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Office of Water
Office of Science and Technology

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EPA Response to Scientific Views from the Public

on

Draft Updated National Recommended Water Quality Criteria for the Protection of Human Health

(Docket ID No. EPA–HQ–OW–2014–0135)

June 2015

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INTRODUCTION

EPA has updated its national recommended ambient water quality criteria (AWQC) for human health for 94 chemical pollutants to reflect the latest scientific information and implementation of existing EPA policies found in *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (2000). EPA issued the draft updated human health criteria on May 13, 2014 and accepted written scientific views from the public until August 13, 2014. EPA considered those scientific views during finalization of the AWQC and prepared the following responses to those public comments.

The final updated human health criteria were developed pursuant to Section 304(a) of the Clean Water Act. EPA's recommended Section 304(a) criteria provide technical information for states and authorized tribes 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.

The public comments (scientific views) summarized in this document are condensed versions of the original comments provided in the Public Docket (EPA–HQ–OW–2014–0135).

LIST OF COMMENTERS

Alaska Department of Environmental Conservation
Alcoa Inc.
American Chemistry Council
American Forest & Paper Association
American Water Works Association
Association of Clean Water Administrators
Association of Missouri Cleanwater Agencies
Central Valley Clean Water Association
City of Everett, Public Works, Everett, Washington
Clearwater Paper Corporation
County of San Diego, Department of Public Works, Watershed Protection Program
Department of Defense
District Department of the Environment
Federal Water Quality Coalition
Florida Department of Environmental Protection
Florida Water Environment Association Utility Council
Hampton Roads Sanitation District
Idaho Department of Environmental Quality
Integral Consulting Inc, on behalf of Syngenta
J.R. Simplot Company
Lower Elwha Klallam Tribe
Minnesota Pollution Control Agency
National Association of Clean Water Agencies
North American Metals Council
North Carolina Conservation Network and Clean Water Action
North Carolina Water Quality Association, Inc.
Northwest Indian Fisheries Commission
Northwest Pulp & Paper Association
Ohio Environmental Protection Agency
Oregon Department of Environmental Quality
Pennsylvania Department of Environmental Protection
Pentachlorophenol Task Force
South Carolina Water Quality Association, Inc.
State of Washington Department of Ecology
Steven Rudnick, Public Citizen
Texas Commission on Environmental Quality
The Boeing Company
Transportation and Storm Water Department, City of San Diego, California
Treated Wood Council
Utility Water Act Group
West Virginia Department of Environmental Protection

West Virginia Municipal Water Quality Association, Inc.
Wet Weather Partnership
Wisconsin Department of Natural Resources

1 OVERALL IMPRESSIONS

1.1 GENERAL SUPPORT

1.1.1 Comment: Several commenters noted that they appreciated EPA's efforts to update and maintain the national recommended human health ambient water quality criteria (AWQC). Some commenters supported EPA's use of the most recent health effects toxicity values (reference doses, cancer slope factors) from various sources for developing ambient water quality criteria instead of relying solely on toxicity information from EPA's Integrated Risk Information System (IRIS). Several commenters also supported EPA's decision to use bioaccumulation factors (BAFs) instead of bioconcentration factors (BCFs).

EPA Response: *EPA appreciates the support. The Clean Water Act (CWA) section 304(a) requires EPA to develop, and from time to time, revise AWQC that will protect and maintain designated uses, including safe drinking water supplies. EPA updated 94 AWQC to reflect the latest scientific information and EPA policies. The updates take into account current exposure factors (body weight, drinking water intake, and fish consumption rate), bioaccumulation factors, and toxicity factors (reference dose, cancer slope factor) and follow the approach described in the EPA* Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health *("2000 Methodology") (USEPA 2000a).*

In addition, refer to EPA's responses to the Exposure Input Parameters (section 3 of this response to comments) – body weight (3.1), drinking water intake (3.2), fish consumption rate (3.3), bioaccumulation factors (3.4), human health toxicity values (3.5), and relative source contribution (3.6) for specific responses.

1.2 GENERAL OPPOSITION

1.2.1 Comment: Some commenters suggested that the draft updated AWQC may be based on changes in policy rather than changes in science and requested that EPA identify and distinguish policy choices from changes in scientific information. Several commenters questioned whether the proposed numeric AWQC were appropriately peer reviewed.

EPA Response: *The updated AWQC reflect implementation of existing EPA policies found in the 2000 Methodology (USEPA 2000a).*

In addition, EPA updated the AWQC for 94 chemical pollutants to reflect the latest scientific information and to take into account current exposure factors (body weight, drinking water intake, fish consumption rate), bioaccumulation factors, and toxicity factors (reference dose, cancer slope factor). See additional clarifications in section 3 of this document.

EPA based these revised criteria recommendations on sound science and policies that have been externally peer reviewed and thoroughly vetted publicly, including:

- *USEPA (U.S. Environmental Protection Agency). 2000*. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). *EPA-822-B-00-004. U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Washington, DC*.
- *USEPA (U.S. Environmental Protection Agency)*. *2000.* Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000), Technical Support Document. Vol. 1, Risk Assessment. *EPA-822-B-00-005. U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Washington, DC.*
- *USEPA (U.S. Environmental Protection Agency). 2003.* Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000), Technical Support Document. Vol. 2, Development of National Bioaccumulation Factors. *EPA-822-R-03-030. U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Washington, DC.*
- *USEPA (U.S. Environmental Protection Agency). 2011.* Exposure Factors Handbook: 2011 Edition. *EPA-600-R-09-052F. U.S. Environmental Protection Agency, Office of Research and Development, Washington, DC.*
- *USEPA (U.S. Environmental Protection Agency). 2012.* Estimation Programs Interface (EPI) Suite™ for Microsoft® Windows, v 4.10. *U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, Washington, DC.*
- *USEPA (U.S. Environmental Protection Agency). 2014.* Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003–2010). *EPA-820-R-14-002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.*

1.2.2 Comment: A commenter noted that, according to the EPA *Framework for Human Health Risk Assessment to Inform Decision Making* ("Framework;" USEPA 2014a), the AWQC's problem formulation section should consist of analytical considerations of the issues that are major factors influencing the technical approach; EPA failed to include the problem formulation information, including a conceptual model and chemical specific analysis plan, for each chemical.

EPA Response: *In updating the criteria, EPA relied upon the policies and processes outlined in the 2000 Methodology (USEPA 2000a). Although the 2000 Methodology predates the EPA Framework (USEPA 2014a), many of the steps, in effect, apply the same approaches outlined in that document. The structure of each of the 94 criteria documents is intended to be consistent with general concepts of effects assessments as described in the EPA Framework (USEPA 2014a). The 2000 Methodology includes steps that are, effectively, a problem formulation, a conceptual model, etc. These analyses were applied uniformly to all chemicals in the context of the crtieria update. The updated AWQC relied on peer reviewed information and were submitted to public comment during development.*

1.2.3 Comment: Some commenters suggested that EPA revise the 2000 Methodology prior to revising the AWQC.

EPA Response: *The 2000 Methodology was developed over more than eight years and included scientific review by EPA's Science Advisory Board (1993), a four-month public comment period (1998), a public meeting (1999), an external peer review workshop (1999), and multiple stakeholder review processes. For these reasons, EPA reasonably chose to update the AWQC following this peer-reviewed, publicly vetted methodology.*

1.2.4 Comment: Several commenters suggested that EPA's assumptions used to calculate the proposed AWQC are overly conservative for the protection of human health.

EPA Response: *EPA based the revised AWQC recommendations on sound science and policies that have been thoroughly vetted publicly (see above). The exposure and toxicity inputs used to derive the AWQC follow the approach described in the 2000 Methodology (USEPA 2000a).*

AWQC for the protection of human health are designed to minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposure to substances through the ingestion of drinking water and consumption of fish obtained from surface water. Following the 2000 Methodology, EPA used a combination of median values, mean values, and percentile estimates for the parameter value defaults to calculate its updated AWQC. EPA's assumptions afford an overall level of protection targeted at the high end of the general population (i.e., the target population or the criteria-basis population) (USEPA 2000a). This approach is reasonably conservative and appropriate to meet the goals of the CWA and the 304(a) criteria program (USEPA 2000a).

EPA made the following standard assumptions for the updated AWQC (USEPA 2000a). The default body weight (80 kg) is an arithmetic mean. National BAFs were computed using mean lipid values and median (i.e., 50th percentile) values for dissolved organic carbon and particulate organic carbon. The default drinking water intake rate and fish consumption rate are 90th percentile estimates. The use of these values result in 304(a) AWQC that are protective of a majority of the population; this is EPA's goal (USEPA 2000a). See additional clarifications in section 3 of this document.

1.2.5 Comment: Commenters noted that there was a lack of transparency in the technical record underlying the draft AWQC. Commenters requested that EPA provide additional documentation on the development of the proposed AWQC.

EPA Response: *EPA has provided documentation of the data and process used to develop each updated AWQC in the final 94 criteria documents. In particular, EPA has added text in each of the criteria documents that describes in a clear, transparent manner the selection process for toxicity values, the approach for development of the bioaccumulation factors (BAFs), and the approach for development of the relative source contributions (RSCs). The documents can be accessed on EPA's website at http://water.epa.gov/scitech/swguidance/standards/criteria/health/.*

1.2.6 Comment: Several commenters recommended the use of a probabilistic risk assessment approach rather than using a deterministic approach to derive numeric AWQC.

EPA Response*: EPA has not implemented probabilistic risk assessment approaches in this update to the AWQC. The use of probabilistic techniques was not reflected in the 2000 Methodology (USEPA 2000a), which served as the guide for the current revisions (for the reasons described above in EPA response to comment 1.2.3). EPA intends to consider probabilistic techniques in future updates of the* 2000 Methodology.

1.2.7 Comment: Some commenters requested that EPA evaluate the potential economic impacts on affected entities before finalizing the criteria and issue additional technical support documents on implementation for CWA purposes before issuing the AWQC as final.

EPA Response: *Water quality criteria developed by EPA under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. As a result, section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water (see also section 5).*

2 PUBLIC COMMENT PERIOD

2.1 REQUEST FOR EXTENSION

2.1.1 Comment: Several commenters requested an extension of the public comment period to allow them to perform a comprehensive review and analysis of the draft updated AWQC and to consider potential impacts. These commenters requested extension times ranging from 30 to 90 days past the original July 14, 2014 public comment period end date.

EPA Response: *In response to stakeholder requests, on June 23, 2014, EPA announced in the* Federal Register *(79 FR 35545) an extension of the public comment period for an additional 30 days, until August 13, 2014. This extension allowed the public to comment on the draft updated AWQC for a total of 90 days.*

3 AWQC INPUT PARAMETERS

3.1 BODY WEIGHT

3.1.1 Comment: Several commenters noted that some populations may not be adequately protected by criteria derived using an assumed body weight of 80 kilograms (kg) (e.g., adults weighing less than 80 kg (particularly women), children, and infants). The commenters requested that EPA clarify how states and tribes should consider calculating or applying criteria to be protective of these populations, including being fully protective of children. One commenter suggested that EPA does not explicitly consider life stage (from preconception to adult) differences to health risks from water and fish pollutants and suggested normalization of the drinking water and fish consumption rates per body weight.

EPA Response: *EPA has updated the default body weight assumption for AWQC to 80.0 kg based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 as recommended in EPA's* Exposure Factors Handbook *(USEPA 2011). This represents the mean body weight for adults ages 21 and older. EPA's previously recommended body weight assumption was 70 kilograms, which was based on the mean body weight of adults from the NHANES III database (1988-1994).*

Regarding protection of individuals weighing less than 80 kg, EPA set the updated AWQC at a level intended to be adequately protective of a human population over a lifetime (USEPA 2000a). For this update, as in previous updates (in 2002 and 2003), exposure factors were chosen for the general adult population only. Also, EPA did not normalize drinking water and fish consumption rates per body weight, which is consistent with the 2000 Methodology (USEPA 2000a).

However, states and tribes may modify EPA's recommendations (including normalization of drinking water intake and fish consumption), as appropriate, for various lifestages. If pregnant women/fetuses or young children are the target populations, then EPA recommends criteria development using specific exposures for those groups (for acute or subchronic toxicity only). For more information on exposure considerations for children and sensitive target populations, see EPA's 2000 Methodology (USEPA 2000a). Updated exposure parameters for sensitive populations may also be found in EPA's Exposure Factors Handbook *(USEPA 2011) and EPA's updated fish consumption report,* Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010) *(USEPA 2014b).*

3.1.2 Comment: One commenter noted that the updated body weight assumption of 80 kg creates two groups of AWQC, those calculated with the updated body weight (80 kg) and those criteria that were not updated and remain calculated with the previous body weight assumption (70 kilograms). The commenter asked EPA to clarify what, if anything, should be done to address this discrepancy.

EPA Response: *For the criteria that are not being updated at this time, EPA acknowledges that the AWQC for these pollutants continue to rely on previously recommended exposure assumptions, including a 70-kilogram body weight assumption. Due to outstanding technical issues, EPA did not update the following chemical pollutants: antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium (III or VI), copper, manganese, methylmercury, nickel, nitrates, nitrosamines, N-nitrosodibutylamine, N-nitrosodiethylamine, N-nitrosopyrrolidine, N-nitrosodimethylamine, N-nitrosodi-n-propylamine, N-nitrosodiphenylamine, polychlorinated biphenyls (PCBs), selenium, thallium, zinc, or 2,3,7,8-TCDD (dioxin).*

EPA intends to update AWQC for additional pollutants as sufficient information becomes available to address technical issues, such as the bioaccumulation of metals, and some non-lipophilic compounds in a scientifically defensible manner. In the meantime, states should *consider adopting the existing criteria recommendations for those compounds that were not addressed in this update. In addition, states or tribes can modify EPA's AWQC to reflect site-specific conditions and inputs, such as body weight, drinking water intake, and fish consumption rates that are protective of specific populations identified by a state or tribe, or adopt different AWQC based on other scientifically defensible methods. EPA must, however, approve any new water quality standards adopted by a state before they can be used for CWA purposes.*

3.2 DRINKING WATER INTAKE

3.2.1 Comment: Several commenters suggested that EPA's draft drinking water intake assumption (3 liters per day [L/d]) presented an unrealistic or overly conservative exposure scenario for most of the population. Some commenters questioned the inclusion of "indirect" sources of water in the intake rate and asked EPA to further justify its selection of the drinking water intake rate.

EPA Response: *In light of the comments received, EPA revised the drinking water intake rate used in the final 2015 updated AWQC. EPA revised the default drinking water intake rate from the proposed 3 L/d 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*[1] *ingestion at the 90th percentile for adults ages 21 and older. EPA selected the per capita rate for the updated drinking water intake rate because it represents the average daily dose estimates; that is, it includes people who reported that they drank water during the survey period and those who reported that they did not, which is appropriate for a national-scale assessment such as CWA section 304(a) AWQC development (USEPA 2011, section 3.2.1).*

In the 2014 draft AWQC, EPA chose a default drinking water intake rate assumption of 3 L/d, which represented a consumer-only estimate of combined direct and indirect water ingestion based on NHANES data from 2003 to 2006 as reported in EPA's Exposure Factors Handbook *(USEPA 2011, Table 3-36) for all sources*[2] *of water at the 90th percentile for adults ages 21 and older. Consumer-only estimated intake rates may be appropriate for more site-specific or local-scale assessments, such as those conducted by EPA Office of Solid Waste and Emergency Response (OSWER), because they represent the quantity of water consumed only by individuals who reported water intake during the survey period, resulting in a higher (more conservative) intake rate (USEPA 2011, section 3.2.1).*

[1] *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).
[2] "All sources" includes water from all supply sources such as community water supply (tap water), bottled water, other sources, and missing/unknown sources.

EPA's updated drinking water intake rate of 2.4 L/d is consistent with the methodology described in the 2000 Methodology (USEPA 2000a). In that document, EPA recommended a default drinking water intake rate of 2 L/d, which represented the per capita ingestion rate of community water 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).

3.2.2 Comment: Commenters noted that most of the population does not drink water from untreated surface water sources. A commenter noted that the default water consumption rates (both the previously recommended 2 L/d and the updated rate of 3 L/d) do not represent a consideration of actual health risk but rather were selected in support of larger goals related to pollution prevention and maintenance of designated uses.

EPA Response: *Since at least the 1980s, EPA has included the drinking water exposure pathway in the development of AWQC in order to provide information to states to protect water bodies designated for drinking water use. The rationale for inclusion of drinking water in the criteria are cited in the 2000 Methodology (USEPA 2000a) as follows:*

> *EPA recommends inclusion of the drinking water exposure pathway 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 assure that this designated use can be protected and maintained. (2) Although rare, there are some public water supplies that provide drinking water from surface water sources without treatment. (3) Even among the majority of water supplies that do treat surface waters, existing treatments may not necessarily be effective for reducing levels of particular contaminants. (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 to bear the costs of upgraded or supplemental water treatment.*

3.2.3 Comment: The NHANES data cited in EPA's *Exposure Factors Handbook* (USEPA 2011) are potentially biased because the drinking water intake values in the NHANES study are based on self-reporting data.

EPA Response: *EPA analyzed the data provided from NHANES 2003 to 2006 to develop distributions of drinking water intake for different age groups and bias has been adequately addressed in the analytical methods applied. Studies presented in the* Exposure Factors Handbook *(USEPA 2011) were carefully selected based on a number of considerations, including first and foremost, study soundness (adequacy of the approach and minimal or defined bias). The NHANES study soundness was rated medium to high (USEPA 2011, Table 3-2). EPA's analysis was peer reviewed and found to be a sound basis for estimation of drinking water intake (Eastern Research Group 2010).*

3.2.4 Comment: There is a divergence in the exposure assumptions used for the AWQC and the exposure assumptions used to calculate maximum contaminant level goals (MCLGs) under the Safe Drinking Water Act (SDWA).

EPA Response: *The CWA's AWQC and the SDWA regulatory programs offer complementary protection to the U.S. population, are carried out under different statutory authorities with differing regulatory processes, and are administered separately under different timelines. Section 304(a) of the CWA requires the Agency to develop AWQC that will protect and maintain designated uses, including waters defined by states in their designated uses as drinking water supplies. AWQC are not intended to reflect consideration of non-human health endpoints or economic impacts, nor do they consider the technological feasibility of meeting the chemical concentrations in ambient water. The SDWA is directed to incorporate technological constraints, including analytical method and water treatment limitations, as well as toxicological information in the development of MCLGs for individual chemicals.*

EPA acknowledges and agrees that the best available drinking water intake and body weight data should be used in evaluating drinking water contaminants. EPA considers new data on human exposures as it would other new scientific data to evaluate regulated and unregulated contaminants under the SDWA. EPA will consider the updated exposure assumptions as it develops drinking water health advisories, revises existing drinking water regulations and develops future drinking water regulations.

The SDWA requires EPA to review each National Primary Drinking Water Regulation (NPDWR) at least once every six years and revise them, if appropriate. The purpose of the review, called the Six Year Review, is to identify those NPDWRs for which current health effects assessments, changes in technology, and/or other factors provide a health or technical basis to support a regulatory revision that will maintain or strengthen public health protection. EPA does not intend to use the updated exposure assumptions to conduct the Six Year Review, however, the updated exposure assumptions would be applied during the development of any proposed revision to a NPDWR resulting from the review.

3.2.5 Comment: One commenter noted that assuming a person's water source would remain the same for 70 years does not reflect U.S. Census data that indicate a person moves 11.7 times in their lifetime. EPA should consider this information in the exposure estimate.

EPA Response: *EPA has not attempted to adjust for duration of residence in its criteria update. Adjustment for this factor is not appropriate because an individual moving to an alternative location may be exposed to similar contaminants at that site. Additionally, the criteria are intended to protect the water quality at a given site regardless of which individual is exposed.*

3.2.6 Comment: A commenter noted that groundwater comprises about 35 - 44 percent of the water consumed in the United States and bottled water comprises about 10 percent, and therefore the Agency should conclude that more than 50 percent of drinking water is derived from sources other than surface water. A commenter noted that bottled water comprises about half of the drinking water consumed away from home (and about 15 percent of the total drinking water consumed) and that bottled water is subject to Food and Drug Administration (FDA) regulations, which include standards of quality, identity, and good manufacturing practices. EPA should revise its drinking water intake estimates to subtract the amount obtained from bottled drinking water.

EPA Response: *The revised drinking water rate is 2.4 L/d, which represents the per capita estimate of combined direct and indirect community water ingestion at the 90^th^ percentile for adults ages 21 and older based on NHANES data from 2003 to 2006 as reported in EPA's* Exposure Factors Handbook *(USEPA 2011, Table 3-23). "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). The per capita rate is representative of the national average regardless of source and is preferred for national-level assessments, such as national AWQC development.*

3.2.7 Comment: One commenter suggested that EPA should apply a "removal factor" to surface water concentrations to reflect the fact that surface water sources are treated. For example, compounds with high partition coefficients and very low water solubility would be sorbed to suspended solids in surface water and would have high removal efficiencies by most public water supply treatment systems.

EPA Response: *EPA does not apply a removal factor in its AWQC development because the values reflect ambient water column values. EPA's longstanding policy is that 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 water utilities or downstream users to bear the costs of upgraded or supplemental water treatment (USEPA 2000a; see EPA response to comment 3.2.2).*

3.2.8 Comment: A commenter noted that EPA's Supplemental Guidance for Superfund (OSWER Directive 9200.1-120, February 6, 2014) recommends a 90th percentile adult drinking water intake value of 2.5 L/d, whereas the updated AWQC uses a 90th percentile value of 3.0 L/d. For decades the recommended drinking water values used for AWQC development and Superfund risk assessment have been the same value (i.e., 2 L/d). EPA needs to explain why the two new (i.e., 2014) drinking water values differ from each other and the rationale for selecting the value of 3 L/d for AWQC development versus the value of 2.5 L/d.

EPA Response: *EPA's Supplemental Guidance for Superfund (OSWER Directive 9200.1-120, February 6, 2014) recommends a 90th percentile adult drinking water intake value of 2.5 L/d, which represents the consumer-only estimate of combined direct and indirect water ingestion based on NHANES data from 2003 to 2006 as reported in EPA's* Exposure Factors Handbook *(USEPA 2011, Table 3-33) for community water at the 90th percentile for adults ages 21 and older. The consumer-only rate is slightly higher than the per capita rate (2.4 L/d) because it only includes individuals who reported water intake during the survey period (and does not include those who reported no intake). The consumer-only rate is recommended for site-specific assessments, whereas the per capita rate is representative of the national average and is preferred for national-level assessments, such as national human health criteria development.*

3.3 FISH CONSUMPTION RATE

3.3.1 Comment: Several commenters requested that EPA provide greater transparency as to how the external peer review comments on its model were addressed and the extent to which the modified EPA model deviates from the National Cancer Institute (NCI) model. One commenter asserted that EPA did not adequately validate the model or address peer review comments related to potential bias. Some commenters requested clarification regarding EPA's modifications to the NCI method and requested access to the model and data.

EPA Response: *EPA updated the default fish consumption rate (FCR) to 22 grams per day (g/d) from 17.5 g/d. This rate represents the 90th percentile consumption rate of fish from inland and nearshore waters for the U.S. adult population 21 years of age and older, based on NHANES data collected from 2003 to 2010 and calculated using a modification of the NCI model (USEPA 2014b). EPA's previously recommended rate of 17.5 g/d was based on the 90th percentile consumption rate of fish from inland and nearshore waters for the U.S. adult population 21 years of age and older, based on CSFII data from 1994-1996, calculated using ratio estimation methods.*

EPA's FCR Report, Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010) *("FCR report;" USEPA 2014b), provides a description of the differences between the EPA and NCI models, includes the equations used by both models, and establishes the consistency of the results obtained using the EPA model with those from the NCI model. EPA modified the NCI method so that the model could process and manage the large NHANES dataset. Modifications were made to allow the model to run at the minimum penalty to robustness, while maintaining model accuracy, as described in the FCR report (USEPA 2014b). A comparison of the results of calculations of FCR percentiles using the NCI and EPA methods is described in section 4.6.2 of the FCR report (USEPA 2014b).*

EPA's method (including the modification to the NCI method) has been externally peer reviewed. EPA's FCR report, the external peer review report, and EPA's responses to the peer review comments are available on EPA's website: http://water.epa.gov/scitech/swguidance/fishshellfish/fishadvisories/technical.cfm#tabs-4.

With regard to accessibility of the NHANES data, Metadata from the modeling have been released by EPA and are accessible at the above website. The model and primary data are available from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.

3.3.2 Comment: Some commenters suggested that EPA's default FCR (22 grams per day) may not protect highly exposed populations that have a significantly higher FCR, such as subsistence fishers and tribes.

EPA Response*: The fish consumption rate used by EPA to update the AWQC reflects the national rate for the U.S. adult population. As stated in the 2000 Methodology, "because the level of fish intake in highly exposed populations varies by geographical location, EPA suggests a four preference hierarchy for states and authorized tribes to follow when deriving consumption rates* *that encourages use of the best local, state, or regional data available...EPA strongly emphasizes that states and authorized tribes should consider developing criteria to protect highly exposed population groups and use local or regional data over the default values as more representative of their target population group(s). The four preference hierarchy is: (1) use of local data; (2) use of data reflecting similar geography/population groups; (3) use of data from national surveys; and (4) use of EPA's default intake rates" (USEPA 2000a).*

3.3.3 Comment: Commenters suggested that EPA's selection of an FCR at the 90th percentile is overly conservative and represents a change in EPA policy.

EPA Response: *EPA followed the 2000 Methodology (USEPA 2000a), which recommends using a 90th percentile FCR to derive AWQC, and is thus not a change in policy. In the 2000 Methodology, the default fish consumption rate, which is protective of 90 percent of the general population, is a risk management decision. This default assumption helps achieve EPA's target goal of protecting the majority of the population, without being inordinately conservative (USEPA 2000a; see also EPA response to comment 1.2.4).*

3.3.4 Comment: Commenters suggested that EPA's FCR is not reflective of the actual consumption of fish for most of the U.S. population, particularly of fish caught and eaten from waters where the AWQC are applicable (i.e., inland and nearshore U.S. waters). Commenters suggested that much of the fish eaten in the U.S. is imported and that apportioning the entire FCR to fish from inland and nearshore waters is not reflective of human exposure to contaminants in fish that most people eat.

EPA Response: *As stated in the October 24, 2000 Memorandum from EPA Office of Science and Technology (OST) Director Geoffrey Grubbs and EPA Office of Wetlands, Oceans, and Watersheds (OWOW) Director Robert Wayland, "EPA interprets 'fishable' uses under section 101(a) of the CWA to include, at a minimum, designated uses providing for the protection of aquatic communities and human health related to consumption of fish and shellfish. In other words, EPA views 'fishable' to mean that not only can fish and shellfish thrive in a waterbody, but when caught, can also be safely eaten by humans. This interpretation also satisfies the section 303(c)(2)(A) requirement that water quality standards protect public health. Including human consumption of fish and shellfish in the definition of section 101(a) 'fishable' uses is not new. For example, in EPA's National Toxics Rule, all waters designated for even minimal aquatic life protection (and therefore a potential fish and shellfish consumption exposure route) are protected for human health (see 57 FR 60859, December 22, 1992)" (USEPA 2000b).*

For the purposes of developing a default national FCR, EPA assumed that all consumed fish were harvested from inland and nearshore U.S. waters (which encompasses EPA's jurisdiction under the CWA). It is unknown whether the proportion of fish harvested from non-U.S. waters is equally distributed across fish consumers. For example, it is possible that high fish consumers eat more locally caught fish as they may be recreational or subsistence fishers. In the case of shrimp, the most commonly consumed fish by U.S. consumers, 82.4 percent were considered to be from nearshore waters and were included in EPA's FCR model, whereas the 17.6 percent of shrimp from ocean waters were not included (USEPA 2014b, Table 1).

3.3.5 Comment: Commenters disagreed with EPA's apportionment of fish consumption across fresh, marine, and coastal waters. One commenter stated that including marine fish caught in near-coastal waters in determining FCR represents a change in EPA policy.

EPA Response: *EPA apportioned fish species consumed by habitat, including inland (freshwater) and nearshore (estuarine and a fraction of marine fish caught in near shore areas) to derive its FCR. This policy is consistent with the 2000 Methodology (USEPA 2000a) and EPA's longstanding interpretation of the "fishable" uses under section 101(a) of the CWA (USEPA 2000b and EPA response to Comment 3.3.4). EPA developed the apportionments based on catch data from the National Oceanic and Atmospheric Administration (NOAA), National Marine Fisheries Service (NMFS), Fisheries Statistics Division.[3] Species apportionments were applied on a global basis to represent what is actually consumed per habitat by the general U.S. population. The final apportionments were compared to earlier apportionments in the previous FCR (USEPA 2002a) and discrepancies were verified. EPA's FCR method, including the apportionment of fish species, was externally peer reviewed (see EPA response to Comment 3.3.1).*

3.3.6 Comment: Several commenters requested that EPA clarify how the fish consumption rates compare in developing AWQC and fish consumption advisories.

EPA Response: *With few exceptions, fish consumption advisories are the responsibility of states and tribes. State and tribal fish advisories identify how much fish can be safely consumed based on the site-specific concentrations of pollutants in those fish.*

3.3.7 Comment: Commenters expressed that, with respect to suppression of fish consumption, concepts of "availability" of fish and "contamination" of fish get mixed up and that it would be helpful to acknowledge the difficulty in accurately quantifying suppression.

EPA Response: *EPA acknowledges that it is important to avoid any suppression effect that may occur when a fish consumption rate for a given subpopulation reflects an artificially diminished level of consumption from an appropriate baseline level of consumption for that subpopulation. See* Human Health Ambient Water Quality Criteria and Fish Consumption Rates: Frequently Asked Questions *(January 18, 2013) (USEPA 2013). EPA notes that the AWQC update does not directly address suppression because the updated national default FCR is based on actual consumption. EPA acknowledges that there are many possible causes of suppressed consumption and that information is often lacking to accurately quantify suppression. Consistent with EPA's 2000 Methodology, states and tribes should consider local data, where available, in determining which FCR to use in deriving human health criteria, and consider whether such data represent a suppressed level of consumption either because of a perception of contamination, lack of access, or other factors.*

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[3] NOAA NMFS "Commercial Fisheries Statistics" http://www.st.nmfs.noaa.gov/commercial-fisheries/commercial-landings/annual-landings/index and "Fisheries of the United States (FUS)" http://www.st.nmfs.noaa.gov/commercial-fisheries/.

3.3.8 Comment: Commenters questioned whether it is EPA or the states who have responsibility for making risk management decisions with regard to risk level and FCR.

EPA Response: *States and tribes must establish scientifically sound criteria that protect designated uses. If EPA finds that water quality standards do not meet this requirement, then EPA may specify changes that would remedy the deficiency. Thus, the CWA and its implementing regulations make this a shared responsibility. Consistent with EPA's 2000 Methodology, states have the initial duty to choose an appropriate FCR and cancer risk level, taking into consideration EPA's 2000 Methodology and any other applicable requirements, but EPA is then charged with an oversight approval/disapproval of the resulting criteria, and, as mentioned above, EPA must disapprove such criteria if they are not protective of applicable designated uses and based on sound science.*

3.4 BIOACCUMULATION FACTORS

3.4.1 Comment: Commenters requested clarification about why EPA used bioaccumulation factors (BAFs) instead of bioconcentration factors (BCFs) to derive the updated AWQC. Several commenters requested that EPA include more discussion of the benefits and limitations of both BCFs and BAFs in the final AWQC.

EPA Response: *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).*

3.4.2 Comments: Some commenters suggested that measured bioaccumulation data should have preference over estimated or modeled data to derive BAFs. There were many comments on the appropriateness of using EPI Suite compared to other models, in particular given the underlying assumptions associated with EPI Suite (e.g., EPI Suite was developed using data from temperate waters). Several commenters noted that EPA did not follow the recommendations of EPA's Scientific Advisory Board (SAB) review of EPI Suite and the SAB comments on model verification. On the other hand, several commenters supported EPA's decision to use the EPI Suite model-derived BAFs instead of laboratory-derived BCFs.

EPA Response: *In light of the public comments, national BAFs used to update the criteria followed EPA's 2000 Methodology and its* Technical Support Document, Volume 2:

Development of National Bioaccumulation Factors *(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 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 are:

- ***BAF Method.*** *This method uses measured BAFs derived from data obtained from field studies. Field-measured BAFs are 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 the geometric mean of the normalized BAFs by species and trophic level; then EPA further averaged the BAFs across species to compute trophic-level baseline BAFs. The national-level BAF adjusts the trophic-level 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 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 trophic-level 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 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 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.

EPA provided model-estimated BAFs from the EPI Suite (USEPA 2012a) to allow for characterization of field-measured or predicted BAFs developed using the four methods described above. These EPI Suite-based BAFs are provided as an additional line of evidence only. The BCFBAF program within EPI Suite estimates fish bioaccumulation factors 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.

3.4.3 Comment: Some commenters suggested that EPA should cap the upper bound of a BAF at 500 or 1000 L/kg.

EPA Response: *EPA recommends following the approach described in EPA's 2000 Methodology and its* Technical Support Document, Volume 2: Development of National Bioaccumulation Factors *(USEPA 2003a). Capping the BAF at an arbitrary value would not reflect the true bioaccumulation potential of a particular chemical and could result in under-protective AWQC.*

3.4.4 Comment: A commenter requested clarification on whether EPA intends the same trophic level breakdown be used for subsistence fishers as for the general population.

EPA Response: *States and tribes may modify EPA's recommendations (including trophic level breakdown), as appropriate. EPA recommends that when choosing exposure factors for criteria development, states should consider values that are relevant to population(s) that is (are) most susceptible to that pollutant (USEPA 2000a).*

3.5 HUMAN HEALTH TOXICITY VALUES

3.5.1 Comment: Several commenters said that EPA's process for selecting among different toxicity values was not clear. A commenter suggested that EPA relied heavily on the results of California's toxicity assessments and outdated EPA guidance and noted that EPA should give preference to its most recent guidance and clearly document and justify the use of other sources of toxicity information.

EPA Response: *In light of the public comments, EPA has expanded the description of how toxicity values were selected to derive the final updated criteria in a manner that is clear and transparent. EPA conducted a systematic search of eight peer-reviewed, publicly available sources to obtain the toxicity value (reference dose or cancer slope factor) for use in developing the updated criteria. EPA's primary source of toxicity values for developing human health criteria is EPA's Integrated Risk Information System (IRIS) program. 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 2015b)*
- *EPA, Office of Pollution Prevention and Toxics (USEPA 2015c)*
- *EPA, Office of Water (USEPA 2015d)*
- *EPA, Office of Solid Waste and Emergency Response (USEPA 2015e)*
- *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.*[4]
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.*

3.5.2 Comment: A commenter suggested that EPA's use of adult exposure factors (i.e., lifetime exposure) for chemicals with toxicity values based on developmental effects results in AWQC that are not protective of children. A commenter suggested that EPA should be examining all of the chemicals included in the AWQC updates characterized as carcinogens for the Age-Dependent Adjustment Factor (ADAF) or chemical-specific Adjustment Factor.

EPA Response: *EPA derived the updated AWQC at a level intended to be adequately protective of a human population over a lifetime (USEPA 2000a). For this update, as in previous updates (in 2002 and 2003), exposure factors were chosen for the general adult population only.*

[4] 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.

3.5.3 Comment: Several commenters noted that the Cancer Slope Factor-based AWQC ("CSF") the numeric CSF used is an upper bound, approximating a very conservative 95 percent confidence level.

EPA Response: *EPA applied previously developed and externally peer-reviewed cancer slope factors in the update of the AWQC. The use of a* 95^{th} *percentile upper confidence bound is consistent with EPA risk assessment policy, which is provided in detail in the 2005* EPA Guidelines for Carcinogen Risk Assessment *(USEPA 2005a).*

3.5.4 Comment: Some commenters noted that EPA allows states to choose 10^{-5} or 10^{-6} risk range; EPA has said that both are acceptable. EPA should clarify this policy. One commenter expressed concern that allowing 10^{-4} risk for high consuming groups is inconsistent with environmental justice practices.

EPA Response: *For this update, EPA followed the 2000 Methodology and calculated its AWQC at a* 10^{-6} *(one in one million) cancer risk level. EPA recommends cancer risk levels of* 10^{-6} *or* 10^{-5} *(one in one hundred thousand) for the general population and notes that states and authorized tribes can choose a more stringent risk level, such as* 10^{-7} *(one in ten million), when deriving human health criteria. EPA's 2000 Methodology also states, "Criteria based on a* 10^{-5} *risk level are acceptable for the general population as long as states and authorized tribes ensure that the risk to more highly exposed subgroups (sport fishers or subsistence fishers) does not exceed the* 10^{-4} *level."*

3.5.5 Comment: A commenter noted that EPA states the RfD has uncertainty spanning an order of magnitude; however, some RfDs include an uncertainty factor (UF) up to 3000. A commenter noted that some uncertainty factors used in reference dose calculations appear to be rounded (e.g., $3 \times 3 \times 10 \times 10 = 1000$) and asked whether there is an EPA policy about this practice.

EPA Response: *The default UFs used by EPA typically cover a single order of magnitude (i.e.,* 10^1*). By convention, EPA uses a value of 3 in place of one-half power (i.e.,* $10^{0.5}$*) when appropriate (USEPA 2002c). These half-power values are factored as whole numbers when they occur singly but as powers or logs when they occur in tandem. For example, EPA expresses a composite uncertainty factor of 3 and 10 as 30 (*3×10^1*), whereas a composite uncertainty factor of 3 and 3 is expressed as 10 (*$10^{0.5} \times 10^{0.5} = 10^1$*) (USEPA 2002c).*

3.6 RELATIVE SOURCE CONTRIBUTION

3.6.1 Comment: Several commenters noted that the basis for EPA's use of the default relative source contribution (RSC) value of 20 percent for all criteria was not justified and/or was too conservative. Several commenters urged EPA to clarify terms and use the Decision Tree approach described in the 2000 Methodology, using data from available sources (e.g., Food and Drug Administration, National Marine Fisheries Service) to determine appropriate chemical-specific RSCs rather than using the default of 20 percent. Several commenters noted that an

RSC should not be used in cases where there is no reasonable anticipation of other significant exposures to that chemical.

EPA Response: *The 2000 Methodology describes the RSC component of the AWQC calculation. The RSC allows a percentage of the RfD 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, and poultry), dermal exposure, and respiratory exposure (USEPA 2000a).*

In response to public comments, EPA described how the RSC was derived for each chemical included in this 2015 update referencing the Exposure Decision Tree described in the 2000 Methodology (USEPA 2000a). To use the Exposure Decision Tree, 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 source 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 2015f).*
- *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 are:

- *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).

3.6.2 Comment: One commenter requested EPA provide a scientific explanation as to why RSCs are included for nonlinear carcinogens (e.g., chloroform) but not linear carcinogens.

EPA Response: *As stated in the 2000 Methodology, "In the case of substances for which the AWQC is set on the basis of a carcinogen based on a nonlinear low-dose extrapolation or for a noncancer endpoint where a threshold is assumed to exist, non-water exposures are considered when deriving the AWQC using the RSC approach. 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 does not exceed that threshold level" (USEPA 2000a).*

3.6.3 Comment: Commenters disagreed with EPA's assumption of a 20 percent default RSC for states that include anadromous fish in the FCR.

EPA Response: *RSCs may need to be modified for a variety of local, state, or regional issues, including depending on which fish species are included in the FCR (e.g., fish from inland, nearshore, and/or ocean waters).*

3.6.4 Comment: Commenters expressed that the "20 percent/80 percent" RSC approach, as a means of "harmonizing" SDWA and CWA, fails to recognize that MCLs may be adjusted to reflect available treatment and available analytical methods, yet CWA criteria must be enforced in the ambient water through permits and has potentially large economic consequences.

EPA Response: *EPA recognizes the differences in regulatory approaches between SDWA and CWA and notes that while the CWA and its implementing regulations do not allow for cost to be considered in adopting scientifically sound water quality criteria that protect applicable designated uses, the Act and regulations do include the means to address economic consequences through use attainability analyses, variances, compliance schedules, etc. EPA's primary consideration in establishing recommendations for protective criteria are to ensure human health protection consistent with designated uses that meet CWA goals, and this consideration leads to addressing other sources of exposure through use of RSC.*

4 CHEMICAL-SPECIFIC ISSUES

4.1 BIOACCUMULATION FACTORS

4.1.1 Comment: A commenter questioned EPA's use of the EPI Suite model to estimate a national BAF for anthracene in the proposed updated AWQC.

EPA Response: *EPA selected a national BAF value of 610 L/kg for anthracene for the final updated AWQC. 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). 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. This national BAF replaces EPA's previously recommended BCF of 30 L/kg.

4.1.2 Comment: Several commenters questioned EPA's use of the EPI Suite model to estimate a national BAF for bis(2-ethylhexyl) phthalate in the proposed updated AWQC.

EPA Response: *EPA selected a national BAF value of 710 L/kg for bis(2-ethylhexyl) phthalate for the final updated AWQC. 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). 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 2010a)*
- *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. This national BAF replaces EPA's previously recommended BCF of 130 L/kg.

4.1.3 Comment: A commenter suggested that EPA should use field or laboratory data instead of the EPI Suite model to develop the BAF for chloroform.

EPA Response: *EPA selected national BAF values of 2.8 L/kg (TL2), 3.4 L/kg (TL3), and 3.8 L/kg (TL4) for chloroform for the final updated AWQC. 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). 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

These national TL BAFs replace EPA's previously recommended BCF of 3.75 L/kg.

4.1.4 Comment: Commenters suggested that EPA should use field or laboratory data instead of the EPI Suite model to develop the BAF for benzo(a)pyrene.

EPA Response: *EPA selected a national BAF value of 3,900 L/kg for benzo(a)pyrene for the final updated AWQC. 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). 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 2010b)*
- *Moderate-high hydrophobicity (log K_{ow} ≥ 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 TL 2 and TL 3 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. This national BAF replaces EPA's previously recommended BCF of 30 L/kg.

4.1.5 Comment: A commenter noted that there is large disparity between the previously used BCF measured values for pentachlorophenol and the proposed EPI Suite estimated BAFs. Another commenter noted that the bioaccumulation of acidic compounds like pentachlorophenol is sensitive to changes in pH because of changes in chemical speciation, questioned the accuracy of EPI Suite estimates, and urged EPA to revise the national BAFs.

EPA Response: *EPA selected national BAF values of 44 L/kg (TL2), 290 L/kg (TL3), and 520 L/kg (TL4) for pentachlorophenol for the final updated AWQC. 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). 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 2010c)*
- *Biomagnification unlikely (ATSDR 2001a)*

EPA was able to locate peer-reviewed, lab-measured BCFs for trophic levels 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

These national trophic level BAFs replace EPA's previously recommended BCF of 11 L/kg.

4.1.6 Comment: Several commenters indicated EPA used an incorrect Kow (1.62) rather than 1.38 for vinyl chloride and did not take its high volatility into account. Commenters noted that vinyl chloride is a highly volatile organic compound that does not bioaccumulate or transfer through food chains, and therefore, it would be expected to be metabolized and eliminated rather than accumulate in tissues for human consumption.

EPA Response: *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). 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

These national TL BAFs replace EPA's previously recommended BCF of 1.17 L/kg.

4.2 HUMAN HEALTH TOXICITY VALUES

4.2.1 Comment: Some commenters noted that EPA should ensure that it uses the best available science for specific chemicals (e.g., chloroform, 1,2-dichloroethane, toluene, vinyl chloride) and criticized EPA's reliance on IRIS values that are more than a decade old.

EPA Response: *EPA followed the systematic selection process described above (see response to comment 3.5.1). Relevant toxicity values for the chemicals mentioned in this comment are summarized below (full text is available in the 94 final AWQC documents):*

Chloroform: 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 2001). EPA identified two other RfD sources based on the systematic search: a 2006 EPA Office of Water (OW) assessment (USEPA 2006) and a 1997 ATSDR assessment (ATSDR 1997). Based on the selection process, 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.

1,2-Dichloroethane: 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). EPA identified two other RfD sources through the systematic search: a 1999 California EPA assessment (CalEPA 1999a) and a 2001 ATSDR assessment (ATSDR 2001b). Based on the selection process, 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, 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 2012b).

EPA selected a CSF of 3.3×10^{-3} per mg/kg-d[5] (0.0033 per mg/kg-d) for 1,2-dichloroethane based on a 2015 Health Canada assessment (HC 2015b). EPA identified two other CSF sources through the systematic search described in section 5: a 1986 EPA IRIS assessment (USEPA 1986) and a 1999 California EPA assessment (CalEPA 1999a). Based on the selection process, 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 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 2005a).

[5] 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).

<u>Toluene</u>: EPA selected an RfD of 9.7 × 10^{-3} mg/kg-d (0.0097 mg/kg-d) for toluene based on a 2015 Health Canada assessment (HC 2015c). EPA identified three other RfD sources for toluene: a 2005 EPA IRIS assessment (USEPA 2005b), a 2000 ATSDR assessment (ATSDR 2000), and a 1999 California EPA assessment (CalEPA 1999b). Based on the selection process, 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 than the IRIS assessment.

<u>Vinyl Chloride</u>: 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). 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. EPA identified two other RfD sources through the systematic search: a 2006 ATSDR assessment (ATSDR 2006) and a 2000 CalEPA assessment (CalEPA 2000). Based on the selection process, 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 to derive an RfD.

EPA selected a CSF of 1.5 per mg/kg-d for vinyl chloride based on a 2000 EPA IRIS assessment (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). The CalEPA assessment is an inhalation assessment and does not include an oral CSF. Based on the selection process, the EPA IRIS CSF is preferred for use in AWQC development at this time.

4.2.2 Comment: A commenter noted the 2000 IRIS assessment for benzene does not follow EPA's 2005 *Guidelines for Carcinogen Risk Assessment* (USEPA 2005a), specifically that there is no generally applicable method for accounting for uptake differences in a quantitative route-to-route extrapolation of dose-response data in absence of good data on the agent of interest.

EPA Response: *EPA selected a CSF range of 1.5 × 10^{-2} per mg/kg-d (0.015 per mg/kg-d) to 5.5 × 10^{-2} per mg/kg-day (0.055 per mg/kg-day) for benzene based on a 2000 EPA IRIS assessment (USEPA 2000e). EPA's IRIS program derived the CSF using principal studies by Rinsky et al. (1981; 1987), Paustenbach et al. (1993), Crump (1994), and USEPA (1998a; 1999) based on the development of leukemia in humans with occupational inhalation exposure to benzene (USEPA 2000e).*

EPA identified one other CSF source through the systematic search described in section 3.5 of this document: a 2001 California EPA assessment (CalEPA 2001). Based on that selection process, the 2000 EPA IRIS CSF is preferred for use in AWQC development at this time. The CalEPA CSF is based on studies that IRIS considered in their assessment but did not use quantitatively (Paxton et al. 1994; Hayes et al. 1997). EPA will consider new toxicological assessments on benzene for AWQC development as they become available.

4.2.3 Comment: One commenter noted that the proposed draft update AWQC document for chlorophenoxy herbicide (2,4-D) (USEPA 2014c) incorrectly cites a reference to USEPA (2005c) on page 7. The commenter notes that the 2005 document refers to an RfD of 0.005 mg/kg-day whereas the USEPA (2012c) document provides the oral RfD of 0.05 mg/kg-day that is used as the basis for the draft updated criterion value.

EPA Response: *EPA has corrected the reference in the final updated 2015 AWQC.*

4.2.4 Comment: Several commenters had questions about the critical study and uncertainty factors used for cyanide. One commenter requested that EPA address method issues with the 40 CFR Part 136 analytical method for cyanide at levels of 3 to 5 µg/L. The commenter also noted that the new proposed EPA criterion is lower than the existing section 304(a) criterion for protection of aquatic life (5 µg/L). Another commenter noted that the analytical method that should be used for determining compliance with any cyanide standard should be measuring free and not total cyanide because the toxicological assessment is based on free cyanide; the commenter requested that EPA update the AWQC to be based on free cyanide instead of total cyanide.

EPA Response: *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 2010b).*

Consistent with EPA's previously published criteria for cyanide (USEPA 2003b), the final updated 2015 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), EPA's recommended criteria may be overly conservative (USEPA 2003b).

4.2.5 Comment: A commenter noted that EPA's decision to use the cancer slope factor derived from a mixture of 2,4-dinitrotoluene (2,4-DNT) and 2,6-DNT for 2,4-DNT does not incorporate updates to body weight and drinking water intake values, uses outdated methods to derive human equivalent doses, and relies on a principle study that utilized a mixture of isomers of DNT despite 20 years of data indicating that only 2,6-DNT is carcinogenic.

EPA Response: *EPA selected a CSF of 6.67 × 10^{-1} per mg/kg-d (0.667 per mg/kg-d) for the final AWQC 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 for 2,4-dinitrotolulene through the systematic search described in section 3.5 of this document: a 1989 EPA IRIS assessment (USEPA 1989). Based on that selection process, 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.

4.2.6 Comment: One commenter requested that EPA assess precursors to toxic disinfection byproducts (DBPs) when setting AWQC, especially where downstream impacts could occur. They also note that EPA should look at the cumulative impact of DBPs, in particular to children and other sensitive populations.

EPA Response: *EPA added the following statement in the problem formulation section of the final criteria documents for each of the four trihalomethanes (THM) – chloroform, bromoform, chlorodibromomethane, and dichlorobromomethane – that were regulated in EPA's Stage 1 and Stage 2 Disinfection Byproduct (DBP) Rule (USEPA 1998b; 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."*

EPA does not have adequate data to evaluate precursors to DBPs at this time. EPA agrees that DBPs create an environmental challenge, and CWA programs are working with SDWA programs to develop complimentary approaches to reduce the impacts associated with DBPs, especially to sensitive lifestages.

4.2.7 Comment: A commenter requested that EPA identify whether hexachlorocyclohexane (HCH) technical (CAS #608-73-1) is a priority pollutant or a non-priority pollutant.

EPA Response: *Hexachlorocyclohexane (HCH) technical (CAS #608-73-1) is not a priority pollutant. However, four of its isomers are on the priority pollutant list: alpha-HCH (CAS #319-84-6), beta-HCH (CAS #319-85-7), gamma-HCH (CAS #58-89-9), and delta-HCH (CAS #319-86-8).*

4.2.8 Comment: One commenter noted that the updated criteria do not currently include N-nitrosodimethylamine (NDMA).

EPA Response: *EPA elected not to update the AWQC for NDMA at this time due to the EPA's ongoing evaluation of nitrosamines for the SDWA Six Year Review (see 79 FR 62715) (USEPA 2014d).*

4.2.9 Comment: One commenter questioned EPA's use of the state of California's Office of Environmental Health Hazard Assessment (OEHHA) cancer potency factor for benzo(a)pyrene.

EPA Response: *EPA did not use the OEHHA CSF to derive the final updated AWQC for benzo(a)pyrene. Due to EPA's ongoing IRIS reassessment of benzo(a)pyrene, EPA used the current IRIS CSF to derive AWQC at this time. EPA selected a CSF of 7.3 per mg/kg-d for benzo(a)pyrene based on a 1991 EPA IRIS assessment (USEPA 1991).*

4.2.10 Comment: One commenter noted that an uncertainty factor of 10,000 was used in the proposed AWQC for pentachlorobenzene.

EPA Response: *EPA selected an RfD of 8×10^{-4} mg/kg-d (0.0008 mg/kg-d) for pentachlorobenzene based on a 1985 EPA IRIS assessment (USEPA 1985). In deriving the RfD, EPA's IRIS program applied a composite uncertainty factor of 10,000 (USEPA 2002c) to account for interspecies extrapolation (10), intraspecies variation (10), subchronic-to-chronic study extrapolation (10), and extrapolation of the NOAEL from the LOAEL (10) (USEPA 1985). EPA identified no other RfD sources for pentachlorobenzene.*

4.2.11 Comment: One commenter noted that there are a few EPA-funded studies which found reasonable correlations between various polycyclic aromatic hydrocarbons (PAHs) in the natural environment and urged the use of surrogates for some of the measurements.

EPA Response: *EPA used benzo(a)pyrene as a surrogate (index chemical) for toxicity values used in the final AWQC derivations for six other PAHs: benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, chrysene, dibenzo(a,h)anthracene, indeno(1,2,3-cd)pyrene.*

4.3 RELATIVE SOURCE CONTRIBUTION

4.3.1 Comment: Several commenters noted that Oregon (2011) recently developed an RSC of 80 percent for endrin using EPA's 2000 Methodology (USEPA 2000a) that had been approved by EPA Region 10. The commenters noted that Oregon had cited the U.S. Department of Health and Human Services' Toxicological Profile for endrin, which concludes that there is no significant source of human exposure to endrin other than water and fish consumption.

EPA Response: *EPA recommends an RSC of 80 percent (0.80) for endrin in its final updated AWQC. 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" (USEPA 2000a, section 4.2.3).*

5 IMPLEMENTATION

5.1 STATE FLEXIBILITY

5.1.1 Comment: Commenters requested clarification from EPA on whether states would be expected to adopt AWQC for those substances contained in EPA's proposal for which they do not currently have AWQC.

EPA Response: *Section 303(a)-(c) of the CWA requires states and authorized tribes to adopt water quality standards for their waters. As part of the water quality standards triennial review process set forth in section 303(c) of the CWA, states and authorized tribes are required to review and revise, as appropriate, their water quality standards at least once every three years.*

States and authorized tribes must adopt water quality criteria that protect designated uses. 40 CFR 131.11(a)(1). Criteria must be based on a sound scientific rationale and contain sufficient parameters or constituents to protect the designated uses. Id. Criteria may be expressed in either narrative or numeric form. EPA's regulations provide that states and authorized tribes should adopt numeric water quality criteria based on:

(1) EPA's recommended section 304(a) criteria; or
(2) EPA's recommended section 304(a) criteria modified to reflect site-specific conditions; or
(3) Other scientifically defensible methods. (40 CFR 131.11(b)).

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 criteria reflect sound science and protect applicable designated uses. EPA recently proposed revisions to its water quality standards regulations that would, if finalized without substantive change, require states during their triennial reviews to consider new or updated section 304(a) recommended criteria and, if they do not adopt new or revised criteria for such pollutants, provide an explanation to EPA and the public as to why the state did not do so. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

5.1.2 Comment: Several commenters noted that the AWQC and associated documents should more clearly reflect the states' options in adopting state water quality standards and more clearly define the respective federal and state roles. Additionally, although the 2000 Methodology (USEPA 2000a) is clear in its intent to provide states with flexibility in adjusting levels in accordance to local or regional data, the guidance does not include specific guidelines regarding type, amount, and quality of additional data required to adjust AWQC.

EPA Response: *As stated above, states may adopt the AWQC that EPA publishes, modify EPA's AWQC to reflect site-specific conditions, or adopt different AWQC based on other scientifically defensible methods. EPA must, however, approve any new water quality standards adopted by a state before they can be used for CWA purposes. Water quality criteria developed by EPA 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. However, there are a number of implementation approaches available for state consideration, including variances, revisions to designated uses, and compliance schedules.*

Variances

A discharger may be interested in a variance where 1) the permitting authority has determined that there is reasonable potential for the discharger to cause or contribute to an excursion above a newly adopted criterion and 2) the state and discharger can show, based on §131.10(g), that the designated use and criteria for the particular waterbody or segment are unattainable immediately or within a limited period of time because the discharger cannot meet its new Water Quality-Based Effluent Limits (WQBELs). In such a case, the state may adopt a discharger-specific variance as long as the variance is consistent with the CWA and implementing regulations.

Revision to Designated Uses

The water quality standards (WQS) regulation at 40 CFR §131.10(g) provides that "[s]tates may remove a designated use… or establish sub-categories of a use if the [s]tate can demonstrate that attaining the designated use is not feasible…" because of at least one of the six factors specified at §131.10(g)(1)-(6):

(1) Naturally occurring pollutant concentrations prevent the attainment of the use; or
(2) Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the use, unless these conditions may be compensated for by the discharge of sufficient volume of effluent without violating state water conservation requirements to enable uses to be met; or
(3) Human caused conditions or sources of pollution prevent the attainment of the use and cannot be remedied or would cause more environmental damage to correct than to leave in place; or
(4) Dams, diversions or other types of hydrologic modifications preclude the attainment of the use, and it is not feasible to restore the water body to its original condition or to operate such modification in a way that would result in the attainment of the use; or
(5) Physical conditions related to the natural features of the water body, such as the lack of a proper substrate, cover, flow, depth, pools, riffles, and the like, unrelated to water quality, preclude attainment of aquatic life protection uses; or
(6) Controls more stringent than those required by sections 301(b) and 306 of the Act would result in substantial and widespread economic and social impact.

<u>Compliance Schedules</u>
EPA's regulations at 40 CFR 122.47 govern the use of schedules of compliance in NPDES permits. A schedule of compliance means a schedule of remedial measures in a permit, including an enforceable sequence of interim actions or milestones leading to compliance with the CWA and its regulations. 40 CFR 122.2. Section 122.47 provides that, "when appropriate," a permit may include a schedule of compliance with a permit's WQBEL, provided that schedule requires compliance "as soon as possible." Schedules of compliance are often used when the discharger requires time to install treatment technology or implement other controls necessary to meet a new or revised WQBEL.

5.2 IMPAIRED WATER BODIES

5.2.1 Comment: A commenter noted that the AWQC will become regulatory limits once they are adopted by state as water quality standards and many, if not most, surface water bodies will fail to meet all of the AWQC. Another commenter noted that use of the new AWQC will result in many new impaired waters, many new TMDLs, many new stringent permit limits, and result in high compliance costs for regulated facilities, with little or no public health benefit.

EPA Response*: Water quality criteria developed by EPA 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. There are many existing tools in water quality standards to help states adjust water quality standards in cases of economic hardship, or to give dischargers appropriate time to comply with more stringent limits. EPA is not aware of any evidence supporting the assertion of widespread additional listings of impaired waters. Ambient monitoring data from the past 10 years indicate an overall 94 percent non-detection rate nationwide for the pollutants with updated AWQC, and only a few pollutants with measurements that exceed the updated recommended criteria compared to previous recommendations, many of which are likely from the same waters.*

5.3 ECONOMIC IMPACTS

5.3.1 Comment: Commenters noted that given the potential economic cost of implementing these AWQC, EPA should promulgate this action as a rulemaking and EPA should analyze the feasibility of implementing the AWQC and ensuring that it does not cause unnecessary burden to State, local and tribal governments.

EPA Response: *AWQC are scientific recommendations to states and tribes authorized to establish water quality standards under the CWA, regarding ambient concentrations of pollutants that protect human health. Under the CWA, states and authorized tribes must establish water quality criteria to protect designated uses. State and tribal decision makers retain the discretion to adopt criteria on a case-by-case basis that differ from this guidance* *provided that the criteria are scientifically defensible and protective of the applicable use(s). EPA's AWQC are not regulations, and thus, do not impose legally binding requirements on EPA, states, tribes, or the regulated community. Moreover, water quality criteria developed by EPA 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.*

5.3.2 Comment: A commenter indicated that the updated criteria include many that did not previously have criteria and asks if EPA will be updating their priority pollutant list and permit requirements to require monitoring.

EPA Response: *All 94 of the AWQC included in this update are pollutants that previously had AWQC; no new AWQC were developed. EPA has no plans to update the list of priority pollutants. The permitting authority, which is the state in most cases, determines monitoring requirements in permits on a case-by-case basis.*

5.3.3 Comment: EPA should address analytical issues of measuring chemicals accurately in ambient waters. For example, commenters noted that EPA's proposed AWQC value for bis (2-ethylhexyl) phthalate is approximately two orders of magnitude lower than the current standard identified in the California Toxics Rule (CTR) and permitting programs will have difficulties accurately measuring this compound.

EPA Response: *Where there is reasonable potential for a proposed discharge to cause or contribute to an exceedance of water quality standards, National Pollutant Discharge Elimination System (NPDES) permit limits must derive from and ensure compliance with all applicable water quality criteria in state water quality standards. If a permit limit derived from the water quality criteria is below the analytical Minimum Level (ML) (i.e., the level at which the pollutant can be accurately quantified by an analytical method), then the limit as calculated must be included in the NPDES permit, and additional permit language would be included prescribing how monitoring data should be reported and how compliance would be assessed. Typically, this additional permit language would indicate that sample analysis must be conducted using the most sensitive of the EPA approved methods, and that results below the ML would demonstrate compliance with the effluent limit. While not common, permitting authorities do periodically encounter this situation and have developed standard procedures and permit language to address limits established below analytical MLs.*

5.3.4 Comment: Several commenters asked EPA to be explicit about the exposure duration of the AWQC. A commenter suggested that EPA should clearly identify those pollutants and AWQC for which long-term exposure is the basis for the AWQC derivation and long-term average application of the AWQC is appropriate. EPA should identify an appropriate averaging period, given the assumptions associated with long-term exposure.

EPA Response: *EPA's current guidance that addresses averaging period for purposes of deriving wasteload allocations for human health criteria can be accessed on EPA's website: http://water.epa.gov/scitech/datait/models/upload/2002_10_25_npdes_pubs_owm0264.pdf.*

6 MISCELLANEOUS

6.1 Comment: A commenter suggested that for each AWQC document, EPA should perform the following:

- Update the reference to the EPA "Framework for Human Health Risk Assessment to Inform Decision Making" and corresponding citation in the "Problem Formulation" section, so that the date is 2014.
- Include a website link to the reference for the USEPA 2014 Estimated Fish Consumption Rates for U.S. Population and Selected Subpopulations (NHANES 2003-2010) (i.e., http://water.epa.gov/scitech/swguidance/fishshellfish/fishadvisories/technical.cfm.
- Conduct a thorough technical edit of all documents to ensure that the correct chemicals are matched with their chemical specific information.

EPA Response: *EPA has updated the reference for the EPA Framework (USEPA 2014a) and added the website link for the USEPA 2014 report* Estimated Fish Consumption Rates for U.S. Population and Selected Subpopulations (NHANES 2003-2010) *in the final AWQC documents. EPA has made every effort to ensure that the final documents are technically accurate, clear, and transparent.*

6.2 Comment: A commenter requested clarification regarding whether EPA will update the methods and parameters used to derive AWQC as defined in Water Quality Guidance for the Great Lakes System (40 CFR 132) to reflect the proposed changes to the AWQC.

EPA Response: *EPA has no plans to revise the Water Quality Guidance for the Great Lakes System (40 CFR 132) at this time.*

7 REFERENCES

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