



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 10

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MAY 10 2019

OFFICE OF THE REGIONAL  
ADMINISTRATOR

Ms. Maia Bellon, Director  
Department of Ecology  
P.O. Box 47600  
Olympia, Washington 98504-7600

Re: The EPA's Reversal of the November 15, 2016 Clean Water Act Section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria and Decision to Approve Washington's Criteria

Dear Ms. Bellon:

On November 15, 2016, the EPA partially approved and partially disapproved certain human health criteria (HHC) that the Washington Department of Ecology (Ecology) submitted to the Agency for review on August 1, 2016.<sup>1</sup> In response to a February 21, 2017, petition from several entities,<sup>2</sup> the EPA has reconsidered its partial disapproval. For the reasons herein, the EPA is approving certain HHC under the Clean Water Act (CWA) section 303(c) that the Agency previously disapproved. Upon reexamination, the EPA concludes that Ecology's HHC are protective of its designated uses and based on sound science.

The EPA initially promulgated HHC for toxic pollutants applicable to waters in the state of Washington in the 1992 National Toxics Rule (NTR).<sup>3</sup> Ecology's August 1, 2016, submittal contained 192 new HHC for 97 priority pollutants that are applicable to all surface waters of the State. Ecology's HHC are located in the Water Quality Standards for Surface Waters of the state of Washington (Chapter 173-201A-240 WAC).

On November 15, 2016, of the 192 new HHC proposed by Ecology, the EPA approved 45 HHC, disapproved 143 HHC, and deferred action on four HHC in Table 240 of Ecology's standards. Under the EPA's inherent authority to reconsider its prior decisions and in accordance with CWA section 303(c)

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<sup>1</sup> November 15, 2016. Letter (EPA Partial Disapproval Letter) and enclosed Technical Support Document (Partial Disapproval TSD) from Daniel D. Opalski, Director, Office of Water and Watersheds, EPA Region 10 to Maia Bellon, Director, Department of Ecology, Re: EPA's Partial Approval/Disapproval of Washington's Human Health Water Quality Criteria and Implementation Tools.

<sup>2</sup> February 21, 2017. Petition for Reconsideration of EPA's Partial Disapproval of Washington's August 1, 2016 submission on Human Health Water Quality Criteria and Implementation Tools, and Repeal of the Final Rule Revision of Certain Federal Water Quality Standards Applicable to Washington, 81 Fed. Reg 85,417 (Nov. 28, 2016), submitted by Northwest Pulp & Paper Association, American Forest and Paper Association, Association of Washington Business, Greater Spokane Incorporated, Treated Wood Council, Western Wood Preservers Institute, Utility Water Act Group, and Washington Farm Bureau.

<sup>3</sup> EPA. 1992. *Toxics Criteria for Those States Not Complying with Clean Water Act*, section 303(c)(2)(B). 40 CFR Part 131.36. <http://water.epa.gov/lawsregs/rulesregs/ntr/>. Amended in 1999 for PCBs. <http://water.epa.gov/lawsregs/rulesregs/ntrfact.cfm>.

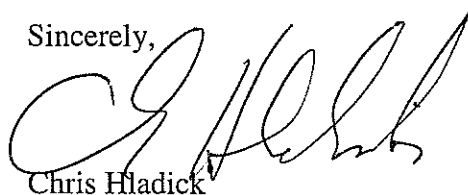
and the implementing regulations at 40 CFR Part 131, the EPA is reversing its disapproval of 141 of Ecology's HHC, including the HHC for polychlorinated biphenyls (PCBs), and instead approving the 141 previously disapproved HHC. In addition, the EPA is reaffirming its November 2016 disapproval of the two HHC associated with arsenic. Lastly, the EPA is approving four criteria for two pollutants (thallium and 2,3,7,8-TCDD (dioxin)) that the EPA previously deferred action on in November 2016.

A summary of the EPA's action is further described in the enclosed *Technical Support Document, The EPA's Reversal of the November 15, 2016 Clean Water Act Section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria and Decision to Approve Washington's Criteria*. The EPA's action applies only to water bodies in the state of Washington and does not apply to waters that are within Indian Country, as defined in 18 U.S.C. § 1151.

In light of this decision, the EPA intends to initiate a notice and comment process through a separate notice of proposed rulemaking to withdraw the related federally promulgated HHC. Pursuant to 40 CFR 131.21(c), the HHC approved in this action will not be in effect for CWA purposes until the corresponding federally promulgated HHC are withdrawn.

The EPA appreciates Ecology's efforts to update its HHC. If you have any questions or concerns, please contact me or Dan Opalski at (206) 553-1855 or opalski.dan@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Hladick", written over a white background.

Chris Hladick  
Regional Administrator

Enclosure

cc: Ms. Heather Bartlett, WA Department of Ecology

# Technical Support Document

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The EPA's Reversal of the November 15, 2016  
Clean Water Act Section 303(c) Partial  
Disapproval of Washington's Human Health  
Water Quality Criteria  
Submitted on August 1, 2016 and Decision to  
Approve Washington's Criteria

May 10, 2019

# Technical Support Document

## The EPA’s Reversal of the November 15, 2016 Clean Water Act Section 303(c) Partial Disapproval of Washington’s Human Health Water Quality Criteria Submitted on August 1, 2016 and Decision to Approve Washington’s Criteria

### Table of Contents

<b>I. Introduction</b> .....	3
<b>II. Background</b> .....	3
<i>A. The Clean Water Act and State Water Quality Standards</i> .....	4
<i>B. How Human Health Criteria are Developed</i> .....	5
<i>C. History of Human Health Criteria in Washington</i> .....	6
<b>III. Washington’s 2016 Submittal of Human Health Criteria and the EPA’s Action</b> .....	7
<i>A. Washington’s Designated Uses Related to Protection of Human Health</i> .....	9
<i>B. Cancer Risk Level</i> .....	10
<i>C. Cancer Slope Factor and Reference Dose</i> .....	10
<i>D. Fish Consumption Rate</i> .....	11
<i>E. Bioconcentration Factors (BCFs)/Bioaccumulation Factors (BAFs)</i> .....	12
<i>F. Relative Source Contributions (RSCs)</i> .....	15
<i>G. Drinking Water Intake</i> .....	18
<i>H. Body Weight</i> .....	18
<i>I. Polychlorinated Biphenyls (PCBs)</i> .....	19
<i>J. Arsenic</i> .....	20
<i>K. Thallium and 2,3,7,8-TCDD (Dioxin)</i> .....	20
<b>IV. Tribal Treaty Rights and Washington’s FCR and Cancer Risk Level</b> .....	21
<b>V. The EPA’s Reversal of the November 15, 2016 Clean Water Act Section 303(c) Partial Disapproval of Washington’s Human Health Water Quality Criteria and Approval of Those Criteria</b> .....	24

## **I. Introduction**

Upon reconsideration, the EPA is reversing the majority of its November 2016 partial disapproval and approving certain human health criteria (HHC) previously submitted to the EPA by the state of Washington. As discussed below, EPA has now concluded that Washington's HHC are both protective of its designated uses and based on sound science.

## **II. Background**

Starting in 2010, the Washington Department of Ecology (Ecology) engaged in extensive public outreach, held numerous meetings with stakeholders, and worked collaboratively with the EPA and tribes to develop and promulgate HHC.<sup>1</sup> On August 1, 2016, Ecology submitted a package of state-promulgated HHC (found at WAC 173-201A-240) to the EPA for review and action pursuant to the EPA's authority under Clean Water Act (CWA) section 303(c). On November 15, 2016, the EPA disapproved 143 of the 192 HHC submitted by Ecology. The EPA's disapprovals were based on: 1) a comparison between Ecology's criteria and criteria that the EPA calculated at the time using the EPA's national recommended HHC and Ecology's fish consumption rate; and 2) a finding that Ecology had not adequately described its rationale for departing from the EPA's national recommendations. In accordance with CWA section 303(c) requirements, concurrent with its partial disapproval of Ecology's submittal, the EPA finalized a federal rule for the 143 HHC that it disapproved, which became effective December 28, 2016.<sup>2</sup>

On February 21, 2017, several groups filed a petition requesting that the EPA reconsider its disapproval action on Washington's HHC and repeal or withdraw the federal rule. Between February and July 2017, three other entities sent the EPA letters requesting that the EPA deny the petition.<sup>3</sup> On August 3, 2018, the EPA provided notice of its intent to reconsider its action in response to the petition.<sup>4</sup> On August 7, 2018, Ecology sent a letter to the EPA opposing reconsideration and indicating the State agency's preference to focus on implementing the federal rule.<sup>5</sup> The EPA recently received correspondence from Ecology,<sup>6</sup> the Attorney General of

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<sup>1</sup> EPA Partial Disapproval Letter at 1.

<sup>2</sup> *Revision of Certain Water Quality Standards Applicable to Washington*, 81 FR 85417 (November 28, 2016)

<sup>3</sup> Earthjustice (on behalf of Waterkeepers Washington), Northwest Indian Fisheries Commission, and the Jamestown S'Klallam Tribe.

<sup>4</sup> August 3, 2018. Letter from David P. Ross, Assistant Administrator, Office of Water, EPA to Ms. Penny Shamblin, Counsel for Utility Water Act Group, Re: Petition for Reconsideration of the EPA's Partial Disapproval of Washington's Human Health Water Quality Criteria and Implementation Tools submitted by the state of Washington on August 1, 2016.

<sup>5</sup> August 7, 2018. Letter from Maia D. Bellon, Director, Washington Department of Ecology, to Mr. David Ross, Assistant Administrator, Office of Water, EPA, Re: The Petition to reconsider Washington's Human Health Water Quality Criteria and Implementation Tools.

<sup>6</sup> May 7, 2019. Letter from Maia D. Bellon, Director, Washington Department of Ecology, to Hon. Andrew R. Wheeler, Administrator, EPA, Re: EPA's Intention to Reconsider Washington State's Water Quality Standards for Human Health Criteria.

the state of Washington,<sup>7</sup> the Northwest Indian Fisheries Commission,<sup>8</sup> and the Lower Elwha Klallam Tribe.<sup>9</sup> These letters focus on concerns relating to revising or repealing the federal water quality standards that the EPA promulgated for Washington and the EPA's authority under the CWA to propose new standards for a state. The EPA's action today is a reversal of the Agency's 2016 partial disapproval of Washington's HHC and a decision to approve those standards. The Agency is not revising or repealing the federal standards. The EPA will consider these issues during the rulemaking process that will follow this approval action. In addition, the letters raise concerns about EPA's authority to act at this time on the HHC submitted by Washington in 2016. EPA disagrees with these concerns. EPA has inherent authority to reconsider its prior adjudications and is doing so for the reasons explained below.<sup>10</sup>

Although Ecology has stated a preference for implementing the federal HHC rule rather than its own promulgated rule, today's decision restores Ecology's role as primary authority for adopting water quality standards in Washington, consistent with the CWA. The State remains free to promulgate the federal standards into state law if it so chooses; however, the EPA intends to publish a notice of proposed rulemaking to withdraw the federal standards because the EPA has determined that the state-promulgated HHC are protective of Washington's designated uses and based on sound science. Upon the EPA's final withdrawal of the federal standards there will be no requirement for the State to implement those standards.

#### *A. The Clean Water Act and State Water Quality Standards*

The CWA approaches restoration and protection of the Nation's waters as a partnership between states and the federal government, assigning certain functions to each in striking the balance of the statute's overall regulatory scheme. Pursuant to this cooperative federalism balance, Congress expressly recognized the role that states would continue to exercise in preventing, reducing, and eliminating pollution: "It is the policy of Congress to recognize, preserve, and protect the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution, to plan the development and use (including restoration, reservation, and enhancement) of land and water resources[.]"<sup>11</sup> As the Supreme Court has explained, the statute "anticipates a partnership between the States and the Federal Government," toward a shared objective of restoring and maintaining the integrity of the Nation's waters.<sup>12</sup>

The CWA assigns to states and authorized tribes the primary authority for adopting water quality standards.<sup>13</sup> After states adopt water quality standards, they must be submitted to the EPA for review and action in accordance with the CWA. State water quality standards must protect

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<sup>7</sup> May 8, 2019. Letter from Bob Ferguson, Attorney General, Washington, to Hon. Andrew R. Wheeler, Administrator, EPA.

<sup>8</sup> May 3, 2019. Letter from Justin Parker, Executive Director, Northwest Indian Fisheries Commission, to Hon. Andrew R. Wheeler, Administrator, and Mr. David Ross, Assistant Administrator, Office of Water, EPA, Re: EPA Action Regarding Washington's Human Health Water Quality Criteria.

<sup>9</sup> May 7, 2019. Letter from Frances G. Charles, Chairwoman, to Hon. Andrew R. Wheeler, Administrator, EPA, Re: Washington State Water Quality Standards (Human Health Criteria)

<sup>10</sup> See *infra* Footnote 31.

<sup>11</sup> 33 U.S.C. § 1251(b).

<sup>12</sup> *Arkansas v. Oklahoma*, 503 U.S. 91, 101 (1992).

<sup>13</sup> 33 U.S.C. 1313(a), (c)

designated uses, be based on sound scientific rationale and contain sufficient parameters or constituents to protect the designated use.<sup>14</sup> State submittals to the EPA must include use designations, standards sufficient to protect the designated uses, methods used and analyses conducted to support the standards, an antidegradation policy, certification by the state's Attorney General or other appropriate authority that the standards were duly adopted pursuant to state law, and general information to aid the EPA in determining the adequacy of the scientific basis of the standards.<sup>15</sup>

section 304(a) of the CWA requires the EPA to develop recommended water quality criteria that states and tribes may use to develop their own water quality standards, including HHC. These 304(a) recommendations are developed by the EPA and updated periodically to reflect the most recent scientific knowledge.<sup>16</sup> Although the EPA's 304(a) recommendations reflect the most recent science, they do not represent the only scientifically defensible method for deriving water quality standards that are protective of designated uses. Indeed, states are not required to adopt the EPA's 304(a) recommended criteria, rather states are encouraged to adopt their own numeric water quality standards based on EPA's 304(a) recommended criteria, 304(a) recommended criteria that are modified to reflect site-specific conditions, or other scientifically defensible methods.<sup>17</sup>

Importantly, in developing 304(a) recommendations, the EPA is required to include "the latest scientific knowledge." By contrast, states are required to adopt HHC that are based on "sound scientific rationale" and "scientifically defensible methods."<sup>18</sup> In other words, states are not required to adopt wholesale the national 304(a) recommendations. Rather, states can take into account the latest scientific information that is part of those recommended criteria as they develop their scientifically defensible state-specific standards, based on risk- and resource-management decisions, so long as the resulting HHC are protective of designated uses and scientifically defensible.

The EPA's role is to review the standards for consistency with the CWA and either approve the standards within 60 days of receipt, or disapprove within 90 days.<sup>19</sup> If the EPA disapproves a state's water quality standards (including HHC) and the state does not remedy the disapproval within 90 days, the EPA is required to promptly propose and promulgate 90 days after proposal a federal water quality standard for the state.<sup>20</sup>

#### *B. How Human Health Criteria are Developed*

The EPA follows its 2000 Human Health Methodology when deriving its national recommended water quality standards, including HHC, under CWA section 304(a).<sup>21</sup> HHC are based on two

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<sup>14</sup> 40 CFR 131.5(a)(2), 131.11(a)

<sup>15</sup> 40 CFR 131.6(a)-(f)

<sup>16</sup> 33 U.S.C. § 1314(a)(1)

<sup>17</sup> 40 CFR 131.11(b)

<sup>18</sup> 40 CFR 131.11(a)(1) and (b)(1)(iii)

<sup>19</sup> 33 USC 1313(c)(2)(A), 40 CFR 131.5(a)

<sup>20</sup> 33 USC 1313(c)(4)

<sup>21</sup> USEPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004.

types of biological endpoints: (1) carcinogenicity and (2) systemic toxicity (i.e., all adverse effects other than cancer). HHC for carcinogenic effects are calculated using an equation with the following input parameters: cancer slope factor (CSF), cancer risk level, body weight, drinking water intake rate, fish consumption rate (FCR), and bioaccumulation factors (BAFs). HHC for non-carcinogenic and nonlinear carcinogenic effects are calculated using a reference dose (RfD) in place of a CSF and cancer risk level, and a relative source contribution (RSC) factor, which is intended to ensure that an individual's total exposure to a given pollutant from all sources does not exceed the RfD. Each of these inputs is discussed in more detail in the EPA's 2000 Human Health Methodology.<sup>22</sup>

In June 2015, the EPA finalized updates to the Agency's national 304(a) HHC recommendations for 94 chemical pollutants.<sup>23</sup> These updated recommendations reflect the latest scientific knowledge and include recommendations regarding body weight, drinking water consumption rate, FCR, BAFs, toxicity values, and RSC values that can be used to calculate HHC. The EPA accepted public comments on the updated 304(a) criteria from May to August 2014 and published responses to those comments when it finalized the criteria recommendations in June 2015.

### *C. History of Human Health Criteria in Washington*

Starting in 2010, the EPA worked with Washington to update the State's HHC. At that time, the only HHC in effect in Washington were from the National Toxics Rule (NTR), promulgated by the EPA in 1992.<sup>24</sup> Ecology first proposed new HHC in January 2015. These HHC were based on a cancer risk level of  $10^{-5}$ , a FCR of 175 grams/day, and a mandate that none of the State's HHC, except for arsenic, would be a higher concentration than the NTR that was in place at the time. These HHC were intended to be coupled with an innovative and comprehensive approach to toxics reduction that the State legislature would enact, referred to as the toxics reduction bill, that the State asserted "would have resulted in reductions to a broad suite of toxics at their sources."<sup>25</sup> After the legislature failed to enact the toxics reduction bill, Ecology's HHC efforts were delayed. On September 14, 2015, the EPA Administrator determined that updated HHC were "necessary" pursuant to CWA section 303(c)(4)(B), and the EPA proposed federal HHC for Washington on September 14, 2015.

On August 1, 2016, Ecology adopted updated HHC that were not linked to any proposed legislation. These updated HHC incorporated some, but not all, of the inputs from EPA's 2015 304(a) recommendations and were based on a cancer risk level of  $10^{-6}$ , a FCR of 175 g/day, and chemical-specific approaches for arsenic and polychlorinated biphenyls (PCBs). These elements of Washington's HHC package are more protective than the State's first proposal due to Ecology promulgating criteria based on a cancer risk level of  $10^{-6}$  for the majority of the carcinogens,

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<sup>22</sup> USEPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004.

<sup>23</sup> 80 Fed. Reg. 36,986 (Jun. 29, 2015), *Final Updated Ambient Water Quality Criteria for the Protection of Human Health*. <https://www.gpo.gov/fdsys/pkg/FR-2015-06-29/html/2015-15912.htm>.

<sup>24</sup> The EPA. 1992. *Toxics Criteria for Those States Not Complying with Clean Water Act*, section 303(c)(2)(B). 40 CFR Part 131.36. <http://water.epa.gov/lawsregs/rulesregs/ntr/>. Amended in 1999 for PCBs. <http://water.epa.gov/lawsregs/rulesregs/ntrfact.cfm>.

<sup>25</sup> Ecology submittal at 12.



instead of using the  $10^{-5}$  cancer risk level proposed in 2015. Ecology's new and revised HHC included 192 new HHC for 97 priority pollutants, applicable to all surface waters of the State and were adopted on August 1, 2016, before the EPA finalized its proposed federal rule for Washington.<sup>26</sup>

On November 15, 2016, the EPA took action under CWA section 303(c) to approve in part, disapprove in part, and defer action in part on the HHC submitted by Ecology. Coincident with the partial disapproval, EPA promulgated federal HHC for Washington for the disapproved criteria. The EPA's federal HHC incorporated all inputs from EPA's 304(a) recommendations.

### **III. Washington's 2016 Submittal of Human Health Criteria and the EPA's Action**

During its 2016 review of Ecology's HHC submittal, the EPA compared Ecology's criteria values against a set of criteria that the EPA calculated based on its 2015 updated national 304(a) recommendations, combined with Ecology's selected FCR of 175 g/day. Because Ecology's HHC incorporated some of the inputs from the EPA's 304(a) recommendations, and the EPA's criteria incorporated all inputs from the 304(a) recommendations, the resulting HHC were different. Some of Ecology's HHC were more stringent than EPA's HHC and some were less stringent. Based on this comparison, the EPA approved 45 of Ecology's HHC that were as stringent or more stringent than EPA's calculated HHC, and the EPA disapproved 143 of Ecology's HHC that were less stringent. The EPA took no action on four new HHC submitted by Ecology for two pollutants (water + organisms and organisms only criteria for thallium and 2,3,7,8-TCDD (dioxin)).

In the majority of cases where the EPA disapproved Ecology's HHC, it was because the State calculated HHC using BCFs instead of using the national default BAFs from the 2015 304(a) recommendations, and because the State used an RSC value of 1 for non-carcinogens instead of the EPA's recommended range of 0.2-0.8. The EPA's partial disapproval asserted that the HHC that were less stringent than the EPA's calculated criteria, were not protective of the applicable designated uses, and that Ecology could remedy the partial disapproval by using the 304(a) recommended BAFs and a RSC of 0.2-0.8 for each of the disapproved HHC. *Id.*

As described above, the EPA's 304(a) default criteria are recommendations for states and authorized tribes to consider when promulgating water quality standards. States are not mandated to adopt the EPA's recommendations in whole or in part and are authorized to make appropriate risk-management decisions, including adopt criteria based on appropriate local information and data, and other scientifically defensible methods. The EPA's partial disapproval recognized the State's lengthy rulemaking effort, and its collaboration with key stakeholders, the EPA and tribes, but nevertheless concluded that "it was necessary to [ ] adopt criteria based on the latest national criteria recommendations in the absence of sufficient rationale for departing from those recommendations."<sup>27</sup> Neither the CWA, the EPA's implementing regulations, the EPA's 2000 Methodology, nor the 2015 304(a) recommendations define or attempt to explain what is

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<sup>26</sup> Ecology. 2016. Letter dated August 1, 2016, from Maia Bellon, Director, Washington Department of Ecology, to Dennis McLerran, Regional Administrator, Region 10, U.S. Environmental Protection Agency, RE: Submittal of Water Quality Standards for Clean Water Act.

<sup>27</sup> Partial Disapproval Letter at 4.

“sufficient rationale” to support a state’s departure from the national recommended criteria. The EPA’s partial disapproval also did not explain what level of rationale would be sufficient, and instead directed that Ecology could remedy the disapproval by adopting the EPA’s 304(a) recommendations in their entirety. In other words, the EPA treated the recommended criteria as mandatory criteria, which is a departure from the CWA, the EPA’s federal regulations and longstanding EPA policy.

The EPA acknowledges that the Agency previously disapproved certain HHC that Ecology submitted for review. Upon further review, EPA has determined that its prior partial disapproval was inappropriate for the reasons explained below. During the reconsideration process, the EPA reviewed Ecology’s submission and more fully considered the State’s rationales and justifications. Administrative agencies possess the inherent authority to reconsider prior decisions, and the EPA is now exercising its authority to revise its earlier disapprovals.<sup>28</sup>

Upon reconsideration, the EPA undertook a holistic review of Washington’s HHC package and evaluated the protectiveness of the HHC based on the suite of risk-management decisions, the totality of the inputs into the HHC equations, and the resulting numeric criteria. The EPA also respects Washington’s lengthy and thoughtful process wherein the State considered the health and safety of its citizens and the appropriateness of applying the EPA’s new national recommendations to the State’s resources.

Additionally, the EPA now acknowledges that Ecology’s regulatory processes were several years underway when the EPA finalized its updated national 304(a) recommendations in 2015, which incorporated new national default BAF and RSC values (among other updates, as noted above). In the years prior to 2015 when Ecology was developing updates to its HHC, the State had access to the EPA’s prior national 304(a) recommendations which incorporated different inputs, including BCFs.

Upon reconsideration, the EPA now concludes that in some cases, it may be appropriate to evaluate a state’s water quality standards, including HHC, based on a combination of existing and prior 304(a) recommendations. This is especially true in cases like Washington’s, where the State spent several years developing HHC before EPA issued updated 304(a) recommendations (and subsequently issued supporting documentation). Responsible state resource managers should be afforded a meaningful opportunity to evaluate the latest scientific information and determine how best to incorporate it into a protective HHC package. The EPA acknowledges that the issuance of new 304(a) recommendations that reflect “the latest scientific information” does not immediately render the EPA’s prior 304(a) recommendations or the underlying science unsound or indefensible. Instead, the updated 304(a) recommendations should be evaluated by

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<sup>28</sup> *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (“[W]e fully recognize that ‘regulatory agencies do not establish rules of conduct to last forever,’ . . . and that an agency must be given ample latitude to ‘adapt their rules and policies to the demands of changing circumstances.’”); *FCC v. Fox Television Studios*, 556 U.S. 502 (“We find no basis in the Administrative Procedure Act or in our opinions for a requirement that all agency change be subjected to more searching review.”); *Belville Mining Co. v. United States*, 999 F.2d 989, 997 (6th Cir. 1993) (“Even where there is no express reconsideration authority for an agency, however, the general rule is that an agency has inherent authority to reconsider its decision, provided that reconsideration occurs within a reasonable time after the first decision.”).

states in totality, within the context of state-specific information, and within the triennial review framework provided in the CWA.

CWA section 303(c) provides that states and authorized tribes are to conduct triennial reviews of WQS, including HHC, for possible revision, and the EPA's regulations require states to adopt new or revised criteria for parameters for which the EPA has published new or updated CWA section 304(a) criteria recommendations, or provide an explanation for not doing so (40 CFR 131.20(a)). Therefore, Ecology will have the opportunity to review and revisit its HHC every three years and can consider the EPA's updated section 304(a) recommendations during its triennial reviews, as appropriate. The EPA understands that Ecology will be starting a triennial review in 2019.

The EPA also recognizes that states and authorized tribes will use discretion in making resource- and risk-management decisions related to the protection of human health. Section 101(b) of the CWA explains that one of the Act's foundational policies is "to recognize, preserve, and protect the primary responsibilities and rights of states." The EPA has reconsidered its disapproval of Ecology's HHC and concludes that the criteria are protective of the State's designated uses and are based on sound science. The EPA is therefore approving the majority of those criteria.

#### *A. Washington's Designated Uses Related to Protection of Human Health*

Washington's human health criteria were developed in accordance with EPA's 2000 Human Health Methodology to protect human health from long-term exposure to toxic pollutants in drinking water and through eating fish containing these pollutants.<sup>29</sup> For human health protection, the EPA recommends that states apply HHC for toxics to all waters with designated uses providing for public water supply protection (and therefore a potential water consumption exposure route), recreation, and/or aquatic life protection (and therefore a potential fish consumption route).<sup>30</sup>

Washington's designated uses for surface waters are found in WAC 173-201A-600 through 612. WAC 173-201A-600(1) states, "All surface waters of the state not named in Table 602 are to be protected for the designated uses of: Salmonid spawning, rearing and migration; primary contact recreation; domestic, industrial, and agricultural water supply; stock watering; harvesting; commerce and navigation; boating; and aesthetic values." Washington's HHC address the general designated uses of fish harvesting, domestic water supply, and primary contact recreation and the specific uses in WAC 173-201A: Fresh waters – Harvesting (fish harvesting), Domestic Water (domestic water supply), and Recreational Uses (primary contact recreation); Marine waters – Shellfish Harvesting (shellfish—clam, oyster, and mussel—harvesting), Harvesting (salmonid and other fish harvesting, and crustacean and other shellfish—crabs, shrimp, scallops, etc.—harvesting), and Recreational Uses (primary contact recreation). See WAC 173-201A-600 and WAC 173-201A-610.

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<sup>29</sup> EPA's 2000 Human Health Methodology. Available at <https://www.epa.gov/wqc/human-health-water-quality-criteria>

<sup>30</sup> Water Quality Standards Handbook, U.S. Environmental Protection Agency, Office of Water, Washington, D.C., EPA-823-B-94-005a (Aug. 1994). Available at <https://www.epa.gov/wqs-tech/water-quality-standards-handbook>

As described below and consistent with the EPA's 2000 Methodology, Ecology's "water + organisms" criteria apply where Washington has designated domestic water supply as a use. Also consistent with the EPA's 2000 Methodology, the "organisms only" criteria apply where Washington has designated one of the uses listed above, but not the domestic water supply use.

### *B. Cancer Risk Level*

The EPA's national 304(a) recommended HHC are typically based on the assumption that carcinogenicity is a "non-threshold phenomenon," which means that there are no "no-effect" levels, because even extremely small doses are assumed to cause a finite increase in the incidence of cancer. Therefore, the EPA calculates 304(a) HHC for carcinogenic effects as pollutant concentrations corresponding to lifetime increases in the risk of developing cancer. The EPA calculates its national 304(a) recommended HHC values at a  $10^{-6}$  (one in one million) cancer risk level and recommends states incorporate lifetime cancer risk levels of  $10^{-6}$  or  $10^{-5}$  (one in one hundred thousand) for the general population. Consistent with the 2000 Methodology, a  $10^{-5}$  risk level is appropriate to protect the general population, as long as the criteria ensure that highly exposed populations (e.g., sport fishers or subsistence fishers) do not exceed a  $10^{-4}$  risk level.<sup>31</sup>

The EPA notes that selecting an appropriate cancer risk level is a risk management decision, and states and authorized tribes can choose a risk level within or more stringent than the EPA's recommended ranges when deriving HHC. If the pollutant is not considered to have the potential for causing cancer in humans (i.e., systemic toxicants), the EPA assumes that the pollutant has a threshold (the reference dose or RfD) below which a physiological mechanism exists to avoid or overcome the adverse effects of the pollutant.

The EPA takes an integrated approach and considers both cancer and non-cancer effects when deriving HHC. Where sufficient data are available, the EPA derives HHC using both carcinogenic and non-carcinogenic toxicity endpoints and recommends the lower of the two values.

Ecology's HHC for carcinogens are calculated using a risk level of  $1 \times 10^{-6}$  (1:1,000,000), except for the chemical-specific risk level for PCBs of  $2.3 \times 10^{-5}$ . These criteria include the use of a fish consumption rate of 175 grams per day, a level representative of high fish consumers in the State.<sup>32</sup> Washington's goal in adopting the criteria was to protect high end consumers (as opposed to the general population) at a risk level of  $10^{-6}$  and for PCBs at a level of  $2.3 \times 10^{-5}$ . Ecology's cancer risk level is consistent with the EPA's 2000 Methodology and, based on the 43 g/day fish consumption rate for the general population provided in Ecology's submittal, protects the general population at a risk level  $5.6 \times 10^{-6}$  for PCBs, and  $2.5 \times 10^{-7}$  for other pollutants.<sup>33</sup>

### *C. Cancer Slope Factor and Reference Dose*

A dose-response assessment is required to understand the quantitative relationships between the

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<sup>31</sup> *Id.* at pp. 2-6 to 2-7.

<sup>32</sup> Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment.* August 2016. Ecology Publication no. 16-10-025. Pages 28-31. <https://fortress.wa.gov/ecy/publications/documents/1610025.pdf>.

<sup>33</sup> Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment.* August 2016. Ecology Publication no. 16-10-025. Pages 28-31. <https://fortress.wa.gov/ecy/publications/documents/1610025.pdf>.

exposure to a pollutant and the onset of human health effects. The EPA evaluates dose-response relationships derived from animal toxicity and human epidemiological studies to derive dose-response metrics. For carcinogenic toxicological effects, the EPA uses an oral CSF to derive HHC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor. For non-carcinogenic effects, the EPA uses the RfD to calculate human health criteria. A RfD is an estimate of a daily oral exposure of an individual to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. A RfD is typically derived from a laboratory animal dosing study in which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose can be obtained. Uncertainty factors are applied to reflect the limitations of the data. The EPA's Integrated Risk Information System (IRIS)<sup>34</sup> was the primary source of toxicity values (i.e., RfD and CSF) for the EPA's 2015 updated national 304(a) recommended HHC.<sup>35</sup>

With one exception, Ecology's HHC include the cancer slope factors and reference dose values consistent with the EPA's 2015 updated national 304(a) recommendations and EPA's 2000 Human Health Methodology. For 2,3,7,8-TCDD (dioxin), Ecology used the most recent reference dose from the EPA's IRIS program which is a scientifically defensible approach and consistent with the CWA and EPA guidance.

#### *D. Fish Consumption Rate*

The EPA's 2015 updated national 304(a) recommended HHC use a default FCR of 22 g/day for consumption of fish and shellfish from inland and nearshore waters, multiplied by pollutant-specific BAFs to account for the amount of the pollutant in the edible portions of the ingested species. The EPA's default FCR of 22 g/day represents the 90th percentile consumption rate of fish and shellfish from inland and nearshore waters for the U.S. adult population 21 years of age and older, based on National Health and Nutrition Examination Survey (NHANES) data from 2003 to 2010.<sup>36,37</sup> Although the EPA uses these default values to calculate national 304(a) recommended HHC, the EPA's 2000 Methodology notes a preference for the use of local data to calculate HHC (e.g., locally derived FCRs, drinking water intake rates and body weights, and

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<sup>34</sup> Integrated Risk Information System (IRIS), U.S. Environmental Protection Agency, Office of Research and Development, Washington, D.C. Available at [www.epa.gov/iris](http://www.epa.gov/iris).

<sup>35</sup> 80 Fed. Reg. 36,986 (Jun. 29, 2015), Final Updated Ambient Water Quality Criteria for the Protection of Human Health. See also, Final 2015 Updated National Recommended Human Health Criteria. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. Available at <https://www.epa.gov/wqc/human-health-water-quality-criteria>.

<sup>36</sup> Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010), U.S. Environmental Protection Agency, Washington, DC, USA, EPA 820-R-14-002 (Apr. 2014). Available at <https://www.epa.gov/fish-tech/estimated-fish-consumption-rates-reports>

<sup>37</sup> The EPA's national FCR is based on the total rate of consumption of fish and shellfish from inland and nearshore waters (including fish and shellfish from local, commercial, aquaculture, interstate, and international sources). This is consistent with a principle that each state does its share to protect people who consume fish and shellfish that originate from multiple jurisdictions. Human Health Ambient Water Quality Criteria and Fish Consumption Rates: Frequently Asked Questions, U.S. Environmental Protection Agency (Jan. 2013). Available at <https://www.epa.gov/wqc/human-health-ambient-water-quality-criteria-and-fish-consumption-rates-frequently-asked>

waterbody-specific bioaccumulation rates) over national default values, where data are sufficient to do so, to better represent local conditions.<sup>38</sup>

When establishing a single value/criterion as a regulatory endpoint, states and the EPA must make several policy decisions regarding the members of the population that will be protected when using the waters for activities protected by the designated uses and the established criteria. In the EPA's 2000 Human Health Methodology, the EPA provides guidance to the states on the use of local and regional data to develop an appropriate fish consumption rate for the use in criteria derivation and encourages the states to use this data to determine the level of protection appropriate for state waters.

Ecology's evaluation of local data indicated that different groups of people harvest fish both recreationally and for subsistence.<sup>39</sup> Ecology made the risk management decision to base the FCR used in the HHC equation on highly exposed populations, which includes tribes, Asian Pacific Islanders, recreational and subsistence fishers, and immigrant populations, among other groups, as opposed to the general population.<sup>40</sup>

Ecology's 175g/day FCR is greater than the 95<sup>th</sup> percentile general population consumption rate for all fish and shellfish, including all salmon, restaurant, locally caught, imported, and from other sources, and represents the average consumption rate for the highest consumers of all fish and shellfish from Puget Sound waters.<sup>41</sup> This FCR selection is consistent with the EPA's 2000 Methodology which recommends deriving an appropriate FCR using an upper bound percentile of the general population and a mean or average of higher consuming populations.<sup>42</sup>

#### *E. Bioconcentration Factors (BCFs)/Bioaccumulation Factors (BAFs)*

BCFs describe the uptake and retention of a pollutant by an aquatic organism from water only while BAFs describe the uptake and retention of a pollutant by an aquatic organism from all sources (e.g., water, ingestion, and sediment). The magnitude of bioconcentration or bioaccumulation by aquatic organisms varies widely depending upon the pollutant but can be extremely high for some highly persistent and hydrophobic pollutants. For highly bioaccumulative pollutants, concentrations in aquatic organisms may pose unacceptable human health risks from fish consumption even when concentrations in water are too low to cause unacceptable health risks from drinking water consumption alone. The EPA's 2000 Human Health Methodology recommends the use of national BAFs in the calculation of ambient water quality criteria; however, the EPA did not develop national default BAFs until 2015.

The EPA's 2000 Human Health Methodology provides guidance on developing BAFs for the

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<sup>38</sup> EPA's 2000 Human Health Methodology, pp. 2-2, 2-10

<sup>39</sup> Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*. August 2016. Ecology Publication no. 16-10-025. Pages 28-31. <https://fortress.wa.gov/ecy/publications/documents/1610025.pdf>.

<sup>40</sup> Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*. August 2016. Ecology Publication no. 16-10-025. Pages 28-31. <https://fortress.wa.gov/ecy/publications/documents/1610025.pdf>.

<sup>41</sup> Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*. August 2016. Ecology Publication no. 16-10-025. Pages 28-31. <https://fortress.wa.gov/ecy/publications/documents/1610025.pdf>.

<sup>42</sup> EPA's 2000 Human Health Methodology, pp. 4-25 to 4-26.

protection of human health.<sup>43</sup> A subsequent technical support document to the 2000 Methodology entitled, *Technical Support Document Volume 2: Development of National Bioaccumulation Factors* (2003) provides added detail to the BAF calculation procedures outlined in the Methodology.<sup>44</sup> In 2009, the EPA published the *Technical Support Document Volume 3: Development of Site-Specific Bioaccumulation Factors*. This document provides guidance on different approaches that investigators can take to develop site-specific BAFs, and the factors that should be considered when selecting an approach for a given situation.<sup>45</sup> In the 2015 national 304(a) recommended HHC update, the EPA primarily used field-measured BAFs<sup>46</sup> and laboratory-measured BCFs with applicable food chain multipliers available from peer-reviewed, publicly available databases to develop national default BAFs for three trophic levels of fish. Where this information was not available, the EPA selected octanol-water partition coefficients ( $K_{ow}$  values) from peer-reviewed sources for use in calculating national BAFs.<sup>47</sup>

The EPA recommends that states use these methods when adopting HHC. The EPA recommends that the bioaccumulation technical support documents be used in conjunction with the 2000 Human Health Methodology. The bioaccumulation methodology documents encourage developing site-specific BAFs because the EPA recognizes that BAFs vary not only between chemicals and trophic levels, but also among different ecosystems and waterbodies.<sup>48</sup> Indeed, the BAF variable in the HHC equations may be more affected by site-specific waterbody factors than any other variable in the HHC equations. National average BAF values for a given chemical and trophic level may not provide the most accurate estimate of bioaccumulation for certain water bodies in the United States. At a given location, the BAF for a chemical may be higher or lower than the national BAF, depending on the nature and extent of site-specific influences.

While the EPA's 2000 Human Health Methodology recommends the use of BAFs in deriving human health criteria, development of BAFs is a time and resource intensive process, and BAFs can vary from site-to-site. Thus, it is difficult to develop BAFs on a statewide scale, and this has rarely been done. Indeed, while the EPA began recommending the use of BAFs in 2000, it was

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<sup>43</sup> EPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. Section 5. Available at: <http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf>

<sup>44</sup> EPA. December 2003. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). Technical Support Document Volume 2: Development of National Bioaccumulation Factors.

Available at:

[http://water.epa.gov/scitech/swguidance/standards/upload/2005\\_05\\_06\\_criteria\\_humanhealth\\_method\\_tsdvol2.pdf](http://water.epa.gov/scitech/swguidance/standards/upload/2005_05_06_criteria_humanhealth_method_tsdvol2.pdf)

<sup>45</sup> EPA. September 2009. Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health (2000). Technical Support Document Volume 3: Development of Site-Specific Bioaccumulation Factors.

Available at:

[http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/upload/2008\\_07\\_01\\_criteria\\_humanhealth\\_method\\_tsdvol3.pdf](http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/upload/2008_07_01_criteria_humanhealth_method_tsdvol3.pdf)

<sup>46</sup> Data for the national default BAFs were collected in the Great Lakes and evaluated primarily for bioaccumulation of PCBs in those waters.

<sup>47</sup> Development of National Bioaccumulation Factors: Supplemental Information for EPA's 2015 Human Health Criteria Update, U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, EPA 822-R-16-001 (Jan. 2016). Available at <https://www.epa.gov/sites/production/files/2016-01/documents/national-bioaccumulation-factors-supplemental-information.pdf>

<sup>48</sup> EPA's 2000 Human Health Methodology, pp. 2-13.

not until the June 2015 304(a) recommendations that the EPA published national default BAF values, and even then only for 94 pollutants.

At the time Ecology was developing its HHC, the EPA had only provided the 2000 Methodology guidance on the calculation of national BAFs. The 304(a) recommendations and default national BAFs were published in June 2015, and then in January 2016, the EPA published supplemental information on development of the national recommended BAFs.<sup>49</sup> By that time, Ecology had spent several years developing its HHC inputs through extensive engagement with State-wide stakeholders and the EPA, and was preparing to finalize its proposed HHC based on the EPA's prior recommended BCFs, not the new national default BAFs.

Given the lack of any Washington-specific BAFs and consistent with prior EPA guidance, Ecology utilized BCFs instead of BAFs in deriving its new and revised HHC. Ecology's submittal included a dozen pages of summary explanation to support its science, policy, and risk-management decision to utilize BCFs instead of the EPA's new national default BAFs.<sup>50</sup> Ecology's submittal raised concerns that data used to develop the EPA's national BAFs may not be appropriate or reflective of Washington's water resources, and referenced local data on the percent lipid of individual species consumed from Washington waters and local data on dissolved organic carbon and particulate organic carbon that may affect bioaccumulation in Washington waters.<sup>51</sup> Ecology noted that BAFs based on trophic level 4 are not consistent with the FCR Ecology used, which includes shellfish as a significant portion of the diet.<sup>52</sup> Ecology raised concerns that the EPA had not provided sufficient publicly available information on the development of the national BAFs and, as a result, Ecology was unable to replicate the EPA's national default BAF values based on available information.<sup>53</sup>

Ecology also noted that the only way to effectively use BAFs in its HHC would be to develop State-specific BAFs which would have caused significant delays in the State's adoption of HHC.<sup>54</sup> Ecology also explained that the EPA currently uses a combination of BAFs and BCFs to calculate its national recommended water quality HHC, and the EPA used a combination of BAFs and BCFs for its 2015 proposed federal regulation for Washington.<sup>55</sup> Ecology asserted that both BAFs and BCFs could represent acceptable science choices for CWA purposes.<sup>56</sup>

The EPA's partial disapproval identifies some of Ecology's rationale (more fully described above) and concludes that, "Ecology did not demonstrate how its selection of outdated BCFs to derive human health criteria is scientifically defensible and protective of the applicable

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<sup>49</sup> USEPA. January 2016. *Development of National Bioaccumulation Factors: Supplemental Information for EPA's 2015 Human Health Criteria Update*. Office of Water, Washington, D.C. EPA 822-R-16-001. <http://www.epa.gov/sites/production/files/2016-01/documents/national-bioaccumulation-factors-supplemental-information.pdf>.

<sup>50</sup> Ecology submittal 44-56.

<sup>51</sup> Ecology submittal 48-50

<sup>52</sup> WA Ecology, WAC 173-201A, Concise Explanatory Statement, p. 65

<sup>53</sup> Ecology submittal 52-54

<sup>54</sup> Ecology submittal 54

<sup>55</sup> Ecology submittal 51

<sup>56</sup> Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*. August 2016. Ecology Publication no. 16-10-025. Page 56.



designated uses.”<sup>57</sup> Instead of explaining why Ecology’s justification of the use of BCFs was insufficient, the EPA’s partial disapproval simply restated that the EPA recommends the use of BAFs and the EPA’s final federal rule for Washington (promulgated coincident with the partial disapproval) uses BAFs. The EPA’s partial disapproval disregarded Ecology’s rationale and failed to explain why the rationale was insufficient, failed to explain why the State’s BCF-derived criteria were not based on sound scientific rationale, and failed to explain why the criteria were not protective of designated uses. The partial disapproval also did not explain how the national default BAFs, derived from data collected in the Great Lakes, are appropriate for Washington’s resources. The EPA explained that to remedy the partial disapproval, Ecology should adopt HHC based on the national default BAFs without explaining why the national default BAFs were more appropriate to support Washington’s designated uses.<sup>58</sup> Importantly, where Ecology’s BCF-based criteria were more stringent than the EPA’s calculated BAF-based criteria, the EPA approved Ecology’s BCF-based criteria.<sup>59</sup> This demonstrates that the use of BCFs can result in protective HHC, and that the EPA only rejected the use of a BCF when it resulted in a higher numeric criteria.

Ecology’s submittal correctly explains that no single input into the HHC equations determines the degree of protection provided by the calculated numeric criteria.<sup>60</sup> Rather, the protectiveness of the criteria must be evaluated based on the suite of risk-management decisions, the totality of the inputs into the equations, and the resulting numeric criteria. Upon reconsideration, the EPA concludes that the BCFs utilized by Ecology are pollutant-specific, are consistent with the BCFs recommended by the EPA in prior national CWA § 304(a) HHC recommendations, and together with the other inputs into the HHC equations result in water quality criteria that are based on sound science and protective of the State’s designated uses, consistent with the rationale provided in Ecology’s submittal.

#### *F. Relative Source Contributions (RSCs)*

The EPA’s 2000 Human Health Methodology recommends applying an RSC of between 0.2 and 0.8 in the calculation of criteria for non-carcinogens to account for other sources of pollutants beyond water and fish.<sup>61</sup> The 2000 Human Health Methodology recommends an RSC ceiling of 0.8 (i.e., 80% of an individual’s total exposure is assumed to be attributed to consuming fish/shellfish and drinking water) to ensure protection of individuals whose exposure could be greater than indicated by current data and to account for unknown sources of exposure beyond consumption of aquatic organisms and water. In the EPA’s 2015 national updated 304(a) recommendations and final federal rule for Washington, the EPA applied a pollutant-specific RSC value of 0.8 or less for all non-carcinogens and nonlinear carcinogens.<sup>62</sup>

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<sup>57</sup> Partial Disapproval TSD at 16.

<sup>58</sup> Partial Disapproval TSD at 25.

<sup>59</sup> Partial Disapproval TSD at 18.

<sup>60</sup> Ecology submittal 55

<sup>61</sup> USEPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. Page 4-8.

<sup>62</sup> *Final Updated Ambient Water Quality Criteria for the Protection of Human Health*, (80 FR 36986, June 29, 2015); *Revision of Certain Water Quality Criteria Applicable to Washington*, (81 FR 85417, 85427-28, November 28, 2016). See also: USEPA. 2015. Final 2015 Updated National Recommended Human Health Criteria. U.S.

Ecology derived HHC using an RSC value of 1 (i.e., 100 percent of an individual's total exposure is assumed to be attributed to consuming fish/shellfish and drinking water). The HHC in the NTR were also based on an RSC of 1.<sup>63</sup> The RSC is one component of the exposure analysis that informs how stringent HHC must be to protect the designated uses. As Ecology explained in its rationale, the EPA's RSC recommendations provide two default approaches: 1) if no sources of exposure other than fish and water consumption are identified, the EPA recommends a default RSC of 0.2 (i.e., 20% of an individual's exposure is from surface waters and 80% of the exposure is from other sources); and 2) if other sources of exposure are well known and documented, the EPA recommends a default RSC of 0.8 (80% of exposure is from surface waters and 20% is from other sources).<sup>64</sup> Ecology's rationale further explained, "as the contribution of a contaminant from water sources becomes smaller, the HHC becomes more stringent and in effect becomes a larger driver for more restrictive limits."<sup>65</sup>

Ecology also explained that, "[t]he use of an RSC to compensate for sources of exposure outside the scope of the Clean Water Act when establishing HHC is a risk management decision that states need to carefully weigh."<sup>66</sup> Ecology noted the limited ability of the CWA, and therefore the State, to control exposure to pollutant sources outside of its regulation of water quality. Ecology ultimately concluded that its HHC water quality standards should be based on human exposure through CWA regulated sources, such as surface waters.<sup>67</sup>

In its Response to Comment document developed during its HHC rulemaking, Ecology explained the balancing it undertook during its process to select inputs that would be protective of the designated uses:

Ecology made decisions on the rule based on an extensive public process, federal and state laws and regulations, and with consideration of state and federal policy and guidance. Some of the choices made by Ecology are associated with an increased level of protection (stringency) such as the FCR, the risk level, toxicity factors, and drinking water intake. Some are associated with decreased protection, such as the relative source contribution. It is incorrect to infer that any one input defines the level of protection or stringency of a criterion.<sup>68</sup>

Finally, Ecology linked its selected FCR inputs to the HHC equations (which includes all fish and shellfish, regardless of source) with its selected RSC and explained its risk management decision as follows:

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Environmental Protection Agency, Office of Water, Washington, D.C. <https://www.epa.gov/wqc/human-health-water-quality-criteria>.

<sup>63</sup> Ecology Rationale at 36.

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

<sup>67</sup> *Id.* at 38.

<sup>68</sup> Ecology Response to Comment at 98.

The decision to include 100% salmon (although many salmon put on most biomass outside waters regulated under the CWA) is a risk management decision that adds additional protection to the criteria beyond the levels recommended in EPA guidance (EPA 2000 guidance (page 4-26) states “EPA recommends the...use of fresh/estuarine species data only”), and offsets other inputs to the equation where risk management choices were made that are less stringent than EPA’s guidance (e.g. use of a RSC = 1). This decision (whether perceived as overly protective or appropriately protective) is part of the process of balancing the inputs to the equation to result in human health criteria that are protective of people who consume fish and shellfish from Washington waters.<sup>69</sup>

The EPA previously disagreed that Ecology’s rationale was sufficient and explained that the EPA recommends a ceiling RSC of 0.8 “to ensure protection of individuals whose exposure could be greater than indicated by current data and to account for unknown sources of exposure.”<sup>70</sup> The EPA’s partial disapproval also explained that the EPA’s 2015 304(a) criteria and the EPA’s final federal HHC for Washington include pollutant-specific RSC values.<sup>71</sup> The EPA did note that because Ecology included anadromous fish in its FCR, the EPA guidance would allow Ecology to “adjust the RSC upward to reflect that marine exposures are already accounted for in the FCR,” but the EPA determined that Ecology had not sufficiently justified departing from the EPA guidance to use the RSC range of 0.2-0.8.<sup>72</sup> The EPA explained that its final federal HHC for Washington retained RSC values of 0.5 and above “recognizing the compelling need to account for the other potential exposure sources, including marine fish not accounted for in the FCR of 175 g/day, consistent with the logic and procedures used in establishing the national 304(a) criteria recommendations.”<sup>73</sup>

Upon reconsideration, the EPA should have evaluated the use of the RSC in context with the overall HHC package. Although the partial disapproval referenced a compelling need for the RSC identified in its 304(a) recommendation, the EPA did not identify the compelling need for that conservative measure in Washington, given the other conservative elements Ecology used to derive its HHC, including the FCR of 175 g/day or the cancer risk level of  $10^{-6}$ . The EPA’s partial disapproval did not appear to address Ecology’s concern that the RSC creates overly conservative assumptions that account for non-CWA exposure risks. Rather, the EPA summarily concluded that “Ecology did not demonstrate how its selection of a RSC value of 1 to derive human health criteria is scientifically defensible and protective of the applicable designated uses.”<sup>74</sup> Finally, the EPA’s partial disapproval appears to treat the 304(a) recommendation to use an RSC range of 0.2-0.8 as a requirement, and then cites to the EPA’s Frequently Asked Questions document to allow the State flexibility to adjust the RSC upward under certain circumstances.<sup>75</sup> As noted above, 304(a) recommendations are not requirements; similarly, an EPA Frequently Asked Questions document does not have the force or effect of law.

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<sup>69</sup> Ecology Response to Comment at 23.

<sup>70</sup> Partial Disapproval TSD at 17-18.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*, citing an EPA Frequently Asked Questions Document.

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

The EPA now concludes that Ecology's use of an RSC of 1, coupled with other more conservative inputs in the HHC equations, appropriately balanced risks and resulted in HHC that are based on sound science and are protective of Washington's designated uses, consistent with the rationale provided in Ecology's submittal.

#### *G. Drinking Water Intake*

The EPA's 2015 updated national 304(a) recommended HHC use a default drinking water intake rate of 2.4 liters per day (L/day). The EPA's default drinking water intake rate of 2.4 L/day represents the per capita estimate of combined direct and indirect community water ingestion at the 90th percentile for adults ages 21 and older.<sup>76</sup> Although the EPA uses these default values to calculate national 304(a) recommended HHC, the EPA's 2000 Methodology notes a preference for the use of local data to calculate HHC (e.g., locally derived FCRs, drinking water intake rates, body weights, and waterbody-specific bioaccumulation rates) over national default values, where data are sufficient to do so, to better represent local conditions.<sup>77</sup>

Ecology derived HHC using a drinking water intake rate of 2.4 L/day. Ecology's selection of a drinking water intake rate of 2.4 L/day to derive human health criteria is consistent with the EPA's 2015 national 304(a) recommendations.<sup>78</sup>

#### *H. Body Weight*

The EPA calculates HHC using a default body weight of 80 kilograms (kg), the average weight of a U.S. adult age 21 and older, based on NHANES data from 1999 to 2006.<sup>79</sup> Although the EPA uses these default values to calculate national 304(a) recommended HHC, the EPA's 2000 Methodology notes a preference for the use of local data to calculate human health criteria (e.g., locally derived FCRs, drinking water intake rates, body weights, and waterbody-specific bioaccumulation rates) over national default values, where data are sufficient to do so, to better represent local conditions.<sup>80</sup>

Ecology derived HHC using a body weight assumption of 80 kg based on new science and local data relevant to Washington and the EPA's 2011 Exposure Factors Handbook.<sup>81</sup> Ecology's selection of a body weight of 80 kg to derive HHC is consistent with the EPA's 2015 304(a) recommendations.

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<sup>76</sup> Exposure Factors Handbook 2011 edition, U.S. Environmental Protection Agency, EPA 600/R-090/052F (Sept. 30, 2011). Available at <http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252>

<sup>77</sup> EPA's 2000 Human Health Methodology, pp. 2-2, 2-10

<sup>78</sup> 80 Fed. Reg. 36,986 (Jun. 29, 2015) Final Updated Ambient Water Quality Criteria for the Protection of Human Health. In this final rule, EPA recommended criteria that accounted for a revised drinking water intake of 2.4 L/day based on the Exposure Factors Handbook: 2011 Edition, U.S. Environmental Protection Agency, Office of Research and Development, EPA 600/R-090/052F (Sept. 2011). Available at <http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252>

<sup>79</sup> 80 Fed. Reg. 36,986 (Jun. 29, 2015), *Final Updated Ambient Water Quality Criteria for the Protection of Human Health*. <https://www.gpo.gov/fdsys/pkg/FR-2015-06-29/html/2015-15912.htm>.

<sup>80</sup> EPA's 2000 Human Health Methodology, pp. 2-2, 2-10

<sup>81</sup> Exposure Factors Handbook: 2011 Edition, U.S. Environmental Protection Agency, Office of Research and Development, EPA 600/R-090/052F (Sept. 2011). Available at <http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252>

### *I. Polychlorinated Biphenyls (PCBs)*

The EPA's national recommended 304(a) HHC for PCBs is 0.000064 µg/L for both water + organisms and organisms only. This national recommendation (published in 2002) is based on a FCR of 17.5 g/day and was not updated in 2015. In its November 15, 2016 action, the EPA disapproved Ecology's HHC for PCBs. Ecology adopted HHC that were the same as those that the EPA promulgated in the NTR (as revised in 1999): 0.00017 µg/L for both water + organisms and organisms only. Ecology elected to use a cancer risk level of  $4 \times 10^{-5}$  for PCBs, consistent with the level of risk/hazard used by the Washington Department of Health in developing fish advisories. Ecology explained that this was a chemical-specific State risk management decision. When Ecology used the  $4 \times 10^{-5}$  cancer risk level along with its other inputs to calculate PCB criteria, the resulting criteria of 0.00029 µg/L were less stringent than the 1999 NTR values. Ecology then decided not to increase the criteria concentrations above the NTR value, and thus adopted the NTR value of 0.00017 µg/L. This value is associated with a cancer risk level of  $2.3 \times 10^{-5}$ .<sup>82</sup>

The EPA disapproved Ecology's PCB HHC because the State used a chemical-specific cancer risk rate. In its partial disapproval, the EPA determined that Ecology did not demonstrate how the selected cancer risk rate was based on scientific rationale or protective of designated uses, and the EPA therefore concluded that the PCB criteria did not comply with CWA section 303(c) and 40 CFR 131.11.<sup>83</sup> The EPA also noted in its partial disapproval that "Ecology did not demonstrate how the criteria were protective of applicable designated use, including the tribal subsistence fishing portion of the fish and shellfish harvesting use as informed by treaty-reserved rights."<sup>84</sup> The EPA asserted that Ecology could remedy the partial disapproval by not using a chemical-specific cancer risk level. The EPA specifically recommended Ecology use a  $10^{-6}$  cancer risk level to derive PCB criteria that are protective of designated uses, including the tribal subsistence fishing use as informed by treaty-reserved fishing rights.<sup>85</sup>

Prior to and following the EPA promulgation of federal HHC for Washington, the State has held meetings with stakeholders and regulated entities to discuss implementation options in National Pollutant Discharge Elimination System permits. In these meetings, Ecology has acknowledged that its permitted facilities will be unable to meet effluent limits based on the federal HHC, including the federal criteria for PCBs. Ecology's implementation plan relies on variances for permits that require PCB limits, and seeking EPA approval for those variances before any permits can be issued or reissued. Ecology does not expect to issue any permits for PCBs until at least 2021.

Upon reconsideration, the EPA concludes the chemical-specific cancer risk rate of  $2.3 \times 10^{-5}$  falls within the range of protective risk rates the EPA has recommended since it issued its 2000 Methodology and is protective of the State's designated uses, consistent with the rationale provided in Ecology's submittal. Nothing in the CWA prevents or prohibits a state from adopting

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<sup>82</sup> Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*. August 2016. Ecology Publication no. 16-10-025. Page 67. <https://fortress.wa.gov/ecy/publications/documents/1610025.pdf>.

<sup>83</sup> Partial Disapproval TSD at 26.

<sup>84</sup> *Id.*

<sup>85</sup> *Id.* As discussed further below, Ecology does not interpret its designated uses to specifically target subsistence fishing based on reserved tribal treaty rights.

a chemical-specific cancer risk rate, as long as the derived criteria are based on sound scientific rationale and protective of the designated use. As discussed further below, the EPA has also reconsidered its reliance on tribal treaty rights as a rationale for disapproving Ecology's HHC for PCBs.

#### *J. Arsenic*

The EPA's national recommended default HHC for arsenic are 0.018 µg/L for water + organisms and 0.14 µg/L organisms only. This national recommendation (published in 1992) is based on a FCR of 6.5 g/day and was not updated in the EPA's 2015 national 304(a) HHC recommendations. The EPA's IRIS program is currently undertaking a toxicological review of inorganic arsenic<sup>86</sup> that could result in the EPA updating its national 304(a) recommended HHC for arsenic.

Ecology adopted HHC of 10 µg/L for arsenic for water + organisms and organisms only. These criteria are equivalent to the Safe Drinking Water Act (SDWA) maximum contaminant level (MCL) that applies in Washington for drinking water protection. Ecology stated this decision was based on scientific information, regulatory precedent by other states in adopting, and the EPA in approving as protective, a HHC of 10 µg/L for arsenic. Ecology also noted there are high concentrations of naturally occurring arsenic in Washington.<sup>87</sup>

In its November 15, 2016 action, the EPA determined that Washington's arsenic criteria for the protection of human health from exposure to arsenic were not protective of Washington's designated uses, and therefore, did not comply with CWA section 303(c) and 40 CFR 131.11. Given the scientific uncertainty surrounding arsenic, the EPA did not promulgate a new federal criterion for arsenic, and instead elected to leave the existing criteria from the NTR (0.018 µg/L water + organisms and 0.14 µg/L organisms only) in effect for CWA purposes in Washington.

Upon reconsideration, the EPA reaffirms its November 15, 2016 decision to leave the existing NTR values in place. The NTR was promulgated in 1992 and Ecology's submission did not provide a compelling rationale for departing from that level of protection. The EPA is therefore leaving in place the existing NTR values of 0.018 µg/L water + organisms and 0.14 µg/L organisms only.

#### *K. Thallium and 2,3,7,8-TCDD (Dioxin)*

The EPA's national recommended 304(a) HHC for thallium (published in 2003) are based on an IRIS RfD from 1990. The EPA's national recommended HHC for dioxin (published in 2002) are based on a cancer slope factor from 1988. The existing national recommended 304(a) HHC for both thallium and dioxin are derived using a FCR of 17.5 g/day. The EPA did not update the

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<sup>86</sup> USEPA. 2015. Assessment Development Plan for the Integrated Risk Information System (IRIS) Toxicological Review of Inorganic Arsenic [CASRN 7440-38-2]. Office of Research and Development. EPA/630/R-14/101. Available at: [http://ofimpub.epa.gov/eims/eimscomm.getfile?p\\_download\\_id=526109](http://ofimpub.epa.gov/eims/eimscomm.getfile?p_download_id=526109).

<sup>87</sup> Department of Ecology. Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment. August 2016. Ecology Publication no. 16-10-025. Page 70. <https://fortress.wa.gov/ecy/publications/documents/1610025.pdf>.

304(a) national recommended criteria for these two pollutants in 2015 because further analysis was necessary to develop scientifically sound recommendations.<sup>88</sup>

For thallium, Ecology used the EPA's existing 304(a) recommendations along with the State's selected FCR of 175 g/day and adopted criteria of 0.24 µg/L for water + organisms and 0.27 µg/L for organisms only. For dioxin, Ecology used the most recent IRIS non-cancer RfD (2012<sup>89</sup>) to calculate and adopt criteria of 0.000000064 µg/L for water + organisms and 0.000000064 µg/L for organisms only for dioxin. For both pollutants, Ecology used an RSC value of 1.

Due to scientific uncertainty with the toxicity factors from IRIS, the EPA took no action on these criteria in 2016. Because the EPA took no action on Washington's adopted criteria and did not promulgate revised criteria for these pollutants, the existing thallium and dioxin criteria from the NTR remain in effect for CWA purposes in Washington.

Under the CWA, the EPA has an obligation to act on Ecology's HHC for thallium and dioxin. Because the EPA has reconsidered its position on Washington's use of an RSC of 1 (as explained above), and because Ecology used existing EPA data on the toxicity of thallium and dioxin (from either the EPA's 304(a) recommendations or IRIS values), along with the State's selected FCR of 175 g/day, the EPA concludes that Washington's HHC for these pollutants are scientifically defensible and protective of the State's designated uses, consistent with the rationale provided in Ecology's submittal. The EPA is therefore approving Ecology's prior submissions.

#### **IV. Tribal Treaty Rights and Washington's FCR and Cancer Risk Level**

As described in detail above, the EPA's 2000 Human Health Methodology and the EPA's 304(a) national recommended HHC provide a framework for states and authorized tribes to develop HHC that are protective of designated uses. In its August 1, 2016 HHC package, Ecology used a FCR of 175 g/day and a cancer risk rate of  $10^{-6}$  (and  $2.3 \times 10^{-5}$  for PCBs) to calculate its generally applicable HHC. Consistent with the 2000 Methodology, states and authorized tribes have discretion to make risk-management decisions in establishing HHC.<sup>90</sup> The FCR Ecology used is nearly eight times more protective than the EPA's national default FCR of 22 g/day and is based on local fish consumption information, consistent with the 2000 Methodology. Also consistent with the 2000 Methodology, Ecology determined that a cancer risk rate of  $10^{-6}$  (and  $2.3 \times 10^{-5}$  for PCBs) would be protective of the general population and high consuming subpopulations.

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<sup>88</sup> USEPA. 2015. EPA Response to Scientific Views from the Public on Draft Updated National Recommended Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. <https://www.epa.gov/sites/production/files/2015-10/documents/epa-response-to-public-comments-to-human-health-final-criteria.pdf>.

<sup>89</sup> Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*. August 2016. Ecology Publication no. 16-10-025. Page 43. <https://fortress.wa.gov/ecy/publications/documents/1610025.pdf>.

<sup>90</sup> USEPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004.

After issuing a partial disapproval of Washington’s HHC for the reasons described above, the EPA issued a final federal rule on November 28, 2016, that included a FCR of 175 g/day. The EPA’s rationale for using the 175 g/day FCR differed from the State’s rationale in using the same FCR in its August 2016 submittal. Specifically, the EPA explained that it interpreted Washington’s “harvesting” designated use to include subsistence fishing, and the EPA asserted that tribes with treaty rights must be treated as the target general population for the purpose of deriving protective criteria (including selection of an appropriate FCR).<sup>91</sup> The EPA’s interpretation was not consistent with Washington’s interpretation of its designated use. Specifically, Washington asserted that “[t]he designated use of harvest in Washington’s water quality standards is a general use, and the population it applies to encompasses all people harvesting from Washington surface waters (not just a category represented by highly exposed groups or sustenance users as the commenter asserts). . . . The current rule takes [i]nto account protection of fish and shellfish resources from toxics for all waters of the state, including the Usual and Accustomed [referring to applicable treaty terms] waters.”<sup>92</sup>

The rationale the EPA articulated in the preamble to its federal HHC in support of the FCR and cancer risk rate selected for Washington was based on a new legal theory and framework within which the EPA and states would be required to adopt new approaches in order to “effectuate and harmonize” tribal reserved treaty rights with the CWA when establishing HHC.<sup>93</sup> Specifically, the EPA purported to harmonize applicable treaty language protecting tribes’ right to fish with the CWA by concluding that the EPA and the State would need to provide the same level of protection to tribal treaty fishers as to the State’s general population, in part by interpreting the State’s designated uses to also mean or include subsistence fishing and identifying tribal populations as the “target general population.”<sup>94</sup> This framework had not been promulgated in any nationally applicable rule or articulated in any national recommended guidance or the 2000 Methodology. The EPA did not provide the public with adequate notice of this framework or solicit public comments on the Agency’s decision to apply this framework to particular state submissions in the first instance.

In important respects, this framework departed from longstanding EPA policy and the Agency’s recommendations for setting HHC, including the 2000 Methodology. Because of this, the EPA has stated that the 2000 Methodology “does not . . . speak to or envision the unique situation of setting WQS [water quality standards] that cover areas where tribes have treaty-reserved rights to practice subsistence fishing.”<sup>95</sup> While the 2000 Methodology did not explicitly address treaty-reserved fishing rights, the EPA was aware long before development of the 2000 Methodology

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<sup>91</sup> EPA, Revision of Certain Federal Water Quality Criteria Applicable to Washington, 81 Fed. Reg. 85,417, 85,424 (Nov. 28, 2016) (“EPA has interpreted the state’s EPA-approved designated fish and shellfish harvesting use to include or encompass a subsistence component based on, and consistent with, the rights reserved to the tribes through the treaties.”).

<sup>92</sup> WA Ecology, WAC 173-201A, Concise Explanatory Statement: Tribal Treaty Rights (August 2016).

<sup>93</sup> See *id.* at 85,422-426; EPA, Revision of Certain Federal Water Quality Criteria Applicable to Washington, 80 Fed. Reg. 55,063, 55,067 (Sept. 14, 2015).

<sup>94</sup> EPA, Revision of Certain Federal Water Quality Criteria Applicable to Washington, 81 Fed. Reg. 85,417, 85,424 (Nov. 28, 2016) (“EPA construes the CWA to require that, when establishing WQS for [waters where tribes have treaty-reserved fishing rights], the tribal members must be considered the target general population for the purposes of setting risk levels to protect the subsistence fishing use.”).

<sup>95</sup> *Id.* at 85,424-85,425.



that certain tribal populations engaged in subsistence fishing practices and that tribal treaties contain subsistence fishing protections. Moreover, the 2000 Methodology speaks directly to “greater consumption among Native American, Pacific Asian American, and other subsistence consumers” and advises states to “ensure that the risk to more highly exposed subgroups (sportfishers or subsistence fishers) does not exceed the  $10^{-4}$  level.”<sup>96</sup>

The EPA’s rationale and new framework were largely immaterial to the EPA’s partial disapproval of Ecology’s HHC. However, it was among the reasons that led the EPA to disapprove Washington’s PCB criteria, based on the concern that criteria associated with a cancer risk level of  $2.3 \times 10^{-5}$  would not be consistent with the EPA’s new framework that required treaty-reserved tribal consumers to be treated as the “target general population” and protected at a cancer risk no greater than  $1 \times 10^{-5}$ .<sup>97</sup>

Upon reconsideration, the EPA has determined that the State’s cancer risk level of  $2.3 \times 10^{-5}$  for PCBs gives due effect to the tribal reserved treaty rights, and that the 2000 Methodology is the appropriate framework through which to assess protection of tribal members with such rights. First, the EPA’s longstanding view, consistent with the 2000 Methodology, is that a state may consider tribes with reserved fishing rights to be highly exposed populations, rather than the target general population, in order to derive criteria, and that such consideration gives due effect to reserved fishing rights. Second, the EPA believes it is permissible under the CWA for a state to choose to protect tribal members at a cancer risk level of at minimum  $10^{-4}$ , consistent with the EPA’s 2000 Methodology and protection afforded to other highly exposed subpopulations. Washington elected to be more protective of high consumers than necessary by selecting a FCR of 175 g/day and setting a cancer risk level of  $2.3 \times 10^{-5}$  for PCBs. The EPA’s statements to the contrary in its disapproval of the State’s PCB criteria departed from the Agency’s historic view of what risk levels would be adequately protective of high consumers and does not reflect the Agency’s longstanding (prior to 2015) or current view.<sup>98</sup>

While the reserved rights in these tribal treaties may be considered by the State and the EPA when setting and reviewing criteria, they do not expand the EPA’s authority under the CWA. Likewise, these treaties do not limit or prohibit the EPA from taking an otherwise lawful action under the CWA. Washington’s selection of a cancer risk level of  $2.3 \times 10^{-5}$  and an FCR of 175 g/day for its PCB criteria is consistent with the EPA’s 2000 Methodology. Washington’s decision to protect high consuming tribal members with PCB criteria based on a  $2.3 \times 10^{-5}$  CRL and an FCR of 175 g/day was more than adequate for this or other populations. Therefore, it was

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<sup>96</sup> See 2000 Methodology, pp. 1-12.

<sup>97</sup> November 15, 2016. Letter and enclosed Technical Support Document from Daniel D. Opalski, Director, Office of Water and Watersheds, EPA Region 10 to Maia Bellon, Director, Department of Ecology, Re: EPA’s Partial Approval/Disapproval of Washington’s Human Health Water Quality Criteria and Implementation Tools (“Ecology did not demonstrate how the criteria were derived using a cancer risk level that is based on scientifically sound rationale and protective of applicable designated uses, including the tribal subsistence fishing portion of the fish and shellfish harvesting use as informed by treaty-reserved fishing rights.”); Revision of Certain Water Quality Criteria Applicable to Washington, (81 FR 85417, 85427-28, November 28, 2016).

<sup>98</sup> For additional discussion and analysis of the EPA’s prior approach for considering tribal treaty rights in the water quality standards program, please see the EPA’s April 4, 2019 CWA 303(c) approval of Idaho’s human health criteria at [https://www.epa.gov/sites/production/files/2019-04/documents/04042019\\_cover\\_letter\\_approval\\_of\\_deq\\_human\\_health\\_criteria\\_signed.pdf](https://www.epa.gov/sites/production/files/2019-04/documents/04042019_cover_letter_approval_of_deq_human_health_criteria_signed.pdf).

improper and unnecessary for the EPA to disapprove the State's PCB criteria in order to "harmonize" the treaties and the CWA.

**V. The EPA's Reversal of the November 15, 2016 Clean Water Act Section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria and Approval of Those Criteria**

Upon reconsideration of Ecology's 2016 submittal, the EPA is now reversing the majority of its November 15, 2016 partial disapproval of Washington's HHC and approving those HHC, and the associated footnotes. See the table below. For the reasons set forth above, the EPA finds that Ecology's HHC are based on sound science and are protective of the State's designated uses. In light of this decision, the Agency intends to initiate a notice and comment process on a separate proposal to withdraw the related federally promulgated HHC. Pursuant to 40 CFR 131.21(c) the EPA's approval of Washington's HHC will not be in effect for CWA purposes until the corresponding federally promulgated HHC are withdrawn.

The EPA recognizes that Ecology's HHC are less stringent than the EPA's federally promulgated criteria which are based on EPA's section 304(a) criteria. However, as explained above, the EPA's section 304(a) criteria are recommendations and states retain discretion to adopt different criteria, that may be less stringent, if the state's criteria are based on sound science and protect the designated use. In issuing this approval, the EPA has determined that, looking at the record and the State's approach as a whole, Ecology's HHC meet the requirements of EPA's regulations because their inputs are based on sound science and the resulting criteria protect the designated uses.

The EPA is therefore reversing the majority of the 2016 partial disapproval of Ecology's HHC and approving those HHC. In making this decision, the EPA also took into consideration that: 1) the CWA designates states as the primary authority for setting water quality standards; 2) the CWA envisions that states and authorized tribes will use their expertise and discretion in making resource- and risk-management decisions related to the protection of human health; 3) the 304(a) criteria are recommendations, not national mandates; 4) Ecology's 2016 HHC submittal included rationale sufficient to depart from the 304(a) national HHC recommendations, including conservative inputs into its HHC equations, and EPA should have deferred to Ecology and not substituted its judgment for the State's resource- and risk-management decisions; and 5) Ecology's regulatory processes were several years underway by the time the EPA finalized its updated national 304(a) recommendations in June 2015 and the CWA envisions the triennial review process as an opportunity for states to review and modify as appropriate their WQS based on the latest science and information.

	Chemical	CAS Number	Washington's Criteria that the EPA Disapproved or Deferred Action on in 2016 that the EPA is Now Approving		EPA Federally Promulgated Criteria	
			Water & Organisms (µg/L)	Organisms Only (µg/L)	Water & Organisms (µg/L)	Organisms Only (µg/L)
1	1,1,1-Trichloroethane	71556	47000	160000	20000	50000
2	1,1,2,2-Tetrachloroethane	79345	0.12	0.46	0.1	0.3
3	1,1,2-Trichloroethane	79005	0.44	1.8	0.35	0.90
4	1,1-Dichloroethylene	75354	1200	4100	700	4000
5	1,2,4-Trichlorobenzene	120821	0.12	0.14	0.036	0.037
6	1,2-Dichlorobenzene	95501	2000	2500	700	800
7	1,2-Dichloroethane	107062	9.3	120	8.9	73
8	1,2-Dichloropropane	78875				
9	1,2-Diphenylhydrazine	122667	0.015	0.023	0.01	0.02
10	1,2-Trans-Dichloroethylene	156605	600	5800	200	1000
11	1,3-Dichlorobenzene	541731	13	16	2	2
12	1,3-Dichloropropene	542756	0.24	2.0	0.22	1.2
13	1,4-Dichlorobenzene	106467	460	580	200	200
14	2,3,7,8-TCDD (Dioxin)	1746016	0.000000064	0.000000064	0.000000013	0.000000014
15	2,4,6-Trichlorophenol	88062				
16	2,4-Dichlorophenol	120832	25	34	10	10
17	2,4-Dimethylphenol	105679				
18	2,4-Dinitrophenol	51285	60	610	30	100
19	2,4-Dinitrotoluene	121142				
20	2-Chloronaphthalene	91587	170	180	100	100
21	2-Chlorophenol	95578				
22	2-Methyl-4,6-Dinitrophenol	534521	7.1	25	3	7
23	3,3'-Dichlorobenzidine	91941				
24	3-Methyl-4-Chlorophenol	59507				

	Chemical	CAS Number	Washington's Criteria that the EPA Disapproved or Deferred Action on in 2016 that the EPA is Now Approving		EPA Federally Promulgated Criteria	
			Water & Organisms (µg/L)	Organisms Only (µg/L)	Water & Organisms (µg/L)	Organisms Only (µg/L)
25	4,4'-DDD	72548	0.000036	0.000036	0.0000079	0.0000079
26	4,4'-DDE	72559	0.000051	0.000051	0.00000088	0.00000088
27	4,4'-DDT	50293	0.000025	0.000025	0.0000012	0.0000012
28	Acenaphthene	83329	110	110	30	30
29	Acrolein	107028				
30	Acrylonitrile	107131				
31	Aldrin	309002	0.0000057	0.0000058	0.000000041	0.000000041
32	alpha-BHC	319846	0.0005	0.00056	0.000048	0.000048
33	alpha-Endosulfan	959988	9.7	10	6	7
34	Anthracene	120127	3100	4600	100	100
35	Antimony	7440360	12	180	6	90
36	Arsenic	7440382			0.018	0.14
37	Asbestos	1332214				
38	Benzene	71432				
39	Benzidine	92875				
40	Benzo(a) Anthracene	56553	0.014	0.021	0.00016	0.00016
41	Benzo(a) Pyrene	50328	0.0014	0.0021	0.000016	0.000016
42	Benzo(b) Fluoranthene	205992	0.014	0.021	0.00016	0.00016
43	Benzo(k) Fluoranthene	207089	0.014	0.21	0.0016	0.0016
44	beta-BHC	319857	0.0018	0.002	0.0013	0.0014
45	beta-Endosulfan	33213659				
46	Bis(2-Chloroethyl) Ether	111444				
47	*Bis(2-Chloro-1-Methylethyl) Ether	108601	(Not submitted)	(Not submitted)	400	900

	Chemical	CAS Number	Washington's Criteria that the EPA Disapproved or Deferred Action on in 2016 that the EPA is Now Approving		EPA Federally Promulgated Criteria	
			Water & Organisms (µg/L)	Organisms Only (µg/L)	Water & Organisms (µg/L)	Organisms Only (µg/L)
48	Bis(2-Ethylhexyl) Phthalate	117817	0.23	0.25	0.045	0.046
49	Bromoform	75252	5.8	27	4.6	12
50	Butylbenzyl Phthalate	85687	0.56	0.58	0.013	0.013
51	Carbon Tetrachloride	56235				
52	Chlordane	57749	0.000093	0.000093	0.000022	0.000022
53	Chlorobenzene	108907	380	890	100	200
54	Chlorodibromomethane	124481	0.65	3	0.60	2.2
55	Chloroform	67663	260	1200	100	600
56	Chrysene	218019	1.4	2.1	0.016	0.016
57	Copper	7440508				
58	Cyanide <sup>D</sup>	57125	19	270	9	100
59	Dibenzo(a,h) Anthracene	53703	0.0014	0.0021	0.000016	0.000016
60	Dichlorobromomethane	75274	0.77	3.6	0.73	2.8
61	Dieldrin	60571	0.0000061	0.0000061	0.000000070	0.000000070
62	Diethyl Phthalate	84662	4200	5000	200	200
63	Dimethyl Phthalate	131113	92000	130000	600	600
64	Di-n-Butyl Phthalate	84742	450	510	8	8
65	Endosulfan Sulfate	1031078	9.7		9	
66	Endrin	72208	0.034	0.035	0.002	0.002
67	Endrin Aldehyde	7421934				
68	Ethylbenzene	100414	200	270	29	31
69	Fluoranthene	206440	16	16	6	6
70	Fluorene	86737	420	610	10	10
71	Gamma-BHC; Lindane	58899	15	17	0.43	0.43

	Chemical	CAS Number	Washington's Criteria that the EPA Disapproved or Deferred Action on in 2016 that the EPA is Now Approving		EPA Federally Promulgated Criteria	
			Water & Organisms (µg/L)	Organisms Only (µg/L)	Water & Organisms (µg/L)	Organisms Only (µg/L)
72	Heptachlor	76448	0.0000099	0.00001	0.00000034	0.00000034
73	Heptachlor Epoxide	1024573	0.0000074	0.0000074	0.0000024	0.0000024
74	Hexachlorobenzene	118741	0.000051	0.000052	0.0000050	0.0000050
75	Hexachlorobutadiene	87683	0.69	4.1	0.01	0.01
76	Hexachlorocyclopentadiene	77474	150	630	1	1
77	Hexachloroethane	67721	0.11	0.13	0.02	0.02
78	Indeno(1,2,3-cd) Pyrene	193395	0.014	0.021	0.00016	0.00016
79	Isophorone	78591				
80	Methyl Bromide	74839	520		300	
81	Methylene Chloride	75092	16	250	10	100
82	Methylmercury	22967926	(Not submitted)	(Not submitted)		0.03
83	Nickel	7440020	150	190	80	100
84	Nitrobenzene	98953	55	320	30	100
85	N-Nitrosodimethylamine	62759				
86	N-Nitrosodi-n-Propylamine	621647				
87	N-Nitrosodiphenylamine	86306				
88	Pentachlorophenol (PCP)	87865	0.046	0.1	0.002	0.002
89	Phenol	108952	18000	200000	9000	70000
90	Polychlorinated Biphenyls (PCBs) <sup>E</sup>	PCB	0.00017	0.00017	0.000007	0.000007
91	Pyrene	129000	310	460	8	8
92	Selenium	7782492	120	480	60	200
93	Tetrachloroethylene	127184	4.9	7.1	2.4	2.9

			Washington's Criteria that the EPA Disapproved or Deferred Action on in 2016 that the EPA is Now Approving		EPA Federally Promulgated Criteria	
	Chemical	CAS Number	Water & Organisms (µg/L)	Organisms Only (µg/L)	Water & Organisms (µg/L)	Organisms Only (µg/L)
94	Thallium	7440280	0.24	0.27	1.7	6.3
95	Toluene	108883	180	410	72	130
96	Toxaphene	8001352				
97	Trichloroethylene	79016	0.38	0.86	0.3	0.7
98	Vinyl Chloride	75014		0.26		0.18
99	Zinc	7440666	2300	2900	1000	1000

\* Bis(2-Chloro-1-Methylethyl) Ether was previously listed as Bis(2-Chloroisopropyl) Ether.

Footnotes for human health criteria in Table 240 (WAC 173-201A-240):

- D. This recommended water quality criterion is expressed as total cyanide, even though the integrated risk information system 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.,  $\text{Fe}_4[\text{Fe}(\text{CN})_6]_3$ ), this criterion may be overly conservative.
- E. This criterion applies to total PCBs, (e.g., the sum of all congener or all isomer or homolog or Aroclor analyses). The PCBs criteria were calculated using a chemical-specific risk level of  $4 \times 10^{-5}$ . Because that calculation resulted in a higher (less protective) concentration than the current criterion concentration (40 C.F.R. 131.36) the state made a chemical-specific decision to stay at the current criterion concentration.