December 18, 2015

Via Federal eRulemaking Portal (http:www.regulations.gov)

Ms. Erica Fleisig
Office of Water
Standards and Health Protection Division (4305T)
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460

Re: Revision of Certain Federal Water Quality Criteria Applicable to Washington
Docket ID No. EPA-HQ-OW-2015-0174

Dear Ms. Fleisig:

The Northwest Pulp & Paper Association, the American Forest & Paper Association, Western States Petroleum Association, Alcoa, Nucor Steel Seattle, Inc., Schnitzer Steel, The Boeing Company, Northwest Food Processors Association, Utility Water Act Group, Treated Wood Council, Western Wood Preservers Institute, American Petroleum Institute, Association of Washington Business, Kaiser Aluminum Washington, LLC, Packaging Corporation of America, WestRock, KapStone Kraft Paper Corp., The Weyerhaeuser Company, Ponderay Newsprint Company, Sonoco Products Company, Inland Empire Paper Company and the Port of Walla Walla are pleased to submit the attached detailed comments on the Environmental Protection Agency (EPA) proposed revision to certain federal water quality criteria applicable to the State of Washington announced in 80 Fed. Reg. 55063 (September 14, 2015).

The commenting entities respectfully request that EPA suspend further action on its proposed rule. On a fundamental level the proposed criteria are inconsistent with the Clean Water Act and the best available science. EPA is driving an entirely new risk management policy that has no basis in science or long-standing risk management policy at the federal and state level. EPA has failed to explain the basis for this new and seemingly arbitrary policy and how the potentially enormous compliance costs are justified when the rule affords no measurable benefit to public health to either the general population or tribal populations in Washington. Our detailed technical concerns with EPA's new policy are attached.

The rule will result in the expenditure of billions of dollars in Washington in an effort to comply with the standards based on this new policy. However, complete attainment is not likely, which will potentially foreclose any new or expanded industrial or municipal facilities within the watersheds of waters deemed impaired for failing to meet the proposed criteria.

EPA should suspend its rule making in order to allow the State of Washington to conclude its rule development process. The State of Washington has announced that it will be

issuing a draft rule in January 2016. It makes no sense for EPA to continue rule making efforts when the federal process will have to be suspended once the state provides EPA a revised water quality standard for review.

At a minimum, EPA needs to provide additional information as to the rule's scientific basis, legal basis and economic impact. Adoption of the rule without additional disclosure and an opportunity for public comment is a clear violation of the obligations of EPA under the Administrative Procedures Act and the Clean Water Act to provide notice and an opportunity for public participation. This is particularly true for the economic impact analysis. The analysis needs to be re-done with a competent review of existing water quality data in Washington and assessment of potential compliance costs.

We appreciate the opportunity to comment on the proposed rule and your careful consideration of the attached detailed comments.

Sincerely,

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Christian McCabe
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4846-8276-7660, v. 1

COMMENTS ON BEHALF OF THE NORTHWEST PULP & PAPER ASSOCIATION, THE AMERICAN FOREST & PAPER ASSOCIATION, WESTERN STATES PETROLEUM ASSOCIATION, ALCOA, NUCOR STEEL SEATTLE, INC., SCHNITZER STEEL, THE BOEING COMPANY, NORTHWEST FOOD PROCESSORS ASSOCIATION, UTILITY WATER ACT GROUP, WESTERN WOOD PRESERVERS INSTITUTE, TREATED WOOD COUNCIL, AMERICAN PETROLEUM INSTITUTE, ASSOCIATION OF WASHINGTON BUSINESS, KAISER ALUMINUM WASHINGTON, LLC, PACKAGING CORPORATION OF AMERICA, WESTROCK, KAPSTONE KRAFT PAPER CORP., THE WEYERHAEUSER COMPANY, PONDERAY NEWSPRINT COMPANY, SONOCO PRODUCTS COMPANY, INLAND EMPIRE PAPER COMPANY AND PORT OF WALLA WALLA ON THE EPA PROPOSED REVISION OF CERTAIN FEDERAL WATER QUALITY CRITERIA APPLICABLE TO WASHINGTON, 80 Fed. Reg. 55063 (September 14, 2015)

Docket ID No. EPA-HQ-OW-2015-0174

December 18, 2015

Prepared by James Tupper and Lynne Cohee, Tupper Mack Wells PLLC

TABLE OF CONTENTS

Page

The Northwest Pulp & Paper Association, the American Forest & Paper Association, Western States Petroleum Association, Alcoa, Nucor Steel Seattle, Inc., Schnitzer Steel, The Boeing Company, Northwest Food Processors Association, Utility Water Act Group, Treated Wood Council, American Petroleum Institute, Western Wood Preservers Institute, Association of Washington Business, Kaiser Aluminum Washington, LLC, Packaging Corporation of America, WestRock, KapStone Kraft Paper Corp., The Weyerhaeuser Company, Ponderay Newsprint Company, Sonoco Products Company, Inland Empire Paper Company and the Port of Walla Walla submit the following comments on the Environmental Protection Agency (EPA) proposed revision to certain federal water quality criteria applicable to the State of Washington announced in 80 Fed. Reg. 55063 (September 14, 2015).*****

Introduction

The commenting entities respectfully request that EPA suspend further action on its proposed rule. The rule will result in the expenditure of billions of dollars in Washington in an effort to comply with the standards. Full compliance is not likely, however, which will potentially foreclose any new or expanded industrial or municipal facilities within the watersheds of waters that are likely to be deemed impaired for failing to meet the proposed ultra-low criteria. On a more fundamental level the proposed criteria are inconsistent with the Clean Water Act (CWA) and the best available science. EPA is driving an entirely new risk management policy that has no basis in science or long-standing risk management policy at the federal and state level. EPA has failed to explain the basis for this new and seemingly arbitrary policy, and has failed to explain how the potentially enormous compliance costs are justified when the rule affords no measurable benefit to public health for either the general population or for tribal populations in Washington.

EPA should suspend rulemaking and defer to the state rule development. The State of Washington has announced that it will be issuing a draft rule in January 2016. It makes no sense for EPA to continue rulemaking efforts when the federal process will have to be suspended once the state provides EPA a revised water quality standard for review.

At a minimum, EPA needs to provide additional information as to the rule's scientific basis, legal basis, and economic impact. Adoption of the rule without additional disclosure and an opportunity for public comment is a clear violation of EPA's obligations under the Administrative Procedures Act (APA) and the Clean Water Act to provide notice and an opportunity for public participation. This is particularly true for the economic impact analysis. The analysis needs to be re-done with a competent review of existing water quality data in Washington and assessment of potential compliance costs.

*****These comments include the attachments identified in the table of contents as well as the documents contained in the Supporting Documents File submitted with these comments. Documents in the Supporting Documents File are identified by page number within in parentheses in footnote citations. We request that the comment letter, attachments and Supporting Documents File be included in the rulemaking docket.

Comment No. 1: The proposed rule does not comply with requirements of the Clean Water Act and the Administrative Procedures Act to provide a basis for the proposed rule and adequate public notice and participation in the rulemaking.

From the inception of rulemaking in early 2013 by the Washington Department of Ecology (Ecology) through publication of EPA's proposed rule, EPA has taken a hardened position on two key factors—fish consumption rates and acceptable risk levels—and refused to engage in any discussion on the merits or basis for its demands. The background information provided in the proposed rule Federal Register notice continues these obfuscations and in several cases misrepresents the cited references and basis for the proposed rule.

EPA drew a line in the sand on these issues with the regulated community in Washington at a meeting on April 9, 2013. That meeting took place in the offices of EPA Region 10 in Seattle, Washington and was attended by EPA Regional Administrator Dennis McLerran and Daniel Opalski, the manager of the Region 10 Office of Water and Watersheds, representatives of Northwest Pulp & Paper, the Association of Washington Business, the Association of Washington Cities, the City of Everett, Weyerhaeuser and Inland Empire Paper Company. Mr. McLerran commenced the meeting by stating that the criteria in Washington should be based on a 175 grams per day (g/day) fish consumption rate and risk policy of one in one million (1×10^{-6} or 10^{-6}). Mr. McLerran explained that this was so because "everyone should be protected to the same level."[1] Mr. McLerran further stated that there had to be regional, meaning EPA regional, consistency on the toxic criteria. Mr. McLerran further stated that he was unwilling to discuss these factors with the regulated community.

EPA has been equally opaque in its dealings with the state of Washington. Ecology presented the risk level policy issue to EPA Region 10 on numerous occasions over the past three years. The origins and basis for the one in one million risk policy were the subjects of several emails to EPA regional staff in January and February 2013.[2] We believe that EPA staff attended the February 8, 2013, and March 28, 2013 Ecology Policy Forum meetings where the current risk policy in Washington and EPA guidance on risk policy were discussed.[3] EPA staff never indicated in response to these emails or at the meetings that there has been any change in EPA policy—or any circumstances that require toxic criteria in Washington to vary from national guidance.

Ecology specifically raised the risk policy issue to EPA national and regional staff at a meeting on March 20, 2013. The regional staff included Lisa Macchio, Mary Lou Soscia, Matthew Szelag, Lon Kissinger and Angela Chung.[4] The following questions and answers were recorded regarding EPA guidance on risk policy:

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[1] D. McLerran, Pers. Communication to NWPPA Members (April 9, 2013).

[2] C. Niemi, Email to L. Kissinger (January 2, 2013)(03933-3934).

[3] *See* Attendance Lists for Meetings on June 24, 2013, November 6, 2013, and July 2014 (03935-3943).

[4] C. Niemi, Handwritten Notes (March 20, 2013)("Dennis [EPA Region 10 Administrator] thinks the OR outcome was the right outcome, regionally wants to explore that position.")(00455-0458).

> Question: Does EPA agree that [the Washington] risk level applies to [the] general population?
>
> Angela Chung: EPA can't answer that now.
>
> Question: Would EPA disapprove a standard based on 10^{-6} for general population as long as 10^{-4} is max for highly exposed?
>
> Angela Chung: EPA can't answer that now.[5]

Ecology raised this issue with EPA staff again in emails and meetings in October and November 2013.[6] At these meetings between agency staff, the risk policy was listed as a topic for discussion. Ecology also presented its range of policy options at a public meeting on November 6, 2013.[7] EPA staff were present for the meeting but made no comment on national guidance for setting risk policy and there is no record of any comments from EPA regarding the policy options presented at this meeting. In meeting after meeting EPA staff remained silent on this issue. This included two public meetings held in 2013 and 2014, at seven delegate table meetings in 2012, 2013 and 2014, and at five Policy Forum meetings in 2013.

The issue was most pointedly raised in a meeting with EPA regional staff on March 11, 2014. After months of silence, Mr. McLerran apparently stated "175 grams a day at 10^{-6} is a baseline for environmental justice."[8] Mr. McLerran reportedly represented that this assertion was based on EPA guidance. In a follow-up email, Ecology requested that Region 10 verify the existence of that guidance. Ecology specifically asked:

> I have a copy of the document: "EPA Policy on Environmental Justice for Tribes and Indigenous Peoples." It is a pre-decisional working draft dated November 14, 2012.
>
> Is that the document Dennis referred to?
>
> …
>
> As we discussed, tribal members, and anyone eating high amounts of fish, are at higher risk. They are at a risk exactly proportionate to the consumption rate and will be at the same ratio (proportion) regardless of where the rule lands. Interpreting this section of the policy to mean that they can't be at a higher risk would frustrate the entire system the HHC equations are based on and make it impossible to comply. **Is there a statement somewhere that one in a million risk rate is the baseline to establish environment justice?**[9]

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[5] *Id.*

[6] M. Gildersleeve, Email to A. Chung and M. Szelag (October 1, 2013)(03944).

[7] Ecology, Preliminary Draft – HHC Tools Summary, Water Quality Standards Rule Making, Human Health Criteria, Summary, (November 6, 2013)(03945).

[8] K. Susewind, Email to D. Opalski (March 11, 2014)(00459-0461).

[9] *Id.* (emphasis added).

Mr. Opalski responded to this email and confirmed that there is no such statement. In an email dated March 11, 2014, he conceded: "Regarding the environmental justice concern, you are right that there isn't anything that will/does call out particular risk levels."[10]

EPA Region 10 provided an additional comment on the Washington proposal in a letter dated July 1, 2014. This letter was in response to two letters from Washington State Senator Doug Ericksen. Sen. Ericksen, in his first letter on April 3, 2014, asked the EPA Regional Administrator, "I specifically would like to know what your agency considers to be an appropriate cancer risk level for the state of Washington."[11] Three weeks later Mr. McLerran responded with a letter that was not responsive to this question.[12] Sen. Ericksen sent a second letter to Mr. McLerran on May 28, 2014, pointing out that "I asked a specific question relating to a very important issue that will affect Washington's economy and public health, but you did not provide me with a specific answer."[13] Sen. Ericksen requested an answer to his question and rephrased it as follows:

(1) Have you or your staff indicated to the Washington Department of Ecology that there is a threshold cancer risk level that must be proposed for the state's criteria to receive approval?
(2) Have you or your staff indicated to Ecology that a cancer risk level of 10^{-6} is required or that it is a level you want the state to propose?
(3) Have you or your staff provided any specific directives to Ecology outlining what you will accept for a cancer risk level for Washington?[14]

Mr. McLerran, in a letter dated July 1, 2014, responded that certain "groups could be provided less protection than they have now" if Washington uses a one in one hundred thousand risk policy.[15] There is no merit to this contention where the state was proposing to increase the consumption rates protected within the long accepted range of insignificant risk at 10^{-4} from 650 grams per day under the National Toxics Rule (NTR) to 1750 grams per day under the draft criteria and where the state was proposing criteria that would have been no less stringent than the current NTR criteria.

By the summer of 2014 it was clear that EPA was struggling to find some post-hoc rationalization for its demands. In some instances EPA staff would abandon any pretense of what is required under the CWA and simply assert its policy preferences are appropriate because "Dennis is concerned" or "Dennis feels."[16] At other times EPA would assert grounds for its demands that later disappeared. In March and July 2014, EPA claimed that its preferred fish consumption rate and risk level was required as a matter of environmental justice. This

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[10] D. Opalski, Email to K. Susewind (March 11, 2014)(03946).

[11] D. Ericksen, Letter to D. McLerran (April 3, 2014)(03947-3948).

[12] D. McLerran, Letter to D. Ericksen (April 24, 2014)(03949).

[13] D. Ericksen, Letter to D. McLerran (May 28, 2014)(03950-3951).

[14] *Id.*

[15] D. McLerran Letter to D. Ericksen (July 1, 2014)(03952-3953).

[16] *See* n. 4. C. Niemi, Handwritten Notes (00455-8) and A. Chung, Pers. Communication, NWPPA Annual Meeting (June 6, 2013).

argument is notably absent from both the EPA comment letter on the Ecology proposed rule and the Federal Register explanation for the basis of the EPA proposed rule.[17]

On March 23, 2015, EPA submitted a formal comment letter on the Ecology proposed rule. The letter was signed by Mr. Opalski, who participated in many of the meetings and telephone conversations and emails discussed above. EPA's letter asserted an entirely new basis for EPA's demands, stating that a one in one million risk level applied to tribal consumption rates is a "compromise position" of Washington tribes.[18] This is a statement that is not supported by any of the tribal letters that EPA has included in the rulemaking docket or the comments from tribes and tribal organizations on the Ecology draft rule. NWPPA submitted a Freedom of Information Act request to EPA for any documents that reflect the claim in the EPA comment letter. Matthew Szelag and Andre Szalay, EPA Region 10 staff, initially responded in a telephone conference that there were no public records to support the statement by EPA. EPA nonetheless produced twenty-six pages of heavily redacted emails and publicly available documents, not one of which includes a communication from or on behalf of any tribe stating that a one in one million risk level is a "compromise position of the tribes."[19] At most some tribal representatives have demanded a 10^{-6} risk level but there is no evidence that any tribal representative has offered any scientific research or data to support what will be a significant change in the risk policy applied in Washington. In any event, even if it were a compromise position of the tribes, this is not a basis under the CWA for EPA to depart from long-standing CWA policies, procedures, and requirements to mandate its preferred position on a state as it develops its criteria.

The March 23, 2015, comment letter is also noteworthy as being the first time EPA asserted that tribal treaty rights require the application of a particular risk level to tribal consumption rates. EPA had never before cited this rationale in prior meetings with the regulated community or in communications or meetings EPA had with Ecology staff. Having asserted this claim, however, EPA has consistently refused to explain how a treaty right to take fish dictates any particular risk management decision. This question was specifically posed to EPA by Ecology on July 15, 2015:

> Does EPA have an OGC [Office of General Counsel] or other legal opinion or rationale on how risk level and treaty tribal rights are connected, and why 10-6 is looked upon by EPA as fulfilling the rights, and 10-5 is not? Could you send me a copy of the opinion/rationale document?[20]

This becomes one of the central questions in the EPA rule—what exactly is the legal and scientific connection between a tribal treaty right and the use of a particular risk level as a factor in the equation that derives water quality criteria. Consistent with its now long-standing refusal to provide a legal, scientific and policy basis for its demands or engage in any meaningful public

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[17] D. Opalski, Letter to C. Niemi EPA Comment on Ecology Draft Rule (March 23, 2015)(07230-7249).

[18] *Id*.

[19] M. Szelag, Email to J. Edgell (July 14, 2015)(06440-2); K. Brown, Email to B. Duncan (June 5, 2015)(06466-6467); M. Szelag, Email to P. Ford (March 17, 2015)(06464-6465), EPA FOIA Response, EPA-R10-2015-008998 (August 2015).

[20] *Id.,* M. Szelag, Email (06442).

process, the EPA general counsel in an internal email directed EPA Region 10 to respond to Ecology by referring Ecology back to EPA's March 23, 2015 comment letter and EPA's February 2, 2015 decision to disapprove in part human health water criteria developed by the State of Maine.[21] It is not surprising that Ecology's subsequent July 2015 draft responses to comments on the proposed Washington State rule concluded that there is no legal basis for requiring criteria based on tribal consumption rates using a 10^{-6} risk level.[22]

EPA's proposed rule exemplifies its continued failure to provide a sound scientific rationale for its demands regarding risk policy and the fish consumption rate. The actions of EPA violate the CWA and the APA and preclude EPA from issuing a final rule based on the Federal Register notice.

Comment No. 2: The proposed rule conflicts with Washington's risk policy for human health water quality criteria.

EPA misrepresents the Washington risk policy in the Federal Register by implying that the risk policy is intended to set a risk level of human health criteria applicable to all consumers at a level of one in one million. EPA knows that the current risk policy in Washington, WAC 173-201A-240(5), is intended to apply the one in one million (or 1×10^{-6}) risk level to the per capita consumption rate of the general population and not to more highly exposed subpopulations. EPA established this as a matter of law in *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995).[23]

EPA fails to acknowledge or disclose in the Federal Register that Ecology has interpreted and publicly stated that its risk policy for human health criteria in the state Water Quality Standards, WAC 173-201A-240(6), is intended to apply to the per capita consumption rate of the general population.[24] EPA also misrepresents that EPA and not Washington set the risk level for application of the National Toxics Rule (NTR) in Washington. Through the NTR process, EPA offered states the option of human health criteria calculated based on either a 10^{-6} or 10^{-5} risk level for the general population. Washington opted to use a 10^{-6} risk level.[25] In the context of the NTR, however, this risk level is applicable to the per capita consumption rate of the general population on the assumption that NTR criteria are protective of higher consuming subpopulations at a 10^{-4} risk level and is consistent with long-standing EPA policy.

EPA and Washington have never assumed that the 10^{-6} risk policy set forth in WAC 173-201A-240(6) would apply to all consumers of fish. Otherwise, Washington would not have adopted, nor would EPA have approved, coverage under the NTR where the criteria are based on

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[21] *Id.*, M. Szelag, Email (06440).

[22] Ecology, Draft Responses to Comments on Proposed State Rule (July 2015) (04758).

[23] EPA, Brief for the Defendant-Appellees, *Dioxin/Organochlorine Center v. Clarke*, Nos. 93-35973 & 93-36000 (May 31, 1994) (00899-0967).

[24] Ecology, Washington State Water Quality Standards: Human Health Criteria and Implementation Tools, Overview of Key Decisions in Rule Amendment, (January 2015)(Publication No. 14-10-058)(00001-0073).

[25] NTR, 57 Fed. Reg. 60848-01, 60868 (00768-847); 40 C.F.R. §131.36(b)(14)(iii)(00848-0860).

a range of acceptable risk levels from 10^{-6} to 10^{-4}.[26] EPA described this in its brief in the *Dioxin* case as a choice "to provide a high level of protection for the average population in order to provide what they [Washington and other states] deem adequate protection for more sensitive populations."[27]

The scope and intent of the 10^{-6} risk policy in WAC 173-201A-240(6) was a central issue in a challenge to a dioxin water quality improvement plan or Total Maximum Daily Load (TMDL) allocation developed by EPA for the Columbia River. The dioxin TMDL was based on the same assumptions for the dioxin criterion in the NTR, including a FCR of 6.5 g/day. The TMDL was challenged in federal court on the basis of evidence that actual FCRs on the Columbia River for recreational fishers and Tribes was as high as 150 grams per day. The challengers contended that EPA should have applied WAC 173-201A-240(6) to derive a water quality criterion for dioxin that would protect all fish consumers to a level of 10^{-6} based on the higher FCR. In *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995), the court concluded that Washington did not intend to mandate a 10^{-6} risk level for every fish consumer. The Ninth Circuit held that "the one-in-a-million risk level mandated by the state water quality standards for the general population does not necessarily reflect state legislative intent to provide the highest level of protection for *all* subpopulations but could reasonably be construed to allow for lower yet adequate protection of specific subpopulations." 57 F.3d at 1524 (emphasis in original).[28]

In *Dioxin/Organochlorine Center*, EPA successfully argued that the mere fact that actual fish consumption in Washington is greater than the FCR in the TMDL (the same as the NTR) does not mean that the national criteria violate the state risk policy to protect human health under WAC 173-201A-240(6). EPA argued that the FCR and risk levels in the federal criteria are based on consumption of maximally contaminated fish, and are not intended to reflect actual consumption rates.[29] EPA also argued that the 6.5 grams per day fish consumption rate was not intended to accurately represent total consumption of fish, but instead the ingestion rate of a given contaminant.[30] According to EPA, the fish consumption rate used in the NTR was "intended to represent only a subset of total fish consumption."[31] The FCR is the assumed amount of "maximum residue fish" consumed.[32] EPA further asserted that consuming anadromous fish, like salmon, is unlikely to cause ingestion of contaminants at a rate equal to consuming maximum residue fish.[33] EPA explained: "[T]he total fish consumption rate of

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[26] WAC 173-201A-240(6). EPA's "policy in the NTR [is] to select the risk level that reflect[s] the policies or preferences of CWA programs in the affected States." 65 Fed. Reg. 31682, 31699 (May 18, 2000)(00861-0898).

[27] *See* n.23. EPA, Brief for the Defendant-Appellees.

[28] The risk policies in the NTR were also affirmed in *Natural Resources Defense Council v. EPA*, 16 F.3d 1395 (4th Cir. 1993)(rejecting argument that 6.5 grams per day FCR failed to protect subpopulations with higher than average fish consumption). EPA's range of acceptable risk levels was also upheld in other contexts. *E.g.*, *Ohio v. EPA*, 997 F.2d 1520, 1533 (D.C. Cir. 1993)(describing range of 10^{-6} to 10^{-4} as adequately protective of human health).

[29] *Natural Resources Defense Council v. EPA*, 16 F.3d 1395, 1402 n.11 (4th Cir. 1993).

[30] *See* n.23. EPA, Brief for the Defendant-Appellees.

[31] *See* n.23. EPA, Brief for the Defendant-Appellees at 44 (00954).

[32] *Id.*

[33] 16 F.3d at 1403; *see also* n.23. EPA, Brief for the Defendant-Appellees at 44 (00954).

various individuals is not determinative; the central question is whether the actual rate of ingestion [of a contaminant] is greater than that assumed by EPA."[34]

To understand Washington's risk policy, one must take into consideration the timing and sequence of the state's adoption of its risk policy and when the state was formally subject to the NTR. The risk policy, WAC 173-201A-240(5), was promulgated as a state regulation in October 1992.[35] The promulgation of the regulation referencing the NTR was included with revisions to the state Water Quality Standards, WAC 173-201A-240(6), five years later in November 1997.[36] In addition to the fact that the NTR does not extend the 10^{-6} risk level to all consumers, there is the intervening ruling in *Dioxin/Organochlorine Center* that the state policy does not reflect any intent to protect high consumers to the 10^{-6} risk level. A basic rule of statutory construction provides that the failure to amend an act following a judicial construction indicates approval of the construction.[37] Thus, if Ecology believed that the risk policy was intended to more broadly apply in Washington it would have amended the regulation prior to incorporating a reference to the NTR in the state Water Quality Standards.

As adopted and approved by EPA, and in light of the federal court decision, the NTR as applied in Washington does not presume all consumers are to be protected to a level of 10^{-6}.[38] The proposed EPA criteria will accordingly be in direct conflict with the federally approved state risk policy. EPA has made a tentative determination that "Washington's existing human health criteria, as promulgated by EPA in the NTR, are no longer protective of designated uses" but has made no such determination with respect to the state risk policy, WAC 173-201A-240(5). In responses to these comments, we ask EPA to explain how the proposed criteria should be applied in light of the state policy that provides a different risk level policy than that used by EPA in the proposed criteria.

Comment No. 3: The proposed rule conflicts with EPA's long-standing policy on acceptable risk levels.

EPA misrepresents its guidance and supporting science for deriving human health water quality criteria. EPA fails to acknowledge that its 2000 Human Health Methodology provides for risk based criteria using a risk level of 10^{-6} or 10^{-5} for the 90th percentile consumption rate for the general population as long as the **median** consumption rate for highly exposed populations is protected to a level of 10^{-4}.[39] The 2000 Human Health Methodology is clear that EPA deems both 10^{-6} and 10^{-5} risk levels as acceptable,[40] so long as the selection provides at least a 10^{-4} risk

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[34] *See* n.23. EPA, Brief for the Defendant-Appellees at 45 (00955); EPA's water quality criteria guidance includes a margin of safety for water consumption. 65 Fed. Reg. 31682, 31693 (May 18, 2000) (00861-0898).

[35] WSR 92-24-037 (00968-0971).

[36] WSR 97-23-064. (00972-1019).

[37] *Hangman Ridge Training Stables, Inc. v. Safeco Title Ins. Co.*, 105 Wn.2d 778, 789, 719 P.2d 531 (1986).

[38] Under controlling Washington law, the sequence of all statutes relating to the same subject matter should be considered. *Dep't of Labor and Industries v. Estate of MacMillan,* 117 Wn.2d 222, 229, 814 P.2d 194 (1991).

[39] *See* n.25. NTR at 60855.

[40] EPA asked states covered by the NTR to tell EPA if they preferred the human health criteria for the state be applied at a risk level of 10^{-5}. *See* n.25. NTR at 60864. In general, the NTR established AWQC for states based on a 10^{-6} risk level. *Id*. at 60860. A state could ask EPA to remove the state from the rule, and adopt human health criteria

level for the highest consumers of fish. "EPA generally regulates pollutants treated as carcinogens in the range of 10^{-6} to 10^{-4} to protect average exposed individuals and more highly exposed populations."[41] "EPA also believes that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sport fishers or subsistence fishers) does not exceed the 10^{-4} level."[42]

EPA guidance addresses the need to consider carefully the impact of criteria on sensitive and subsistence populations. This guidance is reflected in the preference for local data over EPA default values for fish consumption rates.[43] That does not mean, however, that a 10^{-6} risk level becomes a baseline for all population exposures. The EPA guidance directs that more specific information on consumption rates should be used to ensure that the criteria are within the protective range of EPA risk policy guidance:

> EPA understands that fish consumption rates vary considerably, especially among subsistence populations, and it is such great variation among these population groups that may make either 10^{-6} or 10^{-5} protective of those groups at a 10^{-4} risk level. Therefore, depending on the consumption patterns in a given State or Tribal jurisdiction, a 10^{-6} or 10^{-5} risk level could be appropriate. In cases where fish consumption among highly exposed population groups is of a magnitude that a 10^{-4} risk level would be exceeded, a more protective risk level should be chosen.[44]

EPA apparently wants to wish away accepted science on the rationale that the 2000 Human Health Methodology "did not consider how CWA decisions should account for applicable reserved fishing rights." This is simply a false statement. The Columbia River Inter-Tribal Fish Commission submitted a written comment on the draft 2000 guidance that raised treaty and trust obligations under the CWA.[45] As seen in the above quoted passage from the guidance, consumption patterns among subsistence populations and within a given tribal jurisdiction were considered in the document.

Moreover, EPA has updated and amended this guidance numerous times since its publication in 2002 as documented on the EPA web site.[46] EPA actively considered tribal fishing

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for a carcinogen at a 10^{-5} risk level. *Id*. If a state convinced EPA a 10^{-5} risk level was appropriate, public notice and comment would not be required "because the Agency has considered in this rule that criteria based on either 10^{-5} or 10^{-6} risk levels meet the requirements of the Act." *Id*.

[41] *See* n.25. NTR at 60855; *see also* 65 FR 31682, 31699 (May 18, 2000) (00861-0898).

[42] EPA, Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health, EPA-822-B-00-004 at 1-12 (October 2000)(00074-0258); *see also* n.25. NTR at 60848, 60863 (describing 10^{-5} level as "adequately protective").

[43] *Id.* at 1-12, 4-25.

[44] *Id.* at 2-6.

[45] EPA, Fish Consumption and Environmental Justice, at 58 (November 2002)(referencing Columbia River Inter-Tribal Fish Commission, Comments to Administrator Browner on the Draft Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (1999))(00268-0452).

[46] http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/index.cfm.

rights in parallel CWA proceedings in 2001 and 2002 that were nearly contemporaneous to the 2000 guidance and predate each of its updates.[47]

Comment No. 4: EPA has misrepresented its national policy in the Federal Register statement.

EPA should acknowledge that its rationale for the proposed Washington human health criteria based on the claim that "EPA often uses 10^{-6} as a *de minimis* risk level" is an overstatement if not misrepresentation of what EPA has long considered *de minimis* in deriving risk based criteria. EPA, across its environmental programs, the FDA and other federal agencies have consistently deemed 10^{-4} as a *de minimis* risk level when applied to a highly exposed subpopulation. EPA has provided no explanation or justification why this long-standing national consensus is no longer applicable as a matter of science and public health to deriving water quality standards in Washington.

Rather than apply its own guidance and accepted science EPA has cobbled together a rationale that treaty rights afford some *de minimis* level of exposure and that must mean that tribal consumption rates have to be applied to a one in one million risk level to afford that *de minimis* risk protection. In doing so, EPA blatantly ignores the long standing position of EPA and FDA programs that consider any exposure within a range of 10^{-6} to 10^{-4} to be a *de minimis* risk and a level of risk that is acceptable and insignificant for setting human health standards including water quality standards.

In support of its rationale EPA cites one scientific study in the Federal Register, 80 Fed. Reg. at 55068, n. 26:"Castorina, Rosemary and Tracey J. Woodruff (sic), *Assessment of Potential Risk Levels Associated with the U.S. EPA Reference Values*, ENVIRONMENTAL HEALTH PERSPECTIVES, Vol. 111, No. 10, page 1318." This article, which is about air quality and not water quality standards, does not support the implication in the Federal Register that EPA considers a 10^{-6} risk level to be a bright line standard for *de minimis* risk. The authors in fact state, "As a point of comparison, The U.S. EPA has defined 1 in 1,000,000 excess cancer risk as a *de minimis* risk level for cancer (Caldwell et al. 1998; Clean Air Act Amendments 1990; Fiori and Meyeroff, 2002; U.S. EPA 1991), **although regulatory actions are sometimes limited to instances where risk exceeds 1 in 100,000**." (Emphasis added.)

"Fiori and Meyeroff, 2002[48]," one of the references cited in support of the quoted statement in the Castorina article is a proposal for a risk management approach for exposure to mutagens that applies a *de minimis* risk standard. The article provides a short but instructive summary of "regulatory precedents for negligible carcinogenic risk":

> Acceptable risk is a concept that is required because of the adoption of the no threshold theory of carcinogenicity. Setting the acceptable risk level is a risk management decision….When EPA sets an acceptable risk for the general

[47] EPA, Meeting Summary of the Executive Council of the National Environmental Justice Advisory Council December 3, 4, and 6, 2001 (06107-6157); *see also* n. 45. EPA, Fish Consumption and Environmental Justice (00268-0452).

[48] Fiori and Meyeroff, Extending the Threshold of Regulation Concept: *De Minimis* Limits for Carcinogens and Mutagens, 35, REGULATORY TOXICOLOGY AND PHARMACOLOGY, 209-16 (April 2002)(06355-6362).

> population (as for drinking water standards), the upper bound risk level of one excess cancer per 1 million people (i.e., 10^{-6}) is used. (EPA, 1991).[49]

The "EPA 1991" references in both articles are the same, the draft NTR.[50] EPA states in the draft NTR that its risk based criteria are consistent with EPA guidelines that assume carcinogenicity is a "non-threshold phenomenon" and that there is no "safe" or "no-effect levels" of exposure.[51] Consistent with this guidance, EPA elected to use a "relatively stringent" cancer risk level of 10^{-6} as applied to the general population and deemed that protective of "subsistence fishermen" who are more exposed than the general population.[52] It was the position of EPA then, based on the law and best available science, that the use of a 10^{-6} risk level "is in part addressing the potential that highly exposed subpopulations exist by selecting a relatively stringent cancer risk level (10^{-6}) for use in deriving State-wide criteria for carcinogens."[53]

The EPA guidance also illustrates why protecting the highest subpopulation exposure at 10^{-6} would be over-protective of designated uses:

> It is important to understand that criteria for carcinogens are based on chosen risk levels that inherently reflect, in part, the exposure parameters used to derive those values. Therefore, changing the exposure parameters also changes the risk. Specifically, the incremental cancer risk levels are *relative*, meaning that any given criterion associated with a particular cancer risk level is also associated with specific exposure parameter assumptions (e.g., intake rates, body weights). When these exposure parameter values change, so does the relative risk. For a criterion derived on the basis of a cancer risk level of 10^{-6}, individuals consuming up to 10 times the assumed fish intake rate would not exceed a 10^{-5} risk level. Similarly, individuals consuming up to 100 times the assumed rate would not exceed a 10^{-4} risk level. Thus, for a criterion based on EPA's default fish intake rate (17.5 gm/day) and a risk level of 10^{-6}, those consuming a pound per day (i.e., 454 grams/day) would potentially experience between a 10^{-5} and a 10^{-4} risk level (closer to a 10^{-5} risk level). (Note: Fish consumers of up to 1,750 gm/day would not exceed the 10^{-4} risk level.) If a criterion were based on high-end intake rates and the relative risk of 10^{-6}, then an average fish consumer would be protected at a cancer risk level of approximately 10^{-8}. The point is that the risks for different population groups are not the same.[54]

EPA's 2000 Human Health Methodology clearly describes an "accepted risk range" of 10^{-4} to 10^{-6}, and provides that states may adopt a cancer risk level of either 10^{-5} or 10^{-6} for the general population, as long as "the risk to more highly exposed subgroups (sport fishers or

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[49] *Id.* at 210.

[50] EPA, Amendments to the Water Quality Standards Regulation to Establish the Numeric Criteria for Priority Toxic Pollutants Necessary to Bring All States into Compliance with Section 303(c)(2)(B), 56 Fed. Reg. 58420 (November 19, 1991) (06471-6529).

[51] *Id.* at 58434.

[52] *Id.* at 58435.

[53] *Id.*

[54] *See* n. 42, EPA, 2000 Human Health Methodology at 2-7 (00113).

subsistence fishers) does not exceed the 10^{-4} level."[55] Remarkably, EPA's only reference in the proposed rule to this long held policy and practice of addressing the unique health risks to Indian tribes as a high consuming subpopulation is found in a footnote. 80 Fed. Reg. at 55065 n. 6. Rather than acknowledging that its proposed rule is a radical departure from the 2000 Guidance, EPA simply states that the 2000 Human Health Methodology "did not consider how CWA decisions should account for applicable reserved fishing rights, including treaty-reserved rights." *Id*. at 55068 (§IV.C.b).

It defies logic, however, that EPA only discovered in 2015 that Indian tribes hold treaty rights to take fish. As explained below in Comment No. 9, the treaties were entered into in the 1850s. Federal courts began enforcing those rights as early as 1905 and most definitely by the U.S. Supreme Court *Fishing Vessel* decision in 1979. To adopt EPA's position here would effectively mean that EPA is admitting it has been in violation of the Stevens treaties since at least promulgation of the NTR in 1992.

The Federal Register statement for the draft Washington water quality rule additionally fails to acknowledge that the federal government has repeatedly deemed a 10^{-4} risk level to result in a *de minimis* risk when applied to more exposed subpopulations in deriving human health criteria under the CWA. EPA likewise fails to acknowledge that across EPA and FDA programs exposures at the level of risk between 10^{-6} and 10^{-4} are deemed acceptable because they represent an insignificant and essentially zero increased risk of cancer.[56]

"*De minimis"* is a term of art taken from the principle in common law of *de minimis non curat lex* meaning roughly that the "the law does not concern itself about trifles."[57] EPA appears to be reversing decades of scientific research and sound public policy by implying that highly exposed populations will not be as well protected if their exposure risk is at a risk level of 10^{-4}. On the contrary, it has been well understood prior to today that "if only a small population would be at greatest risk, the expected number of excess cancers corresponding to individual risks at the *de minimis* level of 10^{-4} would still be zero."[58] In actual practice, federal agencies across at least 132 regulatory decisions concluded that for small populations the *de minimis* lifetime risk was considered to be 10^{-4}.[59] These regulatory decisions include actions by the Consumer Product Safety Commission, the Food and Drug Administration, the Occupational Safety and Health Administration and EPA programs for water quality, air, pesticide use, drinking water, toxic substances and radiation.[60] A survey of these decisions concluded that "for small-population effects, regulatory action was never taken for individual risk levels below 10^{-4}.[61]

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[55] *Id*. at 1-12.

[56] *See* Attachment A, at 12.

[57] BLACK'S LAW Dictionary 524 (2009).

[58] Attachment B, at 18 (*quoting* D. Kocher, Criteria for Establishing *de minimis* Level of Radionuclides and Hazardous Chemicals in the Environment (1996) (Report ES/ER/TM-187 prepared by the Oak Ridge National Laboratory for the U.S. Department of Energy).

[59] *See* Attachment B, at 18.

[60] Travis, Richter, Crouch, Wilson and Klema, Cancer Risk Management, 21 ENVIRON. SCI. TECHNOLOGY 415, Table 1 (1987).(05083-5088).

[61] *Id.* at 418.(05086).

The accepted range of risk levels from 10^{-6} to 10^{-4} reflects a broader regulatory consensus that this range more than adequately protects human health to an insignificant level of risk that is essentially a zero increased risk of incurring cancer.[62] The abiding principle in the regulation of exposure to carcinogens was that there should be no exposure—that there is no safe level or threshold for exposure. An early expression of this principle is found in the 1954 Delaney Clause regulating chemicals in animal feed on the basis that there should be no toxins in toxic amounts.[63] It was apparent that health and environmental regulation would be impossible under the literal application of this concept. It is impossible to regulate to a zero standard.[64] This led to adoption by EPA and FDA of the Mantel-Bryan equation which is an early precursor to the current methodology for deriving risk based criteria under EPA guidance for human health criteria. Mantel-Bryan proposed using risk levels based at levels of insignificance that would reflect an essential zero risk of cancer at exposures considered in the resulting criteria.[65] As initially conceived, the risk levels were proposed in a range of one in one hundred million to one in a million—10^{-8} to 10^{-6}.[66]

The FDA through the 1970s and 1980s sought to establish amounts of carcinogenic compounds using an appropriate risk that when present as residue in human food would be consistent with "a zero tolerance (no residue)" policy.[67] To achieve this goal FDA made an early proposal based on the one in one-hundred-million risk level.[68] In its final rule, however, the FDA determined that the proposal was too conservative and offered no additional benefit to public health. As a result, the FDA determined that a one in one million risk was "essentially zero."[69]

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[62] *See* n. 24, Ecology, Overview at 18. (00024).

[63] Calabrese, Edward J. "Origin of the Linearity No Threshold (LNT) Dose-Response Concept." ARCHIVES OF TOXICOLOGY at 7-8 (2013)(01097-1109).

[64] Graham, John D. "The Legacy of One in a Million" RISK IN PERSPECTIVE (1993)(01110-1111).

[65] Hutt, Peter B. "A Brief History of Risk Assessment," FDA ORAL HISTORY (November 2000)(01112-1132).

[66] 33 Fed. Reg. 19226, 19226 (July 19, 1973)(01133-1137).

[67] *Id.*

[68] *Id*. at 19227.

[69] FDA, Compounds used in Food-Producing Animals, 38 Fed. Reg. 19227 (July 19, 1973). 37 Fed. Reg. 15747 (Aug. 4, 1972) (FDA adopts the Mantel-Bryan equation and its probit dose-response model as the tool used for quantitative risk assessment. Through Mantel-Bryan, one in 100,000,000 (10^{-8}) becomes a guide for determining safe doses of carcinogenic substances). FDA, Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals, 42 Fed. Reg. 10412 (Feb 22, 1977) (Following public response, industry critique, regulator reevaluation and economic considerations the one in 100,000,000 (10^{-8}) safe dose level is increased to a more lenient one in 1,000,000 (10^{-6})). FDA, Criteria and Procedure for Evaluating Assays for Carcinogenic Residues 44 Fed. Reg. 17070 (Mar. 20, 1979) (The Mantel-Bryan Equation is again adjusted; one in 1,000,000 is maintained). FDA, D&C Green No. 5, 47 Fed. Reg. 24278 (June 4, 1982) (Color additive D&C Green No. 6 permanently listed as acceptable for human consumption by FDA). FDA, Sponsored Compounds in Food-Producing Animals; Criteria and Procedures for Evaluating the Safety of Carcinogenic Residues, 50 Fed. Reg. 45530, 44541 (Oct. 31, 1985) (Responding to the Delaney clause, the FDA argues that one in a million risk level represents a truly insignificant degree of risk but that the agency can't confidently assert a one in one-hundred thousand risk level would adequately protect the general public). FDA, Cosmetics; Proposed Ban on the Use of Methylene Chloride as an Ingredient of Aerosol Cosmetic Products, 50 Fed. Reg. 51551 (Dec. 18, 1985) (FDA claims one in a million risk level represents a "*de minimis*" level of risk). (01138-1280).

It is important for EPA to consider that the trajectory of FDA regulations was to deem a 10^{-8} risk level as too conservative "after considering that and listening to both the industry and to the scientists in FDA, the final regulation as the sensitivity of the methods and the level chosen by FDA ever since then was reduced to 1 in a million."[70] FDA has explained that the 10^{-6} risk means no carcinogenic risk at all, that while there is a mathematical possibility, it is not a real risk in the actual practical world.[71]

EPA engaged in a similar public discussion as the FDA in the 1970s and 1980s.[72] EPA recognized that absolute criteria for carcinogens could not be established given uncertainties including variances of sensitivities and exposure levels.[73] Instead, EPA presented a range of concentrations associated with risk levels of 10^{-5}, 10^{-6}, and 10^{-7}.[74] EPA's objective in deriving these water quality criteria was to estimate concentrations "which do not represent a significant risk to the public."[75]

As discussed above, the EPA risk policy was affirmed in *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995). The same risk policy as applied under CERCLA was affirmed in *State of Ohio v. EPA,* 997 F.2d 1520, 1533 (D.C. Cir. 1993). At issue was whether EPA can allow a lower, one in ten thousand, risk level for the protection of populations near a Superfund site. Washington filed an amicus brief in this proceeding. 997 F.2d at 1524 n.1. The court rejected this contention:

> The States next challenge EPA's use of a cancer risk range between 10^{-6} and 10^{-4} in the NCP, arguing that an exposure level greater than 10^{-6} is never appropriate. A 10^{-4} risk subjects the surrounding population to an increased lifetime cancer risk of 1 in 10,000. A 10^{-6} risk subjects the surrounding population to an increased lifetime cancer risk of 1 in 1,000,000. When EPA develops objectives

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[70] *See* n. 65. Hutt, "A Brief History of Risk Assessment," FDA ORAL HISTORY, at 17 (November 2000)(01112-1132).

[71] *Id.*

[72] EPA, Health Risk and Economic Impact Assessments of Suspected Carcinogens: Interim Procedures & Guidelines 41 Fed. Reg. 21402 (May 25, 1976) (EPA proposes "a balancing of risks and benefits as the basis for final regulatory action" regarding carcinogenic pesticides). EPA, Water Quality Criteria Documents; Availability, 45 Fed. Reg. 79323 (Nov. 28, 1980) (The EPA presents a range of acceptable risk levels in regard to Superfund (CERCLA) cleanup). EPA, National Emission Standards for Hazardous Air Pollutants: Regulations of Radionuclides, 49 Fed. Reg. 43906-43911 (Oct. 31 1984) (EPA prescribes different levels of protection for those who have carrying levels of exposure; distinguishes between individual risk and population risk). EPA, Regulations of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41104 (Oct. 19, 1988). (EPA proposes using one in a million as a definitive acceptable risk level in an effort to supersede the Delaney clause). EPA, Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Toxicity Characteristics Revisions, 55 Fed. Reg. 11798 (Mar. 29, 1990) (EPA opts to use a one in one-hundred-thousand carcinogenic risk level for hazardous waste cleanup). EPA, Guidelines for Exposure Assessment, 57 Fed. Reg. 22888-22938 (May 29, 1992) (Discussion of individual and general population risks). EPA, Final Water Quality Guidelines for the Great Lakes System, 60 Fed. Reg. 15366-01 (March 23, 1995) (EPA approves a one in one-hundred-thousand risk level for the general population of the Great Lakes region because the most exposed populations would still be protected at a one in ten-thousand level, which is deemed adequate). (01281-1742).

[73] 45 Fed. Reg. 79318, 79347 (Nov. 28, 1980)(01743-1767).

[74] *Id.* at 79348.

[75] *Id.* at 79348.

for a remedial action at a site, it selects a remediation goal that "establish[es] acceptable exposure levels that are protective of human health." 40 C.F.R. § 300.430(e)(2)(i). EPA attempts to use health-based ARARs to set the goal, but if ARARs are nonexistent or unsuitable for use, EPA establishes the goal based on criteria in the NCP. 55 Fed. Reg. 8712 (1990). "For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-6} and 10^{-4}...." 40 C.F.R. § 300.430(e)(2)(i)(A)(2). The NCP expresses a preference for remedial actions that achieve a level of 10^{-6} however, the ultimate decision depends on a balancing of nine criteria, including cost. *Id.;* 55 Fed. Reg. 8718 (1990).

The States contend that by permitting cost to play a role in determining the level of exposure, the cancer risk range fails to meet the requirement in § 9621 that remedial actions be "protective of human health." 42 U.S.C. § 9621(b)(1); *see also* 42 U.S.C. § 9621(d)(1). The States' argument necessarily depends, though, on the notion that an exposure level greater than 10^{-6} is not protective of human health. CERCLA requires the selection of remedial actions "that are protective of human health," not as protective as conceivably possible. A "risk range of 10^{-4} to 10^{-6} represents EPA's opinion on what are generally acceptable levels." 55 Fed. Reg. 8716 (1990). Although cost cannot be used to justify the selection of a remedy that is not protective of human health and the environment, it can be considered in selecting from options that are adequately protective.

The States also argue that the actual risk range selected is not adequately protective. EPA concluded, though, that all levels of exposure within the risk range are protective of human health. *Id.* EPA has used 10^{-4} as an upper bound for establishing risk levels in the past, *see* 53 Fed. Reg. 51,394, 51,426 (1988), and "[m]any ARARs, which Congress specifically intended be used as cleanup standards at Superfund sites, are set at risk levels less stringent than 10^{-6}," 55 Fed. Reg. 8717 (1990). The States offer no evidence challenging EPA's position that 10^{-4} represents a safe level of exposure, and in any event, we give EPA's findings on this point significant deference. *See New York v. EPA,* 852 F.2d 574, 580 (D.C.Cir.1988), *cert. denied,* 489 U.S. 1065, 109 S.Ct. 1338, 103 L.Ed.2d 809 (1989).

The States also argue that EPA failed to justify the use of a range, instead of a single point. But EPA explained its decision to use a range. While "[t]he use of 10^{-6} expresses EPA's preference for remedial actions that result in risks at the more protective end of the risk range," 55 Fed. Reg. 8718 (1990), the Agency is also required to consider other factors in selecting an appropriate remedy. "Factors related to exposure, uncertainty and technical limitations may justify modifications of initial cleanup levels that are based on the 10^{-6} risk level." *Id.* A flexible approach to developing remedial goals is justified by the multiple statutory mandates of CERCLA, so long as EPA meets the statutory requirement of protectiveness.

997 F.2d 1520, 1533.

The national policy on acceptable risk is based on an extended scientific evaluation and has withstood legal challenges.[76] The risk policy for human health water quality criteria was resolved in the NTR. The NTR and subsequent EPA guidance documents have consistently articulated a policy to accept human health water quality criteria protecting the general population at a risk level of 10^{-6} or 10^{-5} as long as higher exposed populations are protected to at least a level of 10^{-4}.[77] EPA left it to each state to make its own risk management decision: "Adoption of a 10^{-6} or 10^{-5} risk level, both of which States and authorized Tribes have chosen in adopting water quality standards to date, represents a generally acceptable risk management decision, and EPA intends to continue providing this flexibility to States and Tribes."[78]

A long line of EPA decisions have affirmed the existing risk policy in human health criteria approvals for states on the Great Lakes[79], the California Toxic Rule, 40 C.F.R. § 131.38, and the state of Oregon human health criteria. The 2011 Technical Support Document for the Oregon criteria unequivocally states:

> EPA has identified a risk level range of 1 x 10^{-6} (1:1,000,000) to 1 x 10^{-5} (1:100,000) to be an acceptable risk management goal for the general population….
>
> EPA's 2000 Methodology states that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sport fishers or subsistence fishers) does not exceed the 10^{-4} risk policy.[80]

EPA should acknowledge that its statement that it often uses 10^{-6} as a *de minimis* risk level is simply not an accurate representation of EPA's long-standing policy on acceptable cancer risk levels. EPA should also acknowledge that there is little basis for its "necessity determination" on its own NTR criteria where the current NTR criteria for carcinogens are presumptively protective to a consumption rate of 650 g/day – far in excess of the mean consumption rates for high consuming populations in Washington.

Comment No. 5: EPA has failed to provide any basis in established science to require that a more stringent risk policy be applied in Washington.

EPA is proposing a significantly more stringent risk policy for application to the state of Washington. On the face of the proposed rule the risk policy would be to "target" tribal fish consumption rates as though they are the consumption rate for the general population, and apply a risk level factor that is associated with general population exposures. The result is the use of

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[76] *See* Attachment A at 11-12.

[77] *See* n.25. NTR at 60855; *see also* n. 42, EPA, 2000 Human Health Methodology at 1-12 (October 2000)(00104).

[78] *See* n.42. EPA, 2000 Human Health Methodology at 2-6 (00112); *see also* Attachment A at 13-14.

[79] EPA, Final Water Quality Guidelines for the Great Lakes System, 60 Fed. Reg. 15366-01 (March 23, 1995) (01775-1907)

[80] EPA, Technical Support Document for Action on the State of Oregon's New and Revised Human Health Water Quality Criteria and Associated Implementation Tools Submitted July 12 and 21, 2011, at 27 (October 17, 2011)(01908-2010).

175 g/day for fish consumption in calculating human health water quality criteria. EPA has not explained the basis for this consumption rate. Within various analyses of tribal consumption studies this rate may reflect the 95th percentile of tribal consumption rates, an average tribal consumption rate, or a consumption rate that has been endorsed by one or more tribal leaders or organizations representing tribal interests. EPA couples this approach with a risk management decision that all tribal consumption rates—the highest documented individual consumption rates—must be protected to 10^{-5}.

Under the EPA proposed risk policy, compared to the current state risk policy, the general population consumption rate, results in criteria that will be protective to a level more stringent than 10^{-7}. The 100th percentile of tribal consumption will be protected to 10^{-5}. Ecology concluded that the mean consumption rate for the general population in Washington is 18.8 g/day including all fish.[81] The effective rate for deriving human health water quality criteria is substantially less than this value, as it includes both fish that are store bought and anadromous fish that do not spend sufficient time in Washington waters to bio accumulate toxics. As such, EPA would effectively require that water quality standards applicable to Washington protect the general population at a risk level of 10^{-8}, and median tribal consumption rates at a risk level of 10^{-6}.

Criteria based on existing EPA guidance would be fully protective of tribal consumption without this dramatic change in risk policy. If EPA used 17.5 g/day as the consumption rate for the general population in Washington, at a risk level of 10^{-6}, the resulting criteria would be protective to a consumption rate of 175 g/day at a 10^{-5} risk level and for a consumption rate of 1,750 g/day at a risk of 10^{-4}. The Washington Office of Financial Management estimates that there are 104,000 American Indian and Alaska natives in Washington.[82] If EPA followed established guidance and science and applied a 10^{-6} risk level to the general population the resulting exposures at risk levels of 10^{-5} and 10^{-4} would not predict a single excess cancer risk for this population—a result that is more stringent than EPA guidance which calls for no excess cancer risk at the median consumption rate for high consuming populations at 10^{-4}.

ARCADIS, Summary of Health Risk Assessment Decisions in Environmental Regulations (March 6, 2015), Attachment A, explains in detail why tribal consumers would have the equivalent of a zero increased risk of cancer if EPA complied with its own guidance in setting criteria based on the general population consumption rate. The risk of cancer from all causes far outweighs the possible risk of cancer from exposure to chemicals in the environment. *Id.* at 2. To add some meaning to these risks, the excess cancer risk that may occur as a result of exposure to a carcinogen in the environment in Washington on an annual basis is 0.54% while the lifetime risk of cancer based on a risk level of 10^{-4} used to set water quality criteria is 0.00014%. *Id.* at 8-9. A 10^{-4} risk level is clearly an acceptable and protective upper bound risk level to use in deriving water quality criteria as there is no real increase in the overall risk of incurring cancer. This is especially true when comparing an **annual** risk to a risk level based on a **lifetime** exposure every day for 70 years. In theory only, a 10^{-4} risk level would predict one excess cancer in Washington. *Id*. at 2. This is only theoretical as risk managers across EPA and other federal programs have long considered this level of risk insignificant and, in fact, the

[81] Ecology, Fish Consumption Rate Technical Support Document Version 2.0, 40-44 (January 2013)(Ecology Publication No. 12-09-058)(05398-5591).

[82] *Id.* at 18.

absence of any real risk. *Id.* at 9-21. It is inexplicable why EPA is proposing to ignore and in some sense misrepresent the best available science and policy in risk management.

Overestimating risks in the interest of precaution must consider the consequences of such choices. *Id.* at 5. As ARCADIS explains, there is "a cost to reducing the levels of chemicals in the environment to meet more-stringent limits, a cost that may be measured in dollars, energy usage, or the risk of injury to workers to meet lower standards." *Id.* An estimate of those costs in terms of additional water quality treatment and energy consumption is provided in HDR, Treatment Technology Review and Assessment for Association of Washington Business, Association of Washington Cities and Washington State Association of Counties (December 2013)—Attachment C. HDR evaluated the cost of compliance with the Oregon human health water quality criteria for arsenic and PCBs at values that are the equivalent of the EPA-proposed criteria for Washington. *Id.* at 9, Table 1. The HDR report looked at advanced treatment systems using reverse osmosis and membrane filtration and estimated the range of unit costs for improving a 0.5 Million Gallon a Day (mgd) facility at $60 to $162 per gallon per day. *Id.* at 37. The range of unit costs for improving a 25 mgd facility to advanced treatment is $10 to $35 per gallon per day of treatment capacity. *Id.* For a 5 mgd facility HDR estimated the incremental cost of advanced treatment in total net percent value (as of 2013) at between $75 to $160 million. *Id.* at 38, Table 9.

If these costs are applied to just the 73 major NPDES facilities identified by EPA in its economic impact analysis, the total net present value (as of 2013) would be in the range of $5.5 billion and $11.7 billion. This does not include the 333 minor permits identified by EPA or the thousands of facilities and additional municipalities that are subject to NPDES stormwater permits. HDR also points to substantial collateral impacts above the cost of construction and operation of advance treatment including higher energy consumption, increased greenhouse gas emissions and increased solids production. *Id.* at ES-2.

EPA has failed to provide any meaningful basis for a risk policy that would be the equivalent of 10^{-8} to 10^{-6}. The best the agency can muster after several years of refusing to engage publicly on this issue is the frustrating *non sequitur* that some tribes have treaty rights to fish, and therefore have a right to safe and healthy fisheries, and therefore the tribal consumption rates must be protected to a risk level of 10^{-6}. The logical fallacy in this rationale is in substance no more revealing than the position advanced by EPA over the past three years which is in effect that "we want it this way because we want it this way."

EPA has simply failed to provide a rationale for changing accepted risk management policies. Any obligation of the United States under tribal treaties is the same obligation EPA has to all residents in the state of Washington—the obligation to establish criteria that are protective of beneficial uses including the beneficial uses attributed to high fish consuming populations, which encompass tribal consumers.

Before today EPA has never wavered on the risk management guidance that evolved prior to and since the adoption of the NTR in 1992. In June 2015 EPA published final updated ambient water quality criteria for the protection of public health in accordance with section

304(a)(1) of the Clean Water Act.[83] The risk-based criteria were updated based on the application of a 10^{-6} risk level to a general population consumption rate. EPA did not suggest that its risk management decision placed high consuming populations at risk and certainly did not consider whether there was any scientific basis for protecting those populations at a risk of 10^{-6}. The criteria are in fact based on the same understanding of the range of acceptable risk levels used in developing the NTR and the 2000 Human Health Criteria Guidance.[84] EPA proclaimed, based on this approach, that its recommended criteria "are scientifically derived numeric values that EPA determines will generally protect aquatic life or human health from adverse effects of pollutants in ambient water."[85]

There is no basis for the proposed rule's departure from EPA's consistent approach—reaffirmed just six months ago—that high consuming populations are adequately protected at a risk level of 10^{-4}. And by adequately protected, EPA has meant that the exposures at the levels recommended under national guidance afford an insignificant and essentially zero additional risk of cancer. As discussed in more detail below, EPA has no basis for differentiating its obligations to an entire population including subpopulations of more highly exposed members based on the existence of tribal treaty rights in Washington. EPA and reviewing courts have consistently said that high consuming populations are protected within the existing framework for risk. EPA has offered no scientific (or legal) basis for the assertion that tribal fish consumers in Washington are uniquely at risk and require some additional level of protection.

Comment No. 6: The proposed rule is contrary to the established criteria for environmental justice.

EPA should acknowledge that its proposed rule is inconsistent with current EPA guidance on environmental justice. This undoubtedly explains why EPA abandoned environmental justice as the basis for its demands on the state of Washington that it adopt EPA's preferred risk policy. In 2013 and 2014 Dennis McLerran made the improbable claims that "everyone deserves to be protected to the same level" and that "10^{-6} is a baseline for environmental justice."[86] It is notable that there is virtually no mention of environmental justice in the EPA March 23, 2015 comment letter on Washington's proposed rule and in the Federal Register notice for EPA's own proposed rule. This is not surprising since EPA guidance on environmental justice, including consideration of tribal consumption rates, in fact supports the rule proposed by Washington in January 2015.

In May 2015 EPA published formal guidance on considering environmental justice in agency actions, including rulemaking.[87] The guidance document does not reference and

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[83] EPA, Final Updated Ambient Water Quality Criteria for the Protection of Public Health, 80 Fed. Reg. 36986 (June 29, 2015)(04807-4810).

[84] EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update, EPA-820-F-14-003 at 2 (May 2014)(01772-1774).

[85] *See* n.83. EPA, Final Updated Ambient Water Quality Criteria at 36987.

[86] D. McLerran, Pers. Communication to NWPPA Members (April 9, 2013); *see also* n.8. K. Susewind, Email (00459).

[87] EPA, Guidance on Considering Environmental Justice During the Development of Regulatory Actions (May 2015)(available at http://www3.epa.gov/environmentaljustice/resources/policy) (05991-6046).

therefore implicitly endorses EPA's long-standing policy on the acceptable range of risk levels. The following discussion from the guidance document exemplifies how the agency will determine whether there is a disproportionate impact from an agency action:

> It is important to note that the role of the analyst is to assess and present differences in anticipated impacts across population groups of concern to the decision-maker and the public. The determination of whether there is a potential disproportionate impact that may merit Agency action is ultimately a policy judgment informed by analysis, and is the responsibility of the decision-maker. These analyses will depend on the availability of the scientific and technical data. As noted in the *Draft Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* (U.S. EPA 2013), examples of the type of information that may be useful to provide to decision-makers for considering whether or not effects are disproportionate include: the severity and nature of health consequences; the magnitude of the estimated differences in impacts between population groups; **mean or median exposures or risks to relevant population groups**; distributions of exposures or risk to relevant population groups; characterization of the uncertainty; and a discussion of factors that may make population groups more vulnerable.[88]

Thus, the EPA 2015 environmental justice guidance focuses on the mean or median consumption or exposure rate of a more highly exposed subpopulation in the same manner as the 2000 EPA guidance focuses on the range of acceptable risk levels.

EPA has consistently defended this range as protective of the entire population under the principles of environmental justice. This was addressed in the response to comments for the 1995 Final Water Quality Guidelines for the Great Lakes System where EPA approved the use of a one in one hundred thousand risk level:

> Commentators argued that a 15 gram per day assumption in the methodology would not adequately protect populations that consume greater than this amount (e.g. low-income minority anglers and Native Americans). And that such an approach therefore would be inconsistent with Executive Order 12898 regarding environmental justice (February 16, 1994, 59 Fed. Reg. 7629). **EPA believes that the human health criteria methodology, including the fish consumption rate, will provide adequate health protection for the public, including more highly exposed sub-populations.** In carrying out our regulatory actions under a variety of statutory authorities, including the CWA, EPA has generally viewed an upper bound incremental cancer risk in the range of 10^{-4} to 10^{-6} as adequately protective of public health. As discussed above, the human health criteria methodology is based on a risk level of 10^{-5}. Therefore, if fish are contaminated at the level permitted by the criteria derived under the final Guidance, individuals eating up to 10 times (i.e., 150 grams per day) the assumed fish consumption rate would still be protected to 10^{-4} risk level.[89]

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[88] *Id.* at 6-7 (emphasis added) (06002-6003).

[89] *See* n.79. EPA, Final Water Quality Guidelines for the Great Lakes System at 15 (emphasis added)(01789).

In promulgating the California Toxics Rule in 2000 EPA specifically rejected several comments that the 10^{-6} to 10^{-4} risk policy offended notions of environmental justice.

> EPA believes that this rule is consistent with the terms of the Executive Order (E.O.) on Environmental Justice. EPA rejects the notion that the rule is, in any respect, discriminatory against persons or populations because of their race, color, or national origin. The final rule establishes criteria that are designed to ensure protection of the public, including highly exposed populations. While some groups and individuals, including some low income and minority persons and populations, may face a greater risk of adverse health effects than the general population due to their particular fish consumption patterns, EPA believes that these groups will nonetheless receive a level of public health protection within the range that EPA has long considered to be appropriate in its environmental programs (e.g., 10^{-4} to 10^{-6} incremental cancer risk). **Obviously, as long as there is variability in fish consumption patterns among various segments of the population, it would be impossible for EPA to ensure that all groups would face identical risk from consuming fish. Therefore, EPA has sought to ensure that, after attainment of water quality criteria in ambient waters, no group is subject to increased cancer risks greater than the risk range that the EPA has long considered protective**. EPA disagrees that individuals who consume up to a pound of fish per day would face a 10^{-3} cancer risk. Given that the basis of the criteria are a 6.5 gm/day assumption at a 10^{-6} risk level, individuals who consume a pound of fish per day would be protected within the established acceptable range of 10^{-4} to 10^{-6}, consistent throughout current EPA program office guidance and regulatory actions.[90]

EPA should acknowledge in response to these comments that the agency engaged in extensive consultations and considerations of tribal concerns and treaty interests in developing the 2015 guidance. Trust responsibilities and treaty rights were specifically addressed at a meeting of the EPA National Environmental Justice Advisory Council in December 2001 in Seattle, Washington.[91] Treaty rights are also discussed in a 2002 EPA report on fish consumption and environmental justice.[92] The 2002 document had been part of the EPA "EJ" tool kit documents including the "Plan EJ 2014."[93]

There is no question that the 2015 guidance on environmental justice fully reflects the consideration of tribal consumption rates and concerns about the EPA trust and treaty obligations. EPA should explain in response to these comments how it is possible for its existing guidance on risk levels to be consistent with environmental justice but not consistent with a newly invented interpretation tribal treaty responsibilities.

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[90] EPA, California Toxics Rule Response to Comments Report, CTR-002-005a (Dec. 1999) (emphasis added)(02311-3812).

[91] *See* n.47. EPA, Meeting Summary of the Executive Council of the National Environmental Justice Council.

[92] *See* n.45. EPA, Fish Consumption and Environmental Justice at 8 ("[t]he tribes have fought too hard for too long to let the salmon and their treaty rights to harvest salmon to go extinct")(00291).

[93] EPA, Plan EJ 2014 Legal Tools (December 2011)(03813-3932).

Comment No. 7: The proposed rule is based on a fish consumption rate that is not technically supported or consistent with the state risk policy for deriving human health water quality criteria.

The 175 g/day fish consumption rate used by EPA to derive the proposed human health criteria is not supported by technical information and is not necessary to protect the residents of Washington. It is also inconsistent with past EPA guidance and is in conflict with the Washington risk policy to protect the average consumption rate of the general population, including consumers and non-consumers, to a risk level of 10^{-6}.

EPA is required under the EPA-approved state risk policy to use a fish consumption rate that is less than 19 g/day. Ecology documented 18.8 g/day as the average consumption rate for consumers only for the general population in Washington.[94] Ecology has not provided a consumption rate that reflects both consumers and non-consumers but it must be substantially lower than 18.8 g/day given that Ecology estimated that between 25% and 70% of the general population in the state of Washington does not eat fish.[95]

The fish consumption rate used by EPA in the proposed rule exceeds the fish consumption rate used by any state to derive human health criteria, with the exception of the Oregon human health criteria adopted in 2012.[96] EPA guidance recommends for exposure to carcinogens that states use a fish consumption rate that protects the 90th percentile consumption of the general population while ensuring that subsistence fishers are protected at their average intake rate. EPA guidance recommends a default fish intake rate of 17.5 grams a day to protect the general population.[97] The same guidance recommends that state criteria use an average intake rate of 142.4 grams a day for subsistence fishers. "EPA believes that the assumption of 142.4 grams/day is within the average consumption estimates for subsistence fishers based on studies reviewed."[98]

The rationale for this guidance is to ensure that human health criteria are protective within a broad range of consumption rates in a state from the general population at the 90th to the 99th percentile rates of consumption. EPA guidance describes the use of the general population consumption of 17.5 grams a day at the 90th percentile as a baseline to ensure protection of the 99th percentile of the general population and average consumption rate for more exposed populations including subsistence fishers.[99] EPA confirmed this policy in a conference call with state regulators on April 17, 2013. EPA was asked during that conference call how EPA defines high exposure or high risk population for determining fish consumption rates. Beth Doyle, on behalf of EPA, responded that "EPA used the 99th percentile of the general population, as

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[94] *See* n.81. Ecology, Fish Consumption Rate Technical Support Document Version 2.0 at 95 (05514).

[95] *See* n.81. Ecology, Fish Consumption Rate Technical Support Document Version 2.0.

[96] Ecology, Fish Consumption Rates & Risk Levels for Carcinogens Used in Human Health Criteria Calculations, (November 5, 2013)(00259-00267).

[97] *See* n.24. Ecology, Overview at 15 (00021).

[98] *See* n.42. EPA, 2000 Human Health Methodology at 4-27 (00186).

[99] *See* n.45. EPA, Fish Consumption And Environmental Justice at 28. ("EPA's default value of 142.4 grams/day for subsistence fishers reflects the 99th percentile value of 142.41 grams/day for freshwater and estuarine ingestion by adults.")(00311).

representing what they figured approximated the median consumption rate for subsistence fishers."[100] The fish consumption rate of 175 grams a day used by Ecology is ten times the 90th percentile consumption rate established by EPA guidance for the general population. In response to these comments EPA should acknowledge that 175 g/day is based on the 50th to 90th percentiles of tribal consumption rates. Oregon developed the 175 grams a day fish consumption rate for its criteria using the same consumption studies relied on by EPA in the Federal Register Notice and concluded that the value reflects the 95th percentile consumption rate in the Columbia River Inter-Tribal Fish Commission study and the 90th percentile consumption rates documented for Puget Sound Tribes.

> Consequently, the recommended rate [175 g/day] reflects consumption of salmon, and lamprey relative to rates documented in the CRITFC study (to protect at least 95% of fish consumers in Oregon), as well as marine fish and shellfish relative to the rates documented in the Puget Sound studies (to protect at least 90% of fish consumers in Oregon).[101]

The following table from the TSD summarizes the consumption rates from Tribal studies. The 175 grams per day fish consumption rate used by EPA exceeds the median (50th percentile) for all Tribes and the 90th percentile for all Tribes with the exception of the Tulalips, 206 g/day, and the Suquamish, 489 g/day. The Suquamish consumption rate shown in this table is heavily influenced by high consumption rates reported by a few individuals. In other studies, such as the Tulalip study, similar high rates were excluded from the analysis as "outliers."[102] Oregon DEQ recognized that "[w]ith no adjustments made for the high consumption rates, it was noted that the reported means may be highly influenced by the consumption of just a few individuals."[103]

Table 37. Summary of Fish Consumption Rates, All Finfish and Shellfish

Population	Source of Fish	Number of Adults Surveyed	Mean	Percentiles		
				50th	90th	95th
General population (consumers only)	All sources: EPA method	2,853	56	38	128	168
	All sources: NCI method	6,465	19	13	43	57
Columbia River Tribes	All sources	464	63	41	130	194
	Columbia River	–	56	36	114	171
Tulalip Tribes	All sources	73	82	45	193	268
	Puget Sound	71	60	30	139	237
Squaxin Island Tribe	All sources	117	84	45	206	280
	Puget Sound	–	56	30	139	189
Suquamish Tribe	All sources	92	214	132	489	797
	Puget Sound	91	165	58	397	767

See Polissar et al., 2012, Table E-1.

[100] D. Essig, Email to S. Kirsch (April 5, 2013)(00453-454).

[101] Oregon DEQ, Oregon Human Health Criteria Issue Paper Toxics Rulemaking at 9 (May 24, 2011)(00476-0559).

[102] Oregon DEQ, Human Health Focus Group Report Oregon Fish and Shellfish Consumption Rate Project at 10-12 (June 2008)(00560-631).

[103] *Id.* at 12 (00631).

EPA should acknowledge that the percentiles for tribal consumption rates in this table are overstated. Ecology commissioned a report from the consultants who conducted the Tulalip, Squaxin and Suquamish studies. In a report dated October 3, 2013, the data was analyzed for a hypothetical combination of the Puget Sound Tribes.[104] This analysis calculated the median Tribal consumption rate to be 127.2 g/day for all fish.[105]

ARCADIS also developed a composite distribution of Washington Tribal consumption rates based on the TSD data.[106] That distribution calculates the median 90th and 95th percentiles for Tribal consumption rates to be 55.05, 137.77 and 178.69 grams per day.[107]

The Clean Water Act and EPA regulations require human health water quality criteria to protect exposures that may result from pollutants in state waters. EPA guidance accordingly does not require human health criteria to regulate pollutant levels in marine fish that do not accumulate pollutants in waters of the United States within the jurisdiction of a state. The default value of 17.5 grams a day in EPA guidance thus reflects freshwater/estuarine fish and shellfish only.[108] The range of consumption rates in the 2000 EPA guidance similarly do not include marine fish.[109]

Salmon, as a marine species, should accordingly be excluded from the consumption rate used to derive Washington's criteria. The data on fish tissue samples from salmon in Puget Sound indicates that the predominant fraction of PCBs detected is accumulated while the fish are in the ocean-phase of their life cycle.[110] Including all salmon in the fish consumption rate is not likely to benefit public health for contaminants that are accumulated in marine waters beyond the jurisdiction of the state.[111] Even for the small percentage of salmon that are resident for longer periods of time more stringent water quality standards are not likely to result in significant reductions in the body burden of contaminants.[112]

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[104] Polissar and Hippe, Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes (October 31, 2013)(00632-657).

[105] *Id.,* Table A at 2.

[106] ARCADIS, Derivation of Alternative Human Health Risk-Based Ambient Water Quality Criteria Using Probabilistic Methods for the State of Washington, Attachment A at 7 (February 4, 2014)(00658-0723).

[107] *Id.*

[108] *See* n.42. EPA, 2000 Human Health Methodology at 4-25 (EPA default fish consumption rates represent the ingestion of "freshwater and estuarine fish")(00184).

[109] *Id.* at 4-25; *see also* Ecology, Decision Factors in Development of Human Health Criteria (November 6, 2013)("Current federal guidelines do not use salmon in the fish consumption rate because most do not reside for their full life in water regulated by the Clean Water Act")(00726-727).

[110] *See* National Council for Air and Stream Improvement (NCASI), Comments on Publication No. 11-09-050, Fish Consumption Rates Technical Support Document, Appendix A, page 11 (January 11, 2012) (00728-0740), *see also* NCASI, Comments on Proposed Human Health Criteria and Implementation Tools Rule Proposal, Attachment A at 2 (March 4, 2015) (00741-0767).

[111] *Id.*

[112] Hope, Acquisition of Polychlorinated Biphenyls (PCBs) by Pacific Chinook Salmon: An Exploration of Various Exposure Scenarios, 8 INTEGRATED ENVIRONMENTAL ASSESSMENT AND MANAGEMENT 553, 561 (January 2012)(05073-5082).

Excluding salmon from the fish consumption rate lowers the median consumption rate documented for Puget Sound Tribes to 80.4 g/day—less than half of the FCR used by EPA for the proposed criteria.[113] The ARCADIS analysis independently calculated the "non-salmon" median consumption rate for Washington Tribes at 29.73 g/day.[114] Even if consumption rates are apportioned for that portion of the salmon that are found to accumulate pollutants and are resident in Puget Sound for a longer period in their life cycle, the median tribal consumption rate for all seafood and the portion of anadromous fish intake was estimated by Ecology consultants to be 108 grams per day.[115] The ARCADIS analysis calculated a Washington tribal consumption rate with apportioned salmon at a median rate of consumption to be 37.78 g/day and of 122.63 g/day at the 95th percentile.[116]

Comment No. 8: The EPA improperly relies on alleged suppressed fish consumption rates to justify rule.

EPA improperly bases its proposed criteria on what are alleged to be "suppressed" fish consumption rates for northwest tribal members. 80 Federal Register at 55068. It is impossible to comment on this basis for the rule as EPA does not cite to a single study, document or statistic of any kind to support its contention other than "consultation with Washington tribes and Columbia River basin tribes." *Id.* Reliance on meetings that are closed to the public and on propositions for which there is no documentation or scientific analysis is a facial violation of CWA and APA requirements to provide a scientific basis for proposed standards and an opportunity for public participation.

The only regulatory authority cited in this section of the Federal Register notice is a cross-reference to section II.B.c in the same notice that includes a representation that EPA "generally" recommends "selecting a FCR that reflects consumption that is not suppressed by fish availability or concerns about the safety of available fish." 80 Fed. Reg. at 55065. The sole authority for this proposition is a "Frequently Asked Questions" document that EPA posted online in January 2013. *See* 80 Fed. Reg. 55065, n. 15. EPA has conceded that this posting was done improperly and previously assured state regulators that the document would be withdrawn.[117] EPA has also conceded that it is not sure how suppression should be factored into criteria.[118]

It is difficult to fathom how EPA "generally" recommends consideration for suppressed consumption rates when there is no guidance on how EPA and the states are supposed to factor

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[113] *See* n.104. Polissar and Hippe, Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes at 2 (00633).

[114] *See* n.106. ARCADIS, Derivation of Alternative Human Health Risk-Based Ambient Water Quality Criteria Using Probabilistic Methods for the State of Washington, Attachment A at 7 (00698).

[115] *See* n.104. Polissar and Hippe, Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes at 2 (00633).

[116] *See* n.106. ARCADIS, Derivation of Alternative Human Health Risk-Based Ambient Water Quality Criteria Using Probabilistic Methods for the State of Washington, Attachment A.

[117] S. Braley, Email to M. McCoy, C. Niemi and D. Essig (January 9, 2014); S. Braley, Email to D. Essig and C. Niemi (July 28, 2014)(06692-6693).

[118] D. Essig, Email to B. Burnell (September 30, 2014)(06691).

this into developing water quality criteria.[119] EPA has long advised states to use data to develop criteria (with a preference for local or regional data over national data).[120] EPA is now asserting that it is permissible for it to consider unknown impacts on consumption rates for which there is no data.

The Federal Register notice does not reference any evidence to support a contention that fish consumption in Washington is suppressed due to "concerns about the safety of available fish." There is likewise a lack of any information in the proposed rule docket posted by EPA to support such a contention. EPA should acknowledge the results of a recent fish consumption survey in Idaho on this issue that found only 3% of the population indicated that they limited fish consumption due to health concerns about pollution or contamination.[121]

It is also inappropriate to employ an alleged lack of availability of fish as a factor in setting human health criteria. Human health criteria do not impact fish availability. Imposing repressive human health criteria on the state of Washington will in no way enhance fish runs or increase the availability of fish.

Even if it was appropriate to factor availability of fish in consideration of consumption rates, EPA has failed to cite to any evidence that there is a lack of availability of fish that would drive suppression. There is no documentation for example that tribal members lack access to fish. On the contrary, the tribal consumption studies document that at most two individual tribal members eat as much as 1600 g/day of fish.[122] This is nearly twice the historic rate of consumption used in deriving the Spokane Tribe of Indians human health criteria.[123]

It appears, moreover, that tribal consumption fish rates have been growing and are not suppressed. In 1992, the Columbia River basin tribes claimed a fish consumption rate of 150 g/day.[124] By 2012, the Columbia River Inter-Tribal Fish Commission was claiming that the 95th percentile of tribal members were consuming 175 g/day.[125] In 2015 the Northwest Indian Fisheries Commission Columbia River Inter-Tribal Commission claimed that there are contemporary consumption rates of between 500 and 918 g/day.

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[119] *See* n.17. EPA, Comment on Ecology Draft Rule.

[120] *See* n.42. EPA, 2000 Human Health Methodology at 2-2 (00108).

[121] Idaho Department of Environmental Quality, Considerations in Deciding Which Fish to Include in Idaho's Fish Consumption Rate: Policy Summary at 7. (August 2015)(04792-4802).

[122] *See* n.17. EPA, Comment on Ecology Draft Rule; *see also* n.104. Polissar and Hippe, Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes.

[123] EPA, Letter approving Spokane Tribe of Indians Water Quality Standards, *Technical Support Document* dated December 11, 2013 at 22 (December 9, 2013) (the criteria are based on a FCR of 865 g/day) (01020-1071).

[124] *Dioxin/Organochlorine Ctr. v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995)("In addition, the EPA argues that even assuming consumption of 150 grams of fully contaminated fish, as claimed by DOC, the risk level would still be only 23 in a million.").

[125] EPA, Technical Support Document for Action on the State of Oregon's New and Revised Human Health Water Quality Criteria and Associated Implementation Tools Submitted July 12 and 21, 2011 at 27 (October 17, 2011)(01908-2010).

EPA itself has increased the fish consumption rate from 6.5 g/day in the NTR to 22 g/day in criteria included in the 2015 update to the Section 304 human health criteria. This trend is consistent with national data showing an increase in consumption of fish over time. The U.S. Department of Agriculture has reported that the per capita consumption of fish grew from 12.4 pounds to nearly 16 pounds from 1980 to 2009.[126] This indicates that consumption rates used in setting criteria are adjusting with increasing consumption rates. This is illustrated in the following figure from the Idaho negotiated rulemaking process:[127]

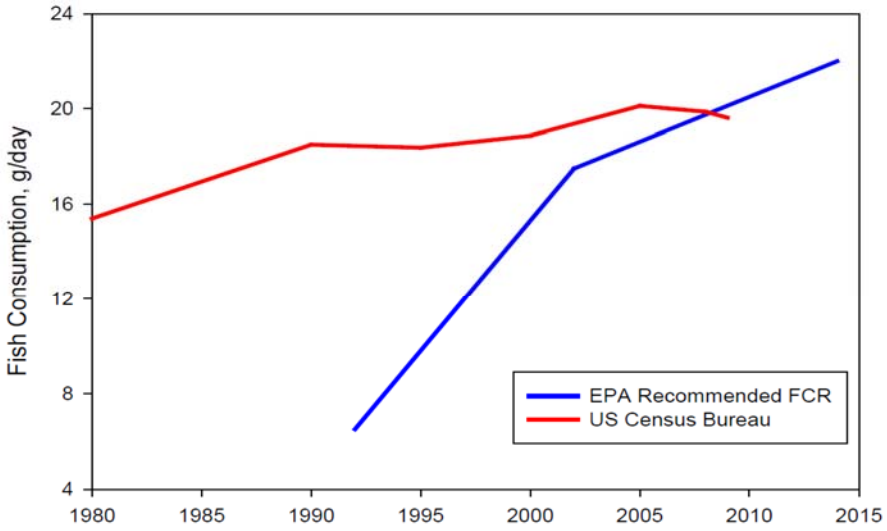

Figure 4. Per capita consumption of fish in the United States and EPA-recommended fish consumption rate (FCR), 1980–2014.

It is not appropriate to speculate on future consumption rates or restoration of consumption rates based on historic information. If fish consumption rates increase over time that information should inform future reviews by EPA of any criteria it makes applicable to the state of Washington.

Comment No. 9: Tribal treaty rights do not provide a legal basis for EPA's proposed rule.

EPA asserts throughout its proposed rule that 1850s treaties reserving to Indian tribes the "right of taking fish" require that Washington's human health criteria (1) utilize the Indian tribal population as the "target general population" for the purposes of deriving the criteria, (2) adopt a cancer risk level of 10^{-6} to be applied to that newly defined "target general population", and (3) use a fish consumption rate that reflects unsuppressed fish consumption. In fact, the federal courts have never interpreted treaty reserved fishing rights this broadly and there is no legal

[126] U.S. Census Bureau, Statistical Abstract of the United States: 2012, Sec. 3, Table 217 (August 2011)(06986).

[127] *See* n.121. Idaho Department of Environmental Quality, Considerations in Deciding Which Fish to Include in Idaho's Fish Consumption Rate: Policy Summary at 7.

support for EPA's attempt to use the treaty fishing right as a rationale for imposing its preferred human health criteria on the State of Washington.[128]

The treaties only reserve to the Indian tribes the right to a fair share of available fish.

The treaties at issue were negotiated by territorial Governor Isaac Stevens in 1854 and 1855 with several northwest Indian tribes, for the principal purpose of extinguishing Indian claims to land in what is now Washington State. *Washington v. Washington State Commercial Passenger Fishing Vessel Ass'n* (*"Fishing Vessel"*), 443 U.S. 658, 661-62 (1979). A critical component of the Stevens Treaties was the reserved "right of taking fish, at all usual and accustomed grounds and stations. . . in common with all citizens of the Territory." Federal courts began to recognize and interpret this treaty right as early as 1905. *See United States v. Winans,* 198 U.S. 371 (1905). This process accelerated with a suit brought in 1970 by fourteen tribes and the federal government against the state of Washington, resulting in the "Boldt decision", which was ultimately upheld by the U.S. Supreme Court in *Fishing Vessel*.

The Supreme Court held that "[b]oth sides have a right, secured by treaty, to take a fair share of the available fish." *Fishing Vessel*, 443 U.S. at 684-85. The right is more than merely a right to compete with nontreaty fishermen, but rather reserves for the tribes "the right to take a share of each run of fish that passes through tribal fishing areas." *Id.* at 679. In determining what constitutes a fair share of fish, the Court viewed a tribal share of 50% of the fish as a ceiling, which could be reduced if a lesser quantity was sufficient to meet the tribes' "moderate living" needs. *Id*. at 685-89. The Supreme Court has also held that the treaties guarantee to tribes access to their usual and accustomed fishing grounds, including those off-reservation. *See Seufert Bros. Co. v. United States*, 249 U.S. 194 (1919); *Winans*, 198 U.S. 371 (1905).

The reserved treaty rights are not, however, unlimited in scope. The right is shared with other citizens and is similar to a cotenancy. *Anderson v. Evans*, 314 F.3d 1006 (9th Cir. 2002). And tribal fishers may be subject to federal and state regulation, as long as that regulation is non-discriminatory and for conservation purposes. *Puyallup Tribe v. Dep't of Game of Washington*, 391 U.S. 392, 398 (1968); *United States v. Oregon*, 657 F.2d 1009, 1016-17 (1981).

Although treaties are to be interpreted liberally in favor of the Indians, it has long been the law that Indian treaties "cannot be re-written or expanded beyond their clear terms to remedy a claimed injustice or to achieve the asserted understanding of the parties." *Choctaw Nation of Indians v. United States*, 318 U.S. 423, 432 (1943); *See also Gros Ventre Tribe v. United States*, 469 F.3d 801, 813 (9th Cir. 2006) ("Whatever duty exists at law today must be expressly set forth in statutes or treaties.").[129]

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[128] According to EPA its position on the legal effect of the treaty fishing right is based upon a legal analysis contained in a January 30, 2015 letter from Hilary Tompkins, of the Department of Interior Office of the Solicitor, to Avi Garbow, EPA General Counsel, written in connection with EPA's disapproval of Maine's WQS ("Maine Tribal Fishing Rights Letter") (When asked by Ecology for "a legal opinion or rationale on how risk level and treaty tribal rights are connected, and why 10^{-6} is looked upon by EPA as fulfilling the rights, and 10^{-5} is not" EPA staff directed Ecology to EPA's disapproval of the Maine standards and associated documents, including the Maine Tribal Fishing Rights Letter. *See* n.19. EPA FOIA Response.

[129] As the Idaho Department of Environmental Quality noted in its recent response to EPA's comments on Idaho's proposed human health water quality criteria, there is also no legal support for EPA's position that tribal fishing

The treaties do not include an implied environmental right nor guarantee a particular quality of fish habitat.

EPA appears to read the treaty right to a share of available fish as containing an implied guarantee of a certain quality of fish habitat.[130] However, rather than finding any such broad environmental servitude, courts have held that at most the treaties impose on the state a duty not to take actions that will harm fish runs.

The issue of whether the treaty right to take fish includes an implied "environmental" right has been addressed in two lines of cases. In Phase II of *U.S. v. Washington*, the Ninth Circuit overturned a district court decision and held that in *Fishing Vessel* the Supreme Court "did not adopt a comprehensive environmental servitude." *U.S. v. Washington*, 694 F.2d 1374, 1381 (1982). That decision was later vacated on procedural grounds. *U.S. v. Washington*, 759 F.2d 1353 (9th Cir. 1985) (en banc). However, the Ninth Circuit "did not overrule its decision or reverse the analysis of the legal issues and its reasoning." *Nez Pearce Tribe v. Idaho Power Co.*, 847 F. Supp. 791, 808 (D. Idaho 1994) (holding that "Indian tribes do not have an absolute right to the preservation of the fish runs in their original 1855 condition, free from all environmental damage caused by the migration of increasing numbers of settlers and the resulting development of the land").

In subsequent litigation, the Western District of Washington held on cross motions for summary judgment that the treaty right to take fish imposes a duty on the State of Washington to refrain from building or operating culverts that hinder fish passage and thus decrease the number of fish available for tribal harvest. *U.S. v. Washington*, No. CV 70-9213, 2007 WL 2437166 (2007). After a bench trial the Court issued a permanent injunction directing the state to correct the barrier culverts. *U.S. v. Washington*, No. CV 70-9213, 2013 WL 1334391 (2013). The district court emphasized that the state's duty not to block fish passage "is not a broad 'environmental servitude' or the imposition of an affirmative duty to take all possible steps to protect fish runs. . . but rather a narrow directive to refrain from impeding fish runs in one specific manner." *U.S. v. Washington*, No. CV 70-9213, 2007 WL 2437166 at *10 (2007); *U.S. v. Washington*, No. 70-9213, 2013 WL 1334391 at *24 (2013) ("it is a narrow and specific treaty-based duty that attaches when the State elects to block rather than bridge a salmon-bearing stream with a roadbed").

In the Maine Tribal Fishing Rights Letter the Department of Interior points to the culverts case decisions as support for finding an implied treaty right not only to take fish, but to a particular fish habitat. As explained above, however, the decisions—currently on appeal to the

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rights mandate that tribes be treated as the general population. EPA is proposing state-wide criteria to protect all Washington citizens, including tribal members. The situation might be different if the criteria to be adopted was limited to areas of tribal jurisdiction, but the criteria is to apply state-wide, except for those areas of the state within tribal jurisdiction. Under these circumstances the tribes are clearly a subpopulation of the entire state, and should be treated as such. Idaho Department of Environmental Quality, Water Quality: Docket No. 58-0102-1201 Proposed Rule Rulemaking and Public Comment Summary, at 21 (07312-7348).

[130] EPA does not appear to be entirely clear on its position as to the scope of the treaty right. At one point in its proposed rule EPA describes the treaty right to take fish as including "an attendant right to not be exposed to unacceptable health risks by consuming those fish." 80 Fed. Reg. at 55066 (§ III.A). Elsewhere EPA states that "the treaties could be interpreted to require a certain level of risk: e.g., a *de minimis* level of risk that would most reasonably approximate conditions at the time the treaties were signed and the fishing rights were reserved", concluding that 10^{-6} is a *de minimis* risk level. 80 Fed. Reg. at 55068 (§ IV.C.b).

Ninth Circuit—are narrowly drawn. In the recent Ninth Circuit oral argument the Department of Justice attorney appearing as trustee for the tribes conceded the narrow scope of the district court's rulings, stating:

> As we see this right, it's a purely negative one. It says to the State you can't take action which blocks fish passage. **It's not a positive right that says the State is responsible for restoring habitat or restoring the fish**. The District Court did not put it in those terms at all. This is only about actions of the State that have a direct effect on the fish runs by blocking a certain amount of habitat.[131]

Even if upheld by the Ninth Circuit, the culverts case decisions do not support a broader reading of the treaty right to take fish as a right to a particular quality of fish habitat.

Not only does EPA incorrectly interpret the treaties as requiring a certain quality of fish habitat, by insisting upon the use of an unsuppressed fish consumption rate EPA further assumes that the alleged implied right is to the environmental habitat in existence at the time that the treaties were executed. But to the extent that the treaties encompass any right to a particular environmental habitat, it is certainly not to the fish habitat as it existed in 1855. The Supreme Court in *Fishing Vessel* specifically rejected this approach, stating that the treaty right to take a fair share of the available fish is a right to "so much as, but not more than, is necessary to provide the Indians with a livelihood—that is to say, a moderate living." *Fishing Vessel*, 443 U.S. at 686. The tribes are simply not entitled to preservation of the fish runs in their original 1855 condition. *See United States v. Adair*, 723 F.2d 1394 (9th Cir. 1983) (confirming to the Klamath Tribe an amount of water necessary to support its reservation hunting and fishing rights as currently exercised to maintain the livelihood of Tribe members, "not as these rights once were exercised by the Tribe in 1864"); *Nez Pearce Tribe*, 847 F. Supp. at 808-810.

Most importantly, even if the treaties did contain some implied right to habitat protection, there is no scientific rationale for EPA's assumption that setting water quality standards that treat the tribal population as the target general population, establishing a cancer risk level of 10^{-6}, and utilizing an unsuppressed fish consumption rate, would be more protective than the approach to standards consistently used by EPA in the past. Nor is there evidence that EPA's past approach to water quality standards—using the general population as the target population, and allowing states to choose a cancer risk level of either 10^{-5} or 10^{-6} so long as high consuming subpopulations are protected to 10^{-4}—either has caused or will cause damage to the fisheries. The situation here is thus unlike the culverts case, where the court found clear evidence that the barrier culverts were diminishing fish quantity and thus adversely affecting the treaty fishing right.[132]

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[131] Transcript of oral argument in *USA v. State of Washington*, Case No. 13-35474 (9th Cir., Oct. 16 2015) at 16 (06964-6985).

[132] Case law regarding the implied-reservation-of-water doctrine do not serve to further expand the treaty right to take fish. *See* Maine Tribal Fishing Rights Letter at 8. Such cases "generally apply to a quantity of water rather than to its quality", and moreover, the treaty fishing right is to a fair share, as opposed to an adequate supply, of fish. *See U.S. v. Washington*, 694 F.2d 1374, 1381 (1982), *vacated on procedural grounds*, 759 F.2d 1353 (9th Cir. 1985) (en banc); *U.S. v. Adair*, 723 F.2d 1394, 1414-15 (1983) (noting that implied reservation of water right did not create a "wilderness servitude" in favor of the tribe, but rather only confirmed to the tribe the quantity of water sufficient to support its "hunting and fishing rights as currently exercised to maintain the livelihood of Tribe members, not as

The Department of Interior incorrectly asserts that the treaty right requires "protection of water quality sufficient to enable the tribes to continue to fish and to consume the fish they are able to catch", that "water quality cannot be impaired to the point that fish have trouble reproducing without violating a tribal fishing right", that "water quality cannot be diminished to the point that consuming fish threatens human health without violating a tribal fishing right" and that the treaty right "depends on a subsidiary right to fish populations safe for human consumption." Maine Tribal Fishing Rights Letter at 10. EPA takes these broad generalizations—not based on case law—and from it announces that the treaty right requires its preferred cancer risk level and FCR. There is simply no basis for doing so.

Comment No. 10: Just as with federal trust responsibilities to the tribes, compliance with the Clean Water Act is sufficient to meet tribal treaty rights.

In recent briefing before the federal district court for the Western District of Washington, EPA successfully asserted that EPA's compliance with the Clean Water Act and its regulations satisfied any federal trust responsibility owed to the Spokane Indian Tribe. *Sierra Club v. McLerren*, Case No. 2:11-cv-01759-BJR Docket No. 91 at 40-43 (January 29, 2014). EPA explained that the scope of its trust responsibility is not defined by common law fiduciary duties or those imposed on a private trustee, but rather must be based on specific statutes and regulations. *Id*. at 41-42 (citing *United States v. Jicarilla Apache Nation*, 131 S. Ct. 2313, 2323, 2325 (2011)). As EPA asserted:

> There is a "distinctive obligation of trust incumbent upon the Government in its dealings with [Indian tribes]." *Gros Ventre Tribe v. United States*, 469 F.3d 801, 810 (9th Cir. 2006) (quoting *United States v. Mitchell*, 463 U.S. 206, 225 (1983)). However, "[w]ithout an unambiguous provision by Congress that clearly outlines a federal trust responsibility, courts must appreciate that whatever fiduciary obligation otherwise exists, it is a limited one only." *Shoshone-Bannock Tribes v. Reno*, 56 F.3d 1476, 1482 (D.C. Cir. 1995). While that general trust relationship allows the federal government to consider and act in the tribes' interests in taking discretionary actions, *it does not impose a duty on the federal government to take action beyond complying with generally applicable statutes and regulations*. *Jicarilla,* 131 S. Ct. at 2325. Accordingly, in the absence of a specific duty that has been placed on the government with respect to the Tribe, the United States' general trust responsibility "is discharged by the agency's compliance with general regulations and statutes not specifically aimed at protecting Indian tribes." *Morongo Band of Mission Indians v. F.A.A.*, 161 F.3d 569, 574 (9th Cir. 1998); *Okanogan Highlands Alliance v. Williams*, 236 F.3d 468, 479 (9th Cir. 2000)

these rights once were exercised by the Tribe in 1864"). Even if, as the Department of Interior asserts, these cases "support a conclusion that EPA should take tribal fishing rights into account when reviewing. . . water quality standards" EPA has, in fact, consistently taken the high consuming subpopulation of tribal fishers exercising their treaty rights into account in past guidance and reviews of state water quality standards. In promulgating HHC for Washington state EPA is going far beyond "taking tribal treaty rights into account", instead asserting that the treaties *require* that the tribes be treated as the target general population rather than a high consuming subpopulation, that they be protected at a cancer risk level of 10^{-6} rather than 10^{-4}, and that the FCR be unsuppressed.

(Bureau of Land Management's approval of gold mine satisfied trust obligations by the agency's compliance with NEPA); *Gros Ventre*, 469 F.3d at 814.[133]

Judge Rothstein ruled in favor of EPA on the trust responsibility issue, agreeing that EPA had discharged its trust duty by complying with the CWA. *Sierra Club v. McLarren*, Case No. 2:11-cv-01759-BJR Docket No. 120 at 23 (March 16, 2015).

Just as in *Sierra Club*, any trust responsibility owed by EPA to Indian tribes based upon the treaty fishing right at issue here is discharged by EPA's compliance with the CWA, the aim of which is to protect the water quality for the entire population. The Stevens treaties do not impose any specific duty on EPA to adopt a particular cancer risk or fish consumption rate for the benefit of the tribes. *See Shoshone-Bannock* (existence of treaty-created right to hunt did not impose duty on the federal government to litigate tribal water rights claims); *Vigil v. Andrus*, 667 F.2d 931, 934 (10th Cir. 1982) (treaty obligation to support and educate Indians did not expressly impose a duty on government to provide free lunches to all Indians); *Center for Biological Diversity v. U.S. Bureau of Land Mgt.*, 2015 WL 794327 *2 (D. Nevada February 24, 2015) (treaty with Goshute and Shoshone Indians did not impose an "enhanced" statutory duty on federal government beyond what [environmental statutes] already require; "the federal government's compliance with the [environmental statutes] satisfies its general trust obligations to Indian tribes"). As EPA itself argued before Judge Rothstein, EPA's responsibility to the tribes is discharged by complying with the CWA. And compliance with the CWA means basing Washington's human health criteria on sound scientific rationale.

Comment No. 11: Neither EPA nor the Department of Interior's legal interpretation of Indian treaties is entitled to deference.

EPA's interpretation of the CWA, a statute which it administers, may under certain circumstances be entitled to deference pursuant to *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S. Ct. 2778 (1984). But EPA's interpretation of Indian treaties is not entitled to deference. *See Maine v. Johnson*, 498 F.3d 37, 45 (1st Cir. 2007). A precondition to deference under *Chevron* is a congressional delegation of administrative authority. *Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 649-50 (1990). EPA has not been delegated the authority to interpret Indian treaties. *Maine*, 498 F.3d at 45. To the contrary, the federal courts have sole jurisdiction over questions of treaty-guaranteed rights. *See* 28 U.S.C. § 1362; *Confederated Salish and Kootenai Tribes of Flathead Reservation, Montana v. Flathead Irr. & Power Project*, 16 F. Supp. 1292, 1295 (D. Mont. 1985). Moreover, to the extent that EPA is relying upon the Department of Interior Solicitor General's interpretation of the Stevens treaties in the Maine Tribal Fishing Rights letter, that interpretation is similarly not entitled to deference. *Cherokee Nation of Oklahoma v. Norton*, 389 F.3d 1074, 1078-79 (10th Cir. 2004) (Department of Interior's position based solely on its analysis of Indian treaties and agreements was not afforded any deference "because Congress did not give [the Department] the discretion to administer those treaties and agreements").

EPA implicitly recognizes its lack of expertise in interpreting the scope of the treaty right to take fish. *See* EPA Proposed Rule, 80 Fed. Reg. at 55,066 (§ II.B.c): "[W]here tribal treaty or other reserved fishing rights apply, selecting a FCR that reflects unsuppressed fish consumption

[133] *Sierra Club v. McLarren*, Case No. 2:11-cv-01759-BJR Docket No. 91 at 42 (January 29, 2014)(04811-4860).

could be necessary in order to satisfy such rights"; *Id*. at 55,068 (§ IV.C.b): "Independently, the treaties themselves *could require higher levels of protection*. The treaties themselves *could be interpreted to require a certain level of risk*; e.g. a *de minimis* level of risk that would most reasonably approximate conditions at the time the treaties were signed and the fishing rights were reserved" (emphasis added). EPA does not have the authority to interpret the legal effect of the tribal treaty rights, and its commentary about what the treaties "could" require is not a sufficient basis upon which to derive water quality standards.

Comment No. 12: EPA's new focus on treaty rights is part of a national effort to compel states to adopt EPA's preferred human health criteria.

An examination of EPA communications and actions between 2013 and 2015 regarding Washington's human health criteria illustrates that the agency's "discovery" of the existence of tribal treaty rights came *after* it adopted the position that the tribes must be considered the target general population and that that high consuming population must be protected to a 10^{-6} risk level. The documents indicate that EPA Region 10 decided that it wanted the cancer risk level for Washington to be 10^{-6}, and then went looking for a theory upon which to base that position. And it adopted the treaty rights theory as part of a national EPA effort to use Indian treaty rights as a means of forcing states to adopt EPA's preferred human health criteria.

In a December 11, 2012 telephone call between EPA staff and Idaho Tribes, EPA was specifically asked whether EPA would require "subsistence fishers to be protected to the same extent as the general population."[134] Christine Psyk, Associate Director for Region 10, responded that "**EPA would not because that requirement does not appear in EPA regulations or guidance.**"[135]

As detailed in Comment No. 1 above, in 2013 Ecology had numerous meetings and communications with EPA national and regional staff as it worked to develop Washington's new human health water quality criteria and attendant risk policy. Throughout that year and into 2014, EPA remained silent as to whether there had been any change in agency policy regarding cancer risk levels. *See supra* 3-4. Nor did EPA communicate any concern regarding the protection of Indian treaty fishing rights.

The issue was most pointedly raised in a meeting with EPA regional staff on March 11, 2014, when after months of silence Mr. McLerran declared that "175 grams a day at 10^{-6} is a baseline for environmental justice."[136] Mr. Opalski admitted immediately after the meeting that there is no such statement in EPA guidance to support this proposition.[137] EPA thus articulated for the first time in March 2014 a position that the cancer risk level must be 10^{-6}, gave as its rationale considerations of environmental justice, and then simultaneously admitted that environmental justice policy does not in fact dictate any particular risk level. EPA was clearly looking for a rationale for its new position on risk policy, but had not found it in environmental

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[134] D. Ostermann, Letter to EPA at 2 (January 9, 2013)(02308-2310).

[135] *Id.* (emphasis added).

[136] *See* n. 4. C. Niemi, Handwritten Notes ("Dennis [EPA Region 10 Administrator] thinks the OR outcome was the right outcome, regionally wants to explore that position.")

[137] *See* n.10. D. Opalski, Email.

justice considerations. EPA at this point still had made no mention of tribal treaty rights in any of its communications with Ecology.

On April 8, 2014 Mr. McLerran wrote to Maia Bellon and informed Ecology that if it did not adopt a final rule by the end of 2014 EPA would move on its own to amend the NTR human health criteria for Washington.[138] With regard to cancer risk level, Mr. McLerran stated that "another element of a final rule is choosing a cancer risk level that provides risk protection for all Washington citizens, including communities that eat higher amounts of fish." Again, no mention was made of changes to EPA's national guidance, nor any reference to tribal treaty rights.

On April 24, 2014, in response to an April 3, 2014 letter from Sen. Doug Ericksen requesting an articulation of what EPA considered to be an appropriate cancer risk level for Washington, Mr. McLerran did not answer the question, but did make vague references to the health protection of all citizens of Washington, including high fish consumers.[139] Mr. McLerran made no reference to environmental justice, Indian tribes, treaties, or fishing rights. On June 19, 2014, EPA Region 10 staff confirmed again that there is no stand-alone environmental justice analysis in developing water quality standards.[140]

In a July 1, 2014 response to a second letter from Senator Ericksen, Mr. McLerran stated that he had in fact "recommended that Ecology retain their current state-wide cancer risk level of 10^{-6}", and listed three reasons for EPA's position.[141] Despite the fact that Region 10 had conceded on March 11, 2014[142] and June 19, 2014[143] that there is no separate environmental justice basis for applying a specific risk level to tribal consumption rates, Mr. McLerran resurrected the environmental justice rationale, stating that the use of a cancer risk level other than 10^{-6} would raise "environmental justice concerns, which are a significant consideration in the EPA review of the State's overall submittal." For the first time, after months of communication with Ecology regarding the development of new HHWQC, Mr. McLerran also referenced treaty fishing rights as potential support for EPA's newly-announced position that Ecology must utilize a cancer risk level of 10^{-6}.

EPA's next formal communication to Ecology regarding its development of human health criteria for Washington came in a December 18, 2014 letter from Mr. McLerran to Ms. Bellon, informing her that EPA had initiated internal federal rulemaking to amend the NTR for Washington's human health criteria.[144] Mr. McLerran reiterated EPA's inaccurate characterization of Washington's approach as a change in the state's cancer risk protection level, and asserted that EPA's rulemaking process would include policy and legal considerations

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[138] D. McLerran, Letter to M. Bellon (April 8, 2014)(04738-4739).

[139] *See* n.11. D. Ericksen, Letter.

[140] A. Chung, Email (June 19, 2014) (02231-2232). It was apparent by the summer of 2014 that EPA would insist on a 10^{-6} regardless of its own policies and all available data. *See* D. Essig, Email to C. Neimi (June 24, 2014)(EPA refuses to fund or cooperate with consumption surveys in Idaho because tribal consumptions need to be protected to 10^{-6} risk level).(06689-06690)

[141] *See* n.15. D. McLerran, Letter.

[142] *See* n.10. D. Opalski, Email.

[143] *See* n.140. A. Chung, Email.

[144] D. McLerran, Letter to M. Bellon (December 18, 2014) (04790-4791).

including "an assessment of downstream waters protection, environmental justice, federal trust responsibility, and tribal treaty rights and how those issues should inform the EPA's analysis of the protectiveness of the water quality criteria." Mr. McLerran seemed to be adopting an "all of the above" rationale for EPA's predetermined opinion that Washington must use a 10^{-6} cancer risk level, resurrecting environmental justice, making reference to tribal treaty rights, and for the first time also pointing to EPA's federal trust responsibility (presumably to Indian tribes) as support for its position.

Notably, Mr. McLerran's letter came just weeks after a December 1, 2014 memorandum issued by Gina McCarthy announcing a new EPA policy regarding tribal treaty rights[145]:

> While treaties do not expand the EPA's authority, the EPA must ensure its actions do not conflict with tribal treaty rights. In addition, EPA programs should be implemented to enhance protection of tribal treaty rights and treaty-covered resources when we have discretion to do so. To help guide the agency's decisions when treaty rights should be considered, the Office of General Counsel and the American Indian Environmental Office will develop an analytical framework, with input and consultation from other EPA offices and tribal governments.[146]

On February 2, 2015, two months after Ms. McCarthy's memorandum, EPA disapproved in part water quality standards adopted by the state of Maine.[147] Although many of EPA's conclusions regarding Maine's water quality standards are specific to Maine's unique Indian Settlement Acts, EPA based much of its decision on the lengthy analysis of Indian treaty fishing rights contained in the January 30, 2015 Maine Tribal Fishing Rights Letter. For the first time, EPA set out in detail its theory that tribal fishing rights mandate that tribes be considered the target subject population for the purposes of development of human health criteria, and that the fishing rights require protection of that target population to a certain level of cancer risk. Never before in its history had EPA disapproved a state's water quality standards based on the existence of Indian treaty rights.

In its March 23, 2015 comments EPA applied this same new treaty right rationale to support its position on Washington's human health criteria. Unlike any past communications regarding proposed human health criteria for Washington, EPA's cover letter to Ecology contained six separate references to "tribal members with treaty-protected fishing rights" and set forth EPA's position that Washington's adoption of a cancer risk level of 10^{-5} would not adequately protect such tribal members.[148] In the comments EPA announced that treaty reserved rights to take fish mandated that the tribal population be treated as the target general population rather than as a high-consuming subpopulation, as in the past.[149] For the first time, EPA asserted

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[145] G. McCarthy, Memorandum Commemorating the 30th Anniversary of the EPA's Indian Policy (December 1, 2014)(05396-5397).

[146] *Id.*

[147] H. Spalding, Letter to P. Aho (February 2, 2015) and Attachment A, Analysis Supporting EPA's February 2, 2015 Decision to Approve, Disapprove, and Make No Decision on, Various Maine Water Quality Standards, Including Those Applied to Waters of Indian Lands in Maine (07254-7305).

[148] *See* n.17. EPA, Comment on Ecology Draft Rule.

[149] *Id.* at 2-3.

that "[a] 10^{-6} cancer risk level is necessary to ensure that the target population of tribal fish consumers exercising their treaty-reserved rights, including those whose consumption is not suppressed, are adequately protected."[150] EPA made no reference in its cover letter or comments to environmental justice or trust responsibility—by this point EPA had apparently rejected those prior rationale in favor of reliance solely on tribal treaty rights. And as with the March 2015 comments on Washington's proposed rule, EPA's own proposed rule does not point to environmental justice as support for its rule.[151]

As the above shows, EPA did not even publicly mention tribal treaty rights before its July 2014 letter to Senator Ericksen, and did not communicate the treaty rights rationale directly to Ecology until December 2014, after nearly three years of meetings and communications regarding Washington's adoption of new human health criteria. After experimenting throughout 2014 with reliance on environmental justice and trust responsibility as rationale for its insistence on a 10^{-6} risk level, it is only in March 2015, shortly after EPA's December 2014 announcement of a new national policy on treaty rights, that EPA fully articulated and adopted its new position that tribal treaty fishing rights mandate certain human health criteria. A newfound focus on tribal treaty rights did not inform EPA's chosen criteria. EPA first decided what it wanted Washington's risk level to be, and then found a basis to support it—a basis, as noted above, that does not consist of sound scientific or legal rationale.

EPA's reliance on treaty rights is not limited to Maine and the Pacific Northwest. EPA's February 2015 disapproval of Maine's water quality standards and its March 2015 comments on Washington's proposed criteria were followed by May 2015 comments on the State of Idaho's proposed revisions to its water quality standards, in which EPA once again articulated its new position that treaty fishing rights mandate that states select fish consumption rates reflecting unsuppressed fish consumption.[152] EPA articulated the treaty rights rationale most recently in its November 6, 2015 further comments on Idaho's proposed rule.[153]

EPA's new national effort to use treaty rights as support for its preferred state water quality standards is further evidenced by an August 15, 2015 proposed guidance for consulting with Indian tribes regarding treaty rights.[154] This proposed guidance references EPA review of state water quality standards and appears aimed at providing support for EPA's new nationwide interpretation of treaty fishing rights as mandating particular state water quality standards:

> Treaties also may contain necessarily implied rights. For example, an explicit treaty right to fish in a specific area may include an implied right to sufficient

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[150] *Id.* at 5. As in its own proposed rule, EPA "explained" its departure from the 2000 Guidance by stating that the Guidance did not consider how CWA decisions should account for treaty fishing rights.

[151] EPA's proposed rule does contain one reference to Executive Order 12898 regarding federal actions to address environmental justice in minority populations, but environmental justice concerns are not described as the basis for EPA's proposed Washington HHC. EPA Proposed Rule, 80 Fed. Reg. at 55074.

[152] EPA, Letter to Idaho DEQ (May 29, 2015)(04746-4753).

[153] EPA, Comments on Idaho's Revised Human Health Toxic Criteria (November 6, 2015)(04759-4789).

[154] EPA, EPA Policy on Consultation and Coordination with Indian Tribes: Draft Guidance for Discussing Tribal Treaty Rights (August 15, 2015)(07250-7253). As will be explained below, executive orders and EPA policy regarding consultation with tribes already exists. This new proposed policy specifically addresses consultation re treaties.

> water quantity or water quality to ensure that fishing is possible. Similarly, an explicit treaty right to hunt, fish or gather may include an implied right to a certain level of environmental quality to maintain the activity or a guarantee of access to the activity site.[155]

EPA's broader approach of mandating a particular state's water quality standards is also illustrated by its consideration of a new Baseline Water Quality Standards Proposed Rule, which would establish national "baseline" federal WQS for Indian reservations not currently covered by EPA-approved water quality standards.[156] By setting EPA-preferred WQS for reservations, and then acting to "[protect] reservation water quality from upstream discharges flowing into reservation waters from other jurisdictions" EPA will essentially grant itself the authority to set state water quality standards without using the process for development set forth in the CWA.

Comments by the National Association of Clean Water Agencies regarding EPA's response to Washington's proposed human health criteria rule provide a cogent summary of EPA's current actions:

> [T]he language in the CWA and the implementing regulations was not intended to give EPA authority to disapprove standards because the state's science and policy decisions are not identical to [EPA's] preference, policies and guidance. . . In the case of Washington's proposed rule, which in fact was consistent with the range of values and approaches included in existing federal guidance, EPA appears to ignore the flexibility afforded to states in its own guidance by insisting that the state's program conform to EPA's preferred approach. These tactics are inconsistent with the CWA's cooperative federalism foundation and history that provides the states the responsibility for developing and approving water quality standards. . . . The structure established by the CWA—where EPA provides criteria recommendations and guidance and the states develop water quality standards based on that information as well as state policy and risk decisions (where a range of acceptable CWA options exist)—must be preserved to ensure that federal preference and the criteria recommendations do not become de facto regulations.[157]

Comment No. 13: Executive orders and EPA policies regarding consultation and coordination with tribes do not support EPA's proposed rule.

EPA repeatedly refers to its consultation with Indian tribes as justification for the selection of an unsuppressed fish consumption rate of 175 g/day and a cancer risk level of 10^{-6}.[158] In fact, EPA admits that it had insufficient evidence of unsuppressed fish consumption rate

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[155] *Id.* at 3.

[156] EPA, Consultation Plan for Considering a Baseline Water Quality Standards Proposed Rule (August 2015)(05066-5072).

[157] K. Kirk, Letter to D. McLerran re EPA Efforts to Influence Washington Rulemaking at 2-3 (May 13, 2015)(04743-4745).

[158] EPA Proposed Rule, 80 Fed. Reg. at 55066 (§ II.B.c) ("If sufficient data regarding unsupressed fish consumption levels are unavailable, consultation with tribes is important in deciding which fish consumption data should be used"); 80 Fed. Reg. at 55067 (§ IV.C.a) (FCR "reflects input received during consultation with tribes", "EPA

for the tribes, and lacking such data, allowed the tribes to dictate both the fish consumption rate and the cancer risk level.[159] EPA thus relies on its obligation to consult and coordinate with Indian tribes—and the tribes' preferences as to the fish consumption rate and cancer risk—rather than complying with the CWA and promulgating human health criteria based on sound scientific rationale. EPA is required to consult and coordinate with Indian tribes. However, that requirement does not allow EPA to circumvent the requirements of the CWA.

EPA's obligation to consult with Indian tribes regarding tribal treaty rights is not new. It dates back to at least 1994, with a memorandum issued by President Clinton.[160] *See* EPA Policy for the Administration of Environmental Programs on Indian Reservations" Memorandum on Government-to-Government Relations with Native American Tribal Governments, 59 Fed. Reg. 22,951 (Apr. 29, 1994) ("1994 Presidential Memorandum"). This Presidential Memorandum was followed by Executive Order 13084 "Consultation and Coordination with Indian Tribal Governments", 63 Fed. Reg. 27655 (May 14, 1998) (references tribal treaty rights in introduction and §§ 2, 5), which was replaced two years later with Executive Order 13175 "Consultation and Coordination with Indian Tribal Governments", 65 Fed. Reg. 67349 (Nov. 6, 2000) (references tribal treaty rights in §§ 2(a), 2(b), 3(a), 5(d)).

In 2009 President Obama issued a Presidential Memorandum on Tribal Consultation, 74 Fed. Reg. 57881 (Nov. 5, 2009) ("2009 Presidential Memorandum"); directing all executive departments and agencies to develop a detailed plan of actions each agency would take to implement Exec. Order No. 13175. In compliance with the 2009 Presidential Memorandum, EPA issued its EPA Policy on Consultation and Coordination with Indian Tribes ("EPA Consultation Policy") on May 4, 2011. As with the executive orders and the presidential memoranda, this policy specifically references tribal treaties. EPA Consultation Policy at 3.[161]

By their terms, the tribal consultation executive orders and presidential memoranda are intended only to improve the internal management of the executive branch, and do not "create any right, benefit, or trust responsibility, substantive or procedural, enforceable at law by a party against the United States, its agencies, or any person." 1994 Presidential Memorandum; Exec. Order No. 13084 § 7; Exec. Order No. 13175 § 10; 2009 Presidential Memorandum. They are

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considered the input received during consultation with tribes when selecting which fish consumption data would be used to estimate a FCR for calculating human health criteria. . . "); 80 Fed. Reg. at 55068 (§ IV.C.b) ("EPA considers 10^{-6} to be sufficiently protective, and the tribes have supported this during consultation"); 80 Fed. Reg. at 55074 (§ VI.F) ("At . . . meetings, the tribes consistently emphasized that the human health criteria should be derived using at least a minimum FCR value of 175 g/day, [and] a cancer risk level of 10^{-6}. . . ."). *See also* n.17 at 5 ("[T]he EPA supports the state's decision to derive the human health criteria using a FCR of 175 g/day so long as the state also retains a cancer risk level of 10^{-6}, *which the tribes have generally viewed as a compromise minimum value in tribal consultation*") (emphasis added)(07237).

[159] *Id.*

[160] The Bureau of Indian Affairs first promulgated internal guidelines for consultation with Indian tribes in 1972, which were broadened in 1977. *Lower Brule Sioux Tribe v. Deer*, 911 F. Supp. 395, 398-99 (D.S.D. 1995). In 1984, EPA issued its own policy establishing coordination and cooperation with tribes as to their environmental interests on reservation lands. EPA, Policy for the Administration of Environmental Programs on Indian Reservations (November 8, 1984)(06436-6439).

[161] Although the EPA Consultation Policy encompasses consultation regarding tribal treaties, EPA in August 2015 released a new draft Guidance for Discussing Tribal Treaty Rights. *See* n.154. EPA, EPA Policy on Consultation and Coordination with Indian Tribes: Draft Guidance for Discussing Tribal Treaty Rights.

"intended primarily as a political tool for implementing the President's personal Indian affairs policy. . . ." *Lower Brule Sioux Tribe v. Deer,* 911 F. Supp. 395, 401 (D. S. D. 1995). They do not have the force of law and do not establish legal standards. *Hoopa Valley Tribe v. Christie,* 812 F.2d 1097, 1103 (9th Cir. 1986) (holding that 1994 Presidential Memorandum does not create any enforceable duty to consult with tribes).

Moreover, compliance with the executive orders and the Memorandum are specifically limited to those actions consistent with existing law. "[A]gencies shall adhere, *to the extent permitted by law*, to the following criteria when formulating and implementing policies that have tribal implications. . . ." Exec. Order No. 13175 § 3 (emphasis added); "Executive departments and agencies shall carry out the provisions of this memorandum *to the extent permitted by law and consistent with their statutory and regulatory authorities* and their enforcement mechanisms." 2009 Presidential Memorandum (emphasis added). Presidential executive orders cannot impose legal requirements on the executive branch that are inconsistent with a statute—such as the CWA—duly enacted by Congress. *United States v. Rhode Island Dep't of Corr.*, 81 F. Supp. 3d 182, 188 (D.R.I. 2015) (*citing Chamber of Commerce of U.S. v. Reich*, 74 F.3d 1322, 1332-34 (D.C. Cir. 1996)); *Utah Ass'n of Counties v. Bush,* 316 F. Supp. 2d 1172, 1184 (D. Utah 2004).

Appropriately, EPA's own consultation policy is entirely procedural, outlining how and when consultation is to occur, and the roles and responsibilities of those involved in the consultation process. EPA Consultation Policy. The policy in no way *requires* that the agency adopt the tribes' position. *Id.* Thus, to the extent that EPA's internal policies impose a duty on EPA to consult with tribes while promulgating water quality standards, that consultation does not require that EPA adopt whatever fish consumption rate or cancer risk level the tribes insist upon during that consultation. *Hoopa Valley Tribe*, 812 F.2d at 1103 (finding that BIA consultation guidelines were not binding, but even if they were, there was no violation of APA where tribe was consulted even though tribe's advice was not accepted); *Lower Brule Sioux Tribe*, 911 F. Supp. at 401 (holding that although BIA guidelines require meaningful tribal consultation "that is not to say the BIA must obey those who are consulted or that the BIA must accept their advice"). Consultation is not the same as obeying those who are consulted. *Hoopa Valley Tribe*, 812 F.2d at 1103.

Executive orders, presidential memoranda and EPA policies simply do not allow tribes to dictate the appropriate cancer risk level and fish consumption rate. EPA has been clear in both its proposed rule and in its comments to Ecology's proposed rule that it has allowed the tribes to do exactly that. The tribes "repeatedly asked" and "consistently emphasized" that the human health criteria "should be derived" using at least a minimum fish consumption rate of 175 g/day and a cancer risk level of 10^{-6}, "which the tribes have generally viewed as a compromise minimum value in tribal consultation."[162] Under the CWA EPA must base water quality standards on sound scientific rationale—not on what the tribes express as their preference during the consultation process. Choosing to use a fish consumption rate of 175 g/day and a cancer risk level of 10^{-6} simply because the tribes "consistently emphasized" it in meetings that EPA "should" do so violates the CWA and its implementing regulations.

[162] *See* n.158.

Comment No. 14: Compliance with downstream water quality standards is not a basis for the proposed rule.

EPA has improperly relied on the need to protect downstream water quality standards as a basis for its demands that the state of Washington use a high tribal consumption rate and 10^{-6} risk policy. This was declared by Mr. McLerran in his meeting with Mr. Opalski and the regulated community in April 2013.[163] It was echoed by EPA staff at meetings with state officials.[164] It was repeated in a July 1, 2014 letter from Mr. McLerran wherein he states he "supports regional consistency among Region 10 states" to protect downstream waters under 40 C.F.R. § 131.10(b).[165] EPA repeats these post-hoc rationalizations in the Federal Register notice. 80 Fed. Reg. at 55068 ("Use of [175 g/day] should thus help provide for the attainment of and maintenance of downstream WQS in Oregon.")

EPA should acknowledge that 40 C.F.R. § 131.10(b) does not require upstream states to adopt the same water quality standards as downstream states. EPA issued a Frequently Asked Questions document in June 2014 that allows the state to comply with this provision in EPA regulations by adopting a narrative provision in its water quality standards that discharges from the state will not cause or contribute to a violation of applicable downstream state water quality standards.[166] The EPA approved water quality standards for Washington satisfy the requirements of 40 C.F.R. § 131.10(b) by expressly providing that all "Upstream actions must be conducted in manners that meet downstream water quality criteria." WAC 173-201A-260(3)(b).

EPA should also acknowledge that Ecology has in fact considered and applied the Oregon human health criteria into account in NPDES permits recently issued on the Columbia River.[167] As of today, these are the only NPDES permits on the Columbia River, both issued by Ecology, that have actually applied the Oregon human health water quality criteria. To our knowledge, Oregon has yet to address its human health criteria in a NPDES permit decision. Ecology has also applied its regulation to protect downstream water quality standards in the Total Maximum Daily Load plan for dissolved oxygen on the Spokane River.[168] Ecology has made the same consideration of the downstream Spokane Tribe of Indians criteria in developing a PCB TMDL on the Spokane River.[169] The actions of Ecology, consistent with the state water

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[163] D. McLerran, Pers. Communication (April 9, 2013).

[164] *See* n.4. C. Niemi, Handwritten Notes and A. Chung, Pers. Communication, NWPPA Annual Meeting (June 6, 2013).

[165] *See* n.15. D. McLerran, Letter.

[166] EPA, Protection of Downstream Waters in Water Quality Standards: Frequently Asked Questions, EPA-820-F-14-001, at 6 (June 2014) ("Adoption of narrative criteria or numeric criteria (or both) that are protective of downstream waters are viable options under 40 C.F.R. 131.10(b).")(03954-3965).

[167] Ecology, Draft Response to Downstream Waters Comments (July 2015)(addressing a NPDES permit issued in Longview)(04949-4954); *see* Ecology, Fact Sheet for NPDES Permit WA0000124 Weyerhaeuser Longview, at 60 (06987-7133); Ecology, Fact Sheet for NPDES Permit WA0000256 Georgia Pacific Consumer Products (Camas), LLC, pp. 35 and 60, Table 25 (March 10, 2015)(07134-7229).

[168] *See* n.166. EPA, Protection of Downstream Waters FAQ.

[169] Ecology, Spokane River PCB Source Assessment 2003-2007 (April 2011)(Ecology Pub. No, 11-03-013)(06808-6963).

quality standards, demonstrate that there is no basis for EPA's demand that the same toxic criteria apply in both Oregon and Washington.

EPA and federal courts have recognized that upstream states are not required to have the same water quality standards as downstream states. EPA, for example, denied a petition for rulemaking by the Ozark Chapter of the Sierra Club to establish the same criteria for states on the Mississippi and Missouri Rivers.[170] EPA made clear that upstream states are not required to adopt criteria that are the same as downstream states:

> The federal regulations state, "In designating uses of a water body and the appropriate criteria for those uses, the State shall take into consideration the water quality standards of downstream waters and shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters." 40 C.F.R. §131.10(b). **The regulations do not compel states to adopt the same criteria and uses, nor do they suggest that this is the only way a state can meet these requirements. The water quality program is structured to provide states with flexibility to determine the best way to meet their obligations under § 131.10(b).**

(Emphasis added.)[171]

In the response to the Mississippi and Missouri River petition EPA pointed out that there is no violation of 40 C.F.R. §131.10(b) simply because upstream states rely on different risk management decisions:

> As discussed in the "Statutory and Regulatory Background" section, EPA publishes section 304(a) criteria based on a 10^{-6} risk level for carcinogens; states may select a specific risk level based on their own risk management decisions. EPA believes that adoption of criteria within a risk level of 10^{-6} (one in a million incremental risk for cancer) or 10^{-5} (one in one hundred thousand incremental risk for cancer) represents an acceptable range of risk management discretion for states and tribes. Within the petition states, each state adopts criteria to protect human health based on risk management decisions. Iowa, Arkansas, Tennessee, and Nebraska have adopted PCB criteria based on a 10^{-5} risk level; Illinois, Kentucky and Missouri have adopted PCB criteria based on a 10^{-6} risk level; and Kansas chose to adopt a PCB criterion to protect human health at a 10^{-7} risk level.[172]

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[170] EPA, Decision on Petition to Publish Water Quality Standards for the Mississippi and Missouri Rivers within Arkansas, Illinois, Iowa, Kansas, Kentucky, Missouri, Nebraska and Tennessee (June 25, 2004)(available at http://www2.epa.gov/sites/production/files/2015-02/documents/sierra-club-petition-response.pdf)(06754-6807).

[171] *Id.* at 4.

[172] *Id.* at 18 (*citing* EPA, 2000 Methodology for Human Health Criteria). *See also* EPA, Response to Comments for Water Quality Standards; Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico, EPA-HQ-OW-2012-0095, 4-5 (2012)(EPA approval of human health criteria for New Jersey that are less stringent that downstream water quality standards)(01072-1085).

EPA Region 10 has advised Washington and Idaho to consider EPA decisions on other state water quality standards in the state risk management decisions.[173] EPA should do the same with respect to its proposed rule. Based on the long-standing precedent, the CWA does not require the risk policy decisions in Washington to match those in Oregon. EPA is obligated to comply with the federally approved risk policy in Washington that is well within the range of risk policies that are protective of public health. "Consistency" with the Oregon criteria is not a requirement of the CWA and is not required under 40 C.F.R. §131.10(b). As such it is not a sufficient or appropriate post-hoc rationalization for EPA to compel implementation of its preferred human health criteria in Washington.

Comment No. 15: The Relative Source Contribution value used by EPA is arbitrary and capricious.

The Relative Source Contribution (RSC) is a factor in the derivation of criteria representing the portion of exposure to a contaminant that is attributable to sources regulated by the CWA.[174] It is arbitrary and capricious for EPA to use a RSC factor of less than 1.0 in deriving the proposed criteria where it is simultaneously using a fish consumption rate that includes all fish whether or not that fish is purchased from a store or a marine fish that does not accumulate pollutants in waters regulated by the state's water quality standards. By using a fish consumption rate that reflects the 90th to 95th percentile of tribal consumption rates that includes all fish, there is no other source of water intake or fish consumption that should be accounted for in a RSC of less than 1.0.

EPA 2014 guidance clearly states that human health considerations in deriving water quality criteria are based on the risk only from exposure to fish and drinking water:

> A complete human exposure evaluation for toxic pollutants of concern for bioaccumulation would encompass not only estimates of exposures due to fish consumption but also exposure from background concentrations and other exposure routes[.] The more important of these include recreational and occupational contact, dietary intake from other than fish, intake from air inhalation, and drinking water consumption. For section 304(a) criteria development, EPA typically considers only exposures to a pollutant that occur through the ingestion of water and contaminated fish and shellfish. This is the exposure default assumption, although the human health guidelines provide for considering other sources where data are available. **Thus the criteria are based on an assessment of risks related to the surface water exposure route only**.[175]

This guidance is the same as EPA set forth in the 2000 Human Health Methodology: "[Ambient Water Quality Criteria] for the protection of human health are designed to minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposure to substances

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[173] L. Macchio, Letter to D. Essig (January 20, 2015)(01086-1088).

[174] *See* n.24. Ecology, Overview at 21 (00027).

[175] EPA, Water Quality Standards Handbook, Chapter 3, Section 3.1.3 (2014)(available at http://www2.epa.gov/wqs-tech/water-quality-standards-handbook)(emphasis added)(06158-6215).

through the ingestion of drinking water and consumption of fish obtained from surface waters."[176]

EPA Region 10 has endorsed the use of an RSC of 1.0 where a state is including all salmon in its criteria development methodology. The state of Oregon applied a RSC of 1.0 in the human health criteria approved by EPA in 2012. The rationale for this risk management decision included a discussion that it is a preferred means to account for salmon consumption compared to a lower or fractional RSC.[177] EPA Region 10 has urged Northwest states to consider EPA action on water quality standards for other states.[178] EPA Region 10 has further endorsed the Oregon approach as "the right outcome."[179]

This endorsement is also set forth in a letter dated September 5, 2014, from EPA to the state of Idaho.[180] EPA submitted this letter to Idaho on the question of whether the state should include or partially include salmon in its consumption rate for developing human health criteria. The letter sets forth alternatives to inclusion of salmon by reducing the RSC. EPA states that an "acceptable approach to reducing the RSC is to fully include salmon consumption in the consumption rate."[181] EPA also approved the Spokane Tribe of Indians human health criteria using a RSC of 1.0 where the tribe used a historical rate of consumption.[182]

EPA should acknowledge that there is significant difference between risk assessment in other programs such as the Safe Drinking Water Act (SDWA) and Superfund Cleanup Program.[183] The SDWA uses a RSC of 20% and 80% of exposure but does so in terms of goals, not water quality criteria.[184] The SDWA is using this range of RSC for establishing Maximum Contaminant Level Goals that are not by definition regulatory limits.[185] This is in contrast to criteria in approved water quality standards that must be enforced through TMDLs and end of the pipe limits in NPDES permits.

In this instance EPA should follow its own handbook for developing water quality criteria and address risk in the proposed standards only in terms of surface water exposure

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[176] *See* n.42. EPA, 2000 Human Health Methodology at 1-11 (00103). *See* D. Essig, Email to C. Niemi (September 6, 2012)(06685-6688).

[177] *See* n.101. Oregon DEQ, Oregon Human Health Criteria Issue Paper Toxics Rulemaking at 9 (00484). Oregon used RSC values recommended by EPA for 15 of 17 chemicals and a RSC value of 1.0 for all other non-carcinogens.

[178] *See* n.173. L. Macchio, Letter.

[179] *See* n.4. C. Niemi, Handwritten Notes. ("Dennis thinks the Oregon outcome is the right outcome.")

[180] L. Macchio, Letter to D. Essig (September 5, 2014)(04242-4244).

[181] *Id.* at 2.

[182] *See* n.123. EPA, Letter approving Spokane Tribe of Indians Water Quality Standards.

[183] *See* n.24. Ecology, Overview at 22.

[184] *Id.*

[185] *Id.; See also* Ecology, Draft Comments from Washington and Idaho on EPA 2013 FAQ (April 17, 2013)(04245-4256).

through drinking water and fish consumption. Where EPA is including all fish in its proposed consumption rate, there is no basis for using a RSC value of less than 1.0.

Comment No. 16: The Arsenic criteria proposed by EPA are not based on substantial evidence and are arbitrary and capricious.

The arsenic criteria proposed by EPA for Washington are arbitrary and capricious and lack a substantial scientific basis. The proposed criteria are derived using the same methodology employed by EPA in adopting the 1992 NTR even though the agency has long understood and acknowledged that its approach was not valid or appropriate in developing human health water quality standards.

On June 29, 2015, EPA published its final updates to the section 304 human health criteria.[186] The updated criteria did not include new criteria for arsenic. EPA stated in the announcement of the proposed updates in 2014, the agency did not have the ability to update the arsenic criteria due to "outstanding technical issues."[187] In responding to these comments EPA should explain the technical issues that specifically precluded an update to the section 304 criteria in June and how those issues were resolved by September 2, 2015, when EPA published on its website a draft of the Federal Register notice.

EPA has publicly acknowledged that the NTR methodology for its arsenic criteria is invalid. This is indicated in the final NTR where EPA places an asterisk next to its arsenic criteria noting that it only applies to "inorganic arsenic."[188] EPA describes in its response to comments that this action reflects that only inorganic arsenic is toxic to humans.[189]

In 1997 EPA approved arsenic criteria from Alaska based on the SDWA MCL and withdrew application of the NTR criteria to the state.[190] In that action EPA stated that "a number of issues and uncertainties arose concerning the health effects of arsenic" since the adoption of the NTR.[191] EPA deemed these issues sufficiently significant to require a careful evaluation of the risks of arsenic exposure. A large area of uncertainty in the regulation of arsenic is the form of arsenic present in marine fish. EPA reported in 1997 that the form of such arsenic is typically organic and thus not relevant to establishing human health criteria.[192] The report recommends that EPA use the SDWA MCL for arsenic as the ambient water quality criteria until EPA updates its risk assessment for arsenic.[193]

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[186] *See* n.83. EPA, Final Updated Ambient Water Quality Criteria at 36987.

[187] *See* n.84. EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update.

[188] *See* n.25. NTR at 60848-01, 60868.

[189] *Id.*

[190] EPA, Withdrawal from Federal Regulations of Applicability to Alaska of Arsenic Human Health Criteria, 62 Fed. Reg. 27707 (May 21, 1997)(04803-4806).

[191] *Id.* at 27708.

[192] EPA, Arsenic and Fish Consumption, 2-5 (December 3, 1997)(05043-5062)

[193] *Id.* at 1.

In 2002 EPA adopted toxic criteria for the state of California but did not include criteria for arsenic.[194] EPA explained that this action was necessary due to the ongoing "issues and uncertainties" and contemplated revision to the SDWA MCL based on a report from the National Research Council (NRC). The NRC recommended to EPA that the MCL be reduced from 50 µg/L to 10 µg/L. EPA stated that after "promulgating a revised MCL for drinking water, the Agency plans to revise the CWA 304(a) human health criteria for arsenic in order to harmonize the two standards."[195] EPA should explain in response to these comments why it has failed to harmonize its proposed arsenic criteria for Washington consistent with its representation that it would do so in 2002.

Nationally, about half of the states have obtained EPA approval for arsenic human health criteria based on the SDWA MCL.[196]

Comment No. 17: The PCB criteria proposed by EPA are not based on substantial evidence and are arbitrary and capricious.

In response to these comments EPA should explain how it has resolved technical issues associated with deriving human health water quality criteria for polychlorinated biphenyls (PCBs) and how EPA reconciles the technical difficulties that it has acknowledged in revising PCB standards under the Toxics Substance Control Act (TSCA). EPA should also explain how it justifies such stringent water quality criteria for PCBs when it authorizes ongoing PCB generation and release to the environment under its TSCA rules and through tribal and federal hatchery operations in the state of Washington.

On June 29, 2015, EPA issued a final update to its CWA section 304(a) criteria for the protection of public health. PCBs were among the chemicals that EPA did not update due to "outstanding technical issues."[197] The scope of these technical issues is described in statements by EPA justifying its failure to revise the TSCA PCB regulations. Dennis McLerran, in a letter addressed to the Spokane River Regional Toxics Task Force through the Department of Ecology, wrote:

> Revising current regulations to reduce inadvertently generated PCBs presents both policy and scientific challenges. Before proposing more stringent regulations on the inadvertent generation of PCBs in pigments, the EPA would seek to further understand the complexities and contributions of not only pigments, but also other congeners that be present [in receiving water]….
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> …The aggregation of PCB congeners may in some instances be problematic for risk assessment because the toxicity of different PCB congeners varies and a fixed water quality concentration for total PCBs may not adequately represent the variable toxicity of the various congeners actually present in a particular water

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[194] EPA, Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California, 65 Fed. Reg. 31682 (May 18, 2000) (00861-898).

[195] *Id.* at 31696.

[196] *See* n.24. Ecology, Overview at 44 (00050).

[197] *See* n.84. EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update at 2.

> body. While the EPA is not proposing to undertake a comprehensive analysis of the remaining PCB congeners, we are examining the characterization of PCBs in water bodies. As stated above, characterizing all of the PCBs in the EPA recommended water quality criteria for PCBs (i.e., expressed as total PCBs) is one topic we are discussing.[198]

If EPA does not have the ability for the reasons set forth in the above letter to revise PCB regulations under TSCA, it does not have the ability to revise the PCB NTR criteria applicable to Washington. EPA affirmed as recently as August 3, 2015, that revising PCB regulations "presents both policy and scientific challenges."[199]

EPA should withdraw the proposed PCB criteria as the uncertainties described above have not been addressed or resolved in the Federal Register notice. It is entirely arbitrary and capricious for the agency to conclude on several occasions that it does not have a substantial basis for revising PCB water quality criteria and then propose revised criteria for Washington that will be potentially devastating to Washington industries, local governments and continued hatchery operations.

EPA also needs to explain in particular how it justifies the ongoing release of PCBs into the environment through its TSCA regulations in the context of the proposed PCB criteria. The TSCA regulations allow PCB concentrations up to 50 ppm in manufactured products. 40 C.F.R. §§ 761.3 and 761.20. This amounts to the equivalent of 50 million pg/L allowed under TSCA compared to the EPA proposed PCB water quality criteria in Washington at 7.3 pg/L. EPA needs to explain how it is now "necessary" to impose water quality criteria that are seven orders of magnitude more stringent than the PCB concentrations it has found not to threaten human health or the environment under TSCA, 40 C.F.R. § 761.20.[200]

EPA needs to address this issue because it will be all but impossible to meet its proposed criteria due to the ongoing release of PCBs that EPA authorizes as adequately protective under TSCA. A recent study in Washington documented the ubiquitous presence of low PCB levels in manufactured products including paints, used motor oil, road striping, dust suppressants, antifreeze, hydro-seed materials, packaging, toothpaste, hand soap, laundry soap and shampoo.[201]

For many dischargers in Washington, the EPA allowed PCB concentrations are a significant portion of the PCBs in their effluent. For pulp and paper mills using recycled materials their primary source of PCBs is from EPA-allowed concentrations in inks and dyes. [202] The same is true for wastewater treatment plants. In a 2015 report, Spokane County reported that PCB-11, a PCB congener associated with EPA allowed PCB concentrations, "was measured at relatively high concentrations…in both the influent and effluent."[203] PCB-11 was the "single

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[198] D. McLerran, Letter to A. Borgias (February 24, 2015)(04239-04240).

[199] L. Mann, Email to M. Macintyre at 2 (August 3, 2015)(05063-5065).

[200] *See* n.25. NTR at 60848-01, 60868.

[201] City of Spokane, PCBs in Municipal Products (Rev.), Table B-1 (July 21, 2015)(06694-6738).

[202] D. Krapas, Slide Show "Dealing with PCBs in the Spokane River" at 3 (October 2, 2012)(06443-6463).

[203] Brown and Caldwell, 2015 Annual Toxics Management Report Spokane County Regional Water Reclamation Facility NPDES Permit WA-0093317 at 2-18 (2015)(04861-4948).

most abundant congener in the effluent.[204] The same study evaluated PCB concentrations from three neighborhoods predominantly developed before 1970, from 1970 to 1985 and after 1985. The study found the highest PCB concentrations from the two most recently developed neighborhoods and concluded that there is "little correlation between the year of construction and the source of PCB contamination."[205]

It is also apparent that tribal and federal fish hatcheries discharge a significant percentage of the annual PCB loading to Washington waters. EPA authorizes the operation of these hatcheries and the contamination of fish released by these hatcheries EPA under the authority of a general NPDES permit.[206] The Department of Ecology has identified hatcheries as a significant source of PCB loading to waters of the state. Ecology has estimated that as much as ten percent of annual PCB loading to Puget Sound is attributable to returning salmon.[207]. In 2011, Ecology calculated that returning salmon contribute up to 0.3 kg/yr based on PCB residues per whole-body fish ranging from 7 µg for pink salmon to 336 µg for Chinook salmon.[208]

Ecology has also acknowledged, in addition to the PCB loading from returning salmon, that PCB contaminated hatchery fish play a significant role in section 303(d) listings for PCBs.[209] Ecology concluded that hatchery fish "may contribute to impairment and, in some cases, may cause the bulk of impairment."[210] *Id.*, at 30.

The 2006 Ecology report on hatchery fish included an analysis of skin-on fillets of pre-release rainbow trout from 11 hatcheries with PCBs concentrations ranging from <2.3 to 67 ng/g (wet weight) with an average of 13.0 ng/g (wet weight) PCBs.[211] Assuming that the fillet concentrations reflect whole-body concentrations, these concentrations corresponded to <103 to 9700 ng total PCBs per fish (using hatchery-specific average fish weights, which ranged from 83 to 678g). Other researchers have found between 39 and 59 ng/g total PCBs in whole-body juvenile Chinook salmon from six west coast hatcheries.[212] The authors concluded, "contaminated salmon may be a significant source of toxicants in the environment and in the food chain."[213] A study of British Columbia hatcheries found on average 25.5 and 48.5 ng/g (wet weight) PCBs in Chinook smolts from two hatcheries and 34.9 ng/g (wet weight) in Coho smolts

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[204] *Id.* at 2-18.

[205] *Id.* at 2-27.

[206] EPA, Preliminary Draft NPDES Permit for Federal Aquaculture Facilities and Aquaculture Facilities Located in Indian Country, Permit No. WAG-130000 (August 2015)(06216-6319).

[207] Ecology, Control of Toxic Chemicals in Puget Sound: Assessment of Selected Toxic Chemicals in Puget Sound 2007-2011 at 93 (2011)(Ecology Pub. 11-03055)(04297-4593).

[208] *Id.*

[209] Ecology, Persistent Organic Pollutants in Feed and Rainbow Trout from Selected Trout Hatcheries (April, 2006)(Ecology Pub. No. 06-03-017)(04681-4732).

[210] *Id.* at 30.

[211] *See* n.209.

[212] L. Johnson *et al*, Contaminant Exposure in Outmigrant Juvenile Salmon from Pacific Northwest Estuaries of the United States, 124 ENVIRON. MONIT. ASSESS. 167-194 (2007)(04955-4982).

[213] *Id.*

from a third (BC) hatchery.[214] An analysis of pre-release juvenile Chinook from eight hatcheries feeding on the Columbia River found whole body concentrations of PCBs ranging from 6.9 to 61 ng/g (wet weight), corresponding to 22 to 323 ng per fish (individual hatchery-specific average weights from 3.2 to 6.2 g).[215] An analysis of pre-release juvenile Chinook salmon from the Soos Creek hatchery on Puget Sound over a three year period found total PCB concentrations ranging from 10 to 50 ng/g (wet weight), corresponding to 90 to 125 ng PCB per fish (fish weight ranged from 2.5-9.4 g).[216] NOAA Fisheries has also documented the significant PCB concentrations in hatchery fish feed and in hatchery origin fish.[217]

Tribal and federal hatcheries are undoubtedly an increasing source of PCB loading to Washington waters. In 2010, the combined hatchery release in Washington was 229.5 million fish including 117.4 million Chinook salmon.[218] In 2015, the Northwest Indian Fisheries Commission reported that tribal hatcheries alone released 40 million salmon and steelhead.[219] EPA apparently believes that this level of PCB loading to Washington waters is consistent with applicable water quality standards and will not cause any degradation to existing beneficial uses. EPA has not sought to regulate these discharges or require any additional monitoring or best management practices in the preliminary draft general hatchery permit in Washington that will authorize tribal hatcheries to continue to release PCBs to the environment.[220]

EPA should withdraw the proposed rule and not take further action on the proposed PCB criteria until the outstanding technical issues are resolved and in light of the on-going PCB loading attributable to EPA authorization of PCB concentrations in manufactured products and in hatchery fish. EPA has concluded through TSCA and its hatchery permits that these levels of PCBs do not pose a threat to human health or the environment. It is arbitrary and capricious for EPA to then turn around and impost more draconian PCB water quality standards as necessary to protect human health.

Comment No. 18: The proposed methylmercury criterion is arbitrary and capricious and not supported by substantial evidence.

EPA should defer action on a methylmercury criterion (MeHg) for the state of Washington. EPA is proposing to adopt a fish tissue concentration criterion of 0.033 mg/kg (wet

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[214] Kelly et al, Persistent Organic Pollutants in Aquafeed and Pacific Salmon Smolts from Hatcheries in British Columbia, Canada, 285 AQUACULTURE 224-233 (2008).

[215] Johnson et al, Contaminant Concentrations in Juvenile Fall Chinook Salmon from Columbia River Hatcheries, 72 N. AMERIC. J. AQUACULTURE73-92 (2010).

[216] Meador et al,. Bioaccumulation of Polychlorinated Biphenyls in Juvenile Chinook Salmon (Oncorhynchus Tshawytscha) Outmigrating through a Contaminated Urban Estuary: Dynamics and Application, 19 ECOTOXICOLOGY141-152 (2010).

[217] NOAA Fisheries, Draft Environmental Impact Statement on Two Joint Tribal Resource Management Plans for Puget Sound Salmon and Steelhead Hatchery Programs, Appendix K (2014)(04257-4273).

[218]The Role of Hatcheries in North American Wild Salmon Production, The Great Salmon Run: Competition Between Wild and Farmed Salmon, Table IV-1 at 44 (06739-6752).

[219] Northwest Indian Fisheries Commission, Tribal Natural Resources Management, A Report from the Treaty Tribes in Western Washington at 4 (2015)(06530-6545).

[220] *See* n.206. EPA, Preliminary Draft NPDES Permit for Federal Aquaculture Facilities and Aquaculture Facilities Located in Indian Country.

weight). This value is derived from the outdated basis for the EPA 2001 recommended criteria for methylmercury.[221] EPA has acknowledged unresolved technical issues and delayed action on updating this value in the 2015 recommended updated human health water quality criteria.[222] EPA should acknowledge technical problems with the 2001 recommendation and defer any action on adopting this criterion as applicable to Washington.

Washington already has in place criteria for mercury based on human health protection that are more stringent than the NTR criteria. [223] The NTR criteria are 0.14 µg/L (organisms and water) and 0.15 µg/L (organisms only), 40 C.F.R. § 131.36(b), compared to the Washington chronic freshwater criterion of 0.012 µg/L, WAC 173-201A-240, Table 240(3). There is no justification for EPA to impose a flawed criterion on the state of Washington when there is already in place a human health based criterion that is fully protective of human health.

Ecology has previously identified to EPA the numerous technical difficulties it will have in implementing the EPA tissue based criterion.[224] These include unresolved technical issues regarding:

- Mixing zones
- Variances
- Field sampling recommendations
- Assessing non-attainment of fish tissue criteria
- Developing TMDLs for water bodies impaired by mercury
- Incorporating methylmercury limits into NPDES permits.[225]

Ecology has explained to EPA that the EPA guidance on implementing the flawed 2001 criterion does not address these outstanding issues.[226] EPA has not responded to these concerns or explained in the Federal Register notice how the state and regulated community in Washington can feasibly implement the proposed methylmercury criteria. EPA should accordingly withdraw the proposed MeHg criterion and take no further action on establishing a MeHg criterion for Washington until the recognized technical issues with outdated and flawed 2001 criterion are resolved.

Additionally, even if the 2001 national criterion was still valid, EPA's proposed MeHg fish tissue criterion of 0.033 mg/kg (wet weight) is not. It is overly conservative and unattainable in Washington (and the rest of the United States) as the levels of mercury in fish are consistently higher than the proposed criterion.

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[221] *See* n.24. Ecology, Overview at 50 (00056).

[222] *See* n.83. EPA, Final Updated Ambient Water Quality Criteria for the Protection of Public Health and *see* n.84. EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update.

[223] *See* n.24. Ecology, Overview at 49 (00055).

[224] *See* n.24. Ecology, Overview at 50 (00056)

[225] *See* n.24. Ecology, Overview.

[226] *Id.*

EPA derived the proposed criterion following the methodology used to develop the national criterion but changed two key variables in the exposure assumptions: (1) the body weight from 70 kg to 80 kg; and (2) the fish consumption rate of 17.5 g/day to 175 g/day. As discussed in our previous comments (Comment # 17), EPA's fish consumption rate of 175 g/day is not defensible and results in overly stringent criteria not only for MeHg, but for PCBs and other pollutants. EPA offers no information or evidence that the nationally-recommended MeHg fish tissue criterion of 0.3 mg/kg would ***not be*** protective of residents in Washington, even tribal groups with relatively high fish consumption rates, assuming the issues previously discussed can be and are resolved. This is not surprising as there is no support in the technical literature that human health would be adversely affected if residents consumed fish having an average MeHg concentration of 0.3 mg/kg. There likewise can be no scientific evidence supporting the assumption that consuming fish—even at moderate to high ingestion rates—with tissue concentrations exceeding 0.033 mg/kg causes, or is likely to cause, adverse health effects.

There also is controversy surrounding the reference dose for MeHg (0.1 µg/kg/day) used in deriving the national and Washington criterion. The National Academy of Science selected this value based on a Faroes Island study.[227] Island residents consumed both fish and pilot whales, and subtle effects were observed in some children. In addition to mercury, the pilot whales contained elevated levels of PCBs and other chlorinated, recalcitrant pollutants. These confounders were not appropriately considered in establishing the mercury reference dose. The most comprehensive study on potential health effects of mercury in children is the Seychelles Island study.[228] In that study, women of childbearing age consumed fish having mercury levels higher than most fish species in the United States and there was no evidence of developmental or neurological adverse effects in the children studied from birth to age five.

Significantly, the proposed MeHg fish tissue criterion is well below observed concentrations of mercury in several fish species collected in Washington waters as documented in various studies.[229] For example, the median concentration of mercury in 97 fish samples collected and analyzed in 2004 and 2005 was 0.154 mg/kg (wet weight), five times the proposed MeHg criterion. A study conducted by USGS in Franklin D. Roosevelt Lake and the upper Columbia River basin reported the mean and minimum mercury concentrations in walleye, smallmouth bass, and rainbow trout, all of which were four to five times higher than EPA's proposed criterion.[230] The walleye mean and minimum fillet concentration was 0.33 mg/kg and

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[227] National Academy of Science, Toxicological effects of methylmercury. Committee on the Toxicological Effects of Methylmercury, Board on Environmental Studies and Toxicology, National Research Council. National Academy Press, (2000)(07570-7934).

[228] Davidson, et al., Effects of Prenatal and Postnatal Methylmercury Exposure from Fish Consumption on Neurodevelopment: Outcomes at 66 months of Age in the Seychelles Child Development Study. 280 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 701–707 (1998)(07349-7355).

[229] Ecology, Washington State Toxics Monitoring Program: Contaminants in Fish Tissue from Freshwater Environments in 2004 and 2005 (2007)(Publication No. 07-03-024)(available at www.ecy.wa.gov/biblio/0703024.html)(07356-7390).

[230] United States Geological Survey, Concentrations of Mercury and Other Trace Elements in Walleye, Smallmouth Bass, and Rainbow Trout in Franklin D. Roosevelt Lake and the Upper Columbia River, Washington, USGS Open-File Report 95-1951995 (1994)(available at http://pubs.er.usgs.gov/publication/ofr95195)(07391-7429); *See also* Munn and Short, Spatial Heterogeneity of Mercury Bioaccumulation by Walleye in Lake Roosevelt and the Upper Columbia River, Washington. 126 *TRANSACTIONS OF THE AMERICAN FISHERIES SOCIETY* 477–487 (1997)(07935-7946).

0.11 mg/kg, respectively; the smallmouth bass mean and minimum fillet concentration was 0.28 mg/kg and 0.17 mg/kg, respectively; and the rainbow trout mean and minimum fillet concentration was 0.20 mg/kg and 0.16 mg/kg, respectively. From a national perspective, for predator (game fish) species for all states combined, the median mercury concentration was 0.285 mg/kg. The 5th percentile concentration was 0.059 mg/kg.[231] Based on these data, adoption of the proposed criterion would lead to widespread and pervasive water quality impairment in Washington streams, rivers, and lakes. The economic impact would be staggering, while the human health benefit would likely be none.

Indeed, the proposal could result in adverse health impacts if people reduce their consumption of fish because of this criterion. The health benefits of eating fish are well-documented relative to the potential risks of contaminants in the fish.

> For major health outcomes among adults, based on both the strength of the evidence and the potential magnitudes of effect, the benefits of fish intake exceed the potential risks. For women of childbearing age, the benefits of modest fish intake, excepting a few selected species, also outweigh risks. [232]

Before proposing an unattainable human health fish tissue criterion, EPA should carefully evaluate the voluminous information regarding the health benefits of consuming fish. The proposed overly-conservative MeHg criterion value of 0.033 mg/kg is misleading to the public and implies that the potential risks of mercury in fish (even at such a low level) outweigh any health benefits. The health benefits are predictable and supported by numerous studies, whereas the adverse effects assumed by EPA are highly speculative and largely theoretical.

Finally, EPA also fails to discuss or consider the protective effect selenium has on potential mercury health effects although many toxicologists have advocated that traditional risk assessments of mercury in fish without concomitant information on tissue selenium levels is scientifically flawed and misleading.[233] Recent reports have explained the mechanisms of this protective effect.[234] When the molar ratio of selenium to mercury in fish tissue exceeds 1.0 in freshwater and marine fish, a protective effect can be assumed.[235] EPA should evaluate the selenium/mercury molar ratios in fish from Washington waters and use this information to assess the need for a human health MeHg fish tissue criterion 10 times more stringent than the nationally recommended MeHg criterion.

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[231] EPA, The National Study of Chemical Residues in Lake Fish Tissue (2009)(EPA-823-R-09-006)(07430-7433).

[232] Mozaffarian and Rimm, Fish Intake, Contaminants, and Human Health: Evaluating the Risks and the Benefits, 296 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 1885 at 1885 (2006)(07434-7449).

[233] Zhang, Chan and Larssen, New Insights into Traditional Health Risk Assessments of Mercury Exposure: Implications for Selenium, 48 ENVIRONMENTAL SCIENCE & TECHNOLOGY 1206 (2014)(07947-7953).

[234] Ralston and Raymond, Dietary Selenium's Protective Effects Against Methylmercury Toxicity, 278 TOXICOLOGY 112 (2010)(07954-7959).

[235] Peterson, et al., How Might Selenium Moderate the Toxic Effects of Mercury in Stream Fish of the Western U.S.?, 43 ENVIRONMENTAL SCIENCE & TECHNOLOGY 3919 (2009)(07450-7467).

Comment No. 19: EPA has improperly used Bioaccumulation Factors rather than Bioconcentration Factors in deriving the proposed criteria.

As part of the process of updating the national human health water quality criteria in 2014, EPA proposed to alter its prior convention of using BCFs to represent bioaccumulation in the criteria derivation equation and instead used modeled BAFs calculated via the EPI Suite software package. In finalizing the human health criteria guidance in 2015, EPA apparently departed from strict reliance on the EPI Suite model and chose to select a value representing bioaccumulation (a BAF or BCF) for each substance using a decision tree published in a 2003 technical document (i.e., Figure 3-1 from EPA-822-R-03-030, December 2003). That decision-tree and information in the chemical-specific criteria support documents suggest that EPA selected BAFs or BCFs for criteria derivation from either measured or predicted BAFs or BCFs from laboratory or field studies.

A considerable body of science exists concerning the accumulation of substances in fish tissue and the choice of a BAF or BCF can have a large influence on the calculated criteria value. Moreover, it is widely recognized that BAFs and BCFs are influenced by several local environmental factors (e.g., food web structure, water temperature, dissolved carbon). Therefore, it is important to understand the basis for EPA's selection of a specific BCF or BAF so that states, the public, and the regulated community may consider the appropriateness of the choice for a particular situation and allow states to modify the national BCF or BAF such that it better represents state-specific conditions.

Unfortunately, the technical documentation issued with EPA's updated 2015 criteria is wholly insufficient to allow technical comment on EPA's selection of BAFs or BCFs, and whether those are appropriate for Washington. This is because EPA has not provided sufficient detail about the origin of the BAF or BCF data upon which the selected value is based nor has EPA provided the specific procedures and choices the agency used to derive the BAF or BCF that was ultimately selected for criteria derivation. This lack of transparency in describing the origin of the BAFs and BCFs violates the APA because it effectively prohibits substantive comment on the technical merits of EPA's choice of a national value and on the appropriateness of that value in specific states or water bodies, such as those EPA is proposing for Washington.

To be transparent, EPA should produce a technical document that clearly identifies the specific procedures used to select each BAF or BCF value and present the data in a manner such that interested and affected parties can reproduce and evaluate EPA's calculations.

Comment No. 20: EPA's Economic Impact Analysis assessment of the potential impact from proposed Arsenic criteria is illusory.

The economic impact analysis for the proposed arsenic criteria misrepresents the baseline conditions in Washington and the well-accepted and documented understanding of ambient water quality concentrations of arsenic in Washington.[236]

[236] *See* Abt Associates, Economic Analysis for the Revision of Certain Federal Water Quality Criteria Applicable to Washington (August 17, 2015); referenced at 80 Fed. Reg. 55072-55073, § § V, VI.A.

In several instances, EPA has assumed that a facility in Washington has an obligation to take additional actions to comply with the existing NTR arsenic criteria. EPA is well aware that Ecology does not enforce the NTR arsenic criteria. Ecology takes this regulatory approach because the criteria are below natural background conditions and because of the weak scientific basis for the NTR criteria documented above by EPA statements and findings in the Federal Register.[237] If EPA assumes that an action is required by new arsenic criteria that are based on the same flawed premises at the NTR criteria, those will be new incremental impacts imposed by EPA and not by the current regulation. Ecology has had the same approach to the NTR arsenic criteria since their adoption in 1992. EPA Region 10 has taken the same approach in the NPDES permits it administers in the state of Washington.

It is absurd for EPA to assume in the economic impact analysis, twenty-four years later (close to five NPDES permit cycles), that the CWA requires a different approach. EPA should accordingly treat the substantial "baseline" compliance costs in the economic impact analysis as incremental costs under the "policy scenarios" described in the document.

The economic impact analysis incorrectly limits the evaluation of receiving water concentrations of arsenic to those circumstances where there is facility specific receiving water data. In those circumstances, EPA concludes that the applicable arsenic criteria will not be EPA proposed criteria but the ambient arsenic concentrations, and in those instances that the facility will have a "one-time" expense to apply for a variance and a nominal cost to renew that variance every five years. This approach ignores the well-recognized fact that groundwater in Washington ranges from 0.7 to over 1.0 µg/L and that surface water ranges from 0.5 to 1.5 µg/L.[238] EPA should assume that every NPDES permit discharges to a water body where the arsenic criteria are based on natural conditions not the proposed criteria. As such, EPA should acknowledge that any facility discharging to waters of Washington will likely require a variance and fully describe the basis, timing and expense of obtaining a variance.

The economic impact analysis randomly assumes that some facilities will have to install reverse osmosis treatment systems to meet the proposed criteria but that other facilities will only have to apply for a variance. It is not likely that reverse osmosis would be sufficient to meet the proposed EPA arsenic criteria. HDR, in Attachment C, has provided an analysis of treatment system capabilities. Treatment systems for ultra-low arsenic criteria would require additional treatment such as membrane filtration prior to reverse osmosis. Attachment C, at 21, Table 4. EPA should provide a clear explanation as to when a facility will have to use reverse osmosis treatment. In particular, EPA should explain whether installation of reverse osmosis treatment will be required to obtain a variance. If so, the projected incremental costs in the economic impact analysis are vastly understated.

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[237] *See* n.24. Ecology, Overview at 46 (00052). *See also* n.83. EPA, Final Updated Ambient Water Quality Criteria for the Protection of Public Health and n.84. EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update.

[238] *Id.*

Comment No. 21: EPA's Economic Impact Analysis fails to include any assessment of compliance with proposed PCB criteria.

EPA has erroneously excluded the incremental cost of compliance with its proposed PCB criteria from the economic impact analysis. Available data indicates that large portions of state waters would be considered impaired under CWA section 303(d) for failing to meet the proposed PCB criteria. EPA has also concluded that essentially every publicly owned wastewater treatment plant in Washington has the potential to cause or contribute to a violation of the PCB criteria and that the facilities will require tertiary membrane filtration treatment to address PCBs. The technology to treat for PCBs in a five Million Gallon a Day (MGD) would be membrane filtration followed by reverse osmosis, with a Net Present Value (2013 dollars) cost of $75 to $175 million as documented in Attachment C—HDR, Treatment Technology Review and Assessment for Association of Washington Business, Association of Washington Cities and Washington State Association of Counties, at 38, Table 9 (December 2013).

The economic impact analysis does not address PCBs on the pretext that there is no water column data in Washington indicating ambient PCB concentrations below the NTR but above the proposed PCB criteria. In section 4.1.2 in the economic impact analysis EPA represents that it evaluated discharge monitoring and permit application data and "ambient pollutant concentrations from the Environmental Information Management (EIM) database." In section 5.1 EPA represents that it evaluated "potential incremental impairment" based on available EIM data. EPA purports in footnote 17 of the document to exclude all "U" data for non-detected results or results that could not be used but "kept" "J" data where an analyte is positively identified and the reported result is an estimate.

It is inexplicable, given these parameters, how EPA can represent in Exhibit 5-1 in the economic impact analysis that there is no PCB water column in the EIM database that is either unqualified or J qualified. In fact, there is substantial PCB water column data for Puget Sound and the major tributaries to Puget Sound. This data was collected by or for Ecology relatively recently in 2009 and 2010.[239] This report has been reviewed and that data in the report has been included in the EIM database.[240] From this report alone there are well over 12,000 PCB sampling results from Haro Strait, the Strait of Juan de Fuca, the Whidbey Basin, Main Basin, South Sound and Hood Canal.[241] This includes PCB water column data for total congeners collected at each of these sites.[242] All of the total congener data is either unqualified or J qualified. This data should have been identified and listed in Exhibit 5-1 in the economic impact analysis.

EPA should acknowledge in response to these comments that all of the total PCB water column data from the 2011 Ecology report is above the PCB criteria proposed for Washington

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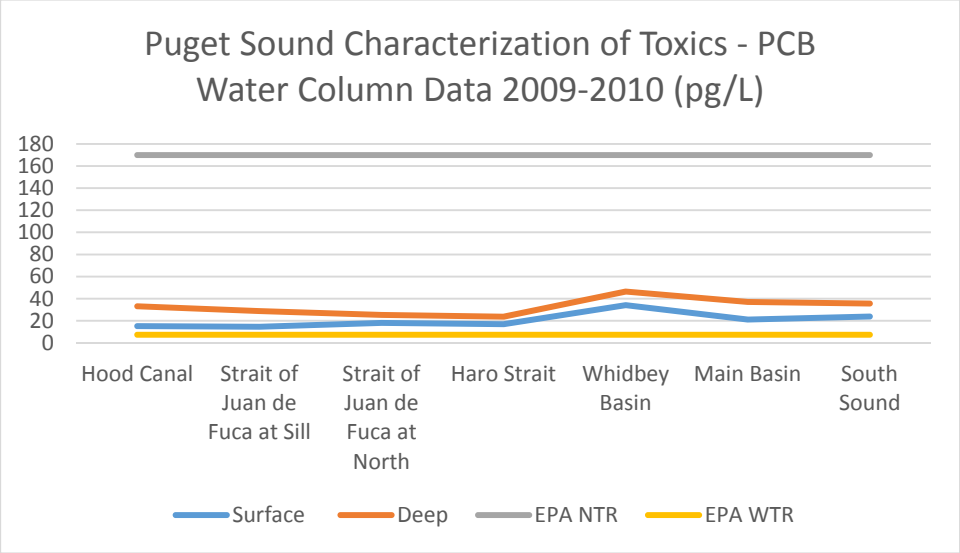
[239] Ecology, Control of Toxic Chemicals in Puget Sound: Characterization of Toxic Chemicals in Puget Sound and Major Tributaries, 2009-10 (January 2011)(05155-5395) (available at https://fortress.wa.gov/ecy/publications/documents/1103008.pdf).

[240] Ecology, Screen-shot of EIM Search Result (December 8, 2015)(available at https://fortress.wa.gov/ecy/eimreporting/Eim/EIMSearchResults.aspx?ResultType=EIMTabs&StudyName=toxic+chemicals+in+puget+sound&StudyNameSearchType=Contains (06753).

[241] Ecology, Email (07311) and attached EIM Data for Puget Sound (December 8, 2015)(05987). The attached data is limited to water column data for total PCBs. The entire data set will be submitted separately.

[242] *Id.*

but below the NTR criteria. The following chart, based on water column data in the EIM database,[243] shows an average or the total PCBs for each monitoring station at the surface and at depth:



It is equally inexplicable why EPA did not consider available data documenting that dischargers are potentially going to cause or contribute to a violation of its proposed PCB criteria. EPA appears to have conveniently placed blinders on its review by relying on discharge monitoring data knowing that such data, if collected, is based on an EPA test method with detection levels that are above even the NTR criteria. In doing so EPA ignored data from Ecology on wastewater treatment plants that document levels of PCB concentrations that are well above the proposed PCB criteria. In fact, every wastewater treatment plant sampled by Ecology (which includes two of the specific facilities evaluated by EPA in the economic impact analysis), with the exception of two facilities with reporting levels of 600 pg/L, were well above the proposed criteria.[244]

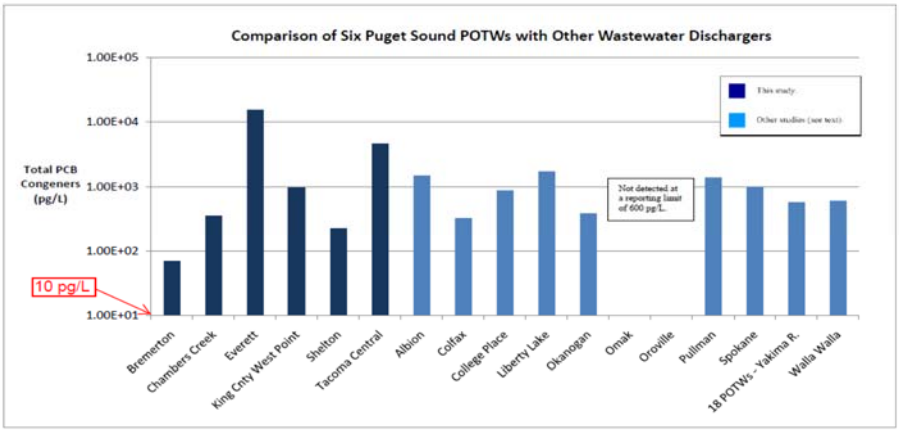


Figure 2. Comparison of Average Total PCB Results among Several POTWs

[243] *Id.*

[244] Ecology, Control of Toxic Chemicals in Puget Sound Summary Technical Report for Phase 3: Loadings from POTW Discharge of Treated Wastewater, Figure 2 (December 2010)(Publication No. 10-10-057)(05746-5986).

The failure of EPA to consider this data is inexcusable where EPA has relied on this information to perform a narrative reasonable potential analysis for three municipalities on the Spokane River. In the 20[12] Fact Sheet for the City of Coeur d'Alene wastewater treatment plant NPDES permit EPA makes the following statement regarding the data presented in Figure 2:

> PCBs have been detected in effluent from POTWs discharging to the Spokane River in the State of Washington (i.e., the City of Spokane and Liberty Lake Sewer and Water District) as well as other POTWs in Washington State operated by the Cities of Medical Lake, Okanogan, College Place, Walla, Pullman, Colfax, Albion, Bremerton, Tacoma, and Everett, and King and Pierce counties. Effluent concentrations of total PCBs at these 14 facilities (a total of 34 samples) ranged from 46.6 to 39,785 pg/L with a median concentration of 810 pg/L...[245]

The Spokane River offers a precedent for how EPA will address low PCB in NPDES permits throughout the state of Washington under its proposed PCB criteria. EPA approved water quality standards for the Spokane Tribe of Indians in 2013 that include a PCB criteria of 1.3 pg/L. In litigation regarding the obligation of EPA to develop a PCB TMDL for the Spokane River EPA has represented in federal court that year-round tertiary membrane filtration treatment is an appropriate best management practice for a wastewater treatment plant.[246]

EPA should assume in its economic impact analysis that most state waters will not meet the proposed criteria and that most NPDES wastewater treatment plants will have to apply membrane filtration treatment. Attachment C, at ES-3, Table ES-1, provides an incremental cost for such treatment including construction costs and operation and maintenance costs of between $75 and $160 million for a 5 mgd plant and net present value unit cost of between $15 and $32 per gallon per day. EPA identified 406 NPDES permits administered by Ecology including 73 "major" permits in its economic impact analysis. If EPA follows the same approach on Puget Sound that it has on the Spokane River, this would amount to a range of compliance costs from nearly $6 billion to over $11 billion just "major" permits identified by EPA.[247]

The economic impact analysis for PCBs should consider stormwater. EPA excluded stormwater from the analysis by failing to identify PCB data in Table 5-1. PCB concentrations are present in stormwater monitoring in the City of Spokane and Western Washington.[248] The median concentration for PCBs in Western Washington stormwater is 0.011 µg/L. The analysis should include some assessment of the economic impact of managing stormwater discharges.

EPA should also address the economic impact of proposed PCB criteria on the continued operations of tribal and federal fish hatcheries. EPA should explain how it intends to regulate

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[245] EPA, City of Coeur d'Alene Revised Fact Sheet NPDES Permit No. ID0022853 at 17 (2013)(07468-7569).

[246] *Sierra Club v. EPA*, Case No.2:11-cv-017959-BJR Doc. No. 129-1 EPA's Plan for Addressing PCBs in the Spokane River (July 14, 2015)(06320-6350).

[247] $75 MM x 73 = $5.5 Billion; $160 MM x 73 = $11.7 Billion.

[248] W. Hobbs, Memorandum Spokane Stormwater (October 15, 2015)(06427-6435); Ecology, Western Washington NPDES Phase I Stormwater Permit: Final S8.D Data Characterization 2009-2013 (February 2015)(Ecology Publication No. 15-03-001)(05592-7745);King County, PCB/PBDE Loading Estimates for the Greater Lake Washington Watershed (September 2013)(06546-6617).

hatcheries that discharge to and release salmon in Puget Sound, Hood Canal, Haro Strait and the Strait of Juan de Fuca. On what basis will EPA allow hatcheries to continue to operate knowing that they are a significant source of PCBs in waters that will be considered impaired for PCBs under the proposed criteria? Specifically, will EPA allow hatcheries to continue to use PCB contaminated feed? Will EPA allow hatcheries to release PCB contaminated fish in waters that are not meeting the water quality criteria? Will EPA allow hatcheries to "seed" tributaries to Puget Sound with fish carcasses that are contaminated with PCBs? Will EPA require monitoring and treatment for water discharges from hatcheries? Will EPA impose PCB management plans on hatcheries to identify sources of PCBs and impose a preference for non-PCB containing equipment and materials including fish feed? EPA is the NPDES permit authority for these facilities and should fully account for the economic impact of its proposed criteria on their continued operations.

The economic impact analysis should also include an assessment of the impact from potential section 303(d) PCB listings based on fish tissue. The economic impact analysis acknowledges that fish tissue data can be a basis for listing under the Ecology Policy 1-11. EPA offers no explanation as to why it failed to consider PCB fish tissue data that is available in the EIM database. This is particularly relevant as Washington is the only state in EPA Region 10 to use fish tissue data as a basis for 303(d) listings. EPA Region 10 has been adamant with the Department of Ecology that it not revise this policy to remove consideration of fish tissue.[249]

EPA should withhold further action on the proposed rule until it has completed an adequate economic impact analysis and provided additional opportunity for public comment on the revised economic impact analysis.

Comment No. 22: The proposed rule constitutes a significant regulatory action under Executive Order 12866 "Regulatory Planning and Review" and Executive Order 13563 "Improving Regulation and Regulatory Review".

Executive Order 12866 "Regulatory Planning and Review" provides that significant regulatory actions must be submitted for review to the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB). E.O. 12866 58 Fed. Reg. 51,735 (October 4, 1993). A "significant regulatory action" is any regulatory action that "will likely result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order." E.O. 12866 § 3(f). As EPA notes in its Guidelines for Preparing Economic Analyses (December 17, 2010), any one of the four criteria listed can trigger a proposed regulatory action to be defined as "significant", while those meeting the first criteria are generally defined as "economically significant." EPA Guidelines for Preparing Economic

[249] K. Susewind, Email to D. Opalski (March 17, 2014)(04740-4742).

Analyses § 2.1.1. OIRA, not the agency, makes the final determination of which rules are considered to be significant. E.O. 12866 § 6(a)(3)(A).

For each matter identified as a significant regulatory action the issuing agency must provide to OIRA a draft of the proposed regulatory action, along with an explanation of the need for the proposed action and how the action will meet that need, and an assessment of the potential costs and benefits of the action. E.O. 12866 § 6(a)(3)(B). For actions that fall into the § 3(f)(1) category of *economically* significant regulatory actions, issuing agencies must go further and provide OIRA with (i) an assessment, including the underlying analysis, of benefits anticipated from the regulatory action together with, to the extent feasible, a quantification of those benefits; (ii) an assessment, including the underlying analysis, of costs anticipated from the regulatory action together with, to the extent feasible, a quantification of those costs, and (iii) an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, and an explanation why the planned regulatory action is preferable to the identified potential alternatives. E.O. 12866 § 6(a)(3)(C).

The principles set out in E.O. 12866 were supplemented and reaffirmed in Executive Order 13563 "Improving Regulation and Regulatory Review" E.O. 13563 76 Fed. Reg. 3821 (January 21, 2011). E.O. 13563 emphasizes that in complying with E.O. 12866 agencies must use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible (§ 1(c)), and that regulations should be adopted through a transparent process involving public participation (§ 2). Each agency is to ensure "the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions." E.O. 13563 § 5.[250]

EPA has determined that its proposed rule is not a "significant regulatory action" under E.O. 12866 and is "therefore, not subject to review under Executive Orders 12866 and 13563." 80 Fed. Reg. 55073 § VI.A. The sole basis given by EPA for this determination is the statement that "the proposed rule does not establish any requirements directly applicable to regulated entities or other sources of toxic pollutants." *Id*. However, E.O. 12866 contains no requirement that the proposed regulatory action be imposed directly on a regulated entity in order to be considered a significant regulatory action. To the contrary, the entire approach of E.O. 12866 is to assess the totality of the costs and benefits of significant rules on society and the economy as a whole. As EPA well knows, it is proposing water quality standards for the State of Washington that if adopted will be translated by Ecology into enforceable limits in NPDES permits. Rather than actually assessing whether the proposed rule falls within the definition of "significant regulatory action", EPA appears to have simply decided at the outset that it did not want to categorize the proposed rule as a significant regulatory action, presumably in order to avoid the full economic analyses by OIRA required by E.O. 12866.

EPA then goes on to state that its proposed water quality standards "may" serve as a basis for development of NPDES permit limits, that Washington has NPDES permitting authority, and

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[250] Both E.O. 13563 and subsequent E.O. 13579 set forth procedures by which agencies engage in retrospective analyses of existing regulations. E.O. 13563 § 6 (05988-90); E.O. 13579 76 Fed. Reg. 41,587 (July 11, 2011)(06363-6366). Executive Order 13610 "Identifying and Reducing Regulatory Burdens" sets out additional requirements, including public participation, for regular retrospective review efforts by OIRA. E.O. 13610 77 Fed. Reg. 28469 (May 10, 2012)(06351-6354).

that the state "retains discretion in implementing standards." 80 Fed. Reg. 55073 § VI.A. EPA thus "in the spirit of Executive Order 12866" hired a consultant to evaluate potential costs to NPDES dischargers associated with state implementation of EPA's proposed rule. Again, as EPA knows, if adopted, its proposed human health criteria *will* be written into NPDES permits for the regulated community—there is nothing permissive about a state's obligation under the CWA to write EPA-promulgated water quality standards into NPDES permits administered by that state.

Under any true analysis it is clear that the proposed rule constitutes an economically significant regulatory action requiring economic analyses by OIRA. A cost analysis prepared in 2013 by HDR Engineering estimated the cost of compliance by regulated industries and local governments with Oregon's water quality standards—virtually identical to those EPA is now proposing for Washington—in a range of $5 billion dollars to $11 billion dollars for just the 73 "major" NPDES permits out of 409 NDPES permits administered by the Department of Ecology. This does include the 18 general permits administered by Ecology or federal individual and general NPDES permits administered by EPA in Washington.[251] Compliance costs would be borne not only by local governments and industries, but would also apply to federal, state, Tribal and other private fish hatchery programs in Washington. Ecology has identified returning salmon as contributing up to 10% of the PCB loadings associated with hatcheries.[252] In 2006 Ecology published a report documenting the PCB loadings associated with hatcheries.[253] As illustrated by Ecology's section 401 certification for the Leavenworth Federal Fish Hatchery, this is a statewide problem.[254] EPA's proposed rule could very well have the unintended consequence of shutting down these very fish hatcheries.

The "economic analysis" that EPA had prepared by Abt Associates "in the spirit" of E.O. 12866 is no substitute for the full economic analyses required by OIRA.[255] *See supra* Comment Nos. 20 and 21. As but one example, E.O. 12866 requires a cost benefit analysis of feasible alternatives to the proposed rule—such as the human health criteria water quality standards recently proposed by Ecology—and an explanation of why EPA's proposed rule is preferable to the identified potential alternative. E.O. 12866 § 6(a)(3)(C). The consideration of alternative approaches is in fact one of the key elements of the E.O. 12866 economic analysis. *See* OMB Circular A-4 (September 17, 2003) at 2,7-9.[256] The analysis "should study alternative levels of stringency to understand more fully the relationship between stringency and the size and

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[251] *See* Attachment C. HDR, Treatment Technology Review and Assessment, Association of Washington Business Association of Washington Cities, Washington State Association of Counties (December 14, 2013).

[252] *See* n.207. Ecology, Control of Toxic Chemicals in Puget Sound, Assessment of Selected Toxic Chemicals in the Puget Sound Basin, 2007-11, and *see* Quality Assurance Project Plan for Phase 3: Characterization of Toxic Chemicals in Puget Sound and Selected Major Tributaries (November 2011)(Publication No. 11-013-055)(06618-6684).

[253] *See* n.209. Ecology, Persistent Organic Pollutants in Feed and Rainbow Trout from Selected Trout Hatcheries.

[254] Ecology, Final 401 Certification for the Leavenworth National Fish Hatchery, Order No. 7192 (January 7, 2010)(04669)

[255] *See* n.236. Abt Associates, Economic Analysis.

[256] OMB Circular A-4 sets out OMB's guidance to agencies on the development of regulatory analysis required by E.O. 12866 § 6(a)(3)(c)(2013) (04983-5030). *See also* OIRA, Regulatory Impact Analysis: Frequently Asked Questions (FAQs) (February 7, 2011)(05031-5042); OIRA, Regulatory Impact Analysis: A Primer (05139-5154).

distribution of benefits and costs among different groups." *Id.* at 8. At least one of the alternatives should be a less stringent alternative to the agency's preferred option.[257] The agency must also consider the option of deferring to regulation at the State or local level and assess whether federal regulation is the best solution. *Id*. at 6. Finally, the agency should conduct both a benefit-cost analysis and cost-effectiveness analysis. The Abt Associates "economic analysis" does not examine any alternatives to EPA's proposed rule. It does not include any consideration of the alternative of leaving it to Ecology to develop appropriate human health criteria. Nor does it involve either benefit-cost or cost-effectiveness analyses.

EPA should acknowledge that the proposed rule constitutes an economically significant regulatory action, and forward the proposed rule to OIRA for a full economic analysis as required by E.O. 12866 and 13563.

Comment No. 23: The proposed rule is inconsistent with concepts of federalism under Executive Order 13132.

Executive Order 13132 provides that federal agencies cannot promulgate rules with "federalism implications" unless the agency meets certain prescribed conditions. E.O. 13132, 64 Fed. Reg. 43255 (August 10, 1999). Rules with "federalism implications" have substantial direct effects on states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. E.O. 13132 § 1(a).

Where a proposed rule has "federalism implications" the agency must adhere to particular criteria. *Id.* § 3. With respect to federal statutes and regulations administered by the states, agencies must grant the states the maximum administrative discretion possible; encourage states to develop their own policies to achieve program objectives and work with appropriate officials in other states; where possible, defer to the states to establish standards; in determining whether to establish uniform national standards, consult with appropriate state and local officials as to the need for national standards and any alternatives that would limit the scope of national standards or otherwise preserve state prerogatives and authority; and where national standards are required by federal statutes, consult with appropriate state and local officials in developing those standards. *Id.* § 3 (c), (d). Where the agency action will limit the policymaking discretion of the states it may only be taken where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance. *Id.* § 3(b). Where there are significant uncertainties as to whether that national action is authorized or appropriate, agencies must consult with appropriate state and local officials to determine whether federal objectives can be attained by other means. *Id.*

Where the proposed rule has federalism implications and also either preempts state and local law, or imposes substantial direct compliance costs on state and local governments and is not required by statute, E.O. 13132 sets forth specific consultation requirements. *Id*. § 4, 6(b), (c). But even where there is neither preemption nor substantial compliance costs, if the proposed rule has federalism implications EPA must consult to the extent practicable with either elected officials or other representatives of state and local governments. *See* EPA's Action Development

[257] *Id.* OIRA, Regulatory Impact Analysis: A Primer at 7; OIRA, Regulatory Impact Analysis: Frequently Asked Questions (FAQs) at 3.

Process--Guidance on Executive Order 13132: Federalism (November 2008) at 8. This includes at a minimum consultation with the "Big 10", a list of ten national organizations representing state and local governments.[258] *Id.* Attachment C, at 45-46.

In fact, EPA's internal policy is broader than E.O. 13132: even if a proposed rule does not have federalism implications, "if it has any adverse impact on state and local governments above a minimal level" then EPA must, at a minimum, consult early with appropriate state and local government representatives, and set forth in the preamble to the rule why E.O. 13132 did not apply, any consultation that occurred, the nature of state and local government concerns, and how EPA addressed those concerns or why EPA decided not to implement the changes suggested. *Id.* at 11.

Contrary to EPA's statement in the proposed rule, the rule does have federalism implications and E.O. 13132 does apply. 80 Fed. Reg. 55074 § VI.E. EPA purports to promulgate the rule pursuant to CWA § 303(c)(4)(B), stating that it is making a "determination of necessity" that Washington's existing human health criteria are not protective of the applicable designated uses, and thus that EPA must promulgate new or revised human health criteria for Washington. 80 Fed. Reg. 55066 § III. Yet EPA also acknowledges that Washington's existing human health criteria were promulgated by EPA—not Washington—in the NTR. Id. § III. EPA did so pursuant to a 1992 determination of necessity. NTR, 57 Fed. Reg. 60848, 60856-60860, 60868.

Since January 2013 Ecology has been engaged in a rulemaking process under the state APA to adopt human health criteria for Washington. This process culminated with a draft rule released by Ecology on September 30, 2014, and a final rule released on January 12, 2015. Under the CWA, states are assigned the primary authority for adopting water quality standards, and once adopted, new or revised standards are submitted to EPA for review and approval or disapproval. CWA §§ 303(a), 303(c)(2)(A), 303(c)(3); 40 C.F.R. § 131, 131.5(a). *See PUD No. 1 of Jefferson Cty. v. Washington Dep't of Ecology,* 511 U.S. 700, 704 (1994); *Pronsolino v. Nastri*, 291 F.3d 1123, 1127 (9th Cir. 2002); *Natural Resources Defense Council, Inc. v. U.S. E. P.A.*, 16 F.3d 1395, 1400 (4th Cir. 1993). EPA could, and under the CWA should, have waited until Ecology promulgated its final rule and submitted that rule to EPA for approval or disapproval pursuant to the CWA. Instead, in December 2014, after Ecology issued its draft rule but before it promulgated its final rule, EPA chose to begin its own rulemaking process. EPA clearly did so because the risk policy adopted in Ecology's draft rule was not EPA's preferred policy. As explained above, EPA ignores the flexibility afforded to states in EPA's own guidance, by insisting that the state's program conform to EPA's preferred approach. EPA's actions are contrary to the cooperative federalism Congress included in the CWA, and the proposed rule would fundamentally alter the state's discretion to make risk management decisions under the CWA.

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[258] The "Big 10" organizations include the National Governors' Association, National Conference of State Legislatures, Council of State Governments, National League of Cities, U.S. Conference of Mayors, National Association of Counties, International City/County Management Association, National Association of Towns and Townships, County Executives of America, and Environmental Council of States. EPA's Action Development Process – Guidance on Executive Order 13132: Federalism (06047-6106); Attachment C, at 45-46.

Because the proposed rule has "federalism implications", E.O. 13132 applies here. EPA's statement that E.O. 13132 does not apply, but that "in the spirit" of E.O. 13132 it is soliciting comments on the proposed rule from state and local officials, is insufficient. *See* 80 Fed. Reg. 55074 § VI.E. EPA's promulgation of the proposed rule is directly contrary to the criteria laid out in E.O. 13132, and the agency has also failed to comply with the Order's consultation provisions. At a minimum, EPA should acknowledge that E.O. 13132 applies to the rule and should comply with the executive order's requirements.

Comment No. 24: The proposed rule fails to consider the increased energy demands required for water quality treatment under Executive Order 13211 "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use".

Pursuant to Executive Order 13211, a "significant energy action" is one that promulgates, or is expected to lead to the promulgation of, a final rule that is a significant regulatory action under E.O. 12866, and likely to have a significant adverse effect on the supply, distribution or use of energy or is designated by the Administrator of OMB/OIRA as a significant energy action. E.O. 13211, 66 Fed. Reg. 28355 (May 22, 2001). For significant energy actions, the federal agency must prepare a Statement of Energy Effects and submit the Statement to OIRA. E.O. 13211 § § 2, 3. The statement, or a summary, must be included in the proposed and final rulemaking notices published by the agency. *Id*. § 3(b). A Statement of Energy Effects is a detailed statement that includes information on any adverse effects on energy supply, distribution, or use, and reasonable alternatives to the action along with the expected effects of such alternatives on energy supply, distribution, or use. *Id.* § 2(b).

EPA's sole reference to E.O. 13211 is, yet again, a conclusory statement with no support: "This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy." 80 Fed. Reg. 55074 § VI.H. As explained in Comment No. 22, the proposed rule is a significant regulatory action under E.O. 12866. Moreover, it will likely have a significant adverse effect on the supply, distribution or use of energy. HDR estimated an increased energy demand of 39.7 MWh/day for membrane filtration treatment.[259] If applied to just the 73 "major" NPDES permits identified by EPA, this is an increase in energy demand that requires review under the Executive Order.

EPA should not take further action on the rule until it has completed this analysis and provided an opportunity for public comment on the analysis.

4835-3307-7804, v. 1

[259] *See* Attachment C, Table 7, at 35.