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-Hexahydro-1,4,5,8-Dimethanonaphthalene
- 1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-Hexahydro-1,4-endo-exo-5,8-Dimethanonaphthalene
- 1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-Hexahydro-exo-1,4-endo-5,8-Dimethanonaphthalene
- Hexachlorohexahydro-endo-exo-Dimethanonaphthalene
- HHDN
- NCI-C00044
- Octalene
- Seedrin

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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June 2015

Update of Human Health Ambient Water Quality Criteria:

alpha-Hexachlorocyclohexane (HCH) 319-84-6

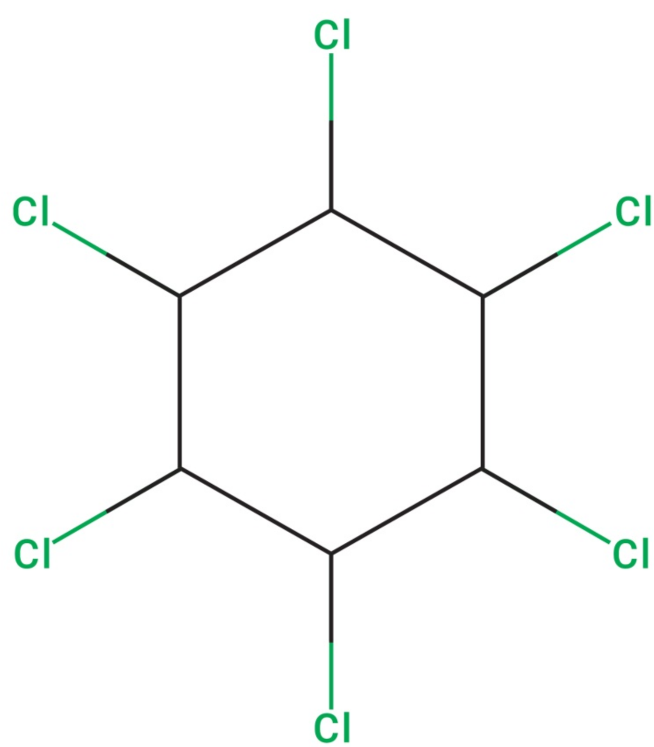

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for alpha-hexachlorocyclohexane (HCH) to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC = ambient water quality criteria
toxicity value = RfD x RSC (mg/kg-d) for noncarcinogenic effects
or
10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC = relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW = body weight
DI = drinking water intake
$\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i = fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i = bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level-(TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 1,700 L/kg (TL2), 1,400 L/kg (TL3), and 1,500 L/kg (TL4) for alpha-HCH. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for alpha-HCH. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Alpha-HCH has the following characteristics:

- Nonionic organic chemical (USDHHS 2012)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 3.8 (ATSDR 2005)
- Low/unknown metabolism

EPA was able to locate peer-reviewed, field-measured BAFs for TLs 2, 3, and 4 (Arnot and Gobas 2006). Therefore, EPA used the Field BAF method (USEPA 2003a) to derive the national BAF values for this chemical:

TL2 = 1,700 L/kg
TL3 = 1,400 L/kg
TL4 = 1,500 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for alpha-HCH. As described in the 2000 Methodology (USEPA 2000a), where data are available, EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, ATSDR (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

In place of an RfD, EPA selected a chronic oral minimal risk level (MRL) of 8×10^{-3} mg/kg-d (0.008 mg/kg-d) for alpha-HCH based on a 2005 ATSDR assessment (ATSDR 2005). A chronic oral MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects for a chronic duration (365 days or longer).

ATSDR identified Fitzhugh et al. (1950) as the critical study and the development of various liver effects in rats exposed to alpha-HCH in the diet for up to 107 weeks as the critical effect for the derivation of the MRL (ATSDR 2005). The study had a NOAEL of 0.8 mg/kg-d. In deriving the MRL, ATSDR applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10) (ATSDR 2005).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified no other RfD sources through the systematic search described in section 5.

5.2.2 Cancer Slope Factor

Under the 1986 *Guidelines for Carcinogen Risk Assessment* (USEPA 1986a), alpha-HCH is classified as Group B2, "probable human carcinogen" (USEPA 1986b).

EPA selected a CSF of 6.3 per mg/kg-d for alpha-HCH based on a 1986 EPA IRIS assessment (USEPA 1986b). EPA's IRIS program derived the CSF using a principal study by Ito et al. (1973) based on development of hepatic nodules and hepatocellular carcinomas in mice orally exposed to alpha-HCH (USEPA 1986b).

In 2002, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the cancer assessment for alpha-HCH and did not identify any critical new studies.

EPA identified no other CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- Food and Drug Administration (FDA) Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- National Oceanic and Atmospheric Administration (NOAA) Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to alpha-HCH from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above.

(See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for alpha-HCH

Input Parameter		Value
RfD		0.008 mg/kg-d
CSF		6.3 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	1,700 L/kg
	TL3	1,400 L/kg
	TL4	1,500 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.008 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 1{,}700 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 1{,}400 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1{,}500 \text{ L/kg}))}$$

$$= 3.66\ \mu g/L$$

$$= 4\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.008 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 1{,}700 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 1{,}400 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1{,}500 \text{ L/kg})}$$

$$= 3.93\ \mu g/L$$

$$= 4\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000 \ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 6.3) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 1{,}700 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 1{,}400 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1{,}500 \text{ L/kg}))}$$

$$= 0.0003627 \ \mu g/L$$

$$= 0.00036 \ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000 \ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 6.3) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \ \mu g/mg}{(0.0076 \text{ kg/d} \times 1{,}700 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 1{,}400 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1{,}500 \text{ L/kg})}$$

$$= 0.0003894 \ \mu g/L$$

$$= 0.00039 \ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for alpha-HCH using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for alpha-HCH are **4 µg/L** for consumption of water and organisms and **4 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for alpha-HCH are **0.00036 µg/L** for consumption of water and organisms and **0.00039 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of alpha-HCH, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for alpha-HCH

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.0026 µg/L	**0.00036 µg/L**
Organism Only	0.0049 µg/L	**0.00039 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to alpha-HCH at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for alpha-HCH take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 1,700, 1,400, and 1,500 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 130 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 934.9 L/kg
TL3 = 1,118 L/kg
TL4 = 1,935 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

In place of an RfD, EPA selected a chronic oral MRL of 0.008 mg/kg-d for alpha-HCH based on a 2005 ATSDR assessment (ATSDR 2005). EPA used the MRL of 0.008 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of alpha-HCH in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA retained a CSF of 6.3 per mg/kg-d for alpha-HCH based on a 1986 EPA IRIS assessment (USEPA 1986b; USEPA 2002c). EPA used this CSF to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the CSF in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- alpha-BHC (CAS Number 319-84-6)
- alpha-benzenehexachloride
- Benzene hexachloride-alpha-isomer
- Cyclohexane, 1,2,3,4,5,6-hexachloro-, alpha-
- Cyclohexane, alpha-1,2,3,4,5,6-hexachloro-
- cyclohexane, 1,2,3,4,5,6-hexachloro-, alpha-isomer
- ENT 9,232
- alpha-HCH
- alpha-hexachloran
- alpha-hexachlorane
- Hexachlorcyclohexan
- alpha-hexachlorcyclohexane
- 1-alpha,2-alpha,3-beta,4-alpha,5-beta,6-beta-hexachlorocyclohexane
- Hexachlorocyclohexane, alpha-
- alpha-1,2,3,4,5,6-hexachlorocyclohexane
- alpha-lindane

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-008
June 2015

Update of Human Health Ambient Water Quality Criteria:

Anthracene
120-12-7

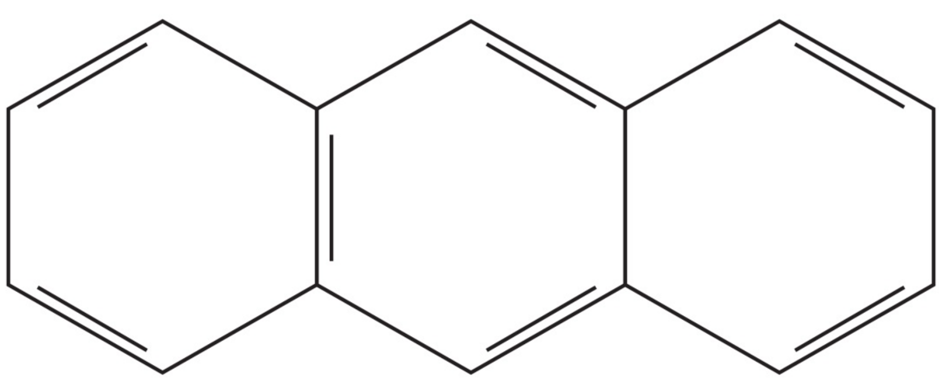

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for anthracene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 610 L/kg for anthracene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for anthracene. Based on the characteristics of this chemical, EPA selected Procedure 2 for deriving a national BAF value. Anthracene has the following characteristics:

- Nonionic organic chemical (USDHHS 2011)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 4.45$ (ATSDR 1995)
- High metabolism (NOAA n.d.)

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for all three TLs (2, 3, and 4). Therefore, EPA used the BCF method estimate for the reported TLs by calculating the geometric mean of the TL2 and TL3 BCF values available for anthracene (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 610 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for anthracene. As described in the 2000

Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 3×10^{-1} mg/kg-d (0.3 mg/kg-d) for anthracene based on a 1989 EPA IRIS assessment (USEPA 1989a). EPA identified a study by EPA (USEPA 1989b) as the critical study in which there were no observed effects in mice at the highest dose tested. The subchronic no-observed-effect level (NOEL) was 1000 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 3000 to account for interspecies extrapolation (10), intraspecies variation (10), subchronic-to-chronic study extrapolation (10), and database deficiency (3) (USEPA 1989a).

EPA identified two other potential RfD sources through the systematic search described in section 5: a 2009 EPA Office of Solid Waste and Emergency Response (OSWER) Provisional Peer Reviewed Toxicity Value (PPRTV) (USEPA 2009a) and a 1995 ATSDR assessment (ATSDR 1995). Based on the selection process described in section 5, the 1989 EPA IRIS RfD is preferred for use in AWQC development at this time. Neither of the other assessments include the relevant (chronic oral) toxicity endpoint.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

5.2.2 Cancer Slope Factor

Under the 1996 EPA *Proposed Guidelines for Carcinogen Risk Assessment* (USEPA 1996), anthracene is classified as Group D, “not classifiable as to human carcinogenicity” (USEPA 1990).

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD’s exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual’s total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR “Toxicological Profiles” (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine’s Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA’s Six-Year Reviews (drinking water data) (USEPA 2009b; USEPA 2009c).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009d).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Anthracene is a low-molecular weight polycyclic aromatic hydrocarbon (PAH) used to make dyes, plastics, pesticides, explosives, and chemotherapeutic agents (ATSDR 1995). It is not registered as a pesticide (USEPA 2015c). Humans can be exposed to anthracene and other PAHs via several sources, including air, food, water, fish and shellfish from inland and nearshore waters, and ocean fish and shellfish. The most common route of exposure of anthracene is inhalation of exhaust from motor vehicles, especially in urban areas with heavy traffic, or near industrial sources. Inhalation exposure is also likely from other products of incomplete combustion, such as emissions from cigarette smoke and coal-, oil-, and wood-burning stoves and furnaces (USDHHS 2011).

The vapor pressure of anthracene (1.7×10^{-5} mm Hg at 25 °C) indicates that it will exist in both the vapor and particulate phases in the ambient atmosphere (USDHHS 2011). Anthracene is not listed as a hazardous air pollutant (USEPA 2013). Recent data from EPA’s 2013 Toxic Release Inventory (USEPA 2015g) indicate that 6,435 pounds of anthracene were released to the air in 2013. Given the anthropogenic sources of PAHs and anthracene’s physical properties, air is a potentially significant source of exposure to this chemical.

Anthracene has been detected in grain, flour, bread, vegetables, fruits, and refined fats and oils and is often associated with grilled food (ATSDR 1995; USDHHS 2011). Thus, ingestion of food is a potentially significant source of exposure to anthracene.

The log K_{ow} for anthracene is 4.45 (ATSDR 1995). The national-level BAF estimate for anthracene is 510 L/kg, which indicates that it has a moderate potential for bioaccumulation (USEPA 2011b). NOAA's Mussel Watch Survey has detected anthracene in ocean fish and shellfish (NOAA 2014), but it was not detected in fish tissue samples collected in EPA's National Lake Fish Tissue Study (USEPA 2009d). Thus, based on the chemical's potential to bioaccumulate and prevalence, ingestion of fish and shellfish is a potentially significant source of exposure to it.

PAHs have been detected in finished drinking water (ATSDR 1995); however, recent information regarding concentrations of anthracene in drinking water could not be identified. Although the chemical has been detected historically, recent information regarding concentrations of it in drinking water was not available. In 2001, eighteen samples taken from untreated surface water collected near municipal drinking water intakes in 10 states were analyzed for anthracene, but it was not detected (USDHHS 2011). Anthracene is not regulated under the Safe Drinking Water Act (SDWA) (USEPA 2014c), and it was not included in EPA's Six-Year Reviews (USEPA 2009b; USEPA 2009c). No Standard of Quality for bottled water for anthracene has been established (IBWA 2012). Therefore, the potential exposure to anthracene from ingestion of drinking water is unknown.

In summary, based on the physical properties and available exposure information for anthracene, air, non-fish food, and fish and shellfish are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for anthracene.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to anthracene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Anthracene

Input Parameter	Value
RfD	0.3 mg/kg-d
CSF	No data
RSC	0.20
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	610 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.3\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{2.4\ \text{L/d} + (0.022\ \text{kg/d} \times 610\ \text{L/kg})}$$

$$= 303\ \mu g/L$$

$$= 300\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.3\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{(0.022\ \text{kg/d} \times 610\ \text{L/kg})}$$

$$= 358\ \mu g/L$$

$$= 400\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for anthracene using a noncarcinogenic toxicity endpoint. The updated human health AWQC for anthracene are **300 μg/L** for consumption of water and organisms and **400 μg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Anthracene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	8,300 µg/L	**300 µg/L**
Organism Only	40,000 µg/L	**400 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to anthracene from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for anthracene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 610 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 30 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 1,212 L/kg
TL3 = 1,169 L/kg
TL4 = 1,151 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA retained an RfD of 0.3 mg/kg-d for anthracene based on a 1989 EPA IRIS assessment (USEPA 1989a; USEPA 2002c). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for anthracene and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of anthracene in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- Anthracene (CAS Number 120-12-7)
- Anthracen [German]
- Anthracin
- Green oil
- HSDB 702
- NSC 7958
- Paranaphthalene
- Tetra olive N2G

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-011
June 2015

Update of Human Health Ambient Water Quality Criteria:

Benzo(a)anthracene
56-55-3

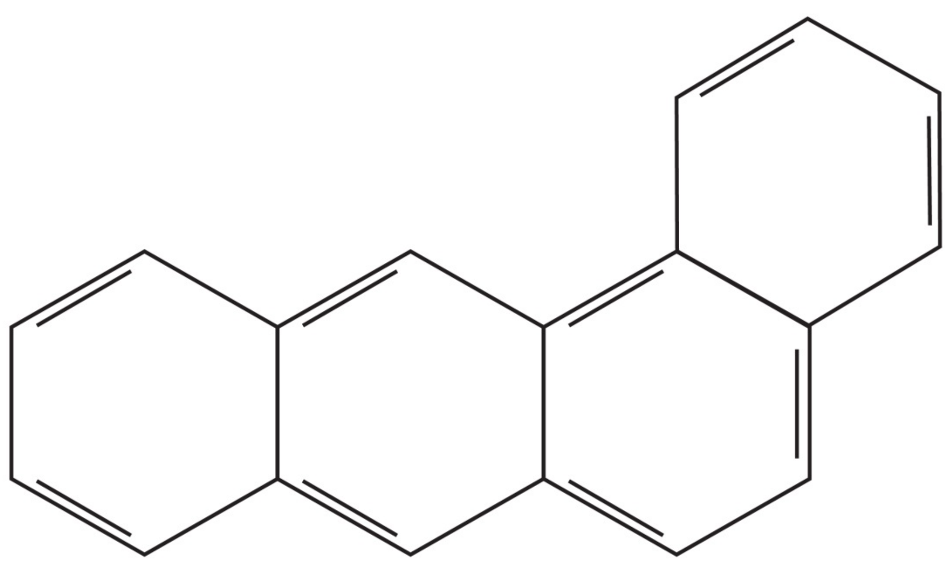

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for benzo(a)anthracene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level-(TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 3,900 L/kg for benzo(a)anthracene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for benzo(a)anthracene. Based on the characteristics of this chemical, EPA selected Procedure 2 for deriving a national BAF value. Benzo(a)anthracene has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 5.61$ (ATSDR 1995)
- High metabolism (NOAA n.d.)

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for this polycyclic aromatic hydrocarbon (PAH) (Arnot and Gobas 2006; Environment Canada 2006). In the absence of chemical specific information, EPA used the field-measured BAF for benzo(a)pyrene, an index PAH, as a surrogate for the estimation of BAFs for other PAHs. This approach is consistent with conclusions of Neff (2002) that benzo(a)pyrene is a good indicator of the presence of pyrogenic PAHs in the environment and these types of PAHs are expected to concentrate in organisms such as fish and shellfish as does benzo(a)pyrene. Therefore, EPA used the benzo(a)pyrene BCF method estimate for the reported TLs by calculating the geometric mean of the TL2 and TL3 BCF values available for benzo(a)pyrene (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 3,900 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for benzo(a)anthracene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

EPA's IRIS program does not currently have an RfD or CSF for benzo(a)anthracene (USEPA 1990). In the absence of chemical specific information, EPA recommends use of benzo(a)pyrene, an index PAH, as a surrogate for the determination of risk to other PAHs. In this approach, the potencies of other PAHs relative to benzo(a)pyrene are determined. EPA's IRIS program is currently reassessing benzo(a)pyrene, which may be used in the future to derive toxicity values for other PAHs, including benzo(a)anthracene. In 2013, EPA's IRIS program published the draft Toxicological Review for benzo(a)pyrene for public review and comment, discussion at a public meeting, and subsequent expert peer review (USEPA 2013a; USEPA 2013b). The 2013 draft Toxicological Review included both a draft RfD and CSF. In addition, in 2010, EPA's IRIS program published draft updated relative potency factors for PAH mixtures (USEPA 2010).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA anticipates updating the AWQC for PAHs following finalization of EPA's IRIS toxicological assessment for benzo(a)pyrene and relative potency factors for PAHs. In the meantime, based on the selection process described in section 5, EPA will use IRIS's current toxicity values for benzo(a)pyrene (USEPA 1991) and IRIS's currently recommended relative potency factors (USEPA 1993) for the purpose of AWQC derivation for benzo(a)anthracene.

5.2.1 Reference Dose

EPA has not selected an RfD for derivation of AWQC for benzo(a)anthracene. EPA's IRIS program does not currently have an oral RfD for benzo(a)anthracene or benzo(a)pyrene, the index PAH (USEPA 1990; USEPA 1991).

EPA identified two RfD sources for benzo(a)anthracene through the systematic search described in section 5: a 1995 ATSDR assessment (ATSDR 1995) and a 2005 California EPA assessment (CalEPA 2005). However, due to EPA's ongoing reassessments, the toxicity values from these assessments will not be used to derive AWQC at this time.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), benzo(a)anthracene is classified as Group B2, "probable human carcinogen" (USEPA 1990).

EPA selected a CSF of 0.73 per mg/kg-d for benzo(a)anthracene based on a 1991 EPA IRIS assessment for benzo(a)pyrene (USEPA 1991). EPA's IRIS program derived a CSF of 7.3 per mg/kg-d using a principal study by Neal and Rigdon (1967), which was based on development of fore-stomach and squamous cell papillomas in mice orally exposed to benzo(a)pyrene (USEPA 1991). EPA applied a relative potency factor of 0.1 to derive the CSF for benzo(a)anthracene (USEPA 1993).

EPA identified one other CSF source for benzo(a)anthracene through the systematic search described in section 5: a 2005 California EPA assessment (CalEPA 2005). However, due to EPA's ongoing reassessments, EPA will use the current IRIS CSF to derive AWQC at this time.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean

fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not

anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using only a carcinogenic toxicity endpoint (CSF) because no RfD sources were identified through the systematic search described in section 5 (Hazard Identification and Dose Response). Therefore, no RSC was applied in the AWQC derivation for this chemical.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to benzo(a)anthracene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Benzo(a)anthracene

Input Parameter	Value
RfD	No data
CSF	0.73 per mg/kg-d
RSC	–
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	3,900 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

EPA identified no RfD sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for noncarcinogenic toxicological effects.

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 0.73) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + (0.022 \text{ kg/d} \times 3{,}900 \text{ L/kg})}$$

$$= 0.001243\ \mu g/L$$

$$= 0.0012\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 0.73) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.022 \text{ kg/d} \times 3{,}900 \text{ L/kg})}$$

$$= 0.001277\ \mu g/L$$

$$= 0.0013\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for benzo(a)anthracene using a carcinogenic toxicity endpoint. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for benzo(a)anthracene are **0.0012 µg/L** for consumption of water and organisms and **0.0013 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Benzo(a)anthracene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.0038 µg/L	**0.0012 µg/L**
Organism Only	0.018 µg/L	**0.0013 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to benzo(a)anthracene at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for benzo(a)anthracene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 3,900 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 30 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the

water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 1,577 L/kg
TL3 = 748.7 L/kg
TL4 = 405.5 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA did not select an RfD for benzo(a)anthracene and therefore did not derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of benzo(a)anthracene in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.73 per mg/kg-d for benzo(a)anthracene based on a 1991 EPA IRIS assessment for benzo(a)pyrene (USEPA 1991). This CSF replaces the previous value of 7.3 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.73 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, a decrease in the CSF in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Relative Source Contribution

No RfD sources were identified for this chemical. Therefore, no RSC was applied in the AWQC derivation for this chemical.

9 Chemical Name and Synonyms

- Benzo(a)anthracene (CAS Number 56-55-3)
- Benz(a)anthracene
- Benz(a)anthracene
- Benzanthracene
- Benzanthrene
- Benzo(b)phenanthrene
- Benzoanthracene
- HSDB 4003
- NSC 30970
- RCRA waste number U018
- Tetraphene
- 1,2-benz(a)anthracene
- 1,2-benzanthracene
- 1,2-benzanthrazen [German]
- 1,2-benzanthrene
- 1,2-benzoanthracene
- 2,3-benzophenanthrene

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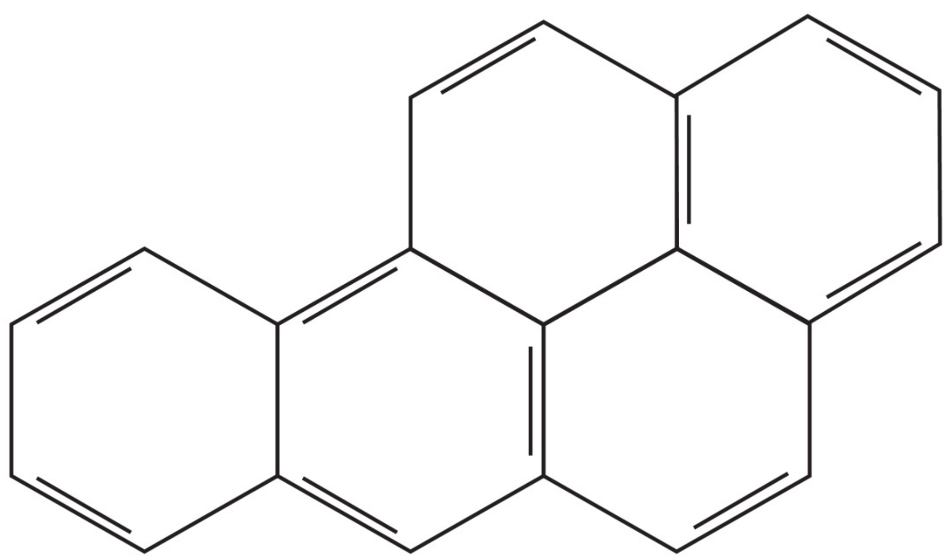
United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-012
June 2015

Update of Human Health Ambient Water Quality Criteria:

Benzo(a)pyrene
50-32-8



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Update of Human Health Ambient Water Quality Criteria:

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Office of Science and Technology
Office of Water
U.S. Environmental Protection Agency
Washington, DC 20460

Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for benzo(a)pyrene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

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[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 3,900 L/kg for benzo(a)pyrene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for benzo(a)pyrene. Based on the characteristics of this chemical, EPA selected Procedure 2 for deriving a national BAF value. Benzo(a)pyrene has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 6.06$ (ATSDR 1995)
- High metabolism (NOAA n.d.)

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for all three TLs (2, 3, and 4). Therefore, EPA used the BCF method estimate for the reported TLs by calculating the geometric mean of the TL2 and TL3 BCF values available for benzo(a)pyrene (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 3,900 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for benzo(a)pyrene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both

noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

EPA's IRIS program is currently reassessing benzo(a)pyrene. In 2013, EPA's IRIS program published the draft Toxicological Review for benzo(a)pyrene for public review and comment, discussion at a public meeting, and subsequent expert peer review (USEPA 2013a; USEPA 2013b). The 2013 draft Toxicological Review included both a draft RfD and CSF.

EPA anticipates updating the AWQC for benzo(a)pyrene following finalization of EPA's IRIS toxicological assessment. In the meantime, based on the selection process described above, EPA will use IRIS's current toxicity values for benzo(a)pyrene (USEPA 1991) for the purpose of AWQC derivation.

5.2.1 Reference Dose

EPA's IRIS program does not currently have an oral RfD for benzo(a)pyrene (USEPA 1991). Therefore, EPA will not derive AWQC for noncarcinogenic effects of benzo(a)pyrene at this time.

EPA identified two RfD sources for benzo(a)pyrene through the systematic search described in section 5: a 1995 ATSDR assessment (ATSDR 1995) and a 2010 California EPA assessment (CalEPA 2010). However, due to EPA's ongoing reassessments, the toxicity values from these assessments will not be used to derive AWQC at this time.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), benzo(a)pyrene is classified as Group B2, "probable human carcinogen" (USEPA 1991).

EPA selected a CSF of 7.3 per mg/kg-d for benzo(a)pyrene based on a 1991 EPA IRIS assessment (USEPA 1991). EPA's IRIS program derived a CSF of 7.3 per mg/kg-d using a principal study by Neal and Rigdon (1967), which was based on development of fore-stomach and squamous cell papillomas in mice orally exposed to benzo(a)pyrene (USEPA 1991).

EPA identified one other CSF source for benzo(a)pyrene through the systematic search described in section 5: a 2010 California EPA assessment (CalEPA 2010). However, due to EPA's ongoing reassessments, EPA will use the current IRIS CSF to derive AWQC at this time.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).

- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using only a carcinogenic toxicity endpoint (CSF) because no RfD sources were identified through the systematic search described in section 5 (Hazard Identification and Dose Response). Therefore, no RSC was applied in the AWQC derivation for this chemical.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to benzo(a)pyrene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Benzo(a)pyrene

Input Parameter	Value
RfD	No data
CSF	7.3 per mg/kg-d
RSC	–
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	3,900 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

EPA identified no RfD sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for noncarcinogenic toxicological effects.

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 7.3) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + (0.022 \text{ kg/d} \times 3{,}900 \text{ L/kg})}$$

$$= 0.0001243\ \mu g/L$$

$$= 0.00012\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 7.3) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.022 \text{ kg/d} \times 3{,}900 \text{ L/kg})}$$

$$= 0.0001277\ \mu g/L$$

$$= 0.00013\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for benzo(a)pyrene using a carcinogenic toxicity endpoint. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for benzo(a)pyrene are **0.00012 µg/L** for consumption of water and organisms and **0.00013 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Benzo(a)pyrene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.0038 µg/L	**0.00012 µg/L**
Organism Only	0.018 µg/L	**0.00013 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to benzo(a)pyrene at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for benzo(a)pyrene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 3,900 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 30 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 2,736 L/kg
TL3 = 983.7 L/kg
TL4 = 395.6 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA did not select an RfD for benzo(a)pyrene this chemical and therefore did not derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of benzo(a)pyrene in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA retained a CSF of 7.3 per mg/kg-d for benzo(a)pyrene based on a 1991 EPA IRIS assessment (USEPA 1991; USEPA 2002c). EPA used this CSF to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the CSF in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Relative Source Contribution

No RfD sources were identified for this chemical. Therefore, no RSC was applied in the AWQC derivation for this chemical.

9 Chemical Name and Synonyms

- Benzo(a)pyrene (CAS Number 50-32-8)
- BaP
- Benzo[a]pyrene
- Benzo(d,e,f)chrysene
- 3,4-benzopirene
- 3,4-benzopyrene
- 6,7-benzopyrene
- Benzo(a)pyrene
- 3,4-benzpyren
- 3,4-benzpyrene
- 3,4-benz(a)pyrene
- Benz(a)pyrene
- 3,4-benzypyrene
- BP
- 3,4-BP
- B(a)P
- RCRA waste number U022

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-013
June 2015

Update of Human Health Ambient Water Quality Criteria:

Benzo(b)fluoranthene
205-99-2

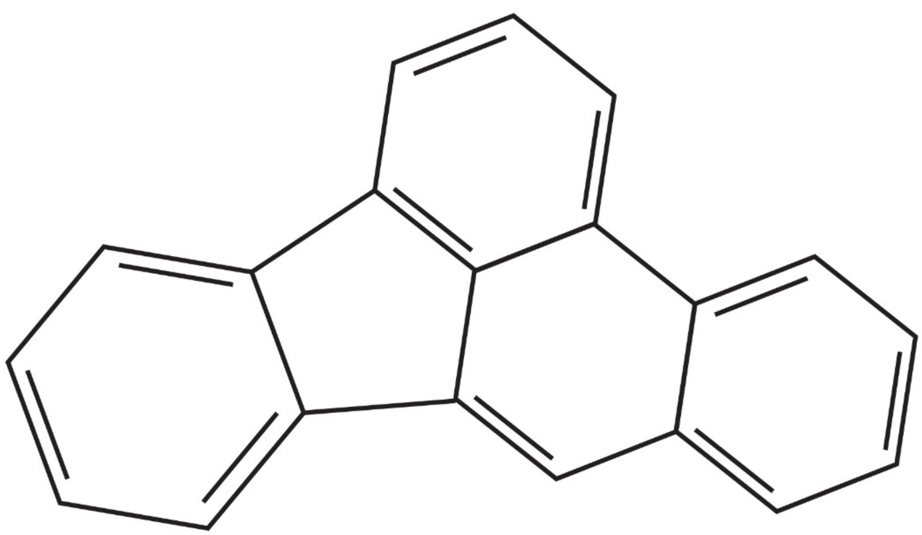

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for benzo(b)fluoranthene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 3,900 L/kg for benzo(b)fluoranthene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for benzo(b)fluoranthene. Based on the characteristics of this chemical, EPA selected Procedure 2 for deriving a national BAF value. Benzo(b)fluoranthene has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 6.04$ (ATSDR 1995)
- High metabolism (NOAA n.d.)

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for this polycyclic aromatic hydrocarbon (PAH) (Arnot and Gobas 2006; Environment Canada 2006). In the absence of chemical specific information, EPA used the field-measured BAF for benzo(a)pyrene, an index PAH, as a surrogate for the estimation of BAFs for other PAHs. This approach is consistent with conclusions of Neff (2002) that benzo(a)pyrene is a good indicator of the presence of pyrogenic PAHs in the environment and that type of PAH is expected to concentrate in organisms such as fish and shellfish as does benzo(a)pyrene. Therefore, EPA used the benzo(a)pyrene BCF method estimate for the reported TLs by calculating the geometric mean of the TL2 and TL3 BCF values available for benzo(a)pyrene (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 3,900 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for benzo(b)fluoranthene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

EPA's IRIS program does not currently have an RfD or CSF for benzo(b)fluoranthene (USEPA 1990). In the absence of chemical-specific information, EPA recommends use of benzo(a)pyrene, an index PAH, as a surrogate for the determination of risk to other PAHs. In this approach, the potencies of other PAHs relative to benzo(a)pyrene are determined. EPA's IRIS program is currently reassessing benzo(a)pyrene, which may be used in the future to derive toxicity values for other PAHs, including benzo(b)fluoranthene. In 2013, EPA's IRIS program published the draft Toxicological Review for benzo(a)pyrene for public review and comment, discussion at a public meeting, and subsequent expert peer review (USEPA 2013a; USEPA 2013b). The 2013 draft Toxicological Review included both a draft RfD and CSF. In addition, in 2010, EPA's IRIS program published draft updated relative potency factors for PAH mixtures (USEPA 2010).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA anticipates updating the AWQC for PAHs following finalization of EPA's IRIS toxicological assessment for benzo(a)pyrene and relative potency factors for PAHs. In the meantime, based on the selection process described above, EPA will use IRIS's current toxicity values for benzo(a)pyrene (USEPA 1991) and IRIS's currently recommended relative potency factors (USEPA 1993) for the purpose of AWQC derivation for benzo(b)fluoranthene.

5.2.1 Reference Dose

EPA has not selected an RfD for derivation of AWQC for benzo(b)fluoranthene. EPA's IRIS program does not currently have an oral RfD for benzo(b)fluoranthene or benzo(a)pyrene, the index PAH (USEPA 1990; USEPA 1991).

EPA identified two RfD sources for benzo(b)fluoranthene through the systematic search described in section 5: a 1995 ATSDR assessment (ATSDR 1995) and a California EPA assessment (CalEPA 2005). However, as described above, due to EPA's ongoing reassessments, the toxicity values from these assessments will not be used to derive AWQC at this time.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), benzo(a)fluoranthene is classified as Group B2, "probable human carcinogen" (USEPA 1990).

EPA selected a CSF of 0.73 per mg/kg-d for benzo(b)fluoranthene based on a 1991 EPA IRIS assessment for benzo(a)pyrene (USEPA 1991). EPA's IRIS program derived a CSF of 7.3 per mg/kg-d using a principal study by Neal and Rigdon (1967), which was based on development of fore-stomach and squamous cell papillomas in mice orally exposed to benzo(a)pyrene (USEPA 1991). EPA applied a relative potency factor of 0.1 to derive the CSF for benzo(b)fluoranthene (USEPA 1993).

EPA identified one other CSF source for benzo(b)fluoranthene through the systematic search described in section 5: a 2005 California EPA assessment (CalEPA 2005). However, due to EPA's ongoing reassessments, EPA will use the current IRIS CSF to derive AWQC at this time.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean

fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using only a carcinogenic toxicity endpoint (CSF) because no RfD sources were identified through the systematic search described in section 5 (Hazard Identification and Dose Response). Therefore, no RSC was applied in the AWQC derivation for this chemical.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to benzo(b)fluoranthene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Benzo(b)fluoranthene

Input Parameter	Value
RfD	No data
CSF	0.73 per mg/kg-d
RSC	–
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	3,900 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

EPA identified no RfD sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for noncarcinogenic toxicological effects.

7.2 AWQC for Carcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / CSF)\ [mg/kg\text{-}d] \times BW\ (kg) \times 1{,}000\ (\mu g/mg)}{DI\ (L/d) + (FCR\ (kg/d) \times BAF\ (L/kg))}$$

$$= \frac{(10^{-6} / 0.73)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + (0.022\ kg/d \times 3{,}900\ L/kg)}$$

$$= 0.001243\ \mu g/L$$

$$= 0.0012\ \mu g/L\ \text{(rounded)}$$

<u>For consumption of organisms only:</u>

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / CSF)\ [mg/kg\text{-}d] \times BW\ (kg) \times 1{,}000\ (\mu g/mg)}{(FCR\ (kg/d) \times BAF\ (L/kg))}$$

$$= \frac{(10^{-6} / 0.73)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.022\ kg/d \times 3{,}900\ L/kg)}$$

$$= 0.001277\ \mu g/L$$

$$= 0.0013\ \mu g/L\ \text{(rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for benzo(b)fluoranthene using a carcinogenic toxicity endpoint. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for benzo(b)fluoranthene are **0.0012 µg/L** for consumption of water and organisms and **0.0013 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Benzo(b)fluoranthene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.0038 µg/L	**0.0012 µg/L**
Organism Only	0.018 µg/L	**0.0013 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to benzo(b)fluoranthene at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for benzo(b)fluoranthene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 3,900 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 30 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the

water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 5,325 L/kg
TL3 = 2,643 L/kg
TL4 = 1,165 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA did not select an RfD for benzo(b)fluoranthene this chemical and therefore did not derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of benzo(b)fluoranthene in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.73 per mg/kg-d for benzo(b)fluoranthene based on a 1991 EPA IRIS assessment for benzo(a)pyrene (USEPA 1991). This CSF replaces the previous value of 7.3 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.73 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, a decrease in the CSF in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Relative Source Contribution

No RfD sources were identified for this chemical. Therefore, no RSC was applied in the AWQC derivation for this chemical.

9 Chemical Name and Synonyms

- Benzo(b)fluoranthene (CAS Number 205-99-2)
- Benz(e)acephenanthrylene
- B(b)F
- Benz(e)acephenanthrylene
- Benzo(e)fluoranthene
- HSDB 4035
- NSC 89265
- 2,3-benzfluoranthene
- 2,3-benzofluoranthene
- 2,3-benzofluoranthrene
- 3,4-benz(e)acephenanthrylene
- 3,4-benzfluoranthene
- 3,4-benzofluoranthene

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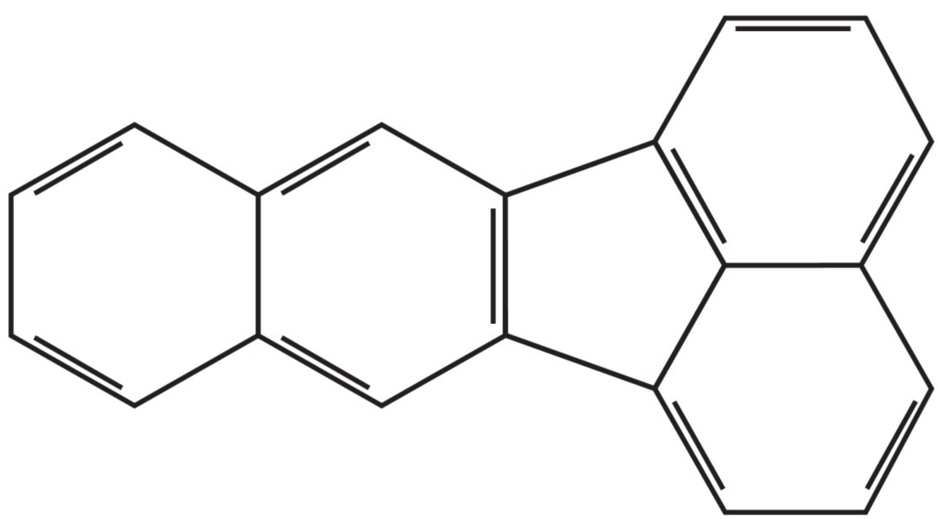
United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-014
June 2015

Update of Human Health Ambient Water Quality Criteria:

Benzo(k)fluoranthene
207-08-9



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Office of Science and Technology
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Washington, DC 20460

Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for benzo(k)fluoranthene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency’s goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

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[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.

[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.

[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 3,900 L/kg for benzo(k)fluoranthene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for benzo(k)fluoranthene. Based on the characteristics of this chemical, EPA selected Procedure 2 for deriving a national BAF value. Benzo(k)fluoranthene has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 6.06$ (ATSDR 1995)
- High metabolism (NOAA n.d.)

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for this polycyclic aromatic hydrocarbon (PAH) (Arnot and Gobas 2006; Environment Canada 2006). In the absence of chemical specific information, EPA used the field-measured BAF for benzo(a)pyrene, an index PAH, as a surrogate for the estimation of BAFs for other PAHs. This approach is consistent with conclusions of Neff (2002) that benzo(a)pyrene is a good indicator of the presence of pyrogenic PAHs in the environment and that type of PAH is expected to concentrate in organisms such as fish and shellfish as does benzo(a)pyrene. Therefore, EPA used the benzo(a)pyrene BCF method estimate for the reported TLs by calculating the geometric mean of the TL2 and TL3 BCF values available for benzo(a)pyrene (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 3,900 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for benzo(k)fluoranthene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

EPA's IRIS program does not currently have an RfD or CSF for benzo(k)fluoranthene (USEPA 1990). In the absence of chemical-information, EPA recommends use of benzo(a)pyrene, an index PAH, as a surrogate for the determination of risk to other PAHs. In this approach, the potencies of other PAHs relative to benzo(a)pyrene are determined. EPA's IRIS program is currently reassessing benzo(a)pyrene, which may be used in the future to derive toxicity values for other PAHs, including benzo(k)fluoranthene. In 2013, EPA's IRIS program published the draft Toxicological Review for benzo(a)pyrene for public review and comment, discussion at a public meeting, and subsequent expert peer review (USEPA 2013a; USEPA 2013b). The 2013 draft Toxicological Review included both a draft RfD and CSF. In addition, in 2010, EPA's IRIS program published draft updated relative potency factors for PAH mixtures (USEPA 2010).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA anticipates updating the AWQC for PAHs following finalization of EPA's IRIS toxicological assessment for benzo(a)pyrene and relative potency factors for PAHs. In the meantime, based on the selection process described above, EPA will use IRIS's current toxicity values for benzo(a)pyrene (USEPA 1991) and IRIS's currently recommended relative potency factors (USEPA 1993) for the purpose of AWQC derivation for benzo(k)fluoranthene.

5.2.1 Reference Dose

EPA has not selected an RfD for derivation of AWQC for benzo(k)fluoranthene. EPA's IRIS program does not currently have an oral RfD for benzo(k)fluoranthene or benzo(a)pyrene, the index PAH (USEPA 1990; USEPA 1991).

EPA identified two RfD sources for benzo(k)fluoranthene through the systematic search described in section 5: a 1995 ATSDR assessment (ATSDR 1995) and a 2005 California EPA assessment (CalEPA 2005). However, due to EPA's ongoing reassessments, the toxicity values from these assessments will not be used to derive AWQC at this time.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), benzo(k)fluoranthene is classified as Group B2, "probable human carcinogen" (USEPA 1990).

EPA selected a CSF of 0.073 per mg/kg-d for benzo(k)fluoranthene based on a 1991 EPA IRIS assessment for benzo(a)pyrene (USEPA 1991). EPA's IRIS program derived a CSF of 7.3 per mg/kg-d using a principal study by Neal and Rigdon (1967), which was based on development of fore-stomach and squamous cell papillomas in mice orally exposed benzo(a)pyrene (USEPA 1991). EPA applied a relative potency factor of 0.01 to derive the CSF for benzo(k)fluoranthene (USEPA 1993).

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using only a carcinogenic toxicity endpoint (CSF) because no RfD sources were identified through the systematic search described in section 5 (Hazard Identification and Dose Response). Therefore, no RSC was applied in the AWQC derivation for this chemical.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to benzo(k)fluoranthene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Benzo(k)fluoranthene

Input Parameter	Value
RfD	No data
CSF	0.073 per mg/kg-d
RSC	–
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	3,900 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

EPA identified no RfD sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for noncarcinogenic toxicological effects.

7.2 AWQC for Carcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 0.073) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + (0.022 \text{ kg/d} \times 3{,}900 \text{ L/kg})}$$

$$= 0.01243\ \mu g/L$$

$$= 0.012\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000 \text{ } (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 0.073) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \text{ } \mu g/mg}{(0.022 \text{ kg/d} \times 3{,}900 \text{ L/kg})}$$

$$= 0.01277 \text{ } \mu g/L$$

$$= 0.013 \text{ } \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for benzo(k)fluoranthene using a carcinogenic toxicity endpoint. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for benzo(k)fluoranthene are **0.012 µg/L** for consumption of water and organisms and **0.013 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Benzo(k)fluoranthene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.0038 µg/L	**0.012 µg/L**
Organism Only	0.018 µg/L	**0.013 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to benzo(k)fluoranthene at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for benzo(k)fluoranthene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 3,900 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 30 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 1,883 L/kg
TL3 = 675.5 L/kg
TL4 = 300.5 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA did not select an RfD for benzo(k)fluoranthene and therefore did not derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of benzo(k)fluoranthene in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.073 per mg/kg-d for benzo(k)fluoranthene based on a 1991 EPA IRIS assessment for benzo(a)pyrene (USEPA 1991). This CSF replaces the previous value of 7.3 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.073 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, a decrease in the CSF in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Relative Source Contribution

No RfD sources were identified for this chemical. Therefore, no RSC was applied in the AWQC derivation for this chemical.

9 Chemical Name and Synonyms

- Benzo(k)fluoranthene (CAS Number 207-08-9)
- Dibenzo(b,jk)fluorene
- HSDB 6012
- 11,12-benzo(k)fluoranthene
- 11,12-benzofluoranthene
- 2,3,1',8'-binaphthylene
- 8,9-benzofluoranthene

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Office of Science and Technology
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Update of Human Health Ambient Water Quality Criteria:

beta-Hexachlorocyclohexane (HCH) 319-85-7

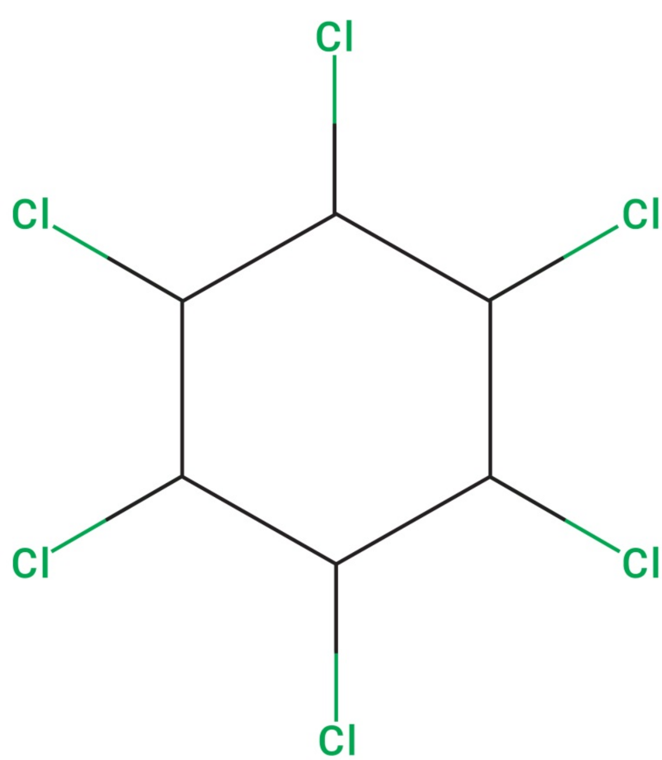

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Table of Contents

1. Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for beta-hexachlorocyclohexane (HCH) to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2. Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3. Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

<u>For consumption of organisms only:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4. Exposure Factors

4.1. Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2. Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3. Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4. Bioaccumulation Factor

4.4.1. Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2. Chemical-specific BAFs

EPA selected national BAF values of 110 L/kg (TL2), 160 L/kg (TL3), and 180 L/kg (TL4) for beta-HCH. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for beta-HCH. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Beta-HCH has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 3.78$ (ATSDR 2005)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 110 L/kg
TL3 = 160 L/kg
TL4 = 180 L/kg

5. Hazard Identification and Dose Response

5.1. Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for beta-HCH. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, ATSDR (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2. Chemical-specific Toxicity Value

5.2.1. Reference Dose

EPA identified one RfD source through the systematic search described in section 5: a 2005 ATSDR assessment (ATSDR 2005) . However, the ATSDR assessment does not include the relevant (chronic oral) toxicity value. Therefore, no RfD is available for AWQC development.

5.2.2. Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986a), beta-HCH is classified as a Group C, "possible human carcinogen" (USEPA 1986b).

EPA selected a CSF of 1.8 per mg/kg-d for beta-HCH based on a 1986 EPA IRIS assessment (USEPA 1986b). EPA's IRIS program derived the CSF using a principal study by Thorpe and Walker (1973) based on development of hepatic nodules and hepatocellular carcinomas in mice orally exposed to beta-HCH (USEPA 1986b).

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[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

In 2002, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the cancer assessment for beta-HCH and identified one or more significant new studies; however, EPA's IRIS program has not reassessed this chemical.

EPA identified no other CSF sources through the systematic search described in section 5.

6. Relative Source Contribution

6.1. Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- Food and Drug Administration (FDA) Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- National Oceanic and Atmospheric Administration (NOAA) Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2. Chemical-specific RSC

EPA derived recommended AWQC for this chemical using only a carcinogenic toxicity endpoint (CSF) because no RfD sources were identified through the systematic search described in section 5 (Hazard Identification and Dose Response). Therefore, no RSC was applied in the AWQC derivation for this chemical.

7. Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to beta-HCH from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Beta-HCH

Input Parameter		Value
RfD		No data
CSF		1.8 per mg/kg-d
RSC		–
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	110 L/kg
	TL3	160 L/kg
	TL4	180 L/kg

7.1. AWQC for Noncarcinogenic Toxicological Effects

EPA identified no RfD sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for noncarcinogenic toxicological effects.

7.2. AWQC for Carcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000 \ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 1.8) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 110 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 160 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 180 \text{ L/kg}))}$$

$= 0.008037 \ \mu g/L$

$= 0.0080 \ \mu g/L$ (rounded)

<u>For consumption of organisms only:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000 \ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 1.8) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \ \mu g/mg}{(0.0076 \text{ kg/d} \times 110 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 160 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 180 \text{ L/kg})}$$

$= 0.01420 \ \mu g/L$

$= 0.014 \ \mu g/L$ (rounded)

7.3. AWQC Summary

EPA derived the AWQC for beta-HCH using a carcinogenic toxicity endpoint. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for beta-HCH are **0.0080 µg/L** for consumption of water and organisms and **0.014 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Beta-HCH

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.0091 µg/L	**0.0080 µg/L**
Organism Only	0.017 µg/L	**0.014 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to beta-HCH at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8. Criteria Characterization

The updated 2015 human health AWQC for beta-HCH take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

<u>Body Weight</u>

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

<u>Drinking Water Intake</u>

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 110, 160, and 180 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 130 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 934.9 L/kg
TL3 = 1,118 L/kg
TL4 = 1,935 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to

representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA did not select an RfD for beta-HCH and therefore did not derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of beta-HCH in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA retained a CSF of 1.8 per mg/kg-d for beta-HCH based on a 1986 EPA IRIS assessment (USEPA 1986b; USEPA 2002c). EPA used this CSF to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the CSF in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Relative Source Contribution

No RfD sources were identified for this chemical. Therefore, no RSC was applied in the AWQC derivation for this chemical.

9. Chemical Name and Synonyms

- beta-BHC (CAS Number 319-85-7)
- Benzenehexachloride, trans-alpha-
- beta-isomer
- beta-BHC
- Cyclohexane, 1,2,3,4,5,6-hexachloro-, beta-
- Cyclohexane, 1,2,3,4,5,6-hexachloro-, trans-
- Cyclohexane, beta-1,2,3,4,5,6-hexachloro-
- Cyclohexane, 1,2,3,4,5,6-hexachloro-, beta-isomer
- ENT 9,233
- beta-HCH
- beta-hexachlorobenzene
- 1-alpha,2-beta,3-alpha,4-beta,5-alpha,6-beta-hexachlorocyclohexane
- Hexachlorocyclohexane, beta-
- beta-1,2,3,4,5,6-hexachlorocyclohexane
- beta-lindane
- Trans-alpha-benzenehexachloride

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-020
June 2015

Update of Human Health Ambient Water Quality Criteria:

Bis(2-ethylhexyl) Phthalate 117-81-7

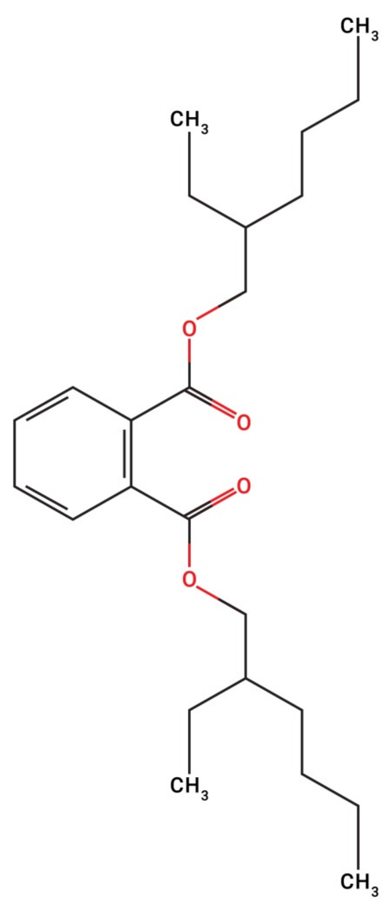

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for bis(2-ethylhexyl) phthalate to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency’s goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

<u>For consumption of organisms only:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 710 L/kg for bis(2-ethylhexyl) phthalate. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for bis(2-ethylhexyl) phthalate. Based on the characteristics of this chemical, EPA selected Procedure 2 for deriving a national BAF value. Bis(2-ethylhexyl) phthalate has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 7.5$ (ATSDR 2002)
- High metabolism (Gobas et al. 2003; Mankidya et al. 2013)

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs or lab-measured BCFs for all three TLs (2, 3, and 4). Therefore, EPA used the BAF method estimate for the reported TLs by calculating the geometric mean of the TL 3 and TL 4 BAF values available for bis(2-ethylhexyl) phthalate (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 710 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for bis(2-ethylhexyl) phthalate. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, ATSDR (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

In place of an RfD, EPA selected a chronic oral minimal risk level (MRL) of 6×10^{-2} mg/kg-d (0.06 mg/kg-d) for bis(2-ethylhexyl)phthalate based on a 2002 ATSDR assessment (ATSDR 2002). A chronic MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a chronic duration (365 days or more).

ATSDR identified a study by David et al. (2000) as the critical study and testicular pathology as the critical effect in male rats fed bis(2-ethylhexyl)phthalate for up to 104 weeks (ATSDR 2002). The chronic study had a NOAEL of 5.8 mg/kg-d. In deriving the chronic MRL, ATSDR applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified one other RfD source through the systematic search described in section 5: a 1986 EPA IRIS assessment. Based on the selection process described in section 5, the 2002 ATSDR MRL is preferred for use in AWQC development at this time. The ATSDR MRL is based on a more recent principal study (David et al. 2000) compared to the IRIS assessment (Carpenter et al. 1953).

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), bis(2-ethylhexyl) phthalate is classified as Group B2, "probable human carcinogen" (USEPA 1987).

EPA selected a CSF of 1.4×10^{-2} per mg/kg-d (0.014 mg/kg-d) for bis(2-ethylhexyl)phthalate based on a 1987 EPA IRIS assessment (USEPA 1987). EPA's IRIS program calculated the CSF using a principal study by the National Toxicology Program (NTP 1982) based on development of hepatocellular carcinomas and adenomas in mice orally exposed to bis(2-ethylhexyl) phthalate (USEPA 1987).

EPA identified no other CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- Food and Drug Administration (FDA) Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- National Oceanic and Atmospheric Administration (NOAA) Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to bis(2-ethylhexyl) phthalate from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above.

(See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Bis(2-ethylhexyl) Phthalate

Input Parameter	Value
RfD	0.06 mg/kg-d
CSF	0.014 per mg/kg-d
RSC	0.20
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	710 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.06\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + (0.022\ kg/d \times 710\ L/kg)}$$

$$= 53.3\ \mu g/L$$

$$= 50\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.06\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.022\ kg/d \times 710\ L/kg)}$$

$$= 61.5\ \mu g/L$$

$$= 60\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000 \text{ } (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 0.014) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \text{ } \mu g/mg}{2.4 \text{ L/d} + (0.022 \text{ kg/d} \times 710 \text{ L/kg})}$$

$$= 0.3171 \text{ } \mu g/L$$

$$= 0.32 \text{ } \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000 \text{ } (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 0.014) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \text{ } \mu g/mg}{(0.022 \text{ kg/d} \times 710 \text{ L/kg})}$$

$$= 0.3658 \text{ } \mu g/L$$

$$= 0.37 \text{ } \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for bis(2-ethylhexyl) phthalate using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for bis(2-ethylhexyl) phthalate are **50 µg/L** for consumption of water and organisms and **60 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for bis(2-ethylhexyl) phthalate are **0.32 µg/L** for consumption of water and organisms and **0.37 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of bis(2-ethylhexyl) phthalate, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Bis(2-ethylhexyl) Phthalate

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	1.2 µg/L	**0.32 µg/L**
Organism Only	2.2 µg/L	**0.37 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to bis(2-ethylhexyl) phthalate at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular

pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for bis(2-ethylhexyl) phthalate take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 710 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 130 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 17,370 L/kg
TL3 = 6,120 L/kg
TL4 = 1,040 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

In place of an RfD, EPA selected a chronic oral MRL of 0.06 mg/kg-d for bis(2-ethylhexyl) phthalate based on a 2002 ATSDR assessment (ATSDR 2002). EPA used the MRL of 0.06 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of bis(2-ethylhexyl) phthalate in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA retained a CSF of 0.014 mg/kg-d for bis(2-ethylhexyl) phthalate based on a 1987 EPA IRIS assessment (USEPA 1987; USEPA 2002c). EPA used this CSF to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the CSF in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Bis(2-ethylhexyl) phthalate (CAS Number 117-81-7)
- BEHP
- Bis(2-ethylhexyl)-1,2-benzene-dicarboxylate
- Bisoflex 81
- Bisoflex DOP
- Compound 889
- DAF 68
- DEHP
- Di(2-ethylhexyl)orthophthalate
- Di(2-ethylhexyl)phthalate
- Dioctyl phthalate
- Di-sec-octyl phthalate
- DOP
- Ergoplast FDO
- Ethylhexyl phthalate
- 2-Ethylhexyl phthalate
- Eviplast 80
- Eviplast 81
- Fleximel
- Flexol DOP
- Flexol plasticizer DOP
- Good-Rite GP 264
- Hatcol DOP
- Hercoflex 260
- Kodaflex DOP
- Mollan O
- NCI- C52733
- Nuoplaz DOP
- Octoil
- Octyl phthalate
- Palatinol AH
- Phthalic acid, Bis(2-ethylhexyl) ester
- Phthalic acid, dioctyl ester
- Pittsburgh PX-138
- Platinol DOP
- RC Plasticizer DOP
- RCRA waste number U028
- Reomol D 79P
- Reomol DOP
- Sicol 150

- Staflex DOP
- Truflex DOP
- Vestinol AH
- Vinicizer 80
- Witcizer 312

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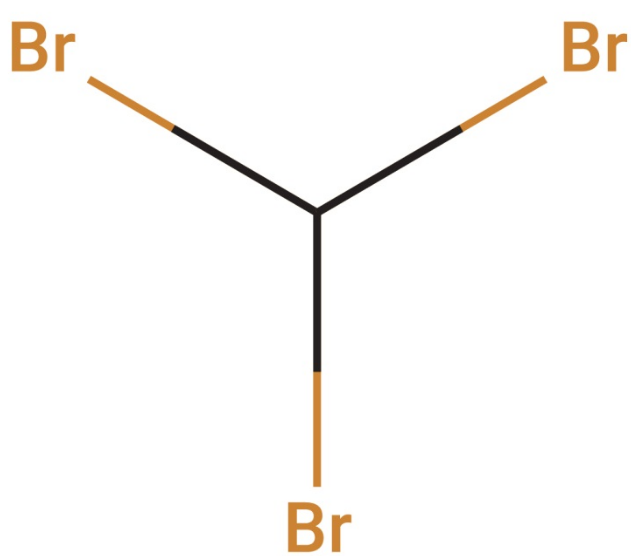
United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-021
June 2015

Update of Human Health Ambient Water Quality Criteria:

Bromoform
75-25-2



EPA 820-R-15-021
June 2015

Update of Human Health Ambient Water Quality Criteria:

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Office of Science and Technology
Office of Water
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Washington, DC 20460

Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC criteria recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for bromoform to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

Bromoform is a trihalomethane (THM) that was regulated in EPA's Stage 1 and Stage 2 Disinfection Byproduct (DBP) Rule (USEPA 1998; USEPA 2006). DBPs are formed by the reaction of disinfectants with constituents in the water, especially natural organic matter (NOM), but also inorganic constituents such as bromide and iodide. The concentration of DBPs within a public water system can vary depending on source water quality, treatment (e.g., type of disinfectant), and distribution system conditions. For example, THM concentrations might be lower when chloramine is used as the disinfectant compared to when chlorine is used.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible

for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

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[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50^{th} percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 5.8 L/kg (TL2), 7.5 L/kg (TL3), and 8.5 L/kg (TL4) for bromoform. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for bromoform. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Bromoform has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 2.4$ (ATSDR 2005)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 5.8 L/kg
TL3 = 7.5 L/kg
TL4 = 8.5 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for bromoform. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 3×10^{-2} mg/kg-d (0.03 mg/kg-d) for bromoform based on a 2005 EPA Office of Water (OW) assessment (USEPA 2005a). EPA OW identified a study by the National Toxicology Program (NTP 1989) as the critical study and hepatocellular vacuolization in the liver as the critical effect in male rats orally exposed to bromoform. The duration-adjusted lower-bound confidence limit on the benchmark dose ($BMDL_{10}$) was 2.6 mg/kg-d. In deriving the RfD, EPA applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10) (USEPA 2005a).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified three other potential RfD sources through the systematic search described in section 5: a 1987 EPA IRIS assessment (USEPA 1987), a 2005 EPA Office of Solid Waste and Emergency Response (OSWER) Provisional Peer Reviewed Toxicity Value (PPRTV) (USEPA 2005b), and a 2005 ATSDR assessment (ATSDR 2005). Based on the selection process described in section 5, the 2005 EPA OW RfD is preferred for use in AWQC development at this time. The 2005 OW assessment evaluated the same principal study as IRIS and ATSDR (NTP 1989), but used more current benchmark dose (BMD) modeling in order to identify the point of departure for the RfD derivation. According to EPA guidance, when data are amenable to modeling, the BMD approach is the preferred approach (USEPA 2012a). The 2005 PPRTV does not include the relevant (chronic oral) toxicity value.

5.2.2 Cancer Slope Factor

Under the 1999 Review Draft *Guidelines for Carcinogen Risk Assessment* (USEPA 1999), bromoform is “likely to be carcinogenic to humans by all routes of exposure” (USEPA 2005a).

EPA selected a CSF of 4.5×10^{-3} per mg/kg-d (0.0045 per mg/kg-d) for bromoform based on a 2005 EPA OW assessment (USEPA 2005a). EPA OW derived the 2005 CSF using a principal study by NTP (1989) based on development of tumors in the large intestine of female rats orally exposed to bromoform as the critical effect (USEPA 2005a).

EPA identified one other CSF source through the systematic search described in section 5: a 1989 IRIS assessment (USEPA 1989). Based on the selection process described in section 5, the 2005 EPA OW CSF is preferred for use in AWQC development at this time. The 2005 OW assessment evaluated the same principal study considered in the IRIS assessment (NTP 1989), but applied more current guidance and modeling approaches. Specifically, the LED_{10} (the lower 95 percent confidence limit on the estimated dose associated with 10 percent extra risk) was selected by OW as the point of departure for derivation of the slope factor in place of a linear multistage (LMS) slope factor. Additionally, the OW CSF uses a cross-species scaling approach based on $BW^{3/4}$, which is consistent with current EPA practice (USEPA 2005a; USEPA 2005c).

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD’s exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual’s total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to bromoform from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Bromoform

Input Parameter		Value
RfD		0.03 mg/kg-d
CSF		0.0045 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	5.8 L/kg
	TL3	7.5 L/kg
	TL4	8.5 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.03 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 5.8 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 7.5 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 8.5 \text{ L/kg}))}$$

$$= 188\ \mu g/L$$

$$= 200\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.03 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 5.8 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 7.5 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 8.5 \text{ L/kg})}$$

$$= 3{,}159\ \mu g/L$$

$$= 3{,}000\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{(10^{-6} / 0.0045) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 5.8 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 7.5 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 8.5 \text{ L/kg}))}$$

$$= 6.966\ \mu g/L$$

$$= 7.0\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{(10^{-6} / 0.0045) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 5.8 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 7.5 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 8.5 \text{ L/kg})}$$

$$= 117.0\ \mu g/L$$

$$= 120\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for bromoform using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for bromoform are **200 µg/L** for consumption of water and organisms and **3,000 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for bromoform are **7.0 µg/L** for consumption of water and organisms and **120 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of bromoform, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Bromoform

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	4.3 µg/L	**7.0 µg/L**
Organism Only	140 µg/L	**120 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to bromoform at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for bromoform take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a

contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 5.8, 7.5, and 8.5 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 3.75 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012b) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 13.85 L/kg
TL3 = 15.18 L/kg
TL4 = 19.49 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.03 mg/kg-d for bromoform based on a 2005 EPA OW assessment (USEPA 2005a). EPA used the RfD of 0.03 mg/kg-d to derive AWQC for noncarcinogenic effects.

EPA did not derive AWQC for noncarcinogenic effects of bromoform in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.0045 per mg/kg-d for bromoform based on a 2005 EPA OW assessment (USEPA 2005a). This CSF replaces the previous value of 0.0079 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.0045 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, a decrease in the CSF in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Bromoform (CAS Number 75-25-2)
- Methane, tribromo-
- Methenyl tribromide
- Tribromomethane

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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June 2015

Update of Human Health Ambient Water Quality Criteria:

Butylbenzyl Phthalate
85-68-7

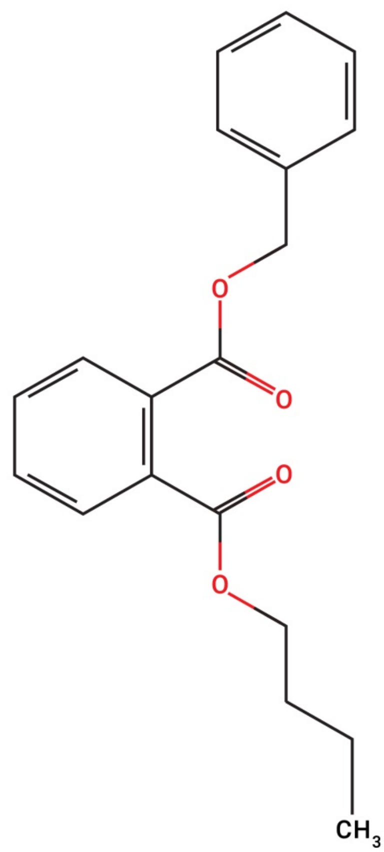

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for butylbenzyl phthalate to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

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[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 19,000 L/kg for butylbenzyl phthalate. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for butylbenzyl phthalate. Based on the characteristics of this chemical, EPA selected Procedure 2 for deriving a national BAF value. Butylbenzyl phthalate has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 4.73$ (USDHHS 2010)
- High metabolism (Gobas et al. 2003; Mankidya et al. 2013)

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for all three TLs (2, 3, and 4). Therefore, EPA used the BAF method estimate for the reported TLs by calculating the geometric mean of the TL3 and TL4 BAF values available for butylbenzyl phthalate (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 19,000 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for butylbenzyl phthalate. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both

noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 1.3 mg/kg-d for butylbenzyl phthalate based on a 2000 Health Canada assessment (HC and EC 2000). Health Canada derived the RfD using a principal study by Hammond et al. (1987) based on the development of pancreatic lesions as the critical effect in Wistar rats orally exposed to butylbenzyl phthalate (HC and EC 2000). The point of departure for this study was the lower-bound confidence limit on the benchmark dose ($BMDL_{05}$) of 132 mg/kg-d. In deriving the RfD, Health Canada applied a composite uncertainty factor of 100 to account for intraspecies variation (10) and interspecies extrapolation (10) (HC and EC 2000). An additional uncertainty factor of 10 to account for subchronic-to-chronic extrapolation was *not* applied as the Health Canada assessment explains, "An additional factor for extrapolation from subchronic to chronic has not been incorporated as, on the basis of a fairly robust database, there is no indication that effect levels are lower in chronic studies than in investigations of shorter duration" (HC and EC 2000). Health Canada also cites the rapid elimination of butylbenzyl phthalate as additional support for the decision not to apply the subchronic-to-chronic uncertainty factor.

EPA identified one other RfD source through the systematic search described in section 5: a 1989 EPA IRIS assessment (USEPA 1989). Based on the selection process described in section 5, the 2000 Health Canada RfD is preferred for use in AWQC development at this time. The Health Canada assessment uses more current benchmark dose (BMD) modeling in order to identify the point of departure for the RfD derivation and an updated cross-species scaling factor of $BW^{3/4}$ (HC and EC 2000; USEPA 2005). According to EPA guidance, when data are amenable to modeling, the BMD approach is the preferred approach (USEPA 2012a).

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), butylbenzyl phthalate is classified as Group C, "possible human carcinogen" (USEPA 1987). Under the 1999 EPA Review Draft *Guidelines for Carcinogen Risk Assessment* (USEPA 1999), butylbenzyl phthalate is considered "likely to be carcinogenic to humans" (USEPA 2002c).

EPA selected a CSF of 1.9×10^{-3} per mg/kg-d (0.0019 per mg/kg-d) for butylbenzyl phthalate based on a 2002 EPA Office of Solid Waste and Emergency Response (OSWER) Provisional Peer Reviewed Toxicity Value (PPRTV) (USEPA 2002c). OSWER calculated the CSF using principal studies by the National Toxicology Program (NTP 1997) based on the development pancreatic carcinogenesis in rats orally exposed to butylbenzyl phthalate (USEPA 2002c).

EPA identified no other CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Butylbenzyl phthalate is used as a plasticizer for polyvinyl and cellulose resins and in organic intermediates (USDHHS 2010). The physical properties and uses of this chemical indicate that the general population might be exposed to it via ingestion of fish and shellfish, ingestion of drinking water, and dermal contact with this chemical or products containing it (USDHHS 2010).

The log K_{ow} for butylbenzyl phthalate is 4.73 (USDHHS 2010). The national-level BAF estimate for butylbenzyl phthalate is 19,000 L/kg, which indicates that the chemical has a very high potential for bioaccumulation (USEPA 2011b). Butylbenzyl phthalate was detected in fish in EPA's National Lake Fish Tissue Survey (USEPA 2009c); it was not included in NOAA's Mussel

Watch Survey (NOAA 2014). Thus, due to its high potential to bioaccumulate, ingestion of fish and shellfish is a potentially significant source of exposure to butylbenzyl phthalate.

Butylbenzyl phthalate is used in plastics found in food packaging (USDHHS 2010). Butylbenzyl phthalate was found in vodka, beverages, dairy, eggs, fat and oils, fish, meat, poultry, vegetables, and other foods (USDHHS 2010). Butylbenzyl phthalate was also found in infant formula powder (USDHHS 2010). Thus, based on its detection in food and beverages, ingestion of food is a potentially significant source of exposure to butylbenzyl phthalate.

Butylbenzyl phthalate has a half-life in water of up to 1 year and has been detected in some surface waters (e.g., Delaware River, Mississippi River, Lake Michigan, St. Lawrence River, and Potomac River) as well as finished drinking water (USDHHS 2010). Butylbenzyl phthalate has also been found in stormwater runoff from roofs, parking areas, vehicle service areas, landscaped areas, urban creeks, and detention ponds (USDHHS 2010). This chemical is not regulated under the Safe Drinking Water Act (USEPA 2014c), and it was not a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). There is no Standard of Quality for butylbenzyl phthalate in bottled water (IBWA 2012). Thus, based on its half-life and detection in surface waters, ingestion of surface water and finished drinking water is a potentially significant source of exposure to butylbenzyl phthalate.

Dermal contact and indoor dust are potential sources of exposure to butylbenzyl phthalate (USDHHS 2010). In separate studies, butylbenzyl phthalate was found in personal air samples of pregnant women in New York, house dust samples, and residential and office dust samples (USDHHS 2010). Thus, dermal contact is a potentially significant source of exposure to butylbenzyl phthalate.

Air is not considered a significant source of exposure because butylbenzyl phthalate has low volatility (USDHHS 2010). The vapor pressure of butylbenzyl phthalate (8.25×10^{-6} mm Hg at 25 °C) indicates that volatilization from water and soil is not an important fate process for the chemical (USDHHS 2010). EPA's Toxic Release Inventory did not report release data for butylbenzyl phthalate in 2013 (USEPA 2015g), and it is not listed as a hazardous air pollutant (USEPA 2013). USDHHS (2010) reports that concentrations of butylbenzyl phthalate measured in air were generally low. Thus, based on its physical properties and information of release in the atmosphere, exposure to butylbenzyl phthalate from air is not considered likely.

In summary, based on the physical properties and available exposure information for butylbenzyl phthalate, EPA considers fish and shellfish, non-fish food, drinking and surface water, and dermal contact and dust to be potential sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for butylbenzyl phthalate.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to butylbenzyl phthalate from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Butylbenzyl Phthalate

Input Parameter	Value
RfD	1.3 mg/kg-d
CSF	0.0019 per mg/kg-d
RSC	0.20
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	19,000 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{1.3\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{2.4\ \text{L/d} + (0.022\ \text{kg/d} \times 19{,}000\ \text{L/kg})}$$

$$= 49.48\ \mu g/L$$

$$= 49\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{1.3\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{(0.022\ \text{kg/d} \times 19{,}000\ \text{L/kg})}$$

$$= 49.76\ \mu g/L$$

$$= 50\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 0.0019) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + (0.022 \text{ kg/d} \times 19{,}000 \text{ L/kg})}$$

$$= 0.1002\ \mu g/L$$

$$= 0.10\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 0.0019) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.022 \text{ kg/d} \times 19{,}000 \text{ L/kg})}$$

$$= 0.1007\ \mu g/L$$

$$= 0.10\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for butylbenzyl phthalate using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for butylbenzyl phthalate are **49** µg/L for consumption of water and organisms and **50** µg/L for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for butylbenzyl phthalate are **0.10** µg/L for consumption of water and organisms and **0.10** µg/L for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of butylbenzyl phthalate, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Butylbenzyl Phthalate

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	1,500 µg/L	**0.10 µg/L**
Organism Only	1,900 µg/L	**0.10 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to butylbenzyl phthalate at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular

pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for butylbenzyl phthalate take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 19,000 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 414 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012b) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 62.46 L/kg
TL3 = 54.54 L/kg
TL4 = 40.08 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA selected an RfD of 1.3 mg/kg-d for butylbenzyl phthalate based on a 2000 Health Canada assessment (HC and EC 2000). This RfD replaces the previous value of 0.2 mg/kg-d (USEPA 2002d). EPA used the RfD of 1.3 mg/kg-d to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, an increase in the RfD in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Cancer Slope Factor

EPA selected a CSF of 0.0019 per mg/kg-d for butylbenzyl phthalate based on a 2002 EPA OSWER PPRTV (USEPA 2002c). EPA used the CSF of 0.0019 per mg/kg-d to derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of butylbenzyl phthalate in its previous criteria update (USEPA 2002d).

<u>Relative Source Contribution</u>

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002d). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- Butylbenzyl phthalate (CAS Number 85-68-7)
- BBP
- 1,2-benzenedicarboxylic acid, butyl phenylmethyl ester
- Benzyl-butylester kyseliny ftalove
- Benzyl butyl phthalate
- Benzyl n-butyl phthalate
- Butyl benzyl phthalate
- N-butyl benzyl phthalate
- Butyl phenylmethyl 1,2-benzenedicarboxylate
- NCI-C54375
- Palatinol BB
- Phthalic acid, benzyl butyl ester
- Santicizer 160
- Sicol 160
- Unimoll BB

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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June 2015

Update of Human Health Ambient Water Quality Criteria:

Carbon Tetrachloride
56-23-5

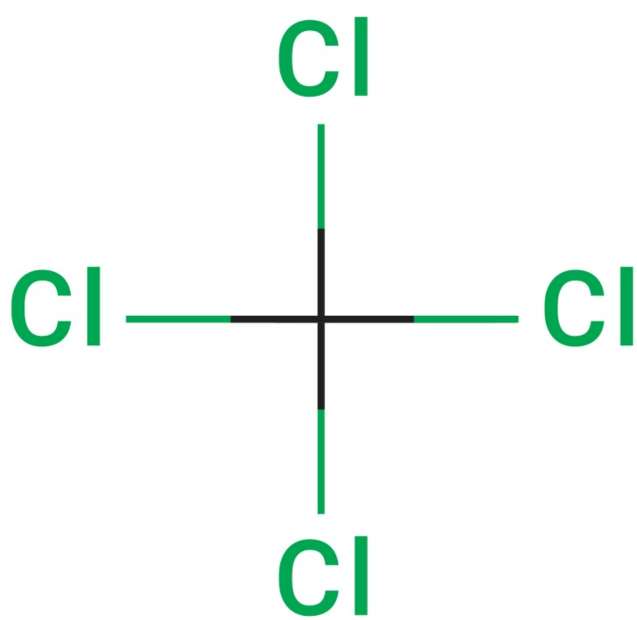

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Table of Contents

1. Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for carbon tetrachloride to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2. Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3. Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))} \qquad \text{(Eq. 1)}$$

<u>For consumption of organisms only:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4. Exposure Factors

4.1. Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2. Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3. Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level-(TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4. Bioaccumulation Factor

4.4.1. Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute trophic-level baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2. Chemical-specific BAFs

EPA selected national BAF values of 9.3 L/kg (TL2), 12 L/kg (TL3), and 14 L/kg (TL4) for carbon tetrachloride. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for carbon tetrachloride. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Carbon tetrachloride has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 2.64 (ATSDR 2005)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 9.3 L/kg
TL3 = 12 L/kg
TL4 = 14 L/kg

5. Hazard Identification and Dose Response

5.1. Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for carbon tetrachloride. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2. Chemical-specific Toxicity Value

5.2.1. Reference Dose

EPA selected an RfD of 4×10^{-3} mg/kg-d (0.004 mg/kg-d) for carbon tetrachloride based on a 2010 EPA IRIS assessment (USEPA 2010a). EPA's IRIS program identified a study by Bruckner et al. (1986) as the critical study and elevated serum sorbitol dehydrogenase (SDH) activity as the critical effect in rats orally exposed to carbon tetrachloride (USEPA 2010a). The subchronic study has a lower-bound confidence limit on the benchmark dose ($BMDL_{2x\text{-}Adj}$[g]) of 3.9 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 1000 to account for intraspecies differences (10), interspecies extrapolation (10), subchronic to chronic extrapolation (3), and deficiencies in the database (3) (USEPA 2010a).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

[g] Animals were dosed 5 days/week; therefore, the $BMDL_{2X}$ (i.e., 95 percent confidence limit on the benchmark dose corresponding to an increase in SDH activity two times the control mean) was multiplied by a factor of 5/7 to derive the $BMDL_{2X\text{-}ADJ}$ (USEPA 2010c).

EPA identified two other RfD sources through the systematic search described in section 5: a 2000 California EPA assessment (CalEPA 2000) and a 2005 ATSDR assessment (ATSDR 2005). Based on the selection process described in section 5, the IRIS RfD is preferred for use in AWQC development at this time. The 2010 EPA IRIS assessment is the most current RfD source.

5.2.2. Cancer Slope Factor

Under the 2005 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 2005), carbon tetrachloride is "likely to be carcinogenic to humans" (USEPA 2010b).

EPA selected a CSF of 7×10^{-2} per mg/kg-d (0.07 per mg/kg-d) for carbon tetrachloride based on a 2010 EPA IRIS assessment (USEPA 2010b). EPA's IRIS program calculated the CSF using principle studies by Nagano et al. (2007) and the JBRC (1998) based on development of hepatocellular adenomas or carcinomas in female mice with inhalation exposure to carbon tetrachloride (USEPA 2010b). Route-to-route extrapolation was performed and the mode of action could not be determined.

EPA identified one other CSF source for carbon tetrachloride through the systematic search described in section 5: a 2000 California EPA assessment (CalEPA 2000). Based on the selection process described in section 5, the IRIS CSF is preferred for use in AWQC development at this time. The 2010 EPA IRIS assessment is the most current CSF source.

6. Relative Source Contribution

6.1. Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology

Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2. Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7. Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to carbon tetrachloride from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Carbon Tetrachloride

Input Parameter		Value
RfD		0.004 mg/kg-d
CSF		0.07 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	9.3 L/kg
	TL3	12 L/kg
	TL4	14 L/kg

7.1. AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.004 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 9.3 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 12 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 14 \text{ L/kg}))}$$

$$= 24.2\ \mu g/L$$

$$= 20\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (\text{kg/d}) \times \text{BAF}_i\ (\text{L/kg}))}$$

$$= \frac{0.004 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 9.3 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 12 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 14 \text{ L/kg})}$$

$$= 261\ \mu g/L$$

$$= 300\ \mu g/L \text{ (rounded)}$$

7.2. AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.07) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 9.3 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 12 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 14 \text{ L/kg}))}$$

$$= 0.432\ \mu g/L$$

$$= 0.4\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.07) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 9.3 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 12 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 14 \text{ L/kg})}$$

$$= 4.66\ \mu g/L$$

$$= 5\ \mu g/L \text{ (rounded)}$$

7.3. AWQC Summary

EPA derived the AWQC for carbon tetrachloride using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for carbon tetrachloride are **20 µg/L** for consumption of water and organisms and **300 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for carbon tetrachloride are **0.4 µg/L** for consumption of water and organisms and **5 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of carbon tetrachloride, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Carbon Tetrachloride

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.23 µg/L	**0.4 µg/L**
Organism Only	1.6 µg/L	**5 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to carbon tetrachloride at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular

pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8. Criteria Characterization

The updated 2015 human health AWQC for carbon tetrachloride take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 9.3, 12, and 14 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 18.75 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 20.2 L/kg
TL3 = 20.11 L/kg
TL4 = 18.82 L/kg

Assuming all other input parameters remain constant, lower BAFs or BCFs result in higher AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish decreases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure increases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.004 mg/kg-d for carbon tetrachloride based on a 2010 EPA IRIS assessment (USEPA 2010a). EPA used the RfD of 0.004 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of carbon tetrachloride in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.07 per mg/kg-d for carbon tetrachloride based on a 2010 EPA IRIS assessment (USEPA 2010b). This CSF replaces the previous value of 0.13 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.07 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, a decrease in the CSF in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9. Chemical Name and Synonyms

- Carbon tetrachloride (CAS Number 56-23-5)
- Acritet
- Benzinoform
- Carbona
- Carbon chloride
- Carbon tet
- Carbo tetrachloride
- Czterochlorek wegla
- ENT 4,705
- Fasciolin
- Flukoids
- Freon 10
- Halon 104
- Mecatorina
- Methane tetrachloride
- Methane, tetrachloro-
- Necatorina
- Necatorine
- Perchloromethane
- R 10
- Tetrachloorkoolstof
- Tetrachloormetaan
- Tetrachlorkohlenstoff, tetra
- Tetrachlormethan
- Tetrachlorocarbon
- Tetrachloromethane
- Tetrachlorure de carbone
- Tetrachorkohlenstoff uvasol
- Tetraclorometano
- Tetracloruro di carbonio
- Tetrafinol
- Tetraform
- Tetrasol
- Univerm
- Ventox

- Vermoestricid
- WLN: GXGGG

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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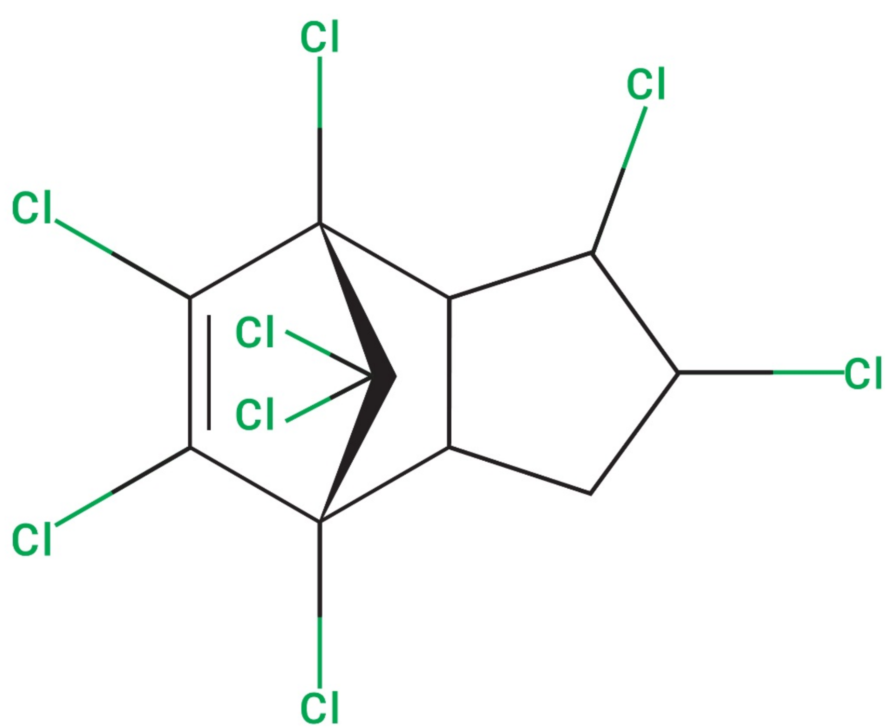
June 2015

Update of Human Health Ambient Water Quality Criteria:

Chlordane
57-74-9



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Office of Science and Technology
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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC criteria recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria (AWQC) recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for chlordane to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency’s goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

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[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.

[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.

[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 5,300 L/kg (TL2), 44,000 L/kg (TL3), and 60,000 L/kg (TL4) for chlordane. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for chlordane. Based on the characteristics of this chemical, EPA selected Procedure 1 for deriving a national BAF value. Chlordane has the following characteristics:

- Nonionic organic chemical (USDHHS 2012)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 5.54$ (ATSDR 1994)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 5,300 L/kg
TL3 = 44,000 L/kg
TL4 = 60,000 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for chlordane. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 5×10^{-4} mg/kg-d (0.0005 mg/kg-d) for chlordane based on a 1997 EPA IRIS assessment (USEPA 1997a). EPA's IRIS program derived the RfD using a principal study by Khasawinah and Grutsch (1989) based on increased incidence of hepatic necrosis as the critical effect in mice following a chronic oral exposure to chlordane (USEPA 1997a). The study NOAEL is 0.15 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 300 to account for interspecies extrapolation (10), intraspecies variation (10), and database uncertainty (3) (USEPA 1997a).

In 2001, EPA's IRIS program conducted a screening-level review of more recent toxicology literature pertinent to the RfD for chlordane and did not identify any new studies.

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[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 1997 California EPA assessment[g] (CalEPA 1997) and a 1994 ATSDR assessment (ATSDR 1994). Based on the selection process described in section 5, the IRIS RfD is preferred for use in AWQC development at this time. The CalEPA RfD is based on a more current principal study (Cassidy et al. 1994); however, EPA's IRIS program considered this study but decided not to use it quantitatively to derive the RfD.[h]

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), chlordane is classified as a Group B2, "probable human carcinogen" (USEPA 1997b). Under the 1996 EPA *Proposed Guidelines for Carcinogen Risk Assessment*, chlordane would be characterized as a "likely carcinogen by all routes of exposure" (USEPA 1996a; USEPA 1996b; USEPA 1997b).

EPA selected a CSF of 3.5×10^{-1} per mg/kg-d (0.35 per mg/kg-d) for chlordane based on a 1997 EPA IRIS assessment (USEPA 1997b). EPA's IRIS program calculated the CSF using principal studies by International Research and Development Corporation (IRDC 1973), National Cancer Institute (NCI 1977), and Khasawinah and Grutsch (1989) based on development of hepatocellular carcinomas in mice orally exposed to chlordane (USEPA 1997b).

In 2001, EPA's IRIS program conducted a screening-level review of more recent toxicology literature pertinent to the cancer assessment for chlordane and did not identify any critical new studies.

EPA identified one other CSF source through the systematic search described in section 5: a 1997 California EPA assessment (CalEPA 1997). Based on the selection process described in section 5, the IRIS CSF is preferred for use in AWQC development at this time. The CalEPA 1997 CSF was numerically the same as EPA IRIS's *previous* 1986 assessment. Thus, the 1997 EPA IRIS assessment is considered the most current CSF source.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and

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[g] California EPA's assessment was published in December 1997, one month after USEPA's Agency consensus date and two months before USEPA's publication date (February 1998). CalEPA reevaluated their public health goal for chlordane in 2006; however, the reevaluation supported their previous 1997 public health goal derivation.
[h] According to EPA IRIS: "Cassidy et al. (1994) tested the hypothesis that chlordane or its isomers/metabolites act to mimic sex steroids or change their concentrations to alter (in this case to masculinize) functions and behaviors... The lack of consistent dose-response relationships among the effects noted in this study, as well the uncertainty of their toxicological significance, preclude a clear interpretation of this study and assignment of any adverse effect levels. These observations show that, if testosterone or its receptors are somehow involved in the effects of chlordane, the dose-response model (or mechanism) for the effects must be extremely complex and is in need of further clarification."

nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to chlordane from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Chlordane

Input Parameter		Value
RfD		0.0005 mg/kg-d
CSF		0.35 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	5,300 L/kg
	TL3	44,000 L/kg
	TL4	60,000 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.0005 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 5{,}300 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 44{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 60{,}000 \text{ L/kg}))}$$

$$= 0.0110\ \mu g/L$$

$$= 0.01\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.0005 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 5{,}300 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 44{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 60{,}000 \text{ L/kg})}$$

$$= 0.0110\ \mu g/L$$

$$= 0.01\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.35) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 5{,}300 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 44{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 60{,}000 \text{ L/kg}))}$$

$$= 0.0003144\ \mu g/L$$

$$= 0.00031\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.35) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 5{,}300 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 44{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 60{,}000 \text{ L/kg})}$$

$$= 0.0003154\ \mu g/L$$

$$= 0.00032\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for chlordane using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for chlordane are **0.01 µg/L** for consumption of water and organisms and **0.01 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for chlordane are **0.00031 µg/L** for consumption of water and organisms and **0.00032 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of chlordane, as reflected in the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Chlordane

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.00080 µg/L	**0.00031 µg/L**
Organism Only	0.00081 µg/L	**0.00032 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to chlordane at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for chlordane take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

<u>Body Weight</u>

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

<u>Drinking Water Intake</u>

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the

AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 5,300, 44,000, and 60,000 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 14,100 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 688,200 L/kg
TL3 = 1,318,000 L/kg
TL4 = 3,205,000 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.0005 mg/kg-d for chlordane based on a 1997 EPA IRIS assessment (USEPA 1997a). EPA used the RfD of 0.0005 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of chlordane in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA retained a CSF of 0.35 per mg/kg-d for chlordane based on a 1997 EPA IRIS assessment (USEPA 1997b; USEPA 2002c). EPA used this CSF to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the CSF in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Chlordane (CAS Number 57-74-9)
- Belt
- CD 68
- Chlorindan
- Chlor Kil
- Corodan
- Dowchlor
- ENT 9, 932
- HCS 3260
- Kypchlor
- M 140
- M 410
- 4,7-Methanoindan, 1,2,4,5,6,7,8,8-Octachloro-3a,4,7,7a-Tetrahydro-
- 4,7-Methano-1H-Indene, 1,2,4,5,6,7,8,8-Octachloro-2,3,3a,4,7,7a-Hexahydro-
- NCI-C00099

- Niran
- Octachlorodihydrodicyclopentadiene
- 1,2,4,5,6,7,8,8-Octachloro-2,3,3a,4,7,7a-Hexahydro-4, 7-Methano-indene
- 1,2,4,5,6,7,8,8-Octachloro-3a,4,7,7a-Hexahydro-4,7-Methylene Indane
- Octachloro-4, 7-Methanohydroindane
- Octachloro-4, 7-Methanotetrahydroindane
- Octa-Klor
- Oktaterr
- Ortho-Klor
- Synklor
- TAT Chlor 4
- Topiclor
- Toxichlor
- Velsicol 1068

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

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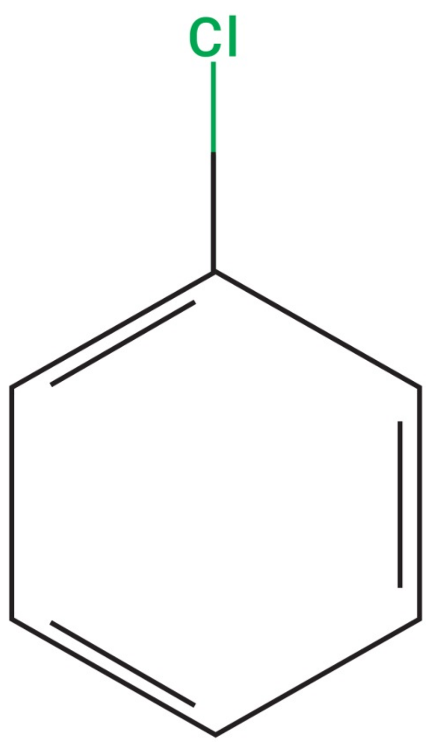
June 2015

Update of Human Health Ambient Water Quality Criteria:

Chlorobenzene
108-90-7



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Office of Science and Technology
Office of Water
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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for chlorobenzene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 14 L/kg (TL2), 19 L/kg (TL3), and 22 L/kg (TL4) for chlorobenzene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for chlorobenzene. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Chlorobenzene has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 2.84 (ATSDR 1990)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 14 L/kg
TL3 = 19 L/kg
TL4 = 22 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for chlorobenzene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014a)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 2×10^{-2} mg/kg-d (0.02 mg/kg-d) for chlorobenzene based on a 1989 EPA IRIS assessment (USEPA 1989). EPA's IRIS program identified studies by Monsanto Company (1967) and Knapp et al. (1971) as the critical studies and histopathologic changes in the liver as the critical effects in Beagles orally exposed to chlorobenzene. The subchronic (13-week) study had a NOAEL of 27.25 mg/kg-d (adjusted dose 19 mg/kg-d). In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 1000 to account for interspecies extrapolation (10), intraspecies variation (10), and subchronic-to-chronic study extrapolation (10) (USEPA 1989).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified three other potential RfD sources through the systematic search described in section 5: a 2006 EPA Office of Solid Waste and Emergency Response (OSWER) Provisional Peer Reviewed Toxicity Value (PPRTV) (USEPA 2006), a 2014 California EPA assessment (CalEPA 2014b), and a 1990 ATSDR assessment (ATSDR 1990). Based on the selection process described in section 5, the 1989 IRIS RfD is preferred for use in AWQC development at this time. Neither the 1990 ATSDR assessment nor the 2006 OSWER PPRTV include the relevant (chronic oral) toxicity value. The 2014 CalEPA assessment is the most current source (CalEPA 2014b); however, the CalEPA RfD is based on a study that IRIS considered during their assessment but did not use quantitatively (Nair et al. 1987).

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), chlorobenzene is classified as Group D, “not classifiable as to human carcinogenicity” (USEPA 1990).

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD’s exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual’s total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR “Toxicological Profiles” (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine’s Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Chlorobenzene is used as a solvent and in the production of various chemicals (ATSDR 1990). It has been measured in the air of urban and suburban areas, and exposure could also occur in workplace environments where the chemical is used or produced (ATSDR 1990). Inhalation of contaminated air and ingestion of contaminated water are likely the most significant sources of exposure to chlorobenzene for humans (ATSDR 1990).

The vapor pressure of chlorobenzene (8.8 mm Hg at 20 °C) indicates that volatilization is expected to be an important fate process for this chemical (ATSDR 1990). EPA's Toxic Release Inventory indicates that over 430,000 pounds of chlorobenzene were released to the air in 2013 (USEPA 2015g), and EPA lists chlorobenzene as a hazardous air pollutant (USEPA 2013). Thus, based on its physical properties and prevalence in the atmosphere, air is a potentially significant source of exposure to chlorobenzene.

Drinking water is also considered a potential exposure pathway for this chemical (ATSDR 1990). Chlorobenzene is regulated under the Safe Drinking Water Act and EPA's drinking water standard (maximum contaminant level) is 100 µg/L (USEPA 2014c). EPA's Six-Year Reviews detected chlorobenzene (USEPA 2009a; USEPA 2009b). The Standard of Quality for bottled water is 50 µg/L (IBWA 2012). Thus, ingestion of drinking water is a potentially significant source of exposure to chlorobenzene.

Recent information could not be identified regarding measured concentrations of chlorobenzene in non-fish food products. Thus, the potential exposure to chlorobenzene from food is unknown.

The log K_{ow} of chlorobenzene is 2.84 (ATSDR 1990). The national-level BAF estimates ranges from 14 L/kg (TL2) to 22 L/kg (TL4), which indicates that chlorobenzene has a low potential for bioaccumulation (USEPA 2011b). Chlorobenzene has been detected in Atlantic croaker, blue crabs, spotted seatrout, and blue catfish (USDHHS 2014). This chemical was not a target analyte in EPA's National Lake Fish Tissue Survey (USEPA 2009c), and it was not included in NOAA's Mussel Watch Survey (NOAA 2014). Although chlorobenzene was reported to be detected in fish in a single study, its physical properties and low potential to bioaccumulate suggest that fish and shellfish are not likely to be a significant source of exposure.

In summary, based on the physical properties and available exposure information for chlorobenzene, air and drinking water are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources of exposure other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from these different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for chlorobenzene.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to chlorobenzene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Chlorobenzene

Input Parameter		Value
RfD		0.02 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	14 L/kg
	TL3	19 L/kg
	TL4	22 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.02 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 14 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 19 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 22 \text{ L/kg}))}$$

$$= 115\ \mu g/L$$

$$= 100\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.02 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 14 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 19 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 22 \text{ L/kg})}$$

$$= 838\ \mu g/L$$

$$= 800\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for chlorobenzene using a noncarcinogenic toxicity endpoint. The updated human health AWQC for chlorobenzene are **100 µg/L** for consumption of water and organisms and **800 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2003b).

Table 2. Summary of EPA's Previously Recommended (2003) and Updated (2015) Human Health AWQC for Chlorobenzene

	2003 Human Health AWQC	2015 Human Health AWQC
Water and Organism	130 µg/L	**100 µg/L**
Organism Only	1,600 µg/L	**800 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to chlorobenzene from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for chlorobenzene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

<u>Body Weight</u>

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

<u>Drinking Water Intake</u>

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 14, 19, and 22 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 10.3 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 24.41 L/kg
TL3 = 25.05 L/kg
TL4 = 25 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to

representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA retained an RfD of 0.02 mg/kg-d for chlorobenzene based on a 1989 EPA IRIS assessment (USEPA 1989; USEPA 2003b). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for chlorobenzene and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of chlorobenzene in its previous criteria update (USEPA 2003b).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. This is the same RSC used in the previous AWQC (USEPA 2003b).

9 Chemical Name and Synonyms

- Chlorobenzene (CAS Number 108-90-7)
- Benzene chloride
- Benzene, chloro-
- Chloorbenzeen (Dutch)
- Chlorbenzol
- Chlorobenzen (Polish)
- Chlorobenzenu (Czech)
- Chlorobenzol
- Clorobenzene (Italian)
- MCB
- Monochloorbenzeen (Dutch)
- Monochlorbenzene
- Monochlorbenzol (German)
- Monochlorobenzene
- Monoclorobenzene (Italian)
- NCI-C54886
- Phenyl chloride
- UN 1134

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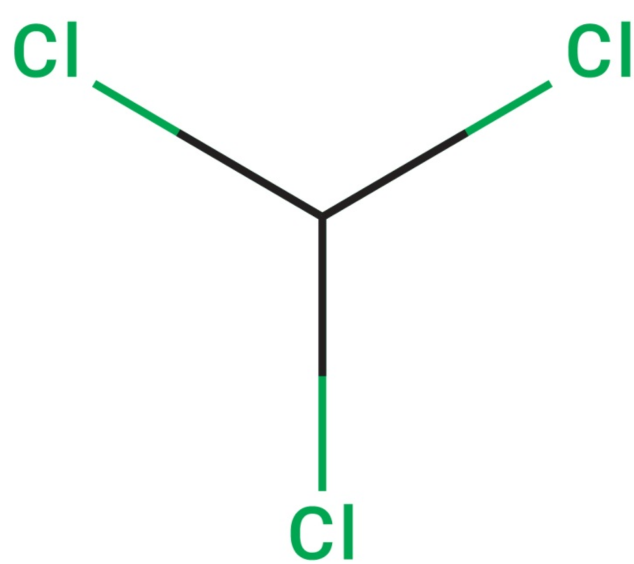
United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-027
June 2015

Update of Human Health Ambient Water Quality Criteria:

Chloroform
67-66-3



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Office of Science and Technology
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Washington, DC 20460

Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for chloroform to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

Chloroform is a trihalomethane (THM) that was regulated in EPA's Stage 1 and Stage 2 Disinfection Byproduct (DBP) Rule (USEPA 1998a; USEPA 2006). DBPs are formed by the reaction of disinfectants with constituents in the water, especially natural organic matter (NOM), but also inorganic constituents such as bromide and iodide. The concentration of DBPs within a public water system can vary depending on source water quality, treatment (e.g., type of disinfectant), and distribution system conditions. For example, THM concentrations might be lower when chloramine is used as the disinfectant compared to when chlorine is used.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible

for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

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[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 2.8 L/kg (TL2), 3.4 L/kg (TL3), and 3.8 L/kg (TL4) for chloroform. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for chloroform. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Chloroform has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Low hydrophobicity (log K_{ow} < 4); log K_{ow} = 1.97 (ATSDR 1997)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 2.8 L/kg
TL3 = 3.4 L/kg
TL4 = 3.8 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for chloroform. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 1×10^{-2} mg/kg-d (0.01 mg/kg-d) for chloroform based on a 2001 EPA IRIS assessment (USEPA 2001a). EPA's IRIS program calculated the RfD using a principal study by Heywood et al. (1979) based on moderate to marked fatty cyst formation in the liver and elevated serum glutamate-pyruvate transaminase as the critical effects in dogs orally exposed to chloroform. The study has a lower-bound confidence limit on the benchmark dose of 1 mg/kg-d as the point of departure (POD). In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10) (USEPA 2001a).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources based on the systematic search described in section 5: a 2006 EPA Office of Water (OW) assessment and a 1997 ATSDR assessment (ATSDR 1997). Based on the selection process described in section 5, the 2001 EPA IRIS assessment is preferred for use in AWQC development at this time. The EPA OW assessment is based on the same principal study and is numerically the same as the IRIS assessment. The 2001 IRIS assessment is more current than the 1997 ATSDR assessment.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), chloroform has been classified as Group B2, "probable human carcinogen" (USEPA 2001b). Under the 1999 EPA Review Draft *Guidelines for Carcinogen Risk Assessment* (USEPA 1999), chloroform is characterized as "likely to be carcinogenic to humans by all routes of exposure under high-exposure conditions that lead to cytotoxicity and regenerative hyperplasia in susceptible tissues" and "not likely to be carcinogenic to humans by any route of exposure under exposure conditions that do not cause cytotoxicity and cell regeneration" (USEPA 1998b; USEPA 2001b).

EPA's IRIS program used a nonlinear dose-response approach for characterizing the cancer risk from chloroform. Available evidence indicates that chloroform-induced carcinogenicity is secondary to cytotoxicity and regenerative hyperplasia; hence, the Agency relies on a nonlinear approach and the use of a margin-of-exposure analysis for cancer risk. EPA's IRIS chose not to rely on a mathematical model to estimate a POD for a cancer risk estimate because the mode of action indicates that cytotoxicity is the critical effect and the RfD value is considered protective for this effect. Thus, the RfD for noncancer effects is also considered adequately protective of public health for cancer effects by the oral route (USEPA 2001b).

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the

chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Chloroform is most often used in the manufacture of other chemicals, and environmental sources are typically from industrial sources (ATSDR 1997). Chloroform is not currently registered for use as a pesticide (USEPA 2015c). The general population is exposed to chloroform primarily from non-fish food, drinking water, and indoor air (USDHHS 2014).

Chloroform is found in beverages (e.g., soft drinks) and various foods (ATSDR 1997). For example, a 5 year study (1996–2000) revealed that chloroform is present in various food items in supermarkets in the United States (USDHHS 2014). It has been reported in different foods in the Everything Added to Food in the United States database (USFDA 2013). Thus, based on its detection in beverages and food, ingestion of food is a potentially significant source of exposure to chloroform.

Water that contains organic material and is chlorinated can generate chloroform (ATSDR 1997). It is commonly detected in tap water throughout much of the United States because of the chlorination of drinking water for disinfection (USDHHS 2014). Chloroform is regulated under the Safe Drinking Water Act and EPA's drinking water standard (maximum contaminant level) of 70 µg/L (USEPA 2014c). Chloroform was not a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). There is a Standard of Quality of 10 µg/L for total trihalomethanes in bottled water (IBWA 2012). Thus, based on its chemical properties and detection in drinking waters, ingestion of drinking water is a potentially significant source of exposure to chloroform.

Air is a potential source of chloroform because the chemical is volatile and also released into the air through fugitive and point source emissions (ATSDR 1997). The vapor pressure of chloroform (160 mm Hg at 20 °C) indicates that volatilization from soil and water is an important fate process (ATSDR 1997). Recent data from EPA's Toxic Release Inventory reports over that 360,000 pounds of chloroform were released to the air in 2013 (USEPA 2015g). Chloroform is listed as a hazardous air pollutant (USEPA 2013). Thus, based on its physical properties and prevalence, air is a potentially significant source of exposure to chloroform.

The log K_{ow} for chloroform is 1.97 (ATSDR 1997). The national-level BAF estimates for chloroform range from 2.8 L/kg (T2) to 3.8 L/kg (TL4), which indicates that chloroform has a low potential for bioaccumulation (USEPA 2011b). Recent exposure information regarding concentrations of chloroform in fish and shellfish from inland and nearshore waters and ocean fish and shellfish could not be identified. Chloroform was not included in EPA's National Lake Fish Tissue Study (USEPA 2009c) or in NOAA's Mussel Watch Survey (NOAA 2014). Thus, the potential exposure to chloroform from ingestion of fish and shellfish is unknown.

In summary, based on the physical properties and available exposure information for chloroform, air, drinking water, and non-fish food are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for chloroform.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to chloroform from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Chloroform

Input Parameter		Value
RfD		0.01 mg/kg-d
CSF		No data
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	2.8 L/kg
	TL3	3.4 L/kg
	TL4	3.8 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.01 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 2.8 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 3.4 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 3.8 \text{ L/kg}))}$$

$$= 64.8\ \mu g/L$$

$$= 60\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg))}}$$

$$= \frac{0.01 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 2.8 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 3.4 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 3.8 \text{ L/kg})}$$

$$= 2{,}289\ \mu g/L$$

$$= 2{,}000\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) The RfD for noncancer effects is considered adequately protective of public health for cancer effects by the oral route (USEPA 2001a). Therefore, the AWQC derived using the RfD are protective of carcinogenic effects.

7.3 AWQC Summary

EPA derived the AWQC for chloroform using a toxicity endpoint that is protective of noncarcinogenic and carcinogenic effects. The updated human health AWQC for chloroform are **60 µg/L** for consumption of water and organisms and **2,000 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Chloroform

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	5.7 µg/L	**60 µg/L**
Organism Only	470 µg/L	**2,000 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic and carcinogenic effects due to chronic (up to a lifetime) exposure to chloroform from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for chloroform take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 2.8, 3.4, and 3.8 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 3.75 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

> TL2 = 6.003 L/kg
> TL3 = 6.591 L/kg
> TL4 = 8.706 L/kg

Assuming all other input parameters remain constant, lower BAFs or BCFs result in higher AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish decreases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure increases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.01 mg/kg-d for chloroform based on a 2001 EPA IRIS assessment (USEPA 2001a). This RfD, which was used to derive AWQC for noncancer effects, is also considered adequately protective of public health for cancer effects by the oral route (USEPA 2001a). EPA did not derive AWQC for noncarcinogenic effects of chloroform in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA did not select a CSF for chloroform because EPA's IRIS program used a nonlinear dose-response approach for characterizing the cancer risk from chloroform in its most recent toxicological assessment (USEPA 2001a). EPA's AWQC derived using the RfD described above (0.01 mg/kg-d) are protective of both noncarcinogenic and carcinogenic effects. EPA used a CSF (0.0061 per mg/kg-d) to derive AWQC for carcinogenic effects of chloroform in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- Chloroform (CAS Number 67-66-3)
- Formyl Trichloride
- Freon 20
- Methane Trichloride
- Methane, Trichloro-
- Methenyl Chloride
- Methenyl Trichloride
- Methyl Trichloride
- NCI-CO2686
- R-20
- TCM
- Trichloroform
- Trichloromethane

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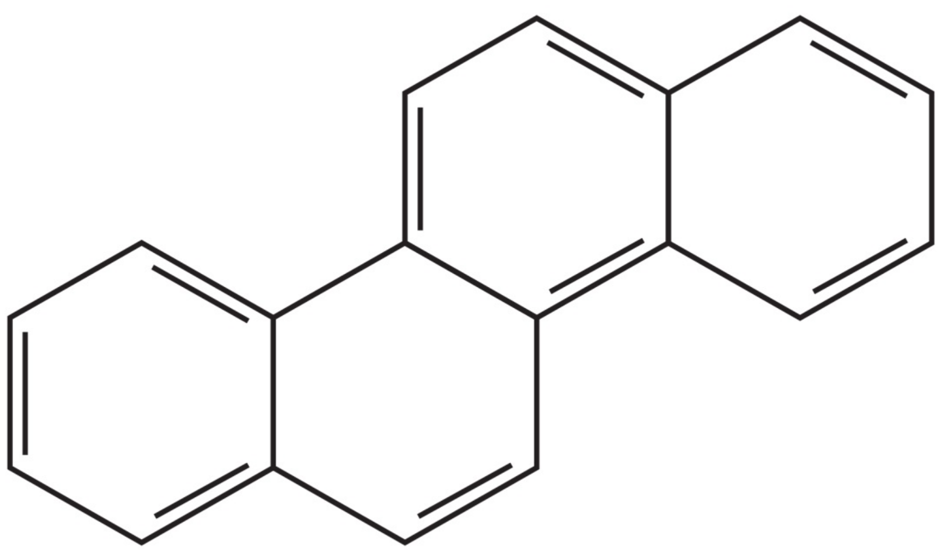
June 2015

Update of Human Health Ambient Water Quality Criteria:

Chrysene
218-01-9



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Office of Science and Technology
Office of Water
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Washington, DC 20460

Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for chrysene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake rate [DI], and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 3,900 L/kg for chrysene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for chrysene. Based on the characteristics of this chemical, EPA selected Procedure 2 for deriving a national BAF value. Chrysene has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log K_{ow} = 5.16 (ATSDR 1995)
- High metabolism (NOAA n.d.)

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for this polycyclic aromatic hydrocarbon (PAH) (Arnot and Gobas 2006; Environment Canada 2006). In the absence of chemical-specific information, EPA used the field-measured BAF for benzo(a)pyrene, an index PAH, as a surrogate for the estimation of BAFs for other PAHs. This approach is consistent with conclusions of Neff (2002) that benzo(a)pyrene is a good indicator of the presence of pyrogenic PAHs in the environment and that type of PAH is expected to concentrate in organisms such as fish and shellfish as does benzo(a)pyrene. Therefore, EPA used the benzo(a)pyrene BCF method estimate for the reported TLs by calculating the geometric mean of the TL2 and TL3 BCF values available for benzo(a)pyrene (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 3,900 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for chrysene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

EPA's IRIS program does not currently have an RfD or CSF for chrysene (USEPA 1990). In the absence of chemical-specific information, EPA recommends use of benzo(a)pyrene, an index PAH, as a surrogate for the determination of risk to other PAHs. In this approach, the potencies of other PAHs relative to benzo(a)pyrene are determined. EPA's IRIS program is currently reassessing benzo(a)pyrene, which may be used in the future to derive toxicity values for other PAHs, including chrysene. In 2013, EPA's IRIS program published the draft Toxicological Review for benzo(a)pyrene for public review and comment, discussion at a public meeting, and subsequent expert peer review (USEPA 2013a; USEPA 2013b). The 2013 draft Toxicological Review included both a draft RfD and a draft CSF. In addition, in 2010, EPA's IRIS program published draft updated relative potency factors for PAH mixtures (USEPA 2010).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA anticipates updating the AWQC for PAHs following finalization of EPA's IRIS toxicological assessment for benzo(a)pyrene and relative potency factors for PAHs. In the meantime, based on the selection process described above, EPA will use IRIS's current toxicity values for benzo(a)pyrene (USEPA 1991) and IRIS's currently recommended relative potency factors (USEPA 1993) for the purpose of AWQC derivation for chrysene.

5.2.1 Reference Dose

EPA has not selected an RfD for derivation of AWQC for chrysene. EPA's IRIS program does not currently have an oral RfD for chrysene or benzo(a)pyrene, the index PAH (USEPA 1990; USEPA 1991).

EPA identified two RfD sources for chrysene through the systematic search described in section 5: a 1995 ATSDR assessment (ATSDR 1995) and a 2005 California EPA assessment (CalEPA 2005). However, due to EPA's ongoing reassessments, the toxicity values from these assessments will not be used to derive AWQC at this time.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), chrysene is characterized as a class B2 "probable human carcinogen" (USEPA 1990).

EPA selected a CSF of 0.0073 per mg/kg-d for chrysene based on a 1991 EPA IRIS assessment for benzo(a)pyrene (USEPA 1991). EPA's IRIS program derived a CSF of 7.3 per mg/kg-d using a principal study by Neal and Rigdon (1967), which was based on development of fore-stomach and squamous cell papillomas in mice orally exposed to benzo(a)pyrene (USEPA 1991). EPA applied a relative potency factor of 0.001 to derive the CSF for chrysene (USEPA 1993).

EPA identified one other CSF source for chrysene through the systematic search described in section 5: a 2005 California EPA assessment (CalEPA 2005). However, due to EPA's ongoing reassessments, EPA will use the current IRIS CSF to derive AWQC at this time.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using only a carcinogenic toxicity endpoint (CSF) because no RfD sources were identified through the systematic search described in section 5 (Hazard Identification and Dose Response). Therefore, no RSC was applied in the AWQC derivation for this chemical.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to chrysene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Chrysene

Input Parameter	Value
RfD	No data
CSF	0.0073 per mg/kg-d
RSC	–
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	3,900 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

EPA identified no RfD sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for noncarcinogenic toxicological effects.

7.2 AWQC for Carcinogenic Toxicological Effects

<u>For consumption of water and organisms:</u>

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 0.0073) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + (0.022 \text{ kg/d} \times 3{,}900 \text{ L/kg})}$$

$$= 0.1243\ \mu g/L$$

$$= 0.12\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000 \ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 0.0073) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000 \ \mu g/mg}{(0.022 \text{ kg/d} \times 3{,}900 \text{ L/kg})}$$

$$= 0.1277 \ \mu g/L$$

$$= 0.13 \ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for chrysene using a carcinogenic toxicity endpoint. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for chrysene are **0.12 µg/L** for consumption of water and organisms and **0.13 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Chrysene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.0038 µg/L	**0.12 µg/L**
Organism Only	0.018 µg/L	**0.13 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to chrysene at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for chrysene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 3,900 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 30 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 8,997 L/kg
TL3 = 4,739 L/kg
TL4 = 1,993 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA did not select an RfD for chrysene and therefore did not derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of chrysene in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.0073 per mg/kg-d for chrysene based on a 1991 EPA IRIS assessment for benzo(a)pyrene (USEPA 1991). This CSF replaces the previous value of 7.3 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.0073 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, a decrease in the CSF in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Relative Source Contribution

No RfD sources were identified for this chemical. Therefore, no RSC was applied in the AWQC derivation for this chemical.

9 Chemical Name and Synonyms

- Chrysene (CAS Number 218-01-9)
- Benz(a)phenanthrene
- Benzo(a)phenanthrene
- HSDB 2810
- NSC 6175
- RCRA waste number U050
- 1,2-benzophenanthrene
- 1,2-benzphenanthrene
- 1,2,5,6-dibenzonaphthalene

10 References

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for cyanide to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

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[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BCF value of 1 L/kg for cyanide. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for cyanide. Based on the characteristics this chemical, EPA selected Procedure 5 for deriving a national BAF value. Cyanide has the following characteristics:

- Inorganic chemical
- Biomagnification unlikely (ATSDR 2006)

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for all three TLs (2, 3, and 4). Therefore, EPA is using the national BCF value of 1 L/kg from EPA's *National Recommended Water Quality Criteria for the Protection of Human Health* for cyanide (USEPA 2003b).

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for cyanide. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both

noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 6×10^{-4} mg/kg-d (0.0006 mg/kg-d) for free cyanide based on a 2010 EPA IRIS assessment for hydrogen cyanide and cyanide salts (USEPA 2010a). EPA IRIS states that the "use of the RfD for free cyanide to calculate RfDs of other cyanide compounds may be merited, but the ability of the individual cyanogenic species to dissociate and release free cyanide in aqueous solution (and at physiological pHs) should be taken into consideration. If dissociation of the compound is expected, then liberated cations should be considered for potential toxicity independent of CN^-. Also, some metallocyanides, such as copper cyanide, have chemical-specific data and are not included in this (IRIS) analysis" (USEPA 2010a).

EPA's IRIS program identified a study by the National Toxicology Program (NTP 1993) as the critical study and decreased cauda epididymis weight as the critical effect in male rats exposed to cyanide in drinking water (USEPA 2010a). The lower-bound confidence limit on the benchmark dose ($BMDL_{1SD}$) is 1.9 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 3000 to account for interspecies extrapolation (10), intraspecies variation (10), subchronic-to-chronic exposure extrapolation (10), and database deficiencies (3) (USEPA 2010a).

EPA identified two other RfD sources through the systematic search described in section 5: a 2006 ATSDR assessment (ATSDR 2006) and a 1997 California EPA assessment (CalEPA 1997). Based on the selection process described in section 5, the IRIS RfD is preferred for use in AWQC development at this time. The 2010 EPA IRIS assessment is the most current RfD source.

5.2.2 Cancer Slope Factor

Under the 2005 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 2005), there is "inadequate information to assess the carcinogenic potential" of cyanide (USEPA 2010b).

EPA identified no CSF source through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).

- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Cyanide is used in some pesticide formulations and as an adjuvant or intensifier for defoliation and weed control (ATSDR 2006). Cyanide itself is not registered as a pesticide (USEPA 2015c). The physical properties and uses of this chemical indicate that the general population might be exposed to it primarily through ingestion of food and water and, to a lesser degree, air (ATSDR 2006).

The vapor pressure of cyanide (630 mm Hg at 20 °C) indicates that volatilization is an important fate process for this chemical (ATSDR 2006). Recent data from EPA's Toxic Release Inventory indicate that almost 135,000 pounds of hydrogen cyanide were released to the air in 2013 (USEPA 2015g). Some cyanide compounds are listed as hazardous air pollutants (USEPA 2013). Cyanide has also been detected in cigarette smoke, automobile exhaust, and house and building fire smoke (ATSDR 2006). Therefore, based on the chemical's physical properties and prevalence, air is a potentially significant source of exposure to it.

Cyanide is regulated under the Safe Drinking Water Act, and EPA's drinking water standard (maximum contaminant level) is 200 µg/L (as free cyanide) (USEPA 2014c). Cyanide has been detected in treated drinking water (ATSDR 2006), and it was detected in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b). The Standard of Quality for bottled water for cyanide is 100 µg/L (IBWA 2012). Therefore, finished drinking water is a potentially significant source of exposure to cyanide.

Cyanide has been detected in food (ATSDR 2006), and ferrocyanide salt is listed in the Everything Added to Food in the United States database (USFDA 2013). Thus, ingestion of food is a potentially significant source of exposure to this chemical.

The average log K_{ow} for hydrogen cyanide is 0.87 (ATSDR 2006). The BCF estimate for cyanide is 1 L/kg, which indicates cyanide has a low potential for bioaccumulation (USEPA 2011b). Recent exposure information regarding concentrations of cyanide in fish and shellfish could not be identified. This chemical was not included in NOAA's Mussel Watch Survey (NOAA 2014), and it was not on the list of analytes in EPA's National Lake Fish Tissue Study (USEPA 2009c). Thus, based on its low potential for bioaccumulation, exposure to this chemical from ingestion of fish and shellfish is not considered likely.

In summary, based on the physical properties and available exposure information for cyanide, air, drinking water, and non-fish food are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to accurately characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for cyanide.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to cyanide from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Cyanide

Input Parameter	Value
RfD	0.0006 mg/kg-d
CSF	No data
RSC	0.20
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BCF	1 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BCF (L/kg)})}$$

$$= \frac{0.0006\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{2.4\ \text{L/d} + (0.022\ \text{kg/d} \times 1\ \text{L/kg})}$$

$$= 3.96\ \mu g/L$$

$$= 4\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BCF (L/kg)})}$$

$$= \frac{0.0006\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{(0.022\ \text{kg/d} \times 1\ \text{L/kg})}$$

$$= 436\ \mu g/L$$

$$= 400\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for cyanide using a noncarcinogenic toxicity endpoint. The updated human health AWQC for cyanide are **4 µg/L** for consumption of water and organisms and **400 µg/L** for consumption of organisms only[g] (Table 2). These updated criteria replace EPA's previously published values (USEPA 2003b).

Consistent with EPA's previously published criteria for cyanide (USEPA 2003b), these updated AWQC are expressed as total cyanide, even though the IRIS RfD used to derive the criterion is based on free cyanide. The multiple forms of cyanide that are present in ambient water have significant differences in toxicity due to their differing abilities to liberate the CN-moiety. Some complex cyanides require even more extreme conditions than refluxing with sulfuric acid to liberate the CN-moiety. Thus, these complex cyanides are expected to have little or no bioavailability to humans. If a substantial fraction of the cyanide present in a water body is present in a complexed form (e.g., Fe4[Fe(CN)6]3), these recommended criteria may be overly conservative (USEPA 2003b).

Table 2. Summary of EPA's Previously Recommended (2003) and Updated (2015) Human Health AWQC for Cyanide

	2003 Human Health AWQC	2015 Human Health AWQC
Water and Organism	140 µg/L	**4 µg/L**
Organism Only	140 µg/L	**400 µg/L***

*See footnote g.

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to cyanide from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

[g] If a water body is not designated as a drinking water supply source, a state can adopt AWQC for consumption of organisms only instead of AWQC for consumption of water and organisms. EPA recommends, however, that the state evaluate whether organism-only AWQC for non-bioaccumulative chemicals pose a risk to swimmers in those water bodies. Because cyanide has no bioaccumulation potential (BCF = 1 L/kg), EPA performed a screening analysis to determine whether the updated AWQC for organisms only is protective of incidental water ingestion from recreational uses (see section 4.1.1.3 in USEPA 2000a). EPA assumed an incidental water ingestion rate of 0.090 L/swimming event, which represents the upper (97th) percentile for children (Table 3-5 in USEPA 2011a) and a body weight of 31.8 kg, which represents the mean body weight of children ages 6 to <11 years (Table 8-1 in USEPA 2011a). No acute oral RfD was identified so EPA relied on an intermediate duration (15–364 days) MRL for cyanide of 0.05 mg CN^-/kg-d (ATSDR 2006). The resulting incidental water ingestion value (for screening purposes only) is 17,667 µg/L [(0.05 mg/kg-d × 31.8 kg × 1,000 µg/mg) / 0.090 L/d]. Therefore, the updated AWQC for consumption of organisms only of 400 µg/L for cyanide is protective of incidental water ingestion from recreational uses. Where a water body is designated as a drinking water supply source EPA recommends the AWQC for consumption of water and organisms for cyanide (4 µg/L) (USEPA 2000a).

8 Criteria Characterization

The updated 2015 human health AWQC for cyanide take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The updated AWQC rely on EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a) to derive national TL-specific BAFs. In cases where data were not available to calculate one or more TL-specific BAFs, EPA relied on the BCF from the previously recommended 2003 criteria (USEPA 2003b). The previously recommended BCF of 1 L/kg was used for cyanide.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 0.9634 L/kg
TL3 = 0.9561 L/kg
TL4 = 0.9202 L/kg

<u>Reference Dose</u>

EPA selected an RfD of 0.0006 mg/kg-d for free cyanide based on a 2010 EPA IRIS assessment for hydrogen cyanide and cyanide salts (USEPA 2010a). This RfD replaces the previous value of 0.02 mg/kg-d (USEPA 2003b). EPA used the RfD of 0.0006 mg/kg-d to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, a decrease in the RfD in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

<u>Cancer Slope Factor</u>

EPA did not select a CSF for cyanide and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of cyanide in its previous criteria update (USEPA 2003b).

<u>Relative Source Contribution</u>

An RSC of 20 percent is included in the AWQC calculation. This is the same RSC used in the previous AWQC (USEPA 2003b).

9 Chemical Name and Synonyms

- Cyanide (CAS Number 57-12-5)
- Prussic acid
- Hydrocyanic acid
- Cyclone B
- Cyanogran
- Cymag
- Cyanobrik
- White cyanide
- Calcyanide
- Calcyan, cyanogas
- Black cyanide

- Potassium dicyanoargentate
- Dicyanogen
- Ethanedinitrile
- Oxalonitrile

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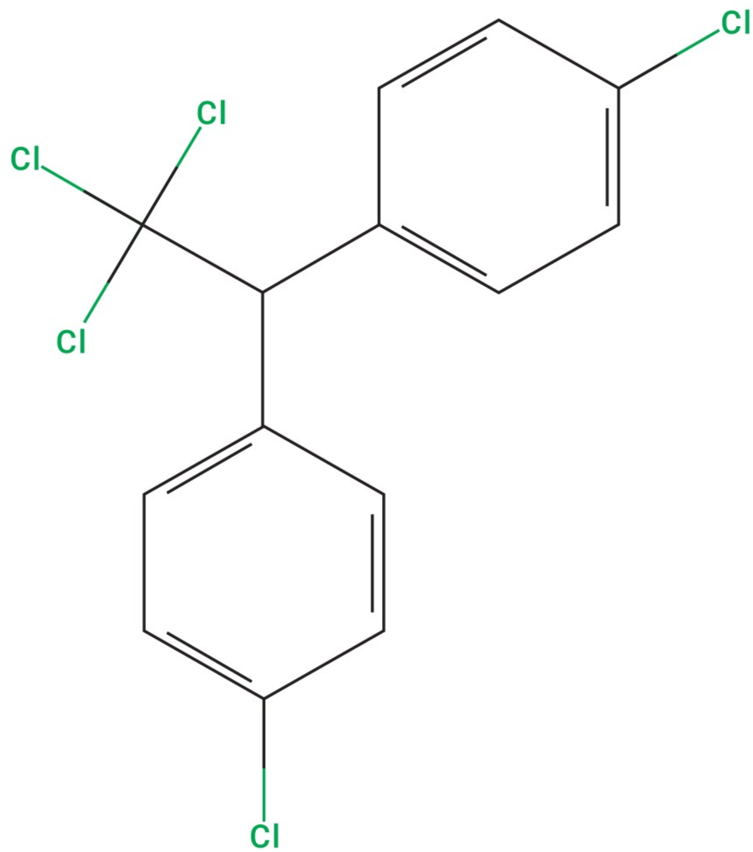
United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-095
June 2015

Update of Human Health Ambient Water Quality Criteria:

p,p′-Dichlorodiphenyltrichloroethane (DDT)
50-29-3



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Office of Science and Technology
Office of Water
U.S. Environmental Protection Agency
Washington, DC 20460

Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for p,p'-dichlorodiphenyltrichloroethane (DDT) to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 35,000 L/kg (TL2), 240,000 L/kg (TL3), and 1,100,000 L/kg (TL4) for DDT. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for DDT. Based on the characteristics of this chemical, EPA selected Procedure 1 for deriving a national BAF value. DDT has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 6.91$ (ATSDR 2002)
- Low/unknown metabolism

EPA was able to locate peer-reviewed, field-measured BAFs for TLs 2, 3, and 4 (USEPA 2003a; Arnot and Gobas 2006). Therefore, EPA used the Field BAF method to derive the national BAF values for this chemical:

TL2 = 35,000 L/kg
TL3 = 240,000 L/kg
TL4 = 1,100,000 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for DDT. As described in the 2000 Methodology (USEPA 2000a), where data are available, EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, ATSDR (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 5×10^{-4} mg/kg-d (0.0005 mg/kg-d) for DDT based on a 1985 EPA IRIS assessment (USEPA 1985). EPA's IRIS program identified a study by Laug et al. (1950) as the critical study and liver lesions as the critical effect in rats orally exposed to DDT (USEPA 1985). The subchronic study had a NOAEL of 0.05 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 100 to account for interspecies extrapolation (10) and intraspecies variation (10); an uncertainty factor for subchronic-to-chronic conversion was not included because of a corroborating chronic study in the database (Fitzhugh 1948).

In 2002, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the RfD for DDT and identified one or more significant new studies; however, EPA's IRIS program has not reassessed this chemical.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified one other potential RfD source through the systematic search described in section 5: a 2002 ATSDR assessment (ATSDR 2002). Based on the selection process described in section 5, the 1985 EPA IRIS RfD is preferred for use in AWQC development at this time. The ATSDR assessment does not include the relevant (chronic oral) toxicity value.

5.2.2 Cancer Slope Factor

Under the 1986 *EPA Guidelines for Carcinogen Risk Assessment* (USEPA 1986), DDT is classified as Group B2, “probable human carcinogen” (USEPA 1987).

EPA selected a CSF of 3.4×10^{-1} per mg/kg-d (0.34 per mg/kg-d) for DDT based on a 1987 EPA IRIS assessment (USEPA 1987). EPA’s IRIS program derived the CSF using the principal studies by Turusov et al. (1973), Terracini et al. (1973), Thorpe and Walker (1973), Tomatis and Turusov (1975), Cabral et al. (1982), and Rossi et al. (1977) based on the development of benign and malignant liver tumors in mice and rats orally exposed to DDT (USEPA 1987).

In 2002, EPA’s IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the cancer assessment for DDT and identified one or more significant new studies; however, EPA’s IRIS program has not reassessed this chemical.

EPA identified no other CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD’s exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual’s total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR “Toxicological Profiles” (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine’s Toxicology

Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- Food and Drug Administration (FDA) Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- National Oceanic and Atmospheric Administration (NOAA) Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to DDT from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for DDT

Input Parameter		Value
RfD		0.0005 mg/kg-d
CSF		0.34 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	35,000 L/kg
	TL3	240,000 L/kg
	TL4	1,100,000 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.0005 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 35{,}000 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 240{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1{,}100{,}000 \text{ L/kg}))}$$

$$= 0.00101\ \mu g/L$$

$$= 0.001\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{0.0005 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 35{,}000 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 240{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1{,}100{,}000 \text{ L/kg})}$$

$$= 0.00101\ \mu g/L$$

$$= 0.001\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.34) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 35{,}000 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 240{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1{,}100{,}000 \text{ L/kg}))}$$

$$= 0.00002963\ \mu g/L$$

$$= 0.000030\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})}$$

$$= \frac{(10^{-6} / 0.34) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.0076 \text{ kg/d} \times 35{,}000 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 240{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 1{,}100{,}000 \text{ L/kg})}$$

$$= 0.00002963\ \mu g/L$$

$$= 0.000030\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for DDT using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for DDT are **0.001 µg/L** for consumption of water and organisms and **0.001 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for DDT are **0.000030 µg/L** for consumption of water and organisms and **0.000030 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of DDT, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for DDT

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.00022 µg/L	**0.000030 µg/L**
Organism Only	0.00022 µg/L	**0.000030 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to DDT at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for DDT take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 35,000, 240,000, and 1,100,000 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 53,600 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 1,022,000 L/kg
TL3 = 1,446,000 L/kg
TL4 = 2,315,000 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.0005 mg/kg-d for DDT based on a 1985 EPA IRIS assessment (USEPA 1985). EPA used the RfD of 0.0005 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of DDT in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA retained a CSF of 0.34 per mg/kg-d for DDT based on a 1987 EPA IRIS assessment (USEPA 1987; USEPA 2002c). EPA used this CSF to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the CSF in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- 4,4’-DDT (CAS Number 50-29-3)
- Agritan
- Anofex
- Arkotine
- Azotox
- Benzene, 1,1’-(2,2,2-trichloroethylidene)bis(4-chloro-)
- Alpha,alpha-bis(p-chlorophenyl)-beta,beta,beta-trichlorethane
- 1,1-bis-(p-chlorophenyl)-2,2,2-trichloroethane
- 2,2-bis(p-chlorophenyl)-1,1,1-trichloroethane
- Bosan supra
- Bovidermol
- Chlorophenothan
- Chlorophenothane
- Chlorophenotoxum
- Citox
- Clofenotane
- DDT
- p,p’-DDT
- Dedelo
- Deoval
- Detox
- Detoxan
- Dibovan
- Dichlorodiphenyltrichloroethane
- 4,4’-dichlorodiphenyltrichloroethane
- Dichlorodiphenyltrichloroethane, p,p’-
- Dicophane
- Didigam
- Didimac
- Diphenyltrichloroethane
- Dodat
- Dykol
- ENT 1,506
- Estonate
- Ethane, 1,1,1-trichloro-2,2-bis(p-chlorophenyl)-

- Genitox
- Gesafid
- Gesapon
- Gesarex
- Gesarol
- Guesapon
- Guesarol
- Gyron
- Havero-extra
- Hildit
- Ivoran
- Ixodex
- Kopsol
- Micro DDT 75
- Mutoxin
- NA 2761
- NCI-C00464
- Neocid
- Parachlorocidum
- Peb1
- Pentachlorin
- Pentech
- Ppzeidan
- R50
- RCRA waste number u061
- Rukseam
- Santobane
- Tech DDT
- 1,1,1-trichloor-2,2-bis(4-chloor fenyl)-ethaan
- 1,1,1-trichlor-2,2-bis(4-chlor-phenyl)-aethan
- 1,1,1-trichloro-2,2-bis(p-chlorophenyl)ethane
- Trichlorobis(4-chlorophenyl)ethane
- 1,1,1-trichloro-2,2-di(4-chlorophenyl)-ethane
- 1,1,1-tricloro-2,2-bis(4-cloro-fenil)-etano
- Zeidane
- Zerdane

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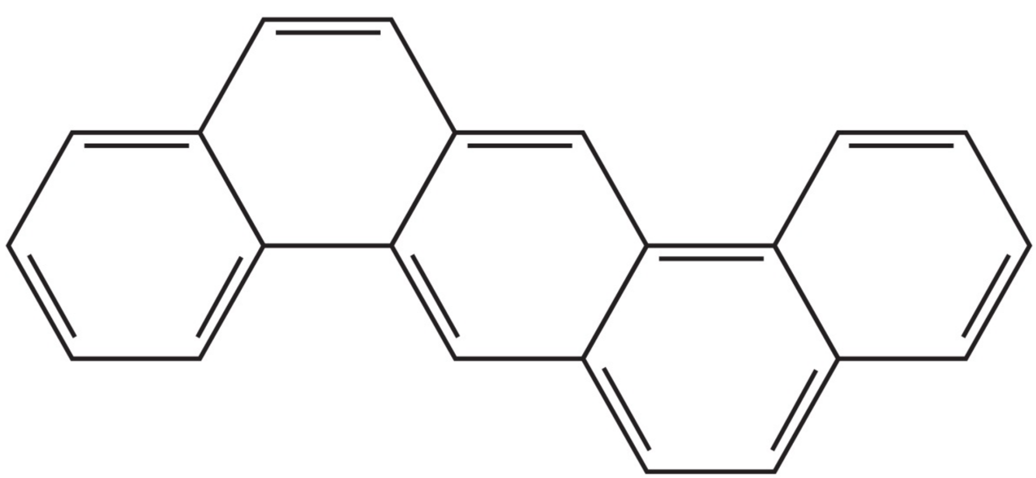
United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-032
June 2015

Update of Human Health Ambient Water Quality Criteria:

Dibenzo(a,h)anthracene
53-70-3



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Washington, DC 20460

Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for dibenzo(a,h)anthracene to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national trophic level-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 3,900 L/kg for dibenzo(a,h)anthracene. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for dibenzo(a,h)anthracene. Based on the characteristics this chemical, EPA selected Procedure 2 for deriving a national BAF value. Dibenzo(a,h)anthracene has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 6.84$ (ATSDR 1995)
- High metabolism (NOAA n.d.)

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs or lab-measured BCFs for this polycyclic aromatic hydrocarbon (PAH) (Arnot and Gobas 2006; Environment Canada 2006). In the absence of chemical-specific information, EPA used the field-measured BAF for benzo(a)pyrene, an index PAH, as a surrogate for the estimation of BAFs for other PAHs. This approach is consistent with conclusions of Neff (2002) that benzo(a)pyrene is a good indicator of the presence of pyrogenic PAHs in the environment and that type of PAH is expected to concentrate in organisms such as fish and shellfish as does benzo(a)pyrene. Therefore, EPA used the benzo(a)pyrene BCF method estimate for the reported TLs by calculating the geometric mean of the TL2 and TL3 BCF values available for benzo(a)pyrene (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 3,900 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for dibenzo(a,h)anthracene. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

EPA's IRIS program does not currently have an RfD or CSF for dibenzo(a,h)anthracene (USEPA 1990). In the absence of chemical specific information, EPA recommends use of the index PAH benzo(a)pyrene as a surrogate for the determination of risk to other PAHs. In this approach, the potencies of other PAHs relative to benzo(a)pyrene are determined. EPA's IRIS program is currently reassessing benzo(a)pyrene, which may be used in the future to derive toxicity values for other PAHs, including dibenzo(a,h)anthracene. In 2013, EPA's IRIS program published the draft Toxicological Review for benzo(a)pyrene for public review and comment, discussion at a public meeting, and subsequent expert peer review (USEPA 2013a; USEPA 2013b). The 2013 draft Toxicological Review included both a draft RfD and a draft CSF. In addition, in 2010, EPA's IRIS program published draft updated relative potency factors for PAH mixtures (USEPA 2010).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA anticipates updating the AWQC for PAHs following finalization of EPA's IRIS toxicological assessment for benzo(a)pyrene and relative potency factors for PAHs. In the meantime, based on the selection process described above, EPA will use IRIS's current toxicity values for benzo(a)pyrene (USEPA 1991) and IRIS's currently recommended relative potency factors (USEPA 1993) for the purpose of AWQC derivation for dibenzo(a,h)anthracene.

5.2.1 Reference Dose

EPA has not selected an RfD for derivation of AWQC for dibenzo(a,h)anthracene. EPA's IRIS program does not currently have an oral RfD for dibenzo(a,h)anthracene or benzo(a)pyrene, the index PAH (USEPA 1990; USEPA 1991).

EPA identified two RfD sources for dibenzo(a,h)anthracene through the systematic search described in section 5: a 1995 ATSDR assessment (ATSDR 1995) and a 2005 California EPA assessment (CalEPA 2005). However, due to EPA's ongoing reassessments, the toxicity values from these assessments will not be used to derive AWQC at this time.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), dibenzo(a,h)anthracene is classified as Group B2, "probable human carcinogen" (USEPA 1990).

EPA selected a CSF of 7.3 per mg/kg-d for dibenzo(a,h)anthracene based on a 1991 EPA IRIS assessment for benzo(a)pyrene (USEPA 1991). EPA's IRIS program derived a CSF of 7.3 per mg/kg-d using a principal study by Neal and Rigdon (1967), which was based on development of fore-stomach and squamous cell papillomas in mice orally exposed benzo(a)pyrene (USEPA 1991). EPA applied a relative potency factor of 1.0 to derive the CSF for dibenzo(a,h)anthracene (USEPA 1993).

EPA identified one other CSF source for dibenzo(a,h)anthracene through the systematic search described in section 5: a 2005 California EPA assessment (CalEPA 2005) . However, due to EPA's ongoing reassessments, EPA will use the current IRIS CSF to derive AWQC at this time.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean

fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not

anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using only a carcinogenic toxicity endpoint (CSF) because no RfD sources were identified through the systematic search described in section 5 (Hazard Identification and Dose Response). Therefore, no RSC was applied in the AWQC derivation for this chemical.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to dibenzo(a,h)anthracene from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Dibenzo(a,h)anthracene

Input Parameter	Value
RfD	No data
CSF	7.3 per mg/kg-d
RSC	–
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	3,900 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

EPA identified no RfD sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for noncarcinogenic toxicological effects.

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 7.3) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + (0.022 \text{ kg/d} \times 3{,}900 \text{ L/kg})}$$

$$= 0.0001243\ \mu g/L$$

$$= 0.00012\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{(10^{-6} / 7.3) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.022 \text{ kg/d} \times 3{,}900 \text{ L/kg})}$$

$$= 0.0001277\ \mu g/L$$

$$= 0.00013\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for dibenzo(a,h)anthracene using a carcinogenic toxicity endpoint. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for dibenzo(a,h)anthracene are **0.00012 µg/L** for consumption of water and organisms and **0.00013 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Dibenzo(a,h)anthracene

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.0038 µg/L	**0.00012 µg/L**
Organism Only	0.018 µg/L	**0.00013 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to dibenzo(a,h)anthracene at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for dibenzo(a,h)anthracene take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 3,900 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 30 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the

water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 24,690 L/kg
TL3 = 10,700 L/kg
TL4 = 2,863 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA did not select an RfD for dibenzo(a,h)anthracene and therefore did not derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of dibenzo(a,h)anthracene its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA retained a CSF of 7.3 per mg/kg-d for dibenzo(a,h)anthracene based on a 1991 EPA IRIS assessment for benzo(a)pyrene (USEPA 1991; USEPA 2002c). EPA used this CSF to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the CSF in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Relative Source Contribution

No RfD sources were identified for this chemical. Therefore, no RSC was applied in the AWQC derivation for this chemical.

9 Chemical Name and Synonyms

- Dibenzo(a,h)anthracene (CAS Number 53-70-3)
- Dibenz(a,h)anthracene
- DB(a,h)A
- DBA
- Dibenz(a,h)anthracene
- Dibenzo(a,h)anthracene
- HSDB 5097
- NSC 22433
- RCRA Waste Number U063
- 1,2,5,6-dibenzanthraceen [Dutch]
- 1,2,5,6-dibenzanthracene
- 1,2:5,6-benzanthracene
- 1,2:5,6-dibenz(a)anthracene
- 1,2:5,6-dibenzanthracene
- 1,2:5,6-dibenzoanthracene

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-033
June 2015

Update of Human Health Ambient Water Quality Criteria:

Dichlorobromomethane
75-27-4

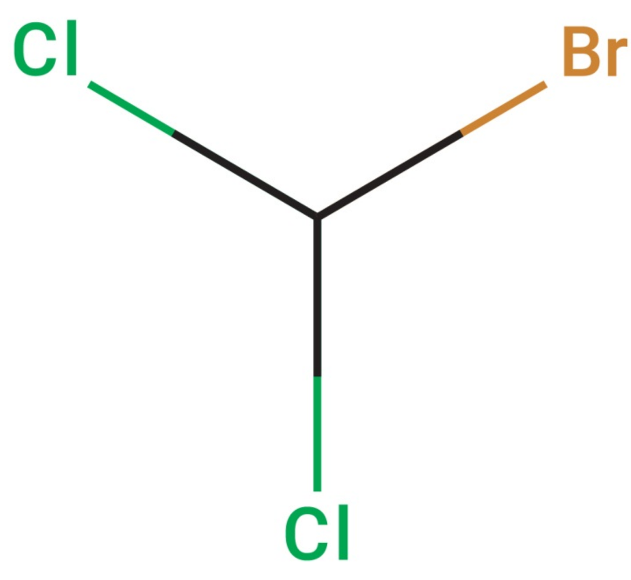

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for dichlorobromomethane to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

Dichlorobromomethane is a trihalomethane (THM) that was regulated in EPA's Stage 1 and Stage 2 Disinfection Byproduct (DBP) Rule (USEPA 1998; USEPA 2006). DBPs are formed by the reaction of disinfectants with constituents in the water, especially natural organic matter (NOM), but also inorganic constituents such as bromide and iodide. The concentration of DBPs within a public water system can vary depending on source water quality, treatment (e.g., type of disinfectant), and distribution system conditions. For example, THM concentrations might be lower when chloramine is used as the disinfectant compared to when chlorine is used.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible

for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

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[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b, Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 3.4 L/kg (TL2), 4.3 L/kg (TL3), and 4.8 L/kg (TL4) for dichlorobromomethane. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for dichlorobromomethane. Based on the characteristics of this chemical, EPA selected Procedure 3 for deriving a national BAF value. Dichlorobromomethane has the following characteristics:

- Nonionic organic chemical (USDHHS 2012)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 2.1$ (ATSDR 1989)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 3.4 L/kg
TL3 = 4.3 L/kg
TL4 = 4.8 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for dichlorobromomethane. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.
3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 3×10^{-3} mg/kg-d (0.003 mg/kg-d) for dichlorobromomethane based on a 2005 EPA Office of Water (OW) assessment (USEPA 2005a). EPA identified Aida et al. (1992) as the critical study and fatty degeneration of the liver as the critical effect in male rats orally exposed to dichlorobromomethane (USEPA 2005a). The duration-adjusted lower-bound confidence limit on the benchmark dose ($BMDL_{10}$) was 0.8 mg/kg-d. EPA applied a composite uncertainty factor of 300 to account for interspecies extrapolation (10), intraspecies variation (10), and database uncertainty (3) (USEPA 2005a).

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[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 1987 IRIS assessment (USEPA 1987) and a 1989 ATSDR assessment (ATSDR 1989). Based on the selection process described in section 5, the 2005 EPA OW RfD is preferred for use in AWQC development at this time. The 2005 OW RfD is based on a more current study (Aida et al. 1992) and used more current benchmark dose (BMD) modeling in order to identify the point of departure for the RfD derivation. According to EPA guidance, when data are amenable to modeling, the BMD approach is the preferred approach (USEPA 2012a).

5.2.2 Cancer Slope Factor

Under the 1999 EPA Review Draft *Guidelines for Carcinogen Risk Assessment* (USEPA 1999), dichlorobromomethane is characterized as "likely to be carcinogenic to humans" by the oral route (USEPA 2005a).

EPA selected a CSF of 3.4×10^{-2} per mg/kg-d (0.034 per mg/kg-d) for dichlorobromomethane based on a 2005 EPA OW assessment (USEPA 2005a). The EPA OW program derived the CSF using a principal study by the National Toxicology Program (NTP 1987) based on development of renal tumors in male mice orally exposed to dichlorobromomethane (USEPA 2005a).

EPA identified one other CSF source through the systematic search described in section 5: a 1992 IRIS assessment (USEPA 1992). Based on the selection process described in section 5, the 2005 EPA OW CSF is preferred for use in AWQC development at this time. The 2005 OW assessment evaluated the same principal study considered in the IRIS assessment (NTP 1987), but applied more current guidance and modeling approaches. Specifically, the LED_{10} (the lower 95 percent confidence limit on the estimated dose associated with 10 percent extra risk) was selected by OW as the point of departure for derivation of the slope factor in place of a linear multistage (LMS) slope factor. Additionally, the OW CSF uses a cross-species scaling approach based on $BW^{3/4}$, which is consistent with current EPA practice (USEPA 2005a; USEPA 2005b).

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to dichlorobromomethane from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Dichlorobromomethane

Input Parameter		Value
RfD		0.003 mg/kg-d
CSF		0.034 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	3.4 L/kg
	TL3	4.3 L/kg
	TL4	4.8 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC }(\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{0.003\ \text{mg/kg-d} \times 0.20 \times 80.0\ \text{kg} \times 1{,}000\ \mu g/mg}{2.4\ \text{L/d} + ((0.0076\ \text{kg/d} \times 3.4\ \text{L/kg}) + (0.0086\ \text{kg/d} \times 4.3\ \text{L/kg}) + (0.0051\ \text{kg/d} \times 4.8\ \text{L/kg}))}$$

$$= 19.3\ \mu g/L$$

$$= 20\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.003\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 3.4\ L/kg) + (0.0086\ kg/d \times 4.3\ L/kg) + (0.0051\ kg/d \times 4.8\ L/kg)}$$

$$= 549.8\ \mu g/L$$

$$= 500\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI } (L/d) + \sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 0.034)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 3.4\ L/kg) + (0.0086\ kg/d \times 4.3\ L/kg) + (0.0051\ kg/d \times 4.8\ L/kg))}$$

$$= 0.9460\ \mu g/L$$

$$= 0.95\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF}) \text{ [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 0.034)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 3.4\ L/kg) + (0.0086\ kg/d \times 4.3\ L/kg) + (0.0051\ kg/d \times 4.8\ L/kg)}$$

$$= 26.95\ \mu g/L$$

$$= 27\ \mu g/L \text{ (rounded)}$$

7.3 AWQC Summary

EPA derived the AWQC for dichlorobromomethane using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for dichlorobromomethane are **20 µg/L** for consumption of water and organisms and **500 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for dichlorobromomethane are **0.95 µg/L** for consumption of water and organisms and **27 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of dichlorobromomethane, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Dichlorobromomethane

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.55 µg/L	**0.95 µg/L**
Organism Only	17 µg/L	**27 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to dichlorobromomethane at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for dichlorobromomethane take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a

contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 3.4, 4.3, and 4.8 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 3.75 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012b) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 6.562 L/kg
TL3 = 7.269 L/kg
TL4 = 10.01 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.003 mg/kg-d for dichlorobromomethane based on a 2005 EPA OW assessment (USEPA 2005a). EPA used the RfD of 0.003 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of dichlorobromomethane in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA selected a CSF of 0.034 per mg/kg-d for dichlorobromomethane based on a 2005 EPA OW assessment (USEPA 2005a). This CSF replaces the previous value of 0.062 per mg/kg-d (USEPA 2002c). EPA used the CSF of 0.034 per mg/kg-d to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, a decrease in the CSF in the AWQC calculations (Eqs. 1 and 2) results in higher AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Dichlorobromomethane (CAS Number 75-27-4)
- Bromodichloromethane
- Dichloromonobromomethane
- Methane, bromodichloro-
- Monobromodichloromethane

10 References

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-034
June 2015

Update of Human Health Ambient Water Quality Criteria:

Dieldrin
60-57-1

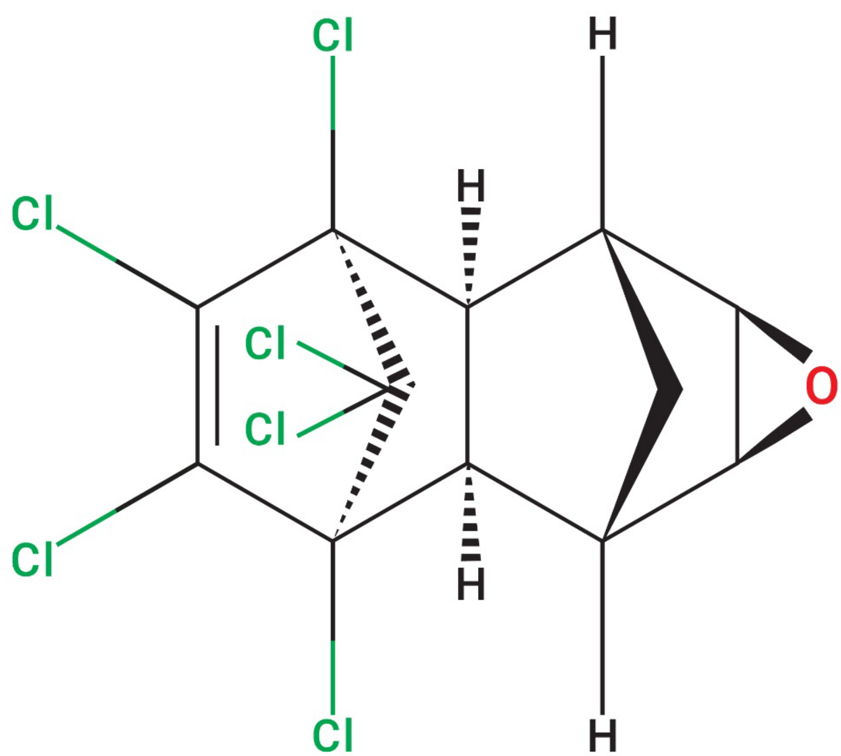

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for dieldrin to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

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[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected national BAF values of 14,000 L/kg (TL2), 210,000 L/kg (TL3), and 410,000 L/kg (TL4) for dieldrin. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for dieldrin. Based on the characteristics of this chemical, EPA selected Procedure 1 for deriving a national BAF value. Dieldrin has the following characteristics:

- Nonionic organic chemical (USDHHS 2014)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 6.2$ (ATSDR 2002)
- Low/unknown metabolism

EPA was not able to locate peer-reviewed, field-measured BAFs, BSAFs, or lab-measured BCFs for TLs 2, 3, and 4. Therefore, EPA used the K_{ow} method to derive the national BAF values for this chemical:

TL2 = 14,000 L/kg
TL3 = 210,000 L/kg
TL4 = 410,000 L/kg

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for dieldrin. As described in the 2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, ATSDR (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 5×10^{-5} mg/kg-d (0.00005 mg/kg-d) for dieldrin based on a 1987 EPA IRIS assessment (USEPA 1987a). EPA's IRIS program identified a study by Walker et al. (1969) as the critical study and the development of liver lesions as the critical effect in female rats (USEPA 1987a). The chronic study has a NOAEL of 0.005 mg/kg-d. In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 100 to account for intraspecies variation (10) and interspecies extrapolation (10).

In 2003, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the RfD for dieldrin and did not identify any critical new studies.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified two other RfD sources through the systematic search described in section 5: a 2002 ATSDR assessment (ATSDR 2002) and a 2003 EPA Office of Water assessment. Based on the selection process described in section 5, the 1987 EPA IRIS RfD is preferred for use in AWQC development at this time. Both of the other assessments were based on the same principal study (Walker et al. 1969) and were numerically the same as the 1987 EPA IRIS RfD.

5.2.2 Cancer Slope Factor

Under EPA's 1986 *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), dieldrin is classified as Group B2, "probable human carcinogen" (USEPA 1987b; USEPA 2003c).

EPA selected a CSF of 16 per mg/kg-d for dieldrin based on a 1987 EPA IRIS assessment (USEPA 1987b). EPA's IRIS program identified studies by Davis (1965), Walker et al. (1973), Thorpe and Walker (1973), National Cancer Institute (NCI 1978a; NCI 1978b), Tennekes et al. (1981), and Meierhenry et al. (1983) as critical studies and the development of liver carcinomas as the critical effect in mice orally exposed to dieldrin (USEPA 1987b). The slope factor is the geometric mean of 13 slope factors calculated from liver carcinoma data in both sexes of several strains of mice. Inspection of the data indicated no strain or sex specificity of carcinogenic response.

In 2003, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the cancer assessment for dieldrin and did not identify any critical new studies.

EPA identified one other CSF source through the systematic search described in section 5: a 2003 EPA Office of Water assessment (USEPA 2003c). Based on the selection process described in section 5, the 1987 EPA IRIS CSF is preferred for use in AWQC development at this time. The EPA Office of Water assessment was based on the same principal studies and was numerically the same as the 1987 EPA IRIS CSF.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- Food and Drug Administration (FDA) Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- National Oceanic and Atmospheric Administration (NOAA) Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

EPA derived recommended AWQC for this chemical using both noncarcinogenic and carcinogenic toxicity endpoints (RfD and CSF). For comparative purposes only, a default RSC of 20 percent was applied for AWQC derivation for noncarcinogenic effects (USEPA 2000a).

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to dieldrin from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Dieldrin

Input Parameter		Value
RfD		0.00005 mg/kg-d
CSF		16 per mg/kg-d
RSC		0.20
BW		80.0 kg
DI		2.4 L/d
FCR	TL2	0.0076 kg/d
	TL3	0.0086 kg/d
	TL4	0.0051 kg/d
BAF	TL2	14,000 L/kg
	TL3	210,000 L/kg
	TL4	410,000 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})}$$

$$= \frac{0.00005 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 14{,}000 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 210{,}000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 410{,}000 \text{ L/kg}))}$$

$$= 0.000200\ \mu g/L$$

$$= 0.0002\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{0.00005\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 14{,}000\ L/kg) + (0.0086\ kg/d \times 210{,}000\ L/kg) + (0.0051\ kg/d \times 410{,}000\ L/kg)}$$

$= 0.000200\ \mu g/L$

$= 0.0002\ \mu g/L$ (rounded)

7.2 AWQC for Carcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI } (L/d) + \sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 16)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + ((0.0076\ kg/d \times 14{,}000\ L/kg) + (0.0086\ kg/d \times 210{,}000\ L/kg) + (0.0051\ kg/d \times 410{,}000\ L/kg))}$$

$= 0.000001248\ \mu g/L$

$= 0.0000012\ \mu g/L$ (rounded)

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value } (10^{-6} / \text{CSF) [mg/kg-d]} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\sum_{i=2}^{4} (\text{FCR}_i\ (kg/d) \times \text{BAF}_i\ (L/kg))}$$

$$= \frac{(10^{-6} / 16)\ mg/kg\text{-}d \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.0076\ kg/d \times 14{,}000\ L/kg) + (0.0086\ kg/d \times 210{,}000\ L/kg) + (0.0051\ kg/d \times 410{,}000\ L/kg)}$$

$= 0.000001249\ \mu g/L$

$= 0.0000012$ (rounded)

7.3 AWQC Summary

EPA derived the AWQC for dieldrin using both noncarcinogenic and carcinogenic toxicity endpoints. The updated human health AWQC for noncarcinogenic effects for dieldrin are **0.0002 µg/L** for consumption of water and organisms and **0.0002 µg/L** for consumption of organisms only. The updated human health AWQC for carcinogenic effects (at a 10^{-6} cancer risk level) for dieldrin are **0.0000012 µg/L** for consumption of water and organisms and **0.0000012 µg/L** for consumption of organisms only. EPA recommends the lower AWQC, based on the carcinogenic effects of dieldrin, as the updated human health AWQC (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Dieldrin

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	0.000052 µg/L	**0.0000012 µg/L**
Organism Only	0.000054 µg/L	**0.0000012 µg/L**

These AWQC are intended to be protective of the general adult population from an increased cancer risk due to exposure to dieldrin at a 10^{-6}, or one in one million, risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

8 Criteria Characterization

The updated 2015 human health AWQC for dieldrin take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a

contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national lower (TL2), mid (TL3), and upper (TL4) TL BAFs used in the updated AWQC (Eqs. 1 and 2 above) are 14,000, 210,000, and 410,000 L/kg wet-weight, respectively. These BAFs were derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). These national TL BAFs replace EPA's previously recommended BCF of 4,670 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 17,280 L/kg
TL3 = 20,740 L/kg
TL4 = 30,820 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national-level BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes. The utilization of the three TLs of fish and shellfish consumed, as opposed to representing all TLs of fish and shellfish consumed by a single value, allows for better exposure representation.

Reference Dose

EPA selected an RfD of 0.00005 mg/kg-d for dieldrin based on a 1987 EPA IRIS assessment (USEPA 1987a). EPA used the RfD of 0.00005 mg/kg-d to derive AWQC for noncarcinogenic effects. EPA did not derive AWQC for noncarcinogenic effects of dieldrin in its previous criteria update (USEPA 2002c).

Cancer Slope Factor

EPA retained a CSF of 16 per mg/kg-d for dieldrin based on a 1987 EPA IRIS assessment (USEPA 1987b; USEPA 2002c). EPA used this CSF to derive AWQC for carcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the CSF in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Relative Source Contribution

An RSC of 20 percent was used for comparative purposes to calculate AWQC for noncarcinogenic effects. Previously, the recommended AWQC were derived for carcinogenic effects only, and therefore, an RSC was not included.

9 Chemical Name and Synonyms

- Dieldrin (CAS Number 60-57-1)
- Alvit
- Compound 497
- Dieldrex
- Dieldrin
- Dieldrine
- Dieldrite
- 1,4:5,8-dimethanonaphthalene, 1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro, endo,exo-
- ENT 16,225
- HEOD
- Hexachloroepoxyoctahydro-endo,exo-dimethanonaphthalene
- 3,4,5,6,9,9-hexachloro-1a,2,2a,3,6,6a,7,7a-octahydro-2,7:3,6-dimethanonaphth(2,3-b)oxirene
- Illoxol
- NA 2761
- NCI-C00124
- Octalox
- Panoram D-31
- Quintox
- RCRA waste number P037

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United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-035
June 2015

Update of Human Health Ambient Water Quality Criteria:

Diethyl Phthalate
84-66-2

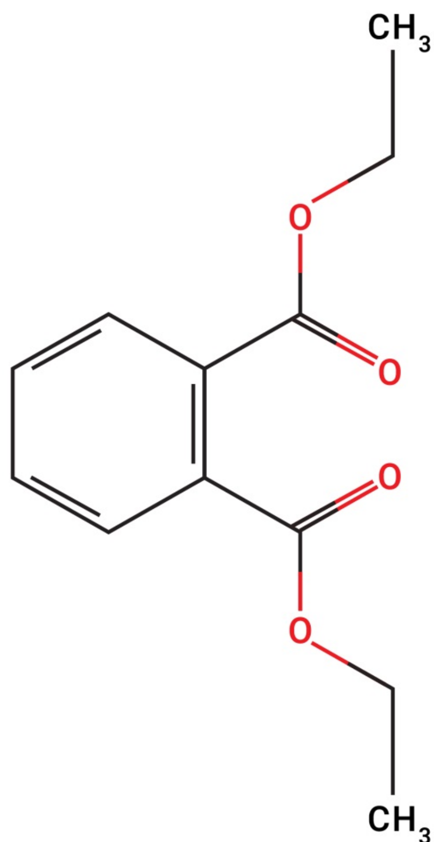

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for diethyl phthalate to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:

AWQC	=	ambient water quality criteria
toxicity value	=	RfD x RSC (mg/kg-d) for noncarcinogenic effects or 10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC	=	relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW	=	body weight
DI	=	drinking water intake
$\sum_{i=2}^{4}$	=	summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i	=	fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i	=	bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

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[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 920 L/kg for diethyl phthalate. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for diethyl phthalate. Based on the characteristics this chemical, EPA selected Procedure 4 for deriving a national BAF value. Diethyl phthalate has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 2.35$ (ATSDR 1995)
- High metabolism (Gobas et al. 2003; Mankidya et al. 2013)

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for all three TLs (2, 3, and 4). Therefore, EPA used the BAF method estimate for the reported TLs by calculating the geometric mean of the TL3 and TL4 BAF values available for diethyl phthalate (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 920 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for diethyl phthalate. As described in the

2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 8×10^{-1} mg/kg-d (0.8 mg/kg-d) for diethyl phthalate based on a 1987 EPA IRIS assessment (USEPA 1987a). EPA identified a study by Brown et al. (1978) as the critical study and decreased growth rate and food consumption and altered organ weights as the critical effects in rats orally exposed to diethyl phthalate. The subchronic study had a NOAEL of 750 mg/kg-d. In deriving the RfD, EPA's IRIS program applied an uncertainty factor of 1000 to account for interspecies extrapolation (10), intraspecies variation (10), and subchronic-to-chronic extrapolation (10) (USEPA 1987a).

In 2002, EPA's IRIS program conducted a screening-level review of more recent toxicology literature pertinent to the RfD for diethyl phthalate and identified several new studies; however, EPA's IRIS program has not reassessed this chemical.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified one other RfD source through the systematic search described in section 5: a 1995 ATSDR assessment (ATSDR 1995). Based on the selection process described in section 5, the 1987 IRIS assessment is preferred for use in AWQC development at this time. The ATSDR assessment does not include the relevant (chronic oral) toxicity factor.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986), diethyl phthalate is classified as Group D, “not classifiable as a human carcinogen” (USEPA 1987b).

EPA identified no CSF source through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD’s exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual’s total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR “Toxicological Profiles” (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine’s Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA’s Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).

- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Diethyl phthalate is used in plastics (e.g., toothbrushes, food packaging, and toys), cosmetics, insecticides, and aspirin (ATSDR 1995). It is also used in the production of solvents for resins and wetting agents (USDHHS 2010). The physical properties and uses of this chemical suggest that the general population might be exposed to it via inhalation and ingestion of food and water containing diethyl phthalate (USDHHS 2010).

Diethyl phthalate will exist solely in the vapor phase in the atmosphere, resulting in the possibility of inhalation exposure (USDHHS 2010). EPA's Toxic Release Inventory did not report release data for diethyl phthalate in 2013 (USEPA 2015g), and it is not listed as a hazardous air pollutant (USEPA 2013). ATSDR (1995) reports that concentrations measured in air were generally low, but more recent concentration data are limited. Inhalation exposure (and possibly dermal contact) in occupational and residential settings can occur from products containing diethyl phthalate such as plastics, cosmetics, and insecticides. The vapor pressure of diethyl phthalate (2.1×10^{-3} mm Hg at 25 °C) indicates that diethyl phthalate will exist solely in the vapor phase in the atmosphere (USDHHS 2010). Therefore, based on its physical properties, air is a potentially significant source of exposure to diethyl phthalate.

Food is a potential source of exposure to diethyl phthalate because it is used in food packaging. It has been detected as a residue in foods packaged with cellulose acetate (ATSDR 1995). Thus, based on the chemical's uses, ingestion of food is a potentially significant source of exposure to it.

Surface waters are a potential source of exposure because diethyl phthalate is highly soluble, has a half-life of more than 3 years in water, and has been detected in some surface waters (ATSDR 1995). It is not regulated under the Safe Drinking Water Act (USEPA 2014c). Exposure to the chemical from ingesting treated drinking water has been reported to be low (ATSDR 1995). Diethyl phthalate was not a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b), and no Standard of Quality for bottled water has been established for it (IBWA 2012). Therefore, based on the chemical's physical properties and half-life, ingestion of surface water is a potentially significant source of exposure to it.

The average log K_{ow} for diethyl phthalate is 2.35 (ATSDR 1995). The national-level BAF estimate for diethyl phthalate is 920 L/kg, which indicates that it has a moderate potential for bioaccumulation (USEPA 2011b). This chemical was not included in NOAA's Mussel Watch Survey (NOAA 2014) or in EPA's National Lake Fish Tissue Study (USEPA 2009c). However, diethyl phthalate has been detected in edible fish in Wisconsin and Washington (USDHHS 2010). It was also detected in various fish species from the Great Lakes (ATSDR 1995). Thus, based on the chemical's potential to bioaccumulate and prevalence, ingestion of fish and shellfish are potentially significant sources of exposure to it.

In summary, EPA considers air, non-fish food, ingestion of surface water, and fish and shellfish to be potentially significant sources of exposure to diethyl phthalate. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for diethyl phthalate.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to diethyl phthalate from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Diethyl Phthalate

Input Parameter	Value
RfD	0.8 mg/kg-d
CSF	No data
RSC	0.20
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	920 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.8 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + (0.022 \text{ kg/d} \times 920 \text{ L/kg})}$$

$$= 565\ \mu g/L$$

$$= 600\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.8 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.022 \text{ kg/d} \times 920 \text{ L/kg})}$$

$$= 632\ \mu g/L$$

$$= 600\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for diethyl phthalate using a noncarcinogenic toxicity endpoint. The updated human health AWQC for diethyl phthalate are **600 μg/L** for consumption of water and organisms and **600 μg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Diethyl Phthalate

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	17,000 µg/L	**600 µg/L**
Organism Only	44,000 µg/L	**600 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to diethyl phthalate from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for diethyl phthalate take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 920 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 73 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 6.747 L/kg
TL3 = 6.636 L/kg
TL4 = 5.889 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA retained an RfD of 0.8 mg/kg-d for diethyl phthalate based on a 1987 EPA IRIS assessment (USEPA 1987a; USEPA 2002c). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for diethyl phthalate and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of diethyl phthalate in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- Diethyl phthalate (CAS Number 84-66-2)
- Anozol
- 1,2-benzenedicarboxylic acid, diethyl ester
- DPX-F5384
- Estol 1550
- Ethyl phthalate
- NCI-C60048
- Neantine
- Palatinol A
- Phthalol
- Phthalsaeurediaethylester
- Placidol E
- RCRA waste number U088

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United States Environmental Protection Agency
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Office of Science and Technology
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June 2015

Update of Human Health Ambient Water Quality Criteria:

Dimethyl Phthalate
131-11-3

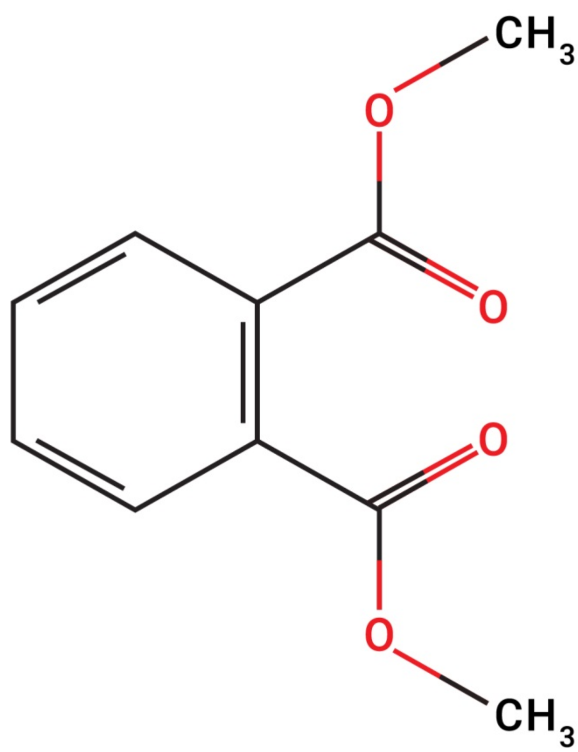

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Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for dimethyl phthalate to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 1)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i \text{ (kg/d)} \times \text{BAF}_i \text{ (L/kg)})} \quad \text{(Eq. 2)}$$

Where:
AWQC = ambient water quality criteria
toxicity value = RfD x RSC (mg/kg-d) for noncarcinogenic effects
or
10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC = relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW = body weight
DI = drinking water intake
$\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i = fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i = bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 4,000 L/kg for dimethyl phthalate. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for dimethyl phthalate. Based on the characteristics this chemical, EPA selected Procedure 4 for deriving a national BAF value. Dimethyl phthalate has the following characteristics:

- Nonionic organic chemical (USDHHS 2012)
- Low hydrophobicity (log $K_{ow} < 4$); log $K_{ow} = 1.6$ (USDHHS 2012)
- High metabolism (Gobas et al. 2003; Mankidya et al. 2013)

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for all three TLs (2, 3, and 4). Therefore, EPA used the BAF method estimate for the reported TLs by calculating the geometric mean of the TL3 and TL4 BAF values available for dimethyl phthalate (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 4,000 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for dimethyl phthalate. As described in the

2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD (acceptable daily intake) of 1×10^1 mg/kg-d (10 mg/kg-d) for dimethyl phthalate based on a 1980 EPA Office of Water (OW) assessment for phthalate esters (USEPA 1980). EPA OW identified a study by Draize et al. (1948) as the critical study and a growth effect as the critical effect in rats orally exposed to dimethyl phthalate. The chronic (104-week) study has a NOAEL of 1,000 mg/g-d. In deriving the RfD, EPA OW applied a composite uncertainty factor of 100; individual uncertainty factors were not specified but were presumably applied to account for interspecies extrapolation (10) and intraspecies differences (10) (USEPA 1980).

EPA identified no other RfD sources through the systematic search described in section 5.

5.2.2 Cancer Slope Factor

Under the 1986 *EPA Guidelines for Carcinogen Risk Assessment* (USEPA 1986), dimethyl phthalate is classified as Group D, "not classifiable as to human carcinogenicity" (USEPA 1987).

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

In 2003, EPA's IRIS program conducted a screening-level review of the more recent toxicology literature pertinent to the cancer assessment for dimethyl phthalate and did not identify any critical new studies.

EPA identified no CSF sources through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD's exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR "Toxicological Profiles" (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine's Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA's Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).
- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Dimethyl phthalate is used as a plasticizer for nitrocellulose and cellulose acetate, resins, rubber, and in solid rocket propellants, as well as in lacquers, plastics, rubber coating agents, safety glass, and molding powders (USDHHS 2012). The physical properties and uses of this chemical indicate that the general population might be exposed to it via inhalation of ambient air and potentially through ingestion of water (USDHHS 2012).

The vapor pressure of dimethyl phthalate (3.08×10^{-3} mm Hg at 25 °C) indicates that it will exist in both the vapor and particulate phases in the atmosphere. The chemical is not expected to volatilize from dry soil surfaces, and it is expected to be nonvolatile from water surfaces (USDHHS 2012). Recent data from EPA's Toxic Release Inventory (USEPA 2015g) indicate that over 132,000 pounds of dimethyl phthalate were released to the air in 2013. Historically, dimethyl phthalate has been detected in various studies conducted in the United States (USDHHS 2012), and it is listed as a hazardous air pollutant (USEPA 2013). Thus, based on dimethyl phthalate's physical properties and prevalence, air is a potentially significant source of exposure to it.

Dimethyl phthalate has been detected in treated drinking water (USDHHS 2012), and it is not regulated under the Safe Drinking Water Act (USEPA 2014c). It was not a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b), and no Standard of Quality for bottled water has been established for it (IBWA 2012). Surface waters are also a potential source; dimethyl phthalate is highly soluble (USDHHS 2012) and has half-life in water of approximately 145 days (USDHHS 2012). Therefore, based on dimethyl phthalate's chemical properties, ingestion of surface and finished drinking water is a potentially significant source of exposure to it.

The log K_{ow} for dimethyl phthalate is 1.6 (USDHHS 2012). The national-level BAF estimate for dimethyl phthalate is 4,000 L/kg, which indicates that it has a high potential for bioaccumulation (USEPA 2011b). Dimethyl phthalate has been detected in fish and aquatic invertebrates (USDHHS 2012). This chemical was not included in NOAA's Mussel Watch Survey (NOAA 2014), and it was not on the list of analytes in EPA's National Lake Fish Tissue Study (USEPA 2009c). Recent exposure information regarding concentrations of dimethyl phthalate in fish and shellfish is lacking. Thus, based on dimethyl phthalate's potential to bioaccumulate, ingestion of fish and shellfish is a potentially significant source of exposure to it.

Current information regarding concentrations of dimethyl phthalate in food could not be identified. Thus, the potential exposure to this chemical from ingestion of food is unknown.

In summary, based on the physical properties and available exposure information for dimethyl phthalate, EPA considers air, drinking water, and fish and shellfish to be potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from those different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for dimethyl phthalate.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to dimethyl phthalate from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Dimethyl Phthalate

Input Parameter	Value
RfD	10 mg/kg-d
CSF	No data
RSC	0.20
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	4,000 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{10 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{2.4 \text{ L/d} + (0.022 \text{ kg/d} \times 4{,}000 \text{ L/kg})}$$

$$= 1{,}770\ \mu g/L$$

$$= 2{,}000\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC } (\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{10 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1{,}000\ \mu g/mg}{(0.022 \text{ kg/d} \times 4{,}000 \text{ L/kg})}$$

$$= 1{,}818\ \mu g/L$$

$$= 2{,}000\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for dimethyl phthalate using a noncarcinogenic toxicity endpoint. The updated human health AWQC for dimethyl phthalate are **2,000 µg/L** for consumption of water and organisms and **2,000 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Dimethyl Phthalate

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	270,000 µg/L	**2,000 µg/L**
Organism Only	1,100,000 µg/L	**2,000 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to dimethyl phthalate from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for dimethyl phthalate take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 4,000 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 36 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the

water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 2.066 L/kg
TL3 = 2.065 L/kg
TL4 = 1.953 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA retained an RfD (acceptable daily intake) of 10 mg/kg-d for dimethyl phthalate based on a 1980 EPA OW assessment for phthalate esters (USEPA 1980; USEPA 2002c). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for dimethyl phthalate and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of dimethyl phthalate in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- Dimethyl phthalate (CAS Number 131-11-3)
- 1,2-benzenedicarboxylic acid, dimethyl ester
- Dimethyl 1,2-benzenedicarboxylate
- Dimethyl benzene-o-dicarboxylate
- DMP
- Methyl phthalate
- Phthalic acid, dimethyl ester

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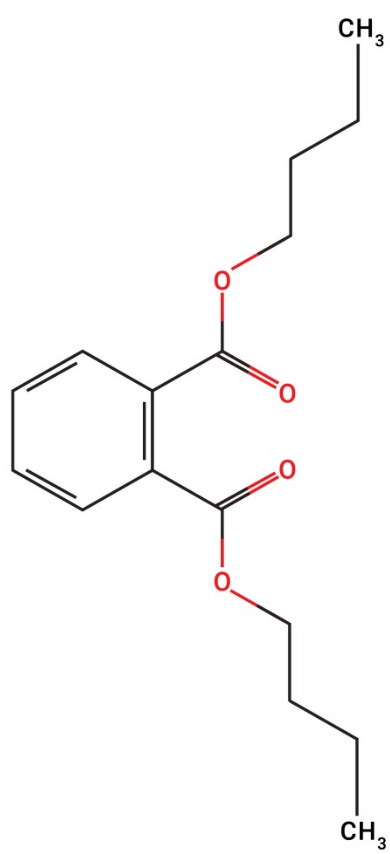
United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 820-R-15-037
June 2015

Update of Human Health Ambient Water Quality Criteria:

Di-n-butyl Phthalate
84-74-2



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Office of Science and Technology
Office of Water
U.S. Environmental Protection Agency
Washington, DC 20460

Table of Contents

1 Introduction: Background and Scope of Update

EPA's recommended ambient water quality criteria (AWQC) for human health are scientifically derived numeric values that EPA has determined will adequately protect human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended section 304(a) criteria provide technical information for states and authorized tribes[a] to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect the designated uses of waters (e.g., public water supply, aquatic life, recreational use, industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes may adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

The water quality criteria that are the subject of this document are national AWQC recommendations for human health issued under CWA section 304(a). Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria recommendations," or similar variants thereof are references to national AWQC recommendations for human health.

In this 2015 update, EPA has revised the human health criteria for di-n-butyl phthalate to reflect the latest scientific information, including updated exposure factors (body weight [BW], drinking water intake [DI] rate, and fish consumption rate [FCR]), bioaccumulation factors (BAFs), and human health toxicity values (reference dose [RfD] multiplied by relative source contribution [RSC] or 10^{-6} divided by cancer slope factor [CSF]). The criteria continue to be based on EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, which is referred to as the "2000 Methodology" in this document (USEPA 2000a). EPA accepted written scientific views from the public on the draft updated human health criteria for this chemical (and 93 others) from May through August 2014.

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[a] Throughout this document, the term *states* means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term *authorized tribe* or *tribe* means an Indian tribe authorized for treatment in a manner similar to a state under CWA section 518 for the purposes of section 303(c) water quality standards.

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

2 Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment. The structure of this criteria document is intended to be consistent with general concepts of effects assessments as described in EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014a).

In developing AWQC, EPA currently follows the assessment method outlined in its 2000 Methodology (USEPA 2000a). The 2000 Methodology describes different approaches for addressing water and non-water exposure pathways to derive human health AWQC depending on the toxicological endpoint of concern, the toxicological effect (noncarcinogenic or carcinogenic), and whether toxicity is considered a linear or threshold effect. Water sources of exposure include both consuming drinking water and eating fish or shellfish from inland and nearshore waters that have been exposed to pollutants in the water body. For pollutants that exhibit a threshold of exposure before deleterious effects occur, as is the case for noncarcinogens and nonlinear carcinogens, EPA applies an RSC to account for other potential human exposures to the pollutant (USEPA 2000a). Other sources of exposure might include, but are not limited to, exposure to a particular pollutant from ocean fish or shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., consumption of fruits, vegetables, grains, meats, or poultry), dermal exposure, and inhalation exposure.

For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC; that is, non-water sources are not explicitly included and no RSC is applied (USEPA 2000a). In these situations, AWQC are derived with respect to the *incremental* lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure. The resulting criterion represents the water concentration that is expected to increase an individual's lifetime risk of cancer from exposure to the particular pollutant by no more than one chance in one million for the general population. EPA calculates AWQC at a 10^{-6} (one in one million) cancer risk level for the general population (USEPA 2000a). The 2000 Methodology recommends that states set human health criteria cancer risk levels for the target general population at either 10^{-5} or 10^{-6} and also notes that states and authorized tribes can choose a more stringent risk level, such as 10^{-7}.

For substances that are carcinogenic, EPA takes an integrated approach and considers both cancer and noncancer effects when deriving AWQC (USEPA 2000a; USEPA 2000b). Where sufficient data are available, EPA derives AWQC using both carcinogenic and noncarcinogenic toxicity endpoints and recommends the lower value for the AWQC. The AWQC might not utilize

the value obtained from the cancer analysis if it is less protective than that derived from the noncancer endpoint.

3 Criteria Formulas: Analysis Plan

Human health AWQC for toxic pollutants are necessary to protect any designated uses related to ingestion of water and ingestion of aquatic organisms. These uses can include, but are not limited to, recreation in and on the water, consumption of fish or shellfish (including consumption associated with fishing or shellfish harvesting), and protection of drinking water supplies.

The derivation of human health AWQC requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. EPA considers the following two primary pathways of human exposure to pollutants present in a particular water body when deriving human health 304(a) AWQC: (1) direct ingestion of drinking water obtained from the water body and (2) consumption of fish or shellfish obtained from the water body.

The equations for deriving human health AWQC for noncarcinogenic effects and carcinogenic effects are presented as Eqs. 1 and 2. EPA derives recommended human health AWQC based on the consumption of both water and aquatic organisms (Eq. 1) and based on the consumption of aquatic organisms alone (Eq. 2). The use of one criterion over the other depends on the designated use of a particular water body or water bodies (i.e., drinking water source and/or fishable waters). EPA recommends applying organism-only AWQC (Eq. 2) to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but the water body is not a drinking water supply source (e.g., non-potable estuarine waters that support fish or shellfish for human consumption) (USEPA 2000a).

EPA recommends including the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) drinking water is a designated use for surface waters under the CWA, and therefore criteria are needed to ensure that this designated use can be protected and maintained; (2) although they are rare, some public water supplies provide drinking water from surface water sources without treatment; (3) even among the majority of water supplies that do treat surface waters, existing treatments might not be effective for reducing levels of particular contaminants; and (4) in consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users that must bear the costs of upgraded or supplemental water treatment (USEPA 2000a).

The equations for deriving the criteria values are as follows (USEPA 2000a):

For consumption of water and organisms:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{b}}{\text{DI (L/d)} + \sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \qquad \text{(Eq. 1)}$$

For consumption of organisms only:

$$AWQC\ (\mu g/L) = \frac{\text{toxicity value (mg/kg-d)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)^{c}}{\sum_{i=2}^{4} (\text{FCR}_i\ \text{(kg/d)} \times \text{BAF}_i\ \text{(L/kg)})} \qquad \text{(Eq. 2)}$$

Where:

AWQC = ambient water quality criteria
toxicity value = RfD x RSC (mg/kg-d) for noncarcinogenic effects
or
10^{-6}/CSF (kg-d/mg) for carcinogenic effects[d]
RSC = relative source contribution (applicable to only noncarcinogenic and nonlinear low-dose extrapolation for carcinogenic effects)
BW = body weight
DI = drinking water intake
$\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TLs), where the letter *i* stands for the TLs to be considered, starting with TL2 and proceeding to TL4
FCR_i = fish consumption rate for aquatic TLs 2, 3, and 4
BAF_i = bioaccumulation factor for aquatic TLs 2, 3, and 4

EPA rounds AWQC to the number of significant figures in the least precise parameter as described in the 2000 Methodology (USEPA 2000a, section 2.7.3).

4 Exposure Factors

4.1 Body Weight

EPA updated the default BW assumption to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as reported in Table 8.1 of EPA's *Exposure Factors Handbook* (USEPA 2011a). The updated BW represents the mean weight for adults ages 21 and older. EPA's previously recommended BW assumption for adults was 70 kg, which was based on the mean BW of adults from the NHANES III database (1988–1994) and a 1989 study conducted by the National Cancer Institute (USEPA 2000a).

[b] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[c] 1,000 µg/mg is used to convert the units of mass from milligrams to micrograms.
[d] 10^{-6} or 1 in 1,000,000 risk level for the general population.

4.2 Drinking Water Intake

EPA updated the default DI to 2.4 L/d, rounded from 2.414 L/d, based on NHANES data from 2003 to 2006 as reported in EPA's *Exposure Factors Handbook* (USEPA 2011a, Table 3-23). This rate represents the per capita estimate of combined direct and indirect community water[e] ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated DI because it represents the average daily dose estimates; that is, it includes both people who drank water during the survey period and those who did not, which is appropriate for a national-scale assessment such as CWA section 304(a) national human health criteria development (USEPA 2011a, section 3.2.1).

EPA's updated DI of 2.4 L/d is consistent with the 2000 Methodology. In that document, EPA recommended a default DI of 2 L/d, which represented the per capita community water ingestion rate at the 86th percentile for adults surveyed in the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis (USEPA 2000a, section 4.3.2.1).

4.3 Fish Consumption Rate

The updated FCR for the general adult population is 22.0 g/d, or 0.0220 kg/d (USEPA 2014b, Table 9a). This FCR represents the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older based on NHANES data from 2003–2010. The 95 percent confidence interval (CI) of the 90th percentile per capita FCR is 19.1 g/d and 25.4 g/d. This updated FCR replaces EPA's previously recommended default FCR of 17.5 g/d, which represented an estimate of the 90th percentile per capita consumption rate of fish from inland and nearshore waters for U.S. adults ages 21 years and older. That default FCR was based on USDA's CSFII 1994–1996 data (USEPA 2002a).

As recommended in the 2000 Methodology, EPA updated the AWQC to reflect trophic level- (TL-) specific FCRs to better represent human dietary consumption of fish. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The TL-specific FCRs are numbered 2, 3, and 4, and they account for different categories of fish and shellfish species based on their position in the aquatic food web: TL2 accounts for benthic filter feeders; TL3 accounts for forage fish; and TL4 accounts for predatory fish (USEPA 2000a).

EPA used the following TL-specific FCRs to derive the updated AWQC: TL2 = 7.6 g/d (0.0076 kg/d) (95 percent CI [6.4, 9.1] g/d); TL3 = 8.6 g/d (0.0086 kg/d) (95 percent CI [7.2, 10.2] g/d); and TL4 = 5.1 g/d (0.0051 kg/d) (95 percent CI [4.0, 6.4] g/d). Each TL-specific FCR represents the 90th percentile per capita consumption rate of fish and shellfish from inland and nearshore waters from that particular TL for U.S. adults ages 21 years and older (USEPA 2014b,

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[e] *Community water* includes direct and indirect use of tap water for household uses and excludes bottled water and other sources (USEPA 2011a, section 3.3.1.2). *Direct ingestion* is defined as direct consumption of water as a beverage, while *indirect ingestion* includes water added during food preparation (e.g., cooking, rehydration of beverages) but not water intrinsic to purchased foods (USEPA 2011a, section 3.1).

Tables 16a, 17a, and 18a). The sum of these three TL-specific FCRs is 21.3 g/d, which is within the 95 percent CI of the overall FCR of 22.0 g/d. EPA recommends using the TL-specific FCRs when deriving AWQC; however, the overall FCR rate (22.0 g/d) may be used if a simplified approach is preferred.

4.4 Bioaccumulation Factor

4.4.1 Approach

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in developing national recommended section 304(a) AWQC. First, the term *bioaccumulation* refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media, such as water, food, and sediment. The term *bioconcentration* refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone might underestimate the extent of accumulation in aquatic biota for those chemicals. Accordingly, the EPA guidelines presented in the 2000 Methodology emphasize using, when possible, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes (USEPA 2000a).

EPA estimated BAFs for this updated AWQC using EPA's 2000 Methodology (USEPA 2000a) and its *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors* (Technical Support Document, Volume 2) (USEPA 2003a). Specifically, these documents provide a framework for identifying alternative procedures to derive national TL-specific BAFs for a chemical based on the chemical's properties (e.g., ionization and hydrophobicity), metabolism, and biomagnification potential (USEPA 2000a; USEPA 2003a).

EPA's approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic organisms that are commonly consumed by humans across the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short periods (e.g., a few days) because human health AWQC are generally designed to protect humans from long-term (lifetime) exposures to waterborne chemicals (USEPA 2003a).

EPA followed the approach described in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a). EPA used peer-reviewed, publicly available information to classify each chemical using this framework to derive the most appropriate BAFs according to EPA's 2000 Methodology (USEPA 2000a). The framework provides six alternatives, or procedures, resulting in up to four possible methods for each chemical, based on the chemical's properties. These four methods follow:

- **BAF Method.** This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs were normalized by adjusting for the water-dissolved portions of the chemical and the lipid fraction of fish tissue for each species, as well as the fraction of the total concentration of chemical in water that is freely dissolved. EPA averaged multiple field BAFs using a geometric mean of the normalized BAFs by species and TL; then EPA further averaged the BAFs across species to compute TL baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the n-octanol-water partition coefficient (K_{ow}). EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **BSAF Method.** This method uses biota-sediment accumulation factors (BSAFs) to estimate BAFs. EPA did not use measured BSAFs to calculate national BAFs because the two major compilations of these data—EPA's Biota-Sediment Accumulation Factor Data Set, Version 1.0 (USEPA 2015a), and the U.S. Army Corps of Engineers' BSAF database (USACE 2015)—have not been peer-reviewed.
- **BCF Method.** This method uses BAFs estimated from laboratory-measured bioconcentration factors (BCFs) with or without adjustment by a food chain multiplier. Similar to field BAFs, laboratory-measured BCFs are normalized with the lipid fraction and the fraction of the total concentration of chemical in water that is freely dissolved, then multiplied by the food chain multiplier where applicable. Multiple values are averaged using a geometric mean across species and then across TL to compute baseline BAFs. The national-level BAF adjusts the TL baseline BAFs by national default values for lipid content, dissolved and particulate organic carbon content, and the K_{ow}. EPA chose the recommended 50th percentile dissolved and particulate organic carbon content for the national-level default values, as described in section 6.3 of the Technical Support Document, Volume 2 (USEPA 2003a).
- **K_{ow} Method.** This method predicts BAFs based on a chemical's K_{ow}, with or without adjustment using a food chain multiplier, as described in section 5.4 of the Technical Support Document, Volume 2 (USEPA 2003a).

Following the decision framework presented in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a), EPA selected one of the six procedures to develop a national-level BAF for this chemical. For a given procedure, EPA selected the method that provided BAF estimates for all three TLs (TL2–TL4) in the following priority:

1. BAF estimates using the BAF method (i.e., based on field-measured BAFs) if possible.
2. BAF estimates using the BCF method if (a) the BAF method did not produce estimates for all three TLs and (b) the BCF method produced national-level BAF estimates for all three TLs.
3. BAF estimates using the K_{ow} method if (a) Procedure 1 or 3 was applicable (see Figure 3-1 of the Technical Support Document, Volume 2 [USEPA 2003a]) and (b) the BAF and BCF methods did not produce BAF estimates for all three TLs.

In cases where the procedure called for the BAF method but there were fewer than three TL estimates and the K_{ow} method did not apply (i.e., Procedures 2, 4, 5, and 6), EPA used the BAF method estimate for the reported TLs by averaging the estimates using a geometric mean when there were two BAFs and using the single estimate when only one was available. EPA did not mix values from the BAF and BCF methods. If the BAF method did not have sufficient reliable data for any TLs, EPA used the BCF method estimates in the same manner. If none of the four methods provided sufficient data, or if none were appropriate for the procedure, EPA used the BCF from the previously recommended 2002/2003 criteria (USEPA 2002b; USEPA 2003b).

EPA primarily used field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases (Arnot and Gobas 2006; Environment Canada 2006) to develop national BAFs. If field-measured BAFs and laboratory-measured BCFs were not available from those sources, EPA selected K_{ow} values from peer-reviewed sources (i.e., Agency for Toxic Substances and Disease Registry [ATSDR] preferentially, followed by U.S. Department of Health and Human Services' Hazardous Substances Data Bank) for use in calculating national BAFs using the K_{ow} method described in EPA's Technical Support Document, Volume 2 (USEPA 2003a). For those chemicals for which the K_{ow} method was not applicable based on the Technical Support Document, Volume 2 (USEPA 2003a), EPA performed open literature searches of peer-reviewed journal articles to find field-measured BAFs or laboratory-measured BCFs.

4.4.2 Chemical-specific BAFs

EPA selected a national BAF value of 2,900 L/kg for di-n-butyl phthalate. EPA followed the framework for selection of methods for deriving national BAFs in Figure 3-1 of the Technical Support Document, Volume 2 (USEPA 2003a) to select a procedure for estimating national BAFs for di-n-butyl phthalate. Based on the characteristics this chemical, EPA selected Procedure 2 for deriving a national BAF value. Di-n-butyl phthalate has the following characteristics:

- Nonionic organic chemical (USDHHS 2010)
- Moderate-high hydrophobicity (log $K_{ow} \geq 4$); log $K_{ow} = 4.21$ (ATSDR 2001)
- High metabolism (Gobas et al. 2003; Mankidya et al. 2013)

EPA was not able to locate peer-reviewed, field-measured BAFs or lab-measured BCFs for all three TLs (2, 3, and 4). Therefore, EPA used the BAF method estimate for the reported TLs by calculating the geometric mean of the TL3 and TL4 BAF values available for di-n-butyl phthalate (Arnot and Gobas 2006; Environment Canada 2006) to derive the national BAF value of 2,900 L/kg for this chemical.

5 Hazard Identification and Dose Response

5.1 Approach

EPA considered all available toxicity values for both noncarcinogenic and carcinogenic toxicological effects to develop this updated AWQC for di-n-butyl phthalate. As described in the

2000 Methodology (USEPA 2000a), where data are available EPA derives AWQC for both noncarcinogenic and carcinogenic effects and recommends the more protective value for the AWQC. (See section 7, Criteria Derivation: Analysis.)

For noncarcinogenic toxicological effects, EPA uses a chronic-duration oral RfD to derive human health AWQC. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data (USEPA 2000a).

For carcinogenic toxicological effects, EPA uses an oral CSF to derive human health AWQC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor.

For this update, EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (RfD or CSF) for use in developing AWQC. EPA's primary source of toxicity values for developing human health AWQC is its Integrated Risk Information System (IRIS) program (USEPA 2015b). EPA also systematically searched for toxicological assessments from the following EPA program offices, other national and international programs, and state programs:

- EPA, Office of Pesticide Programs (USEPA 2015c)
- EPA, Office of Pollution Prevention and Toxics (USEPA 2015d)
- EPA, Office of Water (USEPA 2015e)
- EPA, Office of Solid Waste and Emergency Response (USEPA 2015f)
- U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR 2015)
- Health Canada (HC 2015)
- California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (CalEPA 2014)

After identifying and documenting all available toxicity values, EPA followed a systematic process to select the toxicity values used to derive the AWQC for noncarcinogenic and carcinogenic effects. EPA selected IRIS toxicity values to derive the updated AWQC if *any* of the following conditions were met:

1. EPA's IRIS toxicological assessment was the only available source of a toxicity value.
2. EPA's IRIS toxicological assessment was the most current source of a toxicity value.

3. EPA's IRIS program was reassessing the chemical in question and had published the draft Toxicological Review for public review and comment, discussion at a public meeting, and subsequent expert peer review.[f]
4. The toxicity value from a more current toxicological assessment from a source other than EPA IRIS was based on the same principal study and was numerically the same as an older EPA IRIS toxicity value.
5. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* include the relevant toxicity value (chronic-duration oral RfD or CSF).
6. A more current toxicological assessment from a source other than EPA IRIS was available, but it did *not* introduce new science (e.g., the toxicity value was not based on a newer principal study) or use a more current modeling approach compared to an older EPA IRIS toxicological assessment.

EPA selected the toxicity value from a peer-reviewed, publicly available source other than EPA IRIS to derive the updated AWQC if *any* of the following conditions were met:

1. The chemical is currently used as a pesticide, and EPA Office of Pesticide Programs had a toxicity value that was used in pesticide registration decision-making.
2. A toxicological assessment from a source other than EPA IRIS was the only available source of a toxicity value.
3. A more current toxicological assessment from a source other than EPA IRIS introduced new science (e.g., the toxicity value was based on a newer principal study) or used a more current modeling approach compared to an older EPA IRIS toxicological assessment.

5.2 Chemical-specific Toxicity Value

5.2.1 Reference Dose

EPA selected an RfD of 1×10^{-1} mg/kg-d (0.1 mg/kg-d) for di-n-butyl phthalate based on a 1986 IRIS assessment (USEPA 1986a). EPA's IRIS program identified a study by Smith (1953) as the critical study and increased mortality as the critical effect in rats orally exposed to di-n-butyl phthalate. The subchronic study had a NOAEL of 125 mg/kg-d. In deriving the RfD, EPA's IRIS applied an uncertainty factor of 1000 to account for interspecies extrapolation (10), intraspecies variation (10), and subchronic-to-chronic extrapolation (10) (USEPA 1986a).

In 2001 EPA's IRIS program conducted a screening-level review of more recent toxicology literature pertinent to the RfD for di-n-butyl phthalate and identified one or more new studies; however, EPA's IRIS program has not reassessed this chemical.

[f] Equivalent to Step 4 in the July 2013 EPA Process for Developing IRIS Health Assessments. Available online at http://www.epa.gov/iris/process.htm.

EPA identified one other RfD source through the systematic search described in section 5: a 2001 ATSDR assessment (ATSDR 2001). Based on the selection process described in section 5, the 1986 IRIS assessment is preferred for use in AWQC development at this time. The ATSDR assessment does not include the relevant (chronic oral) toxicity factor.

5.2.2 Cancer Slope Factor

Under the 1986 EPA *Guidelines for Carcinogen Risk Assessment* (USEPA 1986b), di-n-butyl phthalate is classified as Group D, “not classifiable as a human carcinogen” (USEPA 1987).

EPA identified no CSF source through the systematic search described in section 5.

6 Relative Source Contribution

6.1 Approach

The RSC component of the AWQC calculation allows a percentage of the RfD’s exposure to be attributed to the consumption of ambient water and fish and shellfish from inland and nearshore waters when there are other potential exposure sources. The RSC describes the portion of the RfD available for AWQC-related sources (USEPA 2000a); the remainder of the RfD is allocated to other sources of the pollutant. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual’s total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from ocean fish and shellfish consumption (which is not included in the FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.

EPA derived an RSC for each chemical included in this 2015 update by using the Exposure Decision Tree approach described in the 2000 Methodology (USEPA 2000a). To use that approach, EPA compiled information for each chemical on its uses, chemical and physical properties, occurrences in other potential sources (e.g., air, food), and releases to the environment, as well as regulatory restrictions on other sources that are specific to the chemical (e.g., air quality standards, food tolerance levels). The ATSDR “Toxicological Profiles” (ATSDR 2015) were the primary sources for this information. EPA used the Hazardous Substance Data Bank (HSDB) (USDHHS 2015) from the National Library of Medicine’s Toxicology Data Network (TOXNET) as the primary source for chemicals without ATSDR Toxicological Profiles. Both sources are peer-reviewed compilations of chemical information.

EPA used additional references, including the following, to obtain specific types of information and to supplement the information from ATSDR and the HSDB:

- EPA’s Six-Year Reviews (drinking water data) (USEPA 2009a; USEPA 2009b).
- FDA Total Diet Study (USFDA 2015).
- FDA Everything Added to Food in the United States (USFDA 2013).
- EPA National Lake Fish Tissue Study (USEPA 2009c).
- EPA Toxic Release Inventory (USEPA 2015g).

- International Bottled Water Association Standards of Quality (IBWA 2012).
- NOAA Mussel Watch (NOAA 2014).
- Additional sources as needed.

To determine the RSC to be used in the AWQC calculation, EPA then used the information compiled for each chemical to address the questions posed in the Exposure Decision Tree. Some of the important items evaluated in the Exposure Decision Tree follow:

- The adequacy of the data available for each relevant exposure source and pathway.
- The availability of sufficient information to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern (i.e., ambient water and fish/seafood from those waters).
- Whether information on each source is available to make a characterization of exposure.

In cases where there is a lack of environmental or exposure data, or both, the Exposure Decision Tree approach results in a recommended RSC of 20 percent. This 20 percent value for the RSC may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrating that sources and routes of exposure other than water and fish from inland and nearshore waters are not anticipated for the pollutant in question, the RSC may be raised to 80 percent based on the available data (USEPA 2000a).

6.2 Chemical-specific RSC

Di-n-butyl phthalate is used as a softening agent in plastic manufacturing (often polyvinyl chloride plastics and nitrocellulose lacquers) and in cosmetics, lubricants, floor carpets, tapestry, paint, and nail polish (ATSDR 2001). The physical properties and uses of di-n-butyl phthalate indicate that the general population might be exposed to it via inhalation of ambient air and ingestion of water and food.

The vapor pressure of di-n-butyl phthalate (2.01×10^{-5} mm Hg at 25 °C) indicates that it will exist in both the vapor and particulate phases in the atmosphere (USDHHS 2010). Recent data from EPA's Toxic Release Inventory (USEPA 2015g) indicates that 5,459 pounds of di-n-butyl phthalate were released in 2013. In addition, it is listed as a hazardous air pollutant (USEPA 2013). Based on the chemical's physical properties and prevalence, air is a potentially significant source of exposure to it.

Surface waters are a potential source of di-n-butyl phthalate (ATSDR 2001). The chemical is moderately soluble in water (ATSDR 2001), and it is not regulated under the Safe Drinking Water Act (USEPA 2014c). Di-n-butyl phthalate has been detected in some drinking water supplies (at levels around 0.1–0.2 ppb) (ATSDR 2001). Di-n-butyl phthalate was not a chemical of concern in EPA's Six-Year Reviews (USEPA 2009a; USEPA 2009b), and no Standard of Quality for bottled water has been established for it (IBWA 2012). Therefore, based on di-n-butyl phthalate's chemical properties, ingestion of surface and finished drinking water is a potentially significant source of exposure to it.

Di-n-butyl phthalate can be found in food products due to its presence in food packaging (ATSDR 2001). It has also been found in infant formulas (two of six infant formulas sampled), and various foods and beverages (e.g., cereal, milk, eggs, fish, fruits, nuts, beans, processed meat) (USDHHS 2015). Thus, ingestion of food is a potentially significant source of exposure to di-n-butyl phthalate.

The log K_{ow} for di-n-butyl phthalate ranges between 3.7 and 4.72, with an average log K_{ow} of 4.21 (USDHHS 2015). The national-level BAF estimate for di-n-butyl phthalate is 2,900 L/kg, which indicates that it has a high potential for bioaccumulation (USEPA 2011b). Various studies have detected di-n-butyl phthalate in fish and aquatic invertebrates (USDHHS 2015). This chemical was detected in fish samples collected in EPA's National Lake Fish Tissue Study (USEPA 2009c). Di-n-butyl phthalate was not included in NOAA's Mussel Watch Survey (NOAA 2014). Thus, based on di-n-butyl phthalate's potential to bioaccumulate, ingestion of fish and shellfish is a potentially significant source of exposure to the chemical.

In summary, based on the physical properties and available exposure information for di-n-butyl phthalate, air, drinking water, food, and fish and shellfish are potentially significant sources. Following the Exposure Decision Tree in EPA's 2000 Methodology (USEPA 2000a), significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from these different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20 percent (0.20) for di-n-butyl phthalate.

7 Criteria Derivation: Analysis

Table 1 summarizes the model inputs used to derive the 2015 updated human health AWQC that are protective of exposure to di-n-butyl phthalate from consuming drinking water and eating fish and shellfish (organisms) from inland and nearshore waters. The criteria calculations are presented below. These updated criteria recommendations are based on the 2000 Methodology (USEPA 2000a) and the updated exposure assumptions described above. (See section 4, Exposure Factors; section 5, Hazard Identification and Dose Response; and section 6, Relative Source Contribution.)

Table 1. Summary of Input Parameters for 2015 Human Health AWQC for Di-n-butyl Phthalate

Input Parameter	Value
RfD	0.1 mg/kg-d
CSF	No data
RSC	0.20
BW	80.0 kg
DI	2.4 L/d
FCR	0.022 kg/d
BAF	2,900 L/kg

7.1 AWQC for Noncarcinogenic Toxicological Effects

For consumption of water and organisms:

$$\text{AWQC }(\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{\text{DI (L/d)} + (\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.1\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{2.4\ L/d + (0.022\ kg/d \times 2{,}900\ L/kg)}$$

$$= 24.2\ \mu g/L$$

$$= 20\ \mu g/L \text{ (rounded)}$$

For consumption of organisms only:

$$\text{AWQC }(\mu g/L) = \frac{\text{toxicity value (RfD [mg/kg-d]} \times \text{RSC)} \times \text{BW (kg)} \times 1{,}000\ (\mu g/mg)}{(\text{FCR (kg/d)} \times \text{BAF (L/kg)})}$$

$$= \frac{0.1\ mg/kg\text{-}d \times 0.20 \times 80.0\ kg \times 1{,}000\ \mu g/mg}{(0.022\ kg/d \times 2{,}900\ L/kg)}$$

$$= 25.1\ \mu g/L$$

$$= 30\ \mu g/L \text{ (rounded)}$$

7.2 AWQC for Carcinogenic Toxicological Effects

EPA identified no CSF sources through the systematic search described above. (See section 5, Hazard Identification and Dose Response.) Therefore, EPA was unable to derive AWQC for carcinogenic toxicological effects.

7.3 AWQC Summary

EPA derived the AWQC for di-n-butyl phthalate using a noncarcinogenic toxicity endpoint. The updated human health AWQC for di-n-butyl phthalate are **20 µg/L** for consumption of water and organisms and **30 µg/L** for consumption of organisms only (Table 2). These updated criteria replace EPA's previously published values (USEPA 2002b).

Table 2. Summary of EPA's Previously Recommended (2002) and Updated (2015) Human Health AWQC for Di-n-butyl Phthalate

	2002 Human Health AWQC	2015 Human Health AWQC
Water and Organism	2,000 µg/L	**20 µg/L**
Organism Only	4,500 µg/L	**30 µg/L**

These AWQC are intended to be protective of the general adult population from noncarcinogenic effects due to chronic (up to a lifetime) exposure to di-n-butyl phthalate from ingesting water and/or consuming fish and shellfish from inland and nearshore waters.

8 Criteria Characterization

The updated 2015 human health AWQC for di-n-butyl phthalate take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology (USEPA 2000a). The following paragraphs describe the individual influence of each of the revised inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher BW compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult BW among the U.S. population. The updated BW assumption of 80.0 kg, based on recent survey data from the 1999−2006 NHANES data, is 10 kg greater than the previous assumption of 70 kg. Assuming all other input parameters remain constant, a higher average BW in the AWQC calculations (Eqs. 1 and 2 above) results in higher AWQC. That is, as BW increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated DI assumption is 2.4 L/d, which is higher than the previously recommended rate of 2 L/d. Assuming all other input parameters remain constant, a higher DI assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as DI increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Fish Consumption Rate

The updated FCR for fish and shellfish from inland and nearshore waters is 22.0 g/d; the TL-specific FCRs are 7.6 g/d, 8.6 g/d, and 5.1 g/d for TLs 2, 3, and 4, respectively. The previously recommended FCR was 17.5 g/d. Assuming all other input parameters remain constant, a higher FCR assumption in the AWQC calculations (Eqs. 1 and 2 above) results in lower AWQC. That is, as fish consumption increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The national BAF used in the updated AWQC (Eqs. 1 and 2 above) is 2,900 L/kg wet-weight. This BAF was derived using EPA's 2000 Methodology (USEPA 2000a) and its Technical Support Document, Volume 2 (USEPA 2003a). This national BAF replaces EPA's previously recommended BCF of 89 L/kg.

As an additional line of evidence, EPA used model-estimated BAFs from the Estimation Program Interface (EPI) Suite (USEPA 2012) to support field-measured or predicted BAFs developed using the four methods described above. The BCFBAF program within EPI Suite estimates fish BAFs by using K_{ow} and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation, such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the K_{ow} of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. The EPI Suite model estimates are as follows:

TL2 = 236.2 L/kg
TL3 = 209.4 L/kg
TL4 = 159.4 L/kg

Assuming all other input parameters remain constant, higher BAFs or BCFs result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

The utilization of a national BAF rather than a BCF better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant in the organism due to metabolic processes.

Reference Dose

EPA retained an RfD of 0.1 mg/kg-d for di-n-butyl phthalate based on a 1986 IRIS assessment (USEPA 1986a; USEPA 2002c). EPA used this RfD to derive AWQC for noncarcinogenic effects. Assuming all other input parameters remain constant, no change in the values used for the RfD in the AWQC calculations (Eqs. 1 and 2) results in no change in AWQC.

Cancer Slope Factor

EPA did not select a CSF for di-n-butyl phthalate and therefore did not derive AWQC for carcinogenic effects. EPA did not derive AWQC for carcinogenic effects of di-n-butyl phthalate in its previous criteria update (USEPA 2002c).

Relative Source Contribution

An RSC of 20 percent is included in the AWQC calculation. Previously, the AWQC did not include an RSC (or, in other words, the RSC was 100 percent) (USEPA 2002c). Assuming all other input parameters remain constant, a lower RSC in the AWQC calculations (Eqs. 1 and 2) results in lower AWQC.

9 Chemical Name and Synonyms

- Di-n-butyl phthalate (CAS Number 84-74-2)
- 1,2-Benzenedicarboxylic Acid Dibutyl Ester
- o-Benzenedicarboxylic Acid, Dibutyl Ester
- Benzene-o-Dicarboxylic Acid Di-n-Butyl Ester
- Butylphthalate
- Celluflex DPB
- Dibutyl 1,2-Benzene dicarboxylate
- Dibutyl phthalate
- Di-n-Butylphthalate
- Dibutyl-o-Phthalate
- DPB
- Elaol
- Ergoplast FDB
- Genoplast B
- Hexaplast M/B
- N-Butylphthalate
- Palatinol C
- Phthalic Acid Dibutyl Ester
- Polycizer DBP
- PX 104
- RC Plasticizer DBP

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