

COMMENTS ON BEHALF OF

**THE NORTHWEST PULP & PAPER ASSOCIATION,
AMERICAN FOREST & PAPER ASSOCIATION,
WASHINGTON FARM BUREAU,
ASSOCIATION OF WASHINGTON BUSINESS,
WESTERN STATES PETROLEUM ASSOCIATION,
WESTERN WOOD PRESERVERS INSTITUTE,
TREATED WOOD COUNCIL,
INLAND EMPIRE PAPER COMPANY,
NIPPON DYNAWAVE PACKAGING,
PACKAGING CORPORATION OF AMERICA,
PORT TOWNSEND PAPER COMPANY, AND
GREATER SPOKANE, INC.**

**ON THE EPA PROPOSED HUMAN HEALTH WATER QUALITY CRITERIA FOR
THE STATE OF WASHINGTON, 87 Fed. Reg. 19046 (April 1, 2022)**

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

May 31, 2022

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The Northwest Pulp & Paper Association, American Forest & Paper Association, Washington Farm Bureau, Association of Washington Business, Western States Petroleum Association, Western Wood Preservers Institute, Treated Wood Council, Inland Empire Paper Company, Nippon Dynawave Packaging, Packaging Corporation of America, Port Townsend Paper Company, and Greater Spokane, Inc. 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 87 Fed. Reg. 19046 (April 1, 2022).

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

Introduction

Maintaining and improving water quality in the state of Washington is our shared goal. We support sustainable water quality standards that result in cleaner water, preserve aquatic life, and protect human health. To be effective in reaching these goals, the adopted standards must be based on accurate and complete data, recognized scientific principles, and prudent risk management calculations. Most of all, water quality standards must reflect the important balance between protection and attainability to justify significant public and private investments necessary to meet the standards.

Unfortunately, EPA's proposed human health water quality criteria (HHWQC) fail to meet these principles for sustainable regulation. If adopted, the resulting standards will be completely unattainable even with cost-prohibitive water treatment technologies.

It is important to recognize the unintended consequences of the proposed rule. Faced with the inability to meet an unattainable standard and the resulting permit uncertainty, employers are less likely to invest in newer water treatment technologies or other upgrades to modernize and expand their operations. This lack of investment will put at risk important family-wage jobs, including union jobs and those bringing critical economic activity to rural areas.

Similarly, local governments across Washington state will be required to invest untold millions of dollars in new technology even though these investments will not result in compliance with the EPA standards. Those costs will have to be passed on to the citizens of the state in the form of higher utility and tax rates at a time when many are already facing economic challenges. This added burden would compound the skyrocketing cost of living for Washingtonians due to record inflation driving up the costs of housing, food, fuel, and other essentials. These burdens will fall heaviest on the citizens of our state who can least afford another increase in their costs of living.

EPA's proposal to impose unattainable water quality standards stands in contrast to the thorough rulemaking process employed by the State of Washington Department of Ecology (Ecology) when it adopted state water quality standards in 2016. Those state standards, among the most restrictive human health criteria ever adopted under the Clean Water Act (CWA), were based on years of work by Ecology with all stakeholders, a deep consideration of the available

science, and conscientious risk management determinations. In announcing these 2016 standards, Washington state officials voiced justifiable pride in the thorough process used by Ecology and the resulting protections the standards would afford the people of Washington.

For example, in a November 15, 2016, statement issued by Ecology, then-director Maia Bellon publicly expressed disappointment with EPA's rejection of the state HHWQC proposal:

We're disappointed that Washington state's approach wasn't accepted in its entirety. We worked hard to craft new water quality standards that were balanced and made real progress – improving environmental protection and human health while helping businesses and local governments comply.

We were always clear in our goal –to meet EPA's requirements and tailor our proposal to work for Washington state. We believe we did that with the clean water standards we adopted...¹.

As members of Washington's regulated community, we have consistently maintained our commitment to improving water quality. We recognized that while these standards were some of the most protective standards adopted by any state in the nation, they provided a legitimate, if challenging, path to compliance.

In 2016, EPA rejected the state-adopted standards and replaced them with its own, more restrictive, and unattainable standards, which we viewed as arbitrary and capricious. We filed our 2017 petition for rulemaking and reconsideration in the hope of advancing sustainable regulations that balance protection and attainability. In that filing, we did not seek to review the factors used by the state in creating its rule because those standards were the result of many years of discussions among stakeholders and reflected the State of Washington's best judgment on risk management decisions. Instead, we asked that EPA reconsider and accept the approach Ecology had employed in setting standards.

When EPA agreed with that request, the standards developed by Ecology went into effect and are protecting Washington's resources and residents today.

There is no real question as to whether these standards, developed and adopted by state officials after more than four years of analysis, are effectively protecting all consumers, including highly exposed populations, such as tribal members in Washington who consume greater amounts of fish and shellfish.

In contrast to the thorough and inclusive process employed by Ecology to develop its standards, EPA has not conducted independent analyses or developed a meaningful record for its proposed rulemaking. Instead, it has cherry-picked some elements and factors that the state specifically chose, after years of in-depth discussions, for its overall risk management decisions. For instance, the use of 175 g/day fish consumption rate by Ecology is more than adequately protective of all Washington consumers of fish and shellfish, when considered in the broader context of the state's other risk management decisions regarding the risk factor, relative source

¹ Ecology, "Ecology Director Maia Bellon responds to EPA's announcement on Washington's water quality standards Department of Ecology News Release," (November 15, 2016)(07960-07961).

contribution, and bioconcentration issues. EPA should not disregard these other determinations while accepting the fish consumption rate, as all were inter-related components of the state's risk management decision. EPA has not independently justified its decisions to reject Ecology's consideration of the factors, including the state's fish consumption rate, that drive the proposed federal standards.

EPA's position regarding standards for polychlorinated biphenyls (PCBs) is especially egregious, given the intra-agency conflict between the stringent level in the proposed water quality standard and the relatively lax level under the Toxic Substance Control Act (TSCA), the law responsible for federal regulation of chemicals in products. The water quality standard EPA is proposing would limit discharge of PCBs to 7 parts per quadrillion—the equivalent of one drop from a standard eye dropper dissolved in the water of 2,859 Olympic-sized swimming pools. In contrast, EPA's standards for allowable levels of PCBs in new products is 50,000,000,000 parts per quadrillion, a figure more than 7,000,000,000 times higher than the proposed HHWQC. We support pollution prevention opportunities and believe EPA's approach to set an unattainable limit for pollutants such as PCBs through the CWA, while not using TSCA or other tools to address much greater PCB risks, places an unfair and unnecessary burden on both private employers and local governments within the state of Washington.

In the proposal, EPA contends that its PCB standard will not impact facilities operating under CWA permits in Washington. This contention is based on the premise that the only EPA-approved method to test for PCBs is not sensitive enough to measure compliance at such miniscule concentrations. In fact, EPA assigns zero costs to the proposal based on this and other considerations. This is demonstrably not the case. As explained later in this comment letter, EPA is currently placing maximum pressure on Ecology and facilities in Washington to use an unapproved test method for PCBs as the basis to design and install new treatment systems in an effort to achieve its anticipated and unattainable PCB standard. Despite extraordinary costs, the public and private segments of Washington's regulated community still will not achieve compliance.

Additionally, EPA is required to fully assess the potential impact and costs associated with its proposed rule. The potential economic impacts on Washington communities and businesses over the next five to fifteen years are staggering. These impacts will be felt in permit compliance, public and private capital funding, and diversion of resources to address standards that offer no meaningful additional protection for public health. EPA's cursory review of costs was insufficient and contrary to Supreme Court precedent requiring meaningful cost-benefit analysis.

As a result of these shortcomings, EPA's aspirations for the benefits of this rule are just that: aspirational. The water quality standards simply cannot be achieved, and there are legitimate questions regarding whether they can even be accurately measured. This is not a sustainable regulatory framework that will drive meaningful investments in treatment technology or meaningful improvements in water quality.

Finally, EPA's unfortunate decision to ignore and abandon the detailed analysis, diverse stakeholder engagement, and sound decision-making that went into the state of Washington's human health water quality criteria submitted in 2016 violates the basic tenets of the CWA. The CWA and EPA guidance vests responsibility for risk management determination for human

health water quality criteria with the state. EPA’s decision in 2019 to confirm the state’s proposed rule reflected the respective roles of the state and federal governments as contained under the CWA. In contrast, the current effort seeks to replace the science-based state standards with new EPA criteria based solely on EPA’s views on how the state should manage risks—despite the fact that this is unquestionably the state’s prerogative. The Federal Register statement by EPA fails to demonstrate why the state risk management decisions are in any way inconsistent with the CWA, EPA regulations, and EPA guidance.

EPA should reconsider this rulemaking and reaffirm its approval of the stringent state human health criteria adopted by the state in 2016 and already protecting Washington waters and residents.

Comment No. 1: EPA has wrongly and unlawfully determined that the State of Washington human health water quality criteria adopted in 2016 and approved by EPA in 2019 are deficient under the Clean Water Act.

Congress established a federal-state partnership for implementing the CWA. *PUD No. 1 of Jefferson Cnty. v. Wash. Dept. of Ecology*, 511 U.S. 700, 703-04, 114 S.Ct. 1900 (1994); *City of Abilene v. U.S. E.P.A.*, 325 F.3d 657, 659 (5th Cir. 2003) (quoting *Arkansas v. Oklahoma*, 503 U.S. 91, 101, 112 S.Ct. 1046 (1992)). The U.S. Supreme Court has described the CWA as “a program of cooperative federalism.” *New York v. United States*, 505 U.S. 144, 167, 112 S.Ct. 2408 (1992). States are principally responsible for implementing much of the statute. 33 U.S.C. § 1251(b) (“It is the policy of Congress to recognize, preserve, and protect the primary responsibilities and right of States to prevent, reduce, and eliminate pollution.”).

The CWA accordingly assigns to the states the primary authority for adopting water quality standards. 33 U.S.C. § 1313(a), (c). State water quality standards submitted to EPA must protect all designated beneficial uses, be based on sound scientific rationale and contain sufficient parameters or constituents to protect the designated uses. 40 C.F.R. §131.11(a). When establishing criteria, states are encouraged to base numeric values on guidance adopted by EPA pursuant to CWA § 304(a) (“304(a) Guidance”); 304(a) Guidance modified to reflect site-specific conditions; or other scientifically defensible methods. 40 C.F.R. § 131.11(b). The standards must include the six elements set out in 40 C.F.R. § 131.6, including use designations consistent with the CWA, the methods used and analyses conducted to support the WQS, and water quality criteria sufficient to protect the designated uses.²

Once adopted by a state, EPA’s role is to review the standards for consistency with the CWA, and either approve or disapprove the standards. 33 U.S.C. § 1313(c)(2)(A); 40 C.F.R. § 131.5(a). EPA’s review is not open-ended or discretionary. Rather, it reviews the standards with reference to five different factors set out in 40 C.F.R. § 131.5(a). If EPA determines that the standards are consistent with these factors, EPA must, within 60 days of the date of submission, approve the standards. 33 U.S.C. §1313(c)(3); 40 C.F.R. § 131.5(b). If EPA determines that the state-submitted standards are not consistent with these five factors, then EPA has 90 days in

² 40 C.F.R. § 131.20(c) further delineates the information, analyses, methodologies, and policies that states must submit to EPA along with the water quality standards.

which to notify the state and specify the changes necessary to meet the CWA's requirements. *Id.* If the state fails to adopt the changes within 90 days of notification by the EPA, then EPA must promulgate a water quality standard for the state. 33 U.S.C. §§ 1313(c)(3), (c)(4).

Where a state has adopted water quality standards *that have been approved by EPA*—as is the case here—EPA may only impose new standards on the state if EPA has adopted new water quality standards generally. 40 CFR 131.1 (“A State or authorized Tribe’s applicable water quality standard for purposes of the Act remains the applicable standard until EPA approves a change, deletion, or addition to that water quality standard, or until EPA promulgates a more stringent water quality standard.”) The Act does not anticipate that EPA will impose its policy preferences on a state after approving the state’s water quality standards unless EPA has adopted new water quality standards, generally, subsequent to approving the state’s standards. Here, EPA has entirely ignored this aspect of the CWA.

EPA cannot lawfully disregard the risk management decisions made by Ecology to base its human health criterion based on 175 g/day fish consumption rate (FCR) and risk factor of 1×10^{-6} for carcinogens other than PCBs where the state adopted a 2.3×10^{-5} risk factor coupled with the additional risk management decision to not adopt a criterion for PCBs less stringent than the NTR criterion for PCBs. The resulting standards in Washington are protective of the general population consumption rates within a range of risk factors from 10^{-6} and 10^{-5} while protecting tribal consumption rates at better than 10^{-4} . No state, including Washington, is required to apply a 10^{-6} risk factor appropriate for the general population to more highly exposed sub-populations such as tribal consumers. EPA established this as a matter of law in *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995).³

There is no question that the state standards are based on sound scientific rationale consistent with EPA guidance, and comply with all CWA requirements. Nonetheless, EPA rejects the state criterion for PCBs on the basis that the state PCB standard is based on a risk factor less stringent than 10^{-6} or 10^{-5} . In fact, as EPA concedes in its own rulemaking, the state standard protects a high tribal consumption rate, 175 g/day, to one in 43,478 for a high tribal fish consumption rate. 87 Fed. Reg. at 19053. This is more protective than EPA guidance which deems standards as protective of human health where median exposure for more highly exposed populations are protected to at least 10^{-4} . By extension, the state PCB standard is protective to a risk level of approximately 76 g/day at 10^{-5} . This is well above the 95th percentile of general population fish consumption rates in Washington for **all sources** at 57 g/day.⁴ There is no basis for EPA to claim that state PCB criterion is inconsistent with EPA guidance based on the risk factor and FCR employed by Ecology for the current PCB criterion.

Ecology additionally provided a sound basis for the use of factors for relative source contribution (RSC), and bioconcentration factors (BCF). Moreover, it is the State of Washington’s prerogative, not EPA’s, to decide whether the risk factor adopted should be 10^{-5} or 10^{-6} . EPA is ignoring the long-standing principle under its own guidance that it is first and

³ EPA, Brief for the Defendant-Appellees, *Dioxin/Organochlorine Center v. Clarke*, Nos. 93-35973 & 93-36000 (May 31, 1994)(00899-00967).

⁴ Ecology, Fish Consumption Rates: Technical Support Document Version 2.0, 40-44, Table 37 (January 2013)(Ecology Publication No. 12-09-058)(05398-05591 at 05459-05463 and 05514). 57 g/day is presented at the 95th percentile consumption rate for the general population based on the NCI methods.

foremost the prerogative of states to make risk management decisions for human health criteria. Through the National Toxic Rule (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.

It is not appropriate, and indeed arbitrary and capricious, to vary any one factor in the derivation of the standards without affording the state an opportunity to make a decision on the appropriate risk factor to be applied in Washington. This is essential under the concepts of shared responsibilities under the CWA and was part of the NTR—each state was afforded the discretion to make its own risk management decision as to the risk factor applied to the human health criteria applicable in its state. Washington opted to use a 10^{-6} risk level prior to 2016.⁵ Washington continued that approach on a chemical-specific basis coupled with other risk management decisions that EPA is now ignoring.

In the State of Washington, the risk management decision as to the risk factors used to derive human health criteria is made through rulemaking in accordance with the state Administrative Procedures Act (APA). Ch. 34.05 RCW. The determination cannot be made on an ad hoc basis by the director of Ecology, the Attorney General, or the Governor. To the extent EPA is relying on the ad hoc representations of the state through press releases, consultations, or comments by the state on the proposed rule, any such statements on behalf of the state constitute unlawful rulemaking. They are actionable in state court for violations of the APA and cannot be relied on by EPA. The people of the state are entitled under the state APA for notice and opportunity to comment on a state administrative rule and further entitled to assurances that Ecology has complied with the significant legislative rule requirements under the state APA that apply to all rule making by Ecology. RCW 34.05.328. An end-run around this process by EPA would be unlawful.

It is also inappropriate for EPA to pick and choose between factors used by the State of Washington to derive its human health criteria, which already resulted in conservative risk levels in the current standards. Washington made a risk management decision to use a high consumption rate, in most cases a high risk factor, and state specific RSC values and BCF values. If EPA varies these assumptions, it should rely on the only available general population fish consumption data that is scientifically defensible and defer to the state as to the appropriate risk factor to be applied—either 10^{-6} or 10^{-5} . To do otherwise creates standards that are unduly and unnecessarily conservative. As described by Arcadis:

Water quality criteria based on a high-end fish consumption rate (e.g., 175 g/day) and an excess lifetime cancer risk of 1×10^{-6} present a risk that is far more protective than the acceptable range as defined by USEPA (2000) for both the general population and highly exposed subpopulations, such as Native Americans. Why? Because conservative assumptions add up. If a decision maker chooses a conservative value for every variable in a risk calculation, the results will be far more protective than intended. Consider the hypothetical example of a risk assessment that is based on three independent and log-normally distributed parameters. In the case of a fish consumption calculation, those parameters might be the amount of fish eaten each day, the source of the fish, and the number of

⁵ National Toxic Rule (“NTR”), 57 Fed. Reg. 60848-608923 at 60868 (00768-00847 at 00792); 40 C.F.R. §131.36(b)(14)(iii)(00848-00860).

years over the course of a lifetime that people live in a certain place and eat fish from a local source. Each value represents the 95th percentile, or in other words that 9,500 out of 10,000 people have a lower exposure: they eat less fish, do not only eat fish from local waters, or do not eat local fish for their entire life, for example. Combining those three variables would result in a risk estimate that would fall at the 99.78th percentile of the resulting distribution. The risk to 9,978 out of 10,000 people would be lower than the allowable risk level used to establish the standard. So, if 1×10^{-6} was selected as the allowable risk level for a criterion based on those assumptions, 9,978 people would have a risk less than 1×10^{-6} and only 22 would have a risk greater than 1×10^{-6} . Decisions made on the basis of this hypothetical calculation, which compounds conservative factors, are far more protective than intended if the goal was to protect the average member of the population (or the 90th percentile or even the 95th percentile of the population) at the selected allowable risk level. Additionally, USEPA's proposed criteria go beyond the type of compounded conservatism of exposure assumptions described above and designate Native Americans as the general population and then apply acceptable risk levels previously used for the general population to the Native American subpopulation. The effect of this designation is to add an additional level of conservatism such that the general population and high-end consumers such as Native Americans, are protected at levels far greater than required by USEPA guidance cited above (2000).

This may look like an academic calculation. Some readers may think that overestimating risks is a good thing because it allows us to be extra-cautious, and that regulatory decisions based on risk estimates should be as conservative and protective as possible. But the consequences of such choices also need to be considered. There's 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 and therefore carbon dioxide (CO₂) emissions exacerbating climate change, or the risk of injury to workers who have the job of reducing the levels of those chemicals. Chemicals may be used to treat wastewater to meet lower standards, for example, and the sludge that results has to be trucked to a landfill or incinerated. Generating the power used to operate the wastewater treatment plant uses natural resources and creates air emissions. Each of these aspects of the life cycle of wastewater treatment operations, and their related risks, should be weighed against the value of regulatory decisions based on the combination of several conservative assumptions, referred to as compounded conservatism. In addition, although more difficult to quantify, communicating overestimated risks to the public can lead to unnecessary psychological stress in community members that can contribute to real (as opposed to predicted) adverse human health effects (USEPA 2003).

Compounding conservative values for multiple variables (including a high fish consumption rate, long duration of residence, and upper percentile drinking water rate) to estimate risks with a low target excess lifetime cancer risk will have an unintended consequence. It will result in HHWQC that are far more protective of the vast majority of the population than reflected by the target excess lifetime cancer risk. That additional degree of protection must be weighed against the risks

and environmental impacts, as well as increased public utility treatment costs borne by ratepayers and financial implications on private industry, that would result from the additional treatment needed to meet such criteria.⁶

Comment No. 2: The proposed rule conflicts with EPA’s long-standing policy on acceptable risk levels.

In rejecting the State of Washington’s risk management decisions EPA misstates 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} .⁷ The 2000 Human Health Methodology is clear that EPA deems both 10^{-6} and 10^{-5} risk levels as acceptable,⁸ so long as the selection provides at least a 10^{-4} risk 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.”⁹
- “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.”¹⁰

EPA guidance addresses the need to consider 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.¹¹ That does not mean, however, that a 10^{-6} risk level becomes a maximum risk level 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:

⁶ ARCADIS, Derivation of Alternative Human Health Risk-Based Ambient Water Quality Criteria Using Probabilistic Methods for the State of Washington (May 2022), Attachment A at 6-7.

⁷ NTR, 57 Fed. Reg. 60848-608923 at 60855 (00779).

⁸ 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 NTR at 60864 (00788). In general, the NTR established AWQC for states based on a 10^{-6} risk level. *Id.* at 60860 (00784). A state could ask EPA to remove the state from the rule, and adopt human health criteria 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.*

⁹ NTR at 60855 (00779); see also 65 FR 31682, 31699 (May 18, 2000)(00861-00898).

¹⁰ EPA, Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health (“EPA, 2000 Human Health Methodology”), EPA-822-B-00-004 at 1-12 (October 2000)(00074-0258 at 00104); see also NTR at 60848, 60863 (describing 10^{-5} level as “adequately protective”)(00768, 00787).

¹¹ EPA, 2000 Human Health Methodology at 1-12, 4-25 (00104, 00184).

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.¹²

EPA's justification for disregarding the 2000 Human Health Methodology is that it "did not consider how CWA decisions should account for applicable reserved fishing rights." This is patently not true. 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.¹³ As seen in the above quoted passage from the guidance, consumption patterns among subsistence populations and within a given tribal jurisdiction were considered by EPA when developing the 2000 Human Health Methodology.

Moreover, EPA has updated and amended this guidance numerous times since its publication in 2002 as documented on the EPA web site.¹⁴ EPA actively considered tribal fishing rights in parallel CWA proceedings in 2001 and 2002 that were nearly contemporaneous to the 2000 guidance and predate each of its updates.¹⁵

EPA should acknowledge that the PCB risk factor adopted by the state is consistent with EPA guidance. Protecting a high tribal fish consumption rate of 175 g/day is well above the 90th percentile for tribal consumption, and results in a risk of 1 in 44,000, which is more protective than the applicable risk level of 1 in 10,000. Translated to an equivalent risk level at 1 in 100,000, or 1×10^{-5} , the existing state standard is protective to a fish consumption rate of 76 g/day. Based on the only scientifically valid fish consumption rate for the general population in Washington, this is well above the 95th percentile consumption rate Attachment A, at 56 g/day. Attachment A, Table 8a. EPA is simply incorrect in stating that the state risk management decision for Washington is not consistent with EPA policy.

EPA's rationale for the proposed rule—that "EPA often uses 10^{-6} as a *de minimis* risk level"—misstates EPA's long-standing policy on *de minimis* risk (note that, even if the statement were correct, it does not provide a legal basis to impose water quality standards on the State of Washington). 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

¹² *Id.* at 2-6 (00112).

¹³ 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 at 00341).

¹⁴ <http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/index.cfm>.

¹⁵ EPA, Meeting Summary of the Executive Council of the National Environmental Justice Advisory Council December 3, 4, and 6, 2001 (06107-06157); *see also* EPA, Fish Consumption and Environmental Justice, A Report from the National Environmental Justice Advisory Council Meeting of December 3-6, 2001 (November 2002 revised)(00268-00452).

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 recognize the current Washington standards as legally compliant, EPA has once again cobbled together 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 does not acknowledge the inconsistency with 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 position, EPA has cited one scientific study that appeared in the 2015 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, 2002¹⁶,” 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 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).¹⁷

The “EPA 1991” reference in the two articles relied on by EPA is the draft NTR.¹⁸ 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.¹⁹ 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

¹⁶ 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)(06355-06362).

¹⁷ *Id.* at 210 (06356).

¹⁸ 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)(06471-06529).

¹⁹ *Id.* at 58434 (06485).

fishermen” who are more exposed than the general population.²⁰ 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.”²¹

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.²²

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 subsistence fishers) does not exceed the 10^{-4} level.”²³ Remarkably, EPA’s only reference in the proposed rule to this long held policy and practice of addressing the unique health risks to high consuming subpopulations is found in a footnote. 87 Fed. Reg. at 19048 n. 9. Rather than acknowledging that its proposed rule is not justified based on the 2000 Guidance, EPA simply states “EPA notes that states and authorized tribes can also choose a more stringent risk level.” *Id.* at 19048 (§III.B.a).

The current rulemaking disregards the 2000 guidance. In the Federal Register statement for the draft Washington water quality rule in 2015 similarly disregarded that the federal government has consistently deemed a 10^{-4} risk level to result in a *de minimis* risk when applied to more exposed subpopulations when deriving human health criteria under the CWA. EPA again fails to acknowledge that across EPA and FDA programs exposures at the level of risk

²⁰ *Id.* at 58435 (06486).

²¹ *Id.*

²² EPA, 2000 Human Health Methodology at 2-7 (00113).

²³ *Id.* at 1-12 (00104).

between 10^{-6} and 10^{-4} are deemed acceptable because they represent an insignificant and essentially zero increased risk of cancer.²⁴ EPA continues in the current rulemaking to misinterpret the scientific and public health consensus regarding the application of risk factors in setting human health standards.

“*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.”²⁵ EPA disregards 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.”²⁶ 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} .²⁷ 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.²⁸ A survey of these decisions concluded that “for small-population effects, regulatory action was never taken for individual risk levels below 10^{-4} .”²⁹

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.³⁰ 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.³¹ 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.³² 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

²⁴ See Attachment A at 12.

²⁵ BLACK’S LAW Dictionary 524 (2009).

²⁶ J. Louch, V. Tatum, and P. Wiegand (NACASI, Inc.), E. Ebert (Integral Corp.), K. Conner and P. Anderson (ARCADIS-US), A Review of Methods for Deriving Human Health-Based Water Quality Criteria with Consideration of Protectiveness (August 2012), 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).

²⁷ See Attachment B at 18.

²⁸ Travis et al., Cancer Risk Management, 21 ENVIRON. SCI. TECHNOLOGY 415, Table 1 (1987)(05083-05088).

²⁹ *Id.* at 418 (05086).

³⁰ Ecology, Washington State Water Quality Standards: Human health criteria and implementation tools – Overview of key decisions in rule amendment (“Ecology, Overview”)(Pub. No. 14-10-058)(January 2015) at 18 (00001-00073 at 00024).

³¹ Calabrese, Edward J. “Origin of the Linearity No Threshold (LNT) Dose-Response Concept.” ARCHIVES OF TOXICOLOGY at 7-8 (2013)(01097-01109 at 01103-01104).

³² Graham, John D. “The Legacy of One in a Million” RISK IN PERSPECTIVE (1993)(01110-01111).

reflect an essential zero risk of cancer at exposures considered in the resulting criteria.³³ 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} .³⁴

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.³⁵ To achieve this goal FDA made an early proposal based on the one in one-hundred-million risk level.³⁶ 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.”³⁷

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.”³⁸ 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.³⁹

EPA engaged in a similar public discussion as the FDA in the 1970s and 1980s.⁴⁰ EPA recognized that absolute criteria for carcinogens could not be established given uncertainties

³³ Hutt, Peter B. “A Brief History of Risk Assessment,” FDA ORAL HISTORY (November 2000)(01112-01132).

³⁴ FDA, Compounds used in Food-Producing Animals, 38 Fed. Reg. 19226-19230 at 19226 (July 19, 1973)(01133-01137 at 01133).

³⁵ *Id.*

³⁶ *Id.* at 19227 (01134).

³⁷ *Id.* at 19227 (01134). *See also* 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 cannot 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)(01138-01280).

³⁸ Hutt, “A Brief History of Risk Assessment,” FDA ORAL HISTORY, at 17 (November 2000)(01112-01132 at 01130).

³⁹ *Id.*

⁴⁰ 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

including variances of sensitivities and exposure levels.⁴¹ Instead, EPA presented a range of concentrations associated with risk levels of 10^{-5} , 10^{-6} , and 10^{-7} .⁴² EPA's objective in deriving these water quality criteria was to estimate concentrations "which do not represent a significant risk to the public."⁴³

The EPA risk policy discussed above 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). Plaintiffs contended that EPA cannot allow a lower, one in ten thousand, risk level for the protection of populations near a Superfund site. 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 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

(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)(01281-01742).

⁴¹ EPA, Notice of Water Quality Criteria Documents, 45 Fed. Reg. 79318, 79347 (Nov. 28, 1980).

⁴² *Id.* at 79348.

⁴³ *Id.* at 79348.

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.

State of Ohio v. EPA, 997 F.2d at 1533.

EPA’s policy on acceptable risk is based on an extended scientific evaluation and has withstood legal challenges.⁴⁴ 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} .⁴⁵ 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.”⁴⁶

⁴⁴ *See* Attachment A at 13-27.

⁴⁵ NTR at 60855 (00779); *see also* EPA, 2000 Human Health Methodology at 1-12 (00104).

⁴⁶ EPA, 2000 Human Health Methodology at 2-6 (00112); *see also* Attachment A at 13-14.

A long line of EPA decisions have affirmed the existing risk policy in human health criteria approvals for states on the Great Lakes⁴⁷, the California Toxic Rule, 40 C.F.R. § 131.38, and the state of Oregon human health criteria, and, recently, the approval of the Idaho human health criteria using a median tribal FCR and a 10^{-5} risk factor.⁴⁸ The 2011 Technical Support Document for the Oregon criteria unequivocally states:

EPA has identified a risk level range of 1×10^{-6} (1:1,000,000) to 1×10^{-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.⁴⁹

EPA elaborated on this policy with respect to more highly exposed people, saying:

EPA understands that highly exposed populations may be widely distributed geographically throughout a given State or Tribal area. EPA recommends that priority be given to identifying and adequately protecting the most highly exposed population. Thus, if the State or Tribe determines that a highly exposed population is at greater risk and would not be adequately protected by criteria based on the general population, and by the national ... criteria in particular, EPA recommends that the State or Tribe adopt more stringent criteria using alternative exposure assumptions....

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.

...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.

⁴⁷ EPA, Final Water Quality Guidelines for the Great Lakes System, 60 Fed. Reg. 15366 (March 23, 1995)(01775-01907).

⁴⁸ EPA, Technical Support Document: EPA Approval of the State of Idaho's New/Revised Human Health Water Quality Criteria for Toxics and other Water Quality Standards Provisions Submitted on December 13, 2016 (April 4, 2019)(07962-08008).

⁴⁹ 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)(01908-02010 at 01934).

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).

Attachment A, 17-18.

What should be clear is that if EPA relied on the only scientifically valid consumption rate for the general population, 43 g/day, and criteria based on a risk factor of 10^{-5} , the resulting standards would be protective of all consumers. This is illustrated in the Arcadis analysis in tables 8a and 8b.⁵⁰ Across all populations, the resulting criteria would be consistent with EPA guidance. EPA has no legal basis to revise the risk factor for the Washington water quality standards, while continuing to use a 175 g/day FCR. Washington used the FCR in the context of its broader risk management approach—all components are inter-related. EPA had no legal basis to override the state. If the Washington HHWQC are going to be revised, only the state can do it.

Comment No. 3: EPA violates its own methodology by relying on the 175 g/day FCR for its proposed rule.

EPA's use of the 175 g/day value is not consistent with its own methodology for developing FCRs used for deriving human health criteria. Specifically, EPA is relying on fish consumption survey data reported in 1994,⁵¹ but collected years earlier. EPA has not applied statistical corrections to those data that are designed to mitigate problems with the analysis of short-term recall surveys. EPA now considers the use of the National Cancer Institute (NCI) method, or at least an approximation of the NCI method, to be the basis for science based FCRs relative to the approach used by EPA prior to 2015⁵².

EPA has no legal basis to impose its proposed HHWQC on the State of Washington. If it did have a legal basis, EPA would have an obligation to revisit the derivation of the FCR in order to have a defensible rule. In particular, EPA would have to apply the statistical methods described by NCI for developing appropriate distributional parameters derived from short-term food consumption recall survey data. Human health criteria are developed to protect people from lifetime exposure to chemicals in surface water. Over the last decade or two, scientists have come to realize that FCRs observed during short-term dietary surveys are not representative of a person's lifetime FCR. Variations over time in the consumption habits of individuals can be substantial, particularly for episodically consumed foods such as fish. Because human health criteria are derived based on a lifetime of exposure, developing long-term average FCRs from short-term dietary survey data is critical. Researchers at NCI developed a statistical methodology to estimate FCRs from repeated short-term dietary surveys. The NCI method provides distinct

⁵⁰ Attachment A at Tables 8a and 8b.

⁵¹ EPA, Restoring Protective Human Health Criteria in Washington, Proposed Rule, 87 Fed. Reg. 19046-19063 at 19055, n. 81 (April 1, 2022).

⁵² Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations, (NHANES 2003-2010), Final Report, April 2014, EPA-820-R-14-002, at Section 4, 21-46 (08009-08118 at 08038-08063).

advantages over previously proposed methods by accounting for days without consumption, distinguishing within-person variability from between-person variation, allowing for the correlation between the probability of consuming a food and the consumption per day amount, and relating covariate information to usual intake⁵³. EPA, in its 2015 update of national recommended human health criteria and the Idaho Department of Environmental Quality (IDEQ) have used the NCI method to develop estimates of fish consumption^{2,54}; USEPA, IDEQ, and Florida Department of Environmental Protection (FDEP) have employed FCRs (i.e., consumption rates assumed to represent long-term consumption behavior rather than consumption rates from short-term surveys that may result in biased estimates of consumption) to derive HHC^{55,56,57}.

Despite EPA's acknowledgment that the use of the NCI method is appropriate when analyzing fish consumption survey data for purposes of establishing an FCR, discussion of the NCI method and its use is completely absent in the proposal. Because the NCI methodology is designed to correct what would otherwise be high-biased estimates of upper percentiles, the corrected FCR should be lower, perhaps much lower, than the currently used value of 175 g/day. Reliance on the 175 g/day FCR outside the broader context for the state risk management decisions is contrary to the best available science and EPA's own guidance.

It is clear that 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. EPA, if it is going to disregard the state risk management decisions, must use a fish consumption rate of 43 g/day as the only available and verified consumption rate of the general population at the 90th percentile of consumers surveyed under the NCI methodology for a consumption study. EPA has no other data on general population consumption rates in Washington.⁵⁸

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 2012.⁵⁹ 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

⁵³ Tooze JA, et al. 2006. A new statistical method for estimating the usual intake of episodically consumed foods with application to their distribution. *J Am Diet Assoc* 106:1575–1587 (08119-08131).

⁵⁴ Attachment A at Tables 8a and 8b.

⁵⁵ USEPA. June 2015a. *Human Health Ambient Water Quality Criteria: 2015 Update*. EPA 820-F-15-001. Office of Water (08132-08134).

⁵⁶ EPA, Technical Support Document: EPA Approval of the State of Idaho's New/Revised Human Health Water Quality Criteria for Toxics and other Water Quality Standards Provisions Submitted on December 13, 2016 (April 4, 2019)(07962-08008).

⁵⁷ Florida Department of Environmental Protection (FDEP). June 2016. *Technical Support Document: Derivation of Human Health-Based Criteria and Risk Impact Statement*. Division of Environmental Assessment and Restoration (08135-08392).

⁵⁸ Ecology, Fish Consumption Rates: Technical Support Document, Version 2.0 at 95 (05514).

⁵⁹ Ecology, Fish Consumption Rates & Risk Levels for Carcinogens Used in Human Health Criteria Calculations, (November 5, 2013)(00259-00267).

intake rate. EPA guidance recommends a default fish intake rate of 22 grams a day to protect the general population.⁶⁰ 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.”⁶¹

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 22 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.⁶² 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 representing what they figured approximated the median consumption rate for subsistence fishers.”⁶³ The fish consumption rate of 175 g/day by Ecology is over three 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).⁶⁴

The following table from the Technical Support Document 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

⁶⁰ Ecology, Overview at 15 (00021).

⁶¹ EPA, 2000 Human Health Methodology at 4-27 (00186).

⁶² 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).

⁶³ D. Essig, Email to S. Kirsch (April 5, 2013)(00453-00454).

⁶⁴ Oregon DEQ, Human Health Criteria Issue Paper: Toxics Rulemaking at 9 (May 24, 2011)(00476-0559 at 00484).

“outliers.”⁶⁵ 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.”⁶⁶

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

Population	Source of Fish	Number of Adults Surveyed	Mean	Percentiles		
				50 th	90 th	95 th
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.

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.⁶⁷ This analysis calculated the median Tribal consumption rate to be 127.2 g/day for all fish.⁶⁸

EPA should also acknowledge that the 175 g/day FCR was originally derived from the Columbia River Inter-Tribal Fish Commission (CRITFC) fish consumption rate survey (CRITFC 1994) using survey methods that have been shown to not represent the true, long-term fish consumption rate as now defined by EPA and referred to as the usual fish consumption rate (UFCR) by EPA. The State of Washington has reviewed and summarized a range of fish consumption rates developed using both the older survey methods and the newer National Cancer Institute (NCI) methodology used by USEPA and others to derive UFCRs representative of long-term fish consumption. The NCI method is currently believed to be the state-of-the-art approach for conducting dietary intake surveys, including consumption of fish. Idaho considered these survey results in developing its new and revised state HHWQC. These estimates show that the fish consumption rate of 175 g/day used in the proposed HHWQC is based on an outdated

⁶⁵ Oregon DEQ, Human Health Focus Group Report Oregon Fish and Shellfish Consumption Rate Project at 10-12 (June 2008)(00560-00631 at 00575-00577).

⁶⁶ *Id.* at 12 (00577).

⁶⁷ Polissar and Hippe, Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes (October 31, 2013)(00632-00657).

⁶⁸ *Id.*, Table A at 2 (00633).

survey methodology, overstates the long-term fish consumption rate of the general population and tribal populations (as shown below), and is no longer appropriate to use to derive HHWQC.⁶⁹

Method	Population	50%	Mean	75%	90%	95%	99%
Food Frequency Questionnaire	Nez Perce ¹	70.5	123	---	270	437	796
NCI	Nez Perce ¹	49.5	75.0	---	173	232	---
Food Frequency Questionnaire	Shoshone Bannock ¹	74.6	158	---	392	603	1058
NCI	Shoshone Bannock ¹	14.9	34.9	---	94.5	141	---
Standard	General Population ²	37.9	56	78.8	128	168	---
NCI	General Population ²	12.7	18.8	24.8	43.3	56.6	==

¹ Polissar et al. (2016).

² National Survey: NHANES 2003–2006, Adult Respondents, values as reported in Ecology (2013)

EPA has also failed to assess the ratio of its FCR that represents fish, namely salmon, that are not impacted by water quality in state waters. Ecology addressed this in its risk management decision to use a RSC of 1.0. If EPA is going to disregard that risk management decision, the FCR used in the federal standards must reflect the consumption of fish that are likely to be impacted by water quality conditions within the state of Washington. The CWA and EPA regulations require HHWQC 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 22 grams a day in EPA guidance thus reflects freshwater/estuarine fish and shellfish only.⁷⁰ The range of consumption rates in the 2000 EPA guidance similarly do not include marine fish.⁷¹

Salmon, as a marine species, should accordingly be excluded from the consumption rate used to derive criteria for Washington. 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.⁷² Salmon, which accumulate contaminants in marine waters beyond the jurisdiction of the state, will not be materially impacted by these HHWQC.⁷³

⁶⁹ Attachment A at 5.

⁷⁰ EPA, 2000 Human Health Methodology at 4-25 (EPA default fish consumption rates represent the ingestion of “freshwater and estuarine fish”)(00184).

⁷¹ *Id.*; 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”)(00726-00727 at 00726).

⁷² 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)(00728-00740 at 00738), see also NCASI, Comments on Proposed Human Health Criteria and Implementation Tools Rule Proposal, Attachment A at 2 (March 4, 2015)(00741-00767 at 00744).

⁷³ *Id.*

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.⁷⁴

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.⁷⁵ 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.⁷⁶

Comment No. 4: 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 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 10⁻⁶.

Under the EPA proposed rule, 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.⁷⁷ 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, for example, 22 g/day as the consumption rate for the general population in Washington, at a risk level of 10⁻⁶, the resulting

⁷⁴ Hope, Bruce K., 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)(05073-05082 at 05081).

⁷⁵ Polissar and Hippe, Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes at 2 (00633).

⁷⁶ *Id.*

⁷⁷ Ecology, Fish Consumption Rates: Technical Support Document Version 2.0 at 40-44 (05459-05463).

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.⁷⁸ 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 (May 2022), Attachment A, explains in detail why tribal consumers would have essentially 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 absence of any real risk. *Id.* at 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 unintended consequences of such choices. *Id.* at 5. First and foremost, the rule as proposed is unachievable even with cost-prohibitive control technology, which could lead to facility closures and job losses in Washington communities. Additionally, as ARCADIS explains, available pollution control technologies to attempt compliance with the rule, even while unable to provide full compliance, carry “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 (May 24, 2022)—Attachment C. HDR evaluated the cost of compliance with the EPA proposed human health water quality criteria for arsenic, benzo(a)pyrene, mercury, and PCBs. *Id.* at 1. The HDR report looked at advanced treatment systems including reverse osmosis and membrane filtration and estimated the range of unit costs for improving a 0.5 Million Gallon a Day (mgd) facility at \$31 to \$168 per gallon per day. *Id.* at 3. The range of unit costs for improving a 25 mgd facility to advanced treatment is \$18 to \$74 per gallon per day of treatment capacity. *Id.* at 3.

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 2022) would be in the range of \$5.5

⁷⁸ *Id.* at 18 (05437).

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 61.

HDR has pointed out several impacts from advance treatment needed to meet the EPA proposed criteria including:

- Land area for additional system components (which for constrained facility sites may necessitate land acquisition and encroachment into neighboring properties with associated issues and challenges, etc.).
- Increased energy use and atmospheric emissions of greenhouse gases and criteria air contaminants associated with power generation to meet new pumping requirements across the membrane filter systems (UF and RO) and GAC.
- Increased chemical demand associated with membrane filters (UF and RO).
- Increased chemical demand associated with AOP
- Energy and atmospheric emissions associated with granulated charcoal regeneration.
- RO brine reject disposal. The brine recovery systems are energy intensive and increase atmospheric emissions as a consequence of the electrical power generation required for removing water content from brine reject.
- Increase in sludge generation from transitioning from the baseline to the advanced treatment alternatives. There will be additional sludge captured with the chemical addition to the primaries and membrane filters (UF and RO). Additionally, the GAC units will capture more solids.

Id.

HDR projects the advanced treatment options energy demand ranges from 2.0 to 2.8 times greater than the baseline evaluated in its study. This large increase in energy demand is attributed to the energy required to pass water through the membrane barriers and the granular activated carbon. This increase aligns with findings from both research, including EPA research that evaluated various tiers of nutrient levels with the results also suggesting increases 2+ times with the most stringent requiring advanced treatment. HDR forecasts additional energy required to handle the constituents removed as either regenerating/disposing of the GAC or handling the RO brine reject water. *Id.*, at 62, Table 4-5.

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 EPA 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} .

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.

With the exception of the state of Washington, EPA has never revoked or disavowed 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 CWA.⁷⁹ 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.⁸⁰ 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.”⁸¹

There is no basis for the proposed rule’s departure from EPA’s consistent approach 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. 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. 5: 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 Ecology through publication of EPA’s proposed rules in 2015 and 2022, EPA has aggressively pursued its *policy preferences* on two key factors—fish consumption rates and acceptable risk levels—and failed to engage in any discussion on the merits or basis for its preferred policies. The background information provided

⁷⁹ EPA, Final Updated Ambient Water Quality Criteria for the Protection of Public Health, 80 Fed. Reg. 36986 (June 29, 2015)(04807-04810).

⁸⁰ EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update, EPA-820-F-14-003 at 2 (May 2014)(01772-01774 at 01773).

⁸¹ EPA, Final Updated Ambient Water Quality Criteria, 90 Fed. Reg. at 36987 (04808).

in the proposed rule Federal Register notice again pursues these EPA *policy preferences* and, in several cases, misstates the cited references and basis for the proposed rule.

EPA made clear that it had a viewpoint on fish consumption and acceptable risk levels that was not changeable in a meeting with the regulated community in Washington 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 g/day FCR and risk factor 10^{-6} . Mr. McLerran explained that this was so because “everyone should be protected to the same level.”⁸² 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 decade. 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 2013.⁸³ 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.⁸⁴ 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 Szlag, Lon Kissinger and Angela Chung.⁸⁵ The following questions and answers were recorded regarding EPA guidance on risk policy:

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?

⁸² D. McLerran, Pers. Communication to NWPPA Members (April 9, 2013).

⁸³ C. Niemi, Email to L. Kissinger (January 2, 2013)(03933-03934).

⁸⁴ See Attendance Lists for Meetings on June 24, 2013, November 6, 2013, and July 2014 (03935-03943).

⁸⁵ 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.”)(00455-00458).

Angela Chung: EPA can't answer that now.⁸⁶

Ecology raised this issue with EPA staff again in emails and meetings in October and November 2013.⁸⁷ 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, 2013.⁸⁸ 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."⁸⁹ 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?**⁹⁰

Mr. Opalski responded to this email and confirmed that there is no such statement (much less a rule or guidance). 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."⁹¹

⁸⁶ *Id.*

⁸⁷ M. Gildersleeve, Email to A. Chung and M. Szlag (October 1, 2013)(03944).

⁸⁸ Ecology, Preliminary Draft – HHC Tools Summary, Water Quality Standards Rule Making, Human Health Criteria, Summary, (November 6, 2013)(03945).

⁸⁹ K. Susewind, Email to D. Opalski (March 11, 2014)(00459-00461).

⁹⁰ *Id.* (emphasis added).

⁹¹ D. Opalski, Email to K. Susewind (March 11, 2014)(03946).

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 the late 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.”⁹² Three weeks later Mr. McLerran responded with a letter that was not responsive to this question.⁹³ 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.”⁹⁴ 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?⁹⁵

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.⁹⁶ There is no merit to this contention where the state adopted criteria that are 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 insistence that the State of Washington accede to EPA’s 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.”⁹⁷ 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 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 in 2015 and now 2022.⁹⁸

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

⁹² D. Ericksen, Letter to D. McLerran (April 3, 2014)(03947-03948).

⁹³ D. McLerran, Letter to D. Ericksen (April 24, 2014)(03949).

⁹⁴ D. Ericksen, Letter to D. McLerran (May 28, 2014)(03950-03951).

⁹⁵ *Id.*

⁹⁶ D. McLerran Letter to D. Ericksen (July 1, 2014)(03952-03953).

⁹⁷ Attendance Lists for Meetings on June 24, 2013, November 6, 2013, and July 2014 (03935-03943); C. Niemi, Handwritten Notes (00455-00458); and A. Chung, Pers. Communication, NWPPA Annual Meeting (June 6, 2013).

⁹⁸ D. Opalski, Letter to C. Niemi re EPA’s Comments on Proposed Revisions to Washington’s Human Health Criteria and New and Revised Implementation Provisions (March 23, 2015)(07230-07249).

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.⁹⁹ 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."¹⁰⁰ At most some tribal representatives have requested a 10⁻⁶ risk level but there is no evidence in the documentation provided by EPA of any scientific research or data to support what will be a significant change in the risk policy applied in Washington. Nor is there a sufficient 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?¹⁰¹

This becomes one of the central questions in the EPA rule. What are the legal and scientific connections between a tribal treaty 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 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.¹⁰² It is not surprising that Ecology's subsequent July 2015 draft responses to

⁹⁹ *Id.*

¹⁰⁰ M. Szelag, Email to J. Edgell (July 14, 2015)(06440-06442); K. Brown, Email to B. Duncan (June 5, 2015)(06466-06467); M. Szelag, Email to P. Ford (March 17, 2015)(06464-6465), EPA FOIA Response, EPA-R10-2015-008998 (August 2015).

¹⁰¹ *Id.*, M. Szelag, Email (06442).

¹⁰² *Id.*, M. Szelag, Email (06440).

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.¹⁰³

EPA has never disavowed this effort to coerce the State of Washington into adopting standards based on a 175 g/day FCR and 10^{-6} risk factor for carcinogens in either the EPA response to comments for the 2016 EPA rule or in the federal register basis for the current proposed rule. Washington ultimately gave in to EPA on this demand with the exception of the criterion for PCBs. As to PCBs, 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. EPA has placed on its regulatory agenda a revision to 40 CFR Part 131 to explicitly protect tribal reserved rights.¹⁰⁴ EPA appears to acknowledge that it must go through rulemaking to effect any change in the current regulations and guidance for the development of human health criteria based on its interpretation of tribal treaty rights. If so, it must also do that with respect to human health standards it is imposing on the state of Washington.

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 unsupported statement that "everyone deserves to be protected to the same level" and that " 10^{-6} is a baseline for environmental justice."¹⁰⁵ Neither has support in the CWA or EPA guidance or policies. 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.¹⁰⁶ The guidance document does not reference and therefore implicitly endorses EPA's long-standing policy on the acceptable range of risk levels. The following discussion from the guidance document exemplifies how EPA will determine whether there is a disproportionate impact from EPA action:

¹⁰³ Ecology, Draft Responses to Comments on Proposed State Rule (July 2015)(04758).

¹⁰⁴ [EPA, Revising the Federal Water Quality Standards to Protect Tribal Reserved Rights, accessed May 5, 2022.](#)

¹⁰⁵ D. McLerran, Pers. Communication to NWPPA Members (April 9, 2013); *see also* K. Susewind, Email (00459-00461).

¹⁰⁶ EPA, Guidance on Considering Environmental Justice During the Development of Regulatory Actions (May 2015)(available at <http://www3.epa.gov/environmentaljustice/resources/policy>)(05991-06046).

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.¹⁰⁷

Thus, the EPA 2015 environmental justice guidance focuses on the mean or median consumption or exposure rate of a more highly exposed subpopulation, not the maximum consumption or exposure rate of a subpopulation.

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.¹⁰⁸

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.

¹⁰⁷ *Id.* at 6-7 (emphasis added)(06002-06003).

¹⁰⁸ EPA, Final Water Quality Guidelines for the Great Lakes System, 60 Fed. Reg. 15366-15425 at 15 (emphasis added)(01775-01907 at 01789).

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.¹⁰⁹

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.¹¹⁰ Treaty rights are also discussed in a 2002 EPA report on fish consumption and environmental justice.¹¹¹ The 2002 document had been part of the EPA “EJ” tool kit documents including the “Plan EJ 2014.”¹¹²

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. The current Administration is keenly focused on environmental justice. Nonetheless, the 2015 guidance remains in effect and is currently being implemented in the current EPA environmental justice efforts. 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 of tribal treaty responsibilities.

¹⁰⁹ EPA, California Toxics Rule Response to Comments Report, CTR-002-005a (Dec. 1999) (emphasis added)(02311-03812).

¹¹⁰ EPA, Meeting Summary of the Executive Council of the National Environmental Justice Advisory Council December 3, 4, and 6, 2001 (06107-6157).

¹¹¹ 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).

¹¹² EPA, Plan EJ 2014 Legal Tools (December 2011)(03813-03932).

Comment No. 7: The EPA improperly relies on alleged suppressed fish consumption rates to justify rule.

EPA improperly bases its proposed criteria on the concept of suppressed fish consumption rates for northwest tribal members. 87 Fed Reg.at 19049 (April 1, 2022) It is not possible to comment meaningfully 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. 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 III.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.” 87 Fed. Reg. at 19049. EPA has conceded that this posting was done improperly and previously assured state regulators that the document would be withdrawn.¹¹³ EPA has also conceded that it is not sure how suppression should be factored into criteria.¹¹⁴

EPA’s rationale and basis is unclear for its recommendation to “generally” consider suppressed consumption rates when there is no guidance on how EPA and the states are supposed to factor this into developing water quality criteria.¹¹⁵ EPA has long advised states to use data to develop criteria (with a preference for local or regional data over national data).¹¹⁶ 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.¹¹⁷

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

¹¹³ S. Braley, Email to M. McCoy, C. Niemi and D. Essig (January 9, 2014)(06692); S. Braley, Email to D. Essig and C. Niemi (July 28, 2014)(06693).

¹¹⁴ D. Essig, Email to B. Burnell (September 30, 2014)(06691).

¹¹⁵ EPA, Comments on Washington Department of Ecology's Proposed Human Health Criteria and Implementation Tools Rule (March 23, 2015)(07233-07249).

¹¹⁶ EPA, 2000 Human Health Methodology at 2-2 (00108).

¹¹⁷ Idaho Department of Environmental Quality, Considerations in Deciding Which Fish to Include in Idaho’s Fish Consumption Rate: Policy Summary at 7 (August 2015)(04792-04802 at 04800).

EPA policy preferences 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.¹¹⁸ This does not suggest a lack of available fish.

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.¹¹⁹ By 2012, the Columbia River Inter-Tribal Fish Commission was claiming that the 95th percentile of tribal members were consuming 175 g/day.¹²⁰ 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.

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 2009.¹²¹ 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:¹²²

¹¹⁸ EPA, Comments on Washington Department of Ecology's Proposed Human Health Criteria and Implementation Tools Rule (07233-07249); *see also* Polissar and Hippe, Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes (00632-00657).

¹¹⁹ *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.”).

¹²⁰ 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)(01908-02010).

¹²¹ U.S. Census Bureau, Statistical Abstract of the United States: 2012, Sec. 3, Table 217: Per Capita Consumption of Major Food Commodities (August 2011)(06986).

¹²² Idaho Department of Environmental Quality, Considerations in Deciding Which Fish to Include in Idaho’s Fish Consumption Rate: Policy Summary at 7 (August 2015)(04792-04802 at 04800).

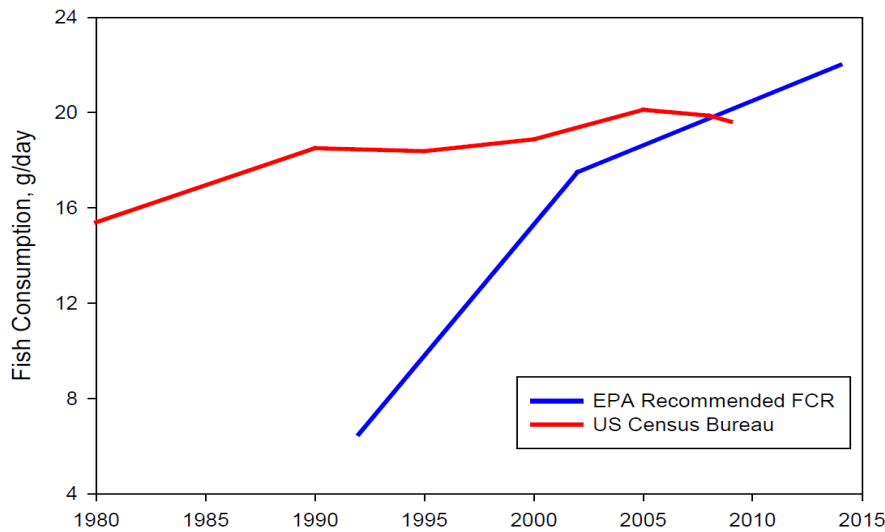


Figure 4. Per capita consumption of fish in the United States and EPA-recommended fish consumption rate (FCR), 1980–2014.

In short, there is no valid basis for EPA to impose its policy preferences on the State of Washington based on speculation unsupported by any evidence.

Comment No. 8: Tribal treaty rights do not provide a legal basis for EPA’s proposed rule.

As in 2016, EPA asserts in the 2022 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. The 2016 Final Rule relied heavily on what EPA characterized as a “treaty-reserved subsistence fishing right” that has no basis in law (contrary to EPA’s assertions in the following citation). *See, e.g.*, 81 Fed. Reg. at 85423 (§ III.B.b) (“[r]elevant case law, including Supreme Court precedents, unequivocally confirms that the treaty-reserved right to take fish includes the right to take fish for subsistence purposes”). The 2022 Proposed Rule similarly references a tribal “legal right to harvest and consume fish and shellfish at subsistence levels.” 87 Fed. Reg. at 19055 (§ V.B.c). *See also* 87 Fed. Reg. at 19054 n. 64 (“As described in EPA’s 2016 final Washington WQS rule, 81 FR 85422-26, numerous tribes in Washington have treaty-reserved rights to fish for their subsistence on waters throughout the State.”).¹²³ In fact, the federal courts have never interpreted the treaty reserved fishing right as a right to take and consume fish at a subsistence

¹²³ The 2016 Final Rule used the term “subsistence” nearly sixty times in describing the tribal treaty right to take fish and contained a lengthy discussion of case law that purported to support EPA’s invented “treaty-reserved subsistence fishing right.” *See* EPA, Revision of Certain Federal Water Quality Criteria Applicable to Washington, 81 Fed. Reg. (November 28, 2016) 85417-85437 at 85421-27. Although EPA’s 2020 Proposed Rule omits much of this language but references those pages of the 2016 Final Rule as support for its interpretation of the tribal treaty right to take fish. *See* 87 Fed. Reg. at 19050 n. 34, 19054 n. 64, 19055 n. 78.

rate. The treaties only reserve to the Indian tribes the right to a fair share of the available fish. There is no legal 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.

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

Reserved treaty rights are not 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, so 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.").

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. Wash. 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). The Supreme Court also held in the early 1900s that the treaties guaranteed to tribes' access to all of 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). Interpretation of the treaty right to take fish 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*.

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 (emphasis supplied). 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 underpinning of much of EPA's position with regard to cancer risk level, target population, and FCR is its assertion that the treaties reserve to tribes a right to take the amount of fish reflecting an unsuppressed, subsistence level of consumption. But in *Fishing Vessel*, the Supreme Court specifically considered and rejected the tribes' argument that the Stevens treaties "had reserved a pre-existing right to as many fish as their commercial and subsistence needs dictated." *Fishing Vessel*, 443 U.S. at 670, 679, 684-687. Other courts have consistently held that the treaty right to take fish does not include a right to take an amount of fish at the subsistence level existing when the treaties were signed. *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 v. Idaho Power Co.*, 847 F. Supp. 791, 808-10 (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”). The Ninth Circuit has also confirmed that the treaty right to take fish does not entitle tribes to a particular minimum allocation of fish. *United States v. Washington*, 759 F.2d 1353, 1358-59 (9th Cir. 1985). There is simply no basis in law for EPA’s assertion that the treaties require that Washington’s human health criteria be based on a subsistence level of fish consumption.¹²⁴

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

EPA appears to continue in the 2022 Proposed Rule to read the treaty right to a share of available fish as containing an implied guarantee of a certain quality of fish habitat. *See* 87 Fed. Reg. at 19054, 19061; 81 Fed. Reg. at 85423 n. 39 (asserting that the treaty right to a share of available fish contains an implied guarantee or “subsidiary right” to a certain quality of fish habitat or environment). 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 affirmative 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 *United States 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.” *United States v. Washington*, 694 F.2d 1374, 1381 (1982). That decision was later vacated on procedural grounds. *United States 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. at 808.

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 to refrain from building or operating culverts that hinder fish passage and thus decrease the number of fish available for tribal harvest. *United States 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. *United States v. Washington*, No. CV 70-9213, 2013 WL 1334391 (2013).

¹²⁴ As the Idaho Department of Environmental Quality noted in its responses to EPA’s comments on Idaho’s proposed human health water quality criteria and in its subsequently submitted criteria, there is also no legal support for EPA’s position that tribal fishing rights mandate that tribes be treated as the general population. Idaho Department of Environmental Quality, Water Quality: Docket No. 58-0102-1201 Proposed Rule Rulemaking and Public Comment Summary, at 21 (07312-07348); Idaho Human Health Criteria Update Justification and Compliance with Clean Water Act (December 2016) at 11 (08393-08429 at 08403). EPA has promulgated state-wide criteria to protect *all* Washington citizens, including tribal members. According to the 2015 census, Washington’s Native American and Alaska Natives populations combined constitute just 1.9% of Washington’s population. *See* <http://www.census.gov/quickfacts/table/PST045216/53.00>. The Indian population in Washington is an obvious subpopulation of the entire state and should be treated as such for purposes of HHQWC.

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.” *United States v. Washington*, 2007 WL 2437166 at *10; *United States v. Washington*, 2013 WL 1334391 at *24 (“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”). The Ninth Circuit Court of Appeals’ affirmance of the district court decision was similarly narrowly based on the lower court’s factual findings that the state had acted affirmatively to build and maintain barrier culverts under its roads, that the consequence of these affirmative actions had been to diminish the supply of fish, and that if the culverts were replaced or modified to allow free passage of fish, several hundred thousand additional mature salmon would be produced every year. *United States v. Washington*, 853 F.3d 946, 966 (9th Cir. 2017), *aff’d by an equally divided court*, ___ U.S. ___, 138 S. Ct. 1832, 201 L.Ed.2d 200 (2018).¹²⁵ See also *United States v. Washington*, 864 F.3d 1017, 1020 (9th Cir. 2017), *denial of rehearing and rehearing en banc* (Ninth Circuit did not hold that the Stevens treaties’ promise of a moderate living “is valid against all human-caused diminutions, or even against all State-caused diminutions;” rather “we hold only that the State violated the Treaties when it acted affirmatively to build roads across salmon bearing streams, with culverts that allowed passage of water but not passage of salmon”).

Most importantly, even if the treaties did contain some implied right to habitat protection, any such right is fully satisfied by the human health criteria adopted by Washington and approved by EPA in 2020. There is no basis for EPA’s position in the 2022 Proposed Rule 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 is required by the CWA or any other law. 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. Finally, Washington’s fish populations are already protected by Washington’s EPA-approved aquatic life criteria. See WAC 173-201A-200, 210, 240.

EPA’s 2019 decision to approve Washington’s adopted human health criteria appropriately rejected the tribal treaty right interpretation put forth by EPA in 2016 and in the 2022 Proposed Rule.

The expansive interpretation of tribal treaty rights put forth in the 2022 Proposed Rule, and in EPA’s 2016 Final Rule, was rejected by EPA just three years ago in the technical support

¹²⁵ Although EPA suggested in its 2016 Final Rule that the Ninth Circuit’s decision in the culverts case supports the concept of an affirmative treaty right to a certain water quality, EPA’s position is directly contrary to that taken by the Department of Justice at oral argument before the 9th Circuit. The DOJ attorney represented to the Court that 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.

Transcript of oral argument in *U.S. v. Washington* at 16 (October 16, 2015)(08430-08450 at 08445).

document issued with its May 2019 decision to approve of the Washington-submitted human health criteria.¹²⁶ EPA noted that the agency’s interpretation of the state’s designated uses to also mean or include subsistence fishing, and identifying tribal populations as the target general population, “*had not been promulgated in any nationally applicable rule or articulated in any national recommended guidance or the 2000 Methodology* [EPA’s interpretation] departed from longstanding EPA policy and the Agency’s recommendations for setting HHC, including the 2000 Methodology.” *Id.* at 24 (emphasis added). EPA explained that the 2000 Methodology spoke directly to the greater consumption of fish by Indian tribes, and that it had been EPA’s longstanding view that a state could consider tribes with treaty fishing rights to be a highly exposed population, rather than a target general population, and that such consideration gave due effect to such fishing rights. *Id.* at 25. EPA further stated that Washington’s election to be more protective of high consumers than necessary by selecting a FCR of 175 g/day and setting a cancer risk level of 10⁻⁵ for PCBs gave due effect to the tribal treaty rights and was consistent with the 2000 Methodology. *Id.* As EPA stated:

While the reserved rights in these tribal treaties may be considered by the State and the EPA when setting and reviewing criteria, they do not expand the EPA’s authority under the CWA. Likewise, these treaties do not limit or prohibit the EPA from taking an otherwise lawful action under the CWA.¹²⁷

The 2022 Proposed Rule contains no reference to the Technical Support Document’s discussion of tribal treaty rights. As noted above, EPA did not issue any new technical support document with the 2022 Proposed Rule. EPA does not refute the agency’s statements in the 2019 Technical Support Document that EPA’s 2016 treaty rights interpretation—now resurrected in the newly proposed rule—has never been promulgated in any other rule, articulated in any guidance, or in the 2000 Methodology.

Comment No. 9: Just as with federal trust responsibilities to the tribes, compliance with the Clean Water Act is sufficient to meet tribal treaty rights.

EPA’s position in the 2022 Proposed Rule is contrary to the position taken in briefing before the federal district court for the Western District of Washington, in which EPA successfully asserted that its compliance with the CWA and its regulations satisfied any federal trust responsibility owed to the Spokane Indian Tribe. *Sierra Club v. McLerran*, 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,

¹²⁶ EPA, Technical Support Document: The EPA’s Reversal of the November 15, 2016, Clean Water Act Section 303(c) Partial Disapproval of Washington’s Human Health Water Quality Criteria Submitted on August 1, 2016 and decision to Approve Washington Criteria (May 10, 2019) at 23-26 (08451-08481 at 08473-08476).

¹²⁷ *Id.* at 25 (08475).

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) (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 814.¹²⁸

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. McLerran*, Case No. 2:11-cv-01759-BJR Docket No. 120 at 23 (March 16, 2015).

Just as in *Sierra Club v. McLerran*, any 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 Tribes v. Reno*, 56 F.3d 1476 (D.C. Cir. 1995)(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); *Ctr. 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. 10: EPA’s use of a tribal treaty rights theory to support extraordinarily stringent and unachievable HHWQC raises serious constitutional problems.

The proposed rule relies in part on EPA’s assertion that the CWA gives it authority to interpret federal treaties with Indian tribes, and then use its interpretations as grounds for

¹²⁸ *Sierra Club v. McLerran*, Case No. 2:11-cv-01759-BJR Docket No. 91 at 42 (January 29, 2014)(04811-04860 at 04852).

concluding that it is necessary for EPA to adopt more-stringent water quality criteria than the CWA would otherwise require. In this case, EPA asserts that its interpretations of treaty rights allow it to bootstrap to extraordinarily stringent HHWQC—so stringent that they are unachievable for the regulated community. The possible ramification is that EPA could interpret federal treaties to require state water quality standards that could severely restrict or effectively prohibit large swaths of economic activity in a state, as EPA has proposed here. The CWA should not, and cannot, properly be interpreted to give EPA such sweeping authority, particularly when there is no clear statutory direction to that effect, as well as no indication of limiting principles from Congress as to how that authority would be applied.

Comment No. 11: EPA has no authority to interpret tribal treaties.

EPA does not have authority to overrule, based on its interpretation of treaty rights, state determinations about what particular uses the state’s water quality standards must protect and to what degree. Those are decisions that the CWA accords to the states in, inter alia, sections 101 and 303 of the CWA. The possible ramification is that EPA could interpret federal treaties to require state water quality standards that would severely restrict or effectively prohibit large swaths of economic activity in a state, as EPA has proposed here. The CWA should not, and cannot, properly be interpreted to give EPA such sweeping authority without a clear statutory direction to that effect, and without clear Congressional direction as to how that authority is to be applied.

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). EPA interpretation of Indian treaties is not entitled, however, to any 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).¹²⁹

¹²⁹ To the extent that EPA may be continuing to rely upon the interpretation of the Stevens treaties 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, that interpretation is similarly not entitled to deference. *Cherokee Nation of Okla. 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”). See 87 Fed. Reg. at 19054 n. 34, 64, 84; 81 Fed. Reg. at 85423 n. 39.

Comment No. 12: EPA’s focus on treaty rights is part of a national effort to compel states to adopt EPA’s preferred human health criteria, without an adequate basis.

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 apparently sought 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.”¹³⁰ Christine Psyk, Associate Director for Region 10, responded that **“EPA would not because that requirement does not appear in EPA regulations or guidance.”**¹³¹

As detailed in Comment No. 5 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 EPA 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.”¹³² Mr. Opalski admitted immediately after the meeting that there is no such statement in EPA guidance to support this proposition.¹³³ 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 apparently was seeking a rationale for its new position on risk policy, but had not found it in environmental 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

¹³⁰ D. Ostermann, Letter to EPA at 2 (January 9, 2013)(02308-02310 at 02309).

¹³¹ *Id.* (emphasis added).

¹³² C. Niemi, Handwritten Notes (“Dennis [EPA Region 10 Administrator] thinks the OR outcome was the right outcome, regionally wants to explore that position.”)(00455-00458).

¹³³ D. Opalski, Email to K. Susewind (March 11, 2014)(03946).

health criteria for Washington.¹³⁴ 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.¹³⁵ 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.¹³⁶

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.¹³⁷ Despite the fact that Region 10 had conceded on March 11, 2014¹³⁸ and June 19, 2014¹³⁹ 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.¹⁴⁰ 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 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

¹³⁴ D. McLerran, Letter to M. Bellon (April 8, 2014)(04738-04739).

¹³⁵ D. Ericksen, Letter to D. McLerran (May 28, 2014)(03950-03951).

¹³⁶ A. Chung, Email (June 19, 2014)(02231-02232). 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).

¹³⁷ D. McLerran, Letter to M. Bellon (December 18, 2014)(04790-04791).

¹³⁸ D. Opalski, Email to K. Susewind (March 11, 2014)(03946).

¹³⁹ A. Chung, Email (June 19, 2014)(02231-02232).

¹⁴⁰ D. McLerran, Letter to M. Bellon (December 18, 2014)(04790-04791).

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 rights¹⁴¹:

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.¹⁴²

On February 2, 2015, two months after Ms. McCarthy's memorandum, EPA disapproved in part water quality standards adopted by the state of Maine.¹⁴³ 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.¹⁴⁴ 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.¹⁴⁵ For the first time, EPA asserted 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

¹⁴¹ G. McCarthy, Memorandum Commemorating the 30th Anniversary of the EPA's Indian Policy (December 1, 2014)(05396-05397).

¹⁴² *Id.*

¹⁴³ H. Spalding, Letter to P. Aho (February 2, 2015)(07305-07310) 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 (07254-07304).

¹⁴⁴ EPA, Comments on Washington Department of Ecology's Proposed Human Health Criteria and Implementation Tools Rule (07233-07249).

¹⁴⁵ *Id.* at 2-3 (07234-07235).

suppressed, are adequately protected.”¹⁴⁶ 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.¹⁴⁷

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. This basis lacks a 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 position that treaty fishing rights mandate that states select fish consumption rates reflecting unsuppressed fish consumption.¹⁴⁸ EPA articulated the treaty rights rationale in its November 6, 2015 further comments on Idaho’s proposed rule.¹⁴⁹

EPA’s national effort to use treaty rights as support for its preferred state water quality standards is further evidenced by the February 19, 2016, guidance for consulting with Indian tribes regarding treaty rights.¹⁵⁰ This 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 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

¹⁴⁶ *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 (07237).

¹⁴⁷ 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, 87 Fed. Reg. at 19060-19061.

¹⁴⁸ EPA, Letter to Idaho DEQ (May 29, 2015)(04746-04753).

¹⁴⁹ EPA, Comments on Idaho’s Revised Human Health Toxic Criteria (November 6, 2015)(04759-04789).

¹⁵⁰ EPA, EPA Policy on Consultation and Coordination with Indian Tribes: Guidance for Discussing Tribal Treaty Rights (February 19, 2016)(08482-08485).

certain level of environmental quality to maintain the activity or a guarantee of access to the activity site.¹⁵¹

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.¹⁵² 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" questions have been raised about EPA 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.¹⁵³

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

EPA 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} .¹⁵⁴ In fact, EPA

¹⁵¹ *Id.* at 3 (08484).

¹⁵² EPA, Consultation Plan for Considering a Baseline Water Quality Standards Proposed Rule (August 2015)(05066-05072).

¹⁵³ K. Kirk, Letter to D. McLerran re EPA Efforts to Influence Washington Rulemaking at 2-3 (May 13, 2015)(04743-04745 at 04744-04745).

¹⁵⁴ EPA 2022 Proposed Rule, 87 Fed. Reg. at 19049 (§ II.B.c) (“[S]electing a FCR that reflects unsuppressed fish consumption could be necessary where tribal treaty or other reserved fishing rights apply. In such circumstances, if sufficient data regarding unsuppressed fish consumption levels are unavailable or inconclusive, states should consult with tribes when deciding which fish consumption data should be used in selecting an FCR”); *Id.* at 19050 (§II.C)

admits that it had insufficient evidence of unsuppressed fish consumption rate for the tribes, and lacking such data, simply adopted both the fish consumption rate and the cancer risk level that the tribes asked for.¹⁵⁵ 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.¹⁵⁶ 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)).

(“[E]PA proposed HHC based on a FCR of 175 g/day and CRL of 10⁻⁶ to reflect consideration of tribal treaty-reserved rights, as informed by consultation with the tribes and fish consumption surveys of tribal members”); *Id.* at 19050 (“The 2016 final rule was informed by . . . consultation with a number of federally recognized tribes”); *Id.* at 19055 n. 78 (“In 2016, tribes in Washington State generally viewed 175 g/day as a *compromise minimum consumption rate* so long as it is coupled with a CRL of 10⁻⁶.”) (emphasis added); *Id.* at 19060 (“The tribes have repeatedly asked EPA to reinstate the 2016 federal HHC for Washington, which EPA is proposing to do in this rule”); *Id.* at 19061 (“FCR of 175 g/day is a “compromise rate”). EPA similarly relied on tribal consultation as a justification for its decision-making in the 2016 proposed and final rules. See 80 Fed. Reg. at 55066 (§ II.B.c) (“If sufficient data regarding unsuppressed 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 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 EPA, Comments on Washington Department of Ecology’s Proposed Human Health Criteria and Implementation Tools Rule (07233-07249) 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 at 07233). See EPA 2016 Final Rule, 81 Fed. Reg. at 85426 (§ III.B.e) (“Consultation with tribes is important to ensure that all data and information relevant to this [FCR suppression data] issue are considered”); 81 Fed. Reg. at 85426 (§ III.C.a) (“The Washington tribes have generally agreed that 175 g/day is acceptable for deriving protective criteria at this time. . . .”); *Id.* at 85427 (§ III.C.b) (“Throughout tribal consultation, the tribes generally supported 175 g/day as an acceptable FCR . . . when accompanied by other protective input parameters. . . .”); *Id.* at 85435 (§ V.F) (“At these 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. . . .”).

¹⁵⁵ *Id.*

¹⁵⁶ 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) (06436-06439).

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. EPA in February 2016 also issued an EPA Policy on Consultation and Coordination with Indian Tribes: Guidance for Discussing Tribal Treaty Rights (“EPA Treaty Rights Consultation Policy”).

In 2021 President Biden issued a Presidential Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships, 86 Fed. Reg. 7491 (Jan. 26, 2021) (“2021 Presidential Memorandum”), reaffirming the policy announced in the 2009 Presidential Memorandum. Like the 2009 memorandum, the 2021 Presidential Memorandum directed executive departments and agencies to develop a plan of actions each agency would take to implement Exec. Order No. 13175. EPA issued such a plan in April 2021.

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; 2021 Presidential Memorandum. They are “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); “This memorandum shall be implemented consistent with applicable law. . . .” 2021 Presidential Memorandum. 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. R.I. 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 Cnty’s. 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.*¹⁵⁷ 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 v. Christie*, 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 v. Deer*, 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. Under the CWA EPA must base water quality standards on sound scientific rationale. EPA does not have authority to impose its policy preference on Washington HHWQC based on tribal input when the current standards clearly meet the requirements of the CWA. And if a policy decision is to be made to voluntarily follow tribal preferences, it is for the State to decide, not EPA.

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

EPA has improperly relied on the purported 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 2013.¹⁵⁸ It was echoed by EPA staff at meetings with state officials.¹⁵⁹ 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).¹⁶⁰ EPA repeats these post-hoc rationalizations in the Federal Register notice. 87 Fed. Reg. at 19055 ("a FCR of 175 g/day helps ensure that Washington's criteria will provide for the attainment and maintenance of Oregon's downstream WQS.")

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

¹⁵⁷ EPA, EPA Policy on Consultation and Coordination with Indian Tribes: Guidance for Discussing Tribal Treaty Rights at 1 (08482). EPA's consultation policy specific to tribal treaty rights similarly states that the policy "does not create any new legal obligations for EPA or expand the authorities granted by EPA's underlying statutes, nor does it alter or diminish any existing EPA treaty responsibilities."

¹⁵⁸ D. McLerran, Pers. Communication (April 9, 2013).

¹⁵⁹ C. Niemi, Handwritten Notes (00455-00458); and A. Chung, Pers. Communication, NWPPA Annual Meeting (June 6, 2013).

¹⁶⁰ D. McLerran, Letter to M. Bellon (December 18, 2014)(04790-04791).

standards.¹⁶¹ 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 taken into account the Oregon human health criteria when recently issuing NPDES permits on the Columbia River.¹⁶² 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.¹⁶³ Ecology has made the same consideration of the downstream Spokane Tribe of Indians criteria in developing a PCB TMDL on the Spokane River.¹⁶⁴ The actions of Ecology, consistent with the state water 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.¹⁶⁵ 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).**

¹⁶¹ 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).”)(03954-03965 at 03959).

¹⁶² Ecology, Draft Response to Downstream Waters Comments (July 2015)(addressing a NPDES permit issued in Longview)(04949-04954); *see* Ecology, Fact Sheet for NPDES Permit WA0000124 Weyerhaeuser Longview at 60 (06987-07133 at 07046); Ecology, Fact Sheet for NPDES Permit WA0000256, Georgia Pacific Consumer Products (Camas), LLC, at 35 and 60, Table 25 (March 10, 2015)(07134-07229 at 07168, 07193).

¹⁶³ EPA, Protection of Downstream Waters in Water Quality Standards: Frequently Asked Questions (03954-03965).

¹⁶⁴ Ecology, Spokane River PCB Source Assessment 2003-2007 (April 2011)(Ecology Pub. No, 11-03-013)(06808-06963).

¹⁶⁵ 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>)(06754-06807).

(Emphasis added.)¹⁶⁶

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.¹⁶⁷

EPA Region 10 has advised Washington and Idaho to consider EPA decisions on other state water quality standards in the state risk management decisions.¹⁶⁸ 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.

EPA revised in 2015 its water quality standards regulations applicable to states. 80 Federal Register 51019. (August 21, 2015). EPA did not require state and authorized tribes to adopt identical standards as those of downstream states. Instead, the agency maintained the requirement that states and tribes “consider relevant provisions in section 131.10, including downstream protection....” 80 Federal Register at 51026.

¹⁶⁶ *Id.* at 4 (06759).

¹⁶⁷ *Id.* at 18 (*citing* EPA, 2000 Methodology for Human Health Criteria) (06773). *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 at 4-5 (2012)(EPA approval of human health criteria for New Jersey that are less stringent than downstream water quality standards)(01072-01085 at 01075-01076).

¹⁶⁸ L. Macchio, Letter to D. Essig (January 20, 2015)(01086-01088).

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

EPA has relied in the 2022 Proposed Rule on the same Relative Source Contribution (RSC) values developed for its 2016 rule. 87 Fed. Reg. 19055. The 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.¹⁶⁹ 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 FCR that includes all fish whether or not that fish is purchased from a store or is 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.**¹⁷⁰

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 through the ingestion of drinking water and consumption of fish obtained from surface waters.”¹⁷¹

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

¹⁶⁹ Ecology, Overview at 21 (00027).

¹⁷⁰ 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)(06158-06215).

¹⁷¹ EPA, 2000 Human Health Methodology at 1-11 (00103). See D. Essig, Email to C. Niemi (September 6, 2012)(06685-06688).

to a lower or fractional RSC.¹⁷² EPA Region 10 has urged Northwest states to consider EPA action on water quality standards for other states.¹⁷³ EPA Region 10 has further endorsed the Oregon approach as “the right outcome.”¹⁷⁴

This endorsement is also set forth in a letter dated September 5, 2014, from EPA to the state of Idaho.¹⁷⁵ 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.”¹⁷⁶ 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.¹⁷⁷

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.¹⁷⁸ The SDWA uses a RSC of 20% and 80% of exposure but does so in terms of goals, not water quality criteria.¹⁷⁹ The SDWA is using this range of RSC for establishing Maximum Contaminant Level Goals that are not by definition regulatory limits.¹⁸⁰ 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 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

¹⁷² Oregon DEQ, 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.

¹⁷³ L. Macchio, Letter to D. Essig (January 20, 2015)(01086-01088).

¹⁷⁴ C. Niemi, Handwritten Notes. (“Dennis thinks the Oregon outcome is the right outcome.”)(00455-0458).

¹⁷⁵ L. Macchio, Letter to D. Essig (September 5, 2014)(04242-04244).

¹⁷⁶ *Id.* at 2 (04243).

¹⁷⁷ EPA, Letter approving Spokane Tribe of Indians 2010 Revision to Their Surface Water Quality Standards (December 19, 2013)(01020-01071).

¹⁷⁸ Ecology, Overview at 22 (00028).

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*; *See also* Ecology, Draft Comments from Washington and Idaho on EPA 2013 Human Health Ambient Water Quality Criteria and Fish Consumption Rates FAQ (April 17, 2013)(04245-04256).

acknowledged that its approach for arsenic 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.¹⁸¹ 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.”¹⁸² 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 April 1, 2022, when EPA published the current draft rule.

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.”¹⁸³ EPA describes in its response to comments that this action reflects that only inorganic arsenic is toxic to humans.¹⁸⁴

In 1997 EPA approved arsenic criteria from Alaska based on the SDWA MCL and withdrew application of the NTR criteria to the state.¹⁸⁵ 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.¹⁸⁶ 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.¹⁸⁷ 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.¹⁸⁸

In 2002 EPA adopted toxic criteria for the state of California but did not include criteria for arsenic.¹⁸⁹ 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.”¹⁹⁰ EPA should explain in response to these comments why it has failed to

¹⁸¹ EPA, Final Updated Ambient Water Quality Criteria for the Protection of Public Health at 36987 (04808).

¹⁸² EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update (01772-01774).

¹⁸³ See n. 18. NTR, 56 Fed. Reg at 60868 (00792).

¹⁸⁴ *Id.*

¹⁸⁵ EPA, Withdrawal from Federal Regulations of Applicability to Alaska of Arsenic Human Health Criteria, 62 Fed. Reg. 27707 (May 21, 1997)(04803-04806).

¹⁸⁶ *Id.* at 27708 (04804).

¹⁸⁷ EPA, Arsenic and Fish Consumption at 2-5 (December 3, 1997)(05043-5062 at 05046-05049).

¹⁸⁸ *Id.* at 1 (05045).

¹⁸⁹ EPA, Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California, 65 Fed. Reg. 31682 (May 18, 2000)(00861-00898).

¹⁹⁰ *Id.* at 31696 (00875).

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.¹⁹¹

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.”¹⁹² 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 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]....

...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 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.¹⁹³

If EPA does not have the ability for the reasons set forth in the above letter to revise PCB regulations under TSCA, it certainly does not have the ability to revise the PCB criterion adopted

¹⁹¹ Ecology, Overview at 44 (00050).

¹⁹² EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update at 2 (01773).

¹⁹³ D. McLerran, Letter to A. Borgias (February 24, 2015)(04239-04241).

by Washington and previously approved by EPA. EPA affirmed as recently as August 3, 2015, that revising PCB regulations “presents both policy and scientific challenges.”¹⁹⁴

As of today, EPA has apparently concluded this work but has refused to share the information publicly. In a letter dated November 15, 2021, the acting regional administrator for EPA Region 10 announced that some portion of the work has been completed and that final report would be issued within the “next six months.”¹⁹⁵ Despite requests for this information, EPA refuses to release the results of this work that by the agency’s own representation will be used to inform the development of water quality standards.

EPA should withdraw the proposed PCB criterion 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 failed to respond to previous comments on this issue and it is not addressed in the current rule making.

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 billion pg/L allowed under TSCA compared to the EPA proposed PCB water quality criteria for Washington at 7 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. § 761.20.¹⁹⁶

EPA needs to address this issue because even if the technology existed to consistently treat effluent down to 7 ppq, which the HDR study demonstrates does not exist, it still would be all but impossible to meet its proposed criteria due to the ongoing release of PCBs that EPA authorizes under a standard it deems adequately protective of human health 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.¹⁹⁷

For many dischargers in Washington, the EPA allowed PCB concentrations under TSCA are a significant portion of the PCBs in their effluent. For pulp and paper mills using recycled materials, PCBs in effluent can be the result of inadvertent byproducts from pigments in inks and dyes.¹⁹⁸ 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

¹⁹⁴ L. Mann, Email to M. Macintyre at 2 (August 3, 2015)(05063-5065 at 05064).

¹⁹⁵ M. Pirzadeh, Letter to Doug Krapas (November 15, 2021)(08486-08487).

¹⁹⁶ NTR at 60868 (00792).

¹⁹⁷ City of Spokane, PCBs in Municipal Products (Rev.), Table B-1 (July 21, 2015)(06694-06738 at 06737-06738).

¹⁹⁸ D. Krapas, Slide Show “Dealing with PCBs in the Spokane River” at 3 (October 2, 2012)(06443-06463 at 06445).

measured at relatively high concentrations...in both the influent and effluent.”¹⁹⁹ PCB-11 was the “single most abundant congener in the effluent.”²⁰⁰ 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.”²⁰¹

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 under the authority of a general NPDES permit.²⁰² 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.²⁰³ 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.²⁰⁴

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.²⁰⁵ Ecology concluded that hatchery fish “may contribute to impairment and, in some cases, may cause the bulk of impairment.”²⁰⁶ *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.²⁰⁷ 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.²⁰⁸ The authors concluded, “contaminated salmon may be a significant source of toxicants in the environment and in the

¹⁹⁹ Brown and Caldwell, 2015 Annual Toxics Management Report Spokane County Regional Water Reclamation Facility NPDES Permit WA-0093317 at 2-18 (2015)(04861-04948 at 04896).

²⁰⁰ *Id.*

²⁰¹ *Id.* at 2-27 (04905).

²⁰² EPA, Preliminary Draft NPDES Permit for Federal Aquaculture Facilities and Aquaculture Facilities Located in Indian Country, Permit No. WAG-130000 (August 2015)(06216-06319).

²⁰³ Ecology, Control of Toxic Chemicals in Puget Sound: Assessment of Selected Toxic Chemicals in Puget Sound 2007-2011 at 93 (2011)(Ecology Pub. 11-03-055)(04297-04593 at 04391).

²⁰⁴ *Id.*

²⁰⁵ Ecology, Persistent Organic Pollutants in Feed and Rainbow Trout from Selected Trout Hatcheries (April, 2006)(Ecology Pub. No. 06-03-017)(04681-04732).

²⁰⁶ *Id.* at 30 (04714).

²⁰⁷ Ecology, Persistent Organic Pollutants in Feed and Rainbow Trout from Selected Trout Hatcheries (April, 2006)(Ecology Pub. No. 06-03-017)(04681-04732).

²⁰⁸ 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)(04955-04982).

food chain.”²⁰⁹ 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 from a third (BC) hatchery.²¹⁰ 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).²¹¹ 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).²¹² NOAA Fisheries has also documented the significant PCB concentrations in hatchery fish feed and in hatchery origin fish.²¹³

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.²¹⁴ In 2015, the Northwest Indian Fisheries Commission reported that tribal hatcheries alone released 40 million salmon and steelhead.²¹⁵ 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.²¹⁶

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 impose more draconian PCB water quality standards as necessary to protect human health.

²⁰⁹ *Id.*

²¹⁰ Kelly et al., Persistent Organic Pollutants in Aquafeed and Pacific Salmon Smolts from Hatcheries in British Columbia, Canada, 285 AQUACULTURE 224-233 (2008)(08488-08497).

²¹¹ Johnson et al., Contaminant Concentrations in Juvenile Fall Chinook Salmon from Columbia River Hatcheries, 72 N. AMERIC. J. AQUACULTURE 73-92 (2010)(08498-08517).

²¹² Meador et al., Bioaccumulation of Polychlorinated Biphenyls in Juvenile Chinook Salmon (*Oncorhynchus Tshawytscha*) Outmigrating through a Contaminated Urban Estuary: Dynamics and Application, 19 ECOTOXICOLOGY 141-152 (2010)(08518-08530).

²¹³ NOAA Fisheries, Draft Environmental Impact Statement on Two Joint Tribal Resource Management Plans for Puget Sound Salmon and Steelhead Hatchery Programs, Appendix K: Chemicals Used in Hatchery Operations (2014)(04257-04273).

²¹⁴ 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 (06739-06752 at 06740).

²¹⁵ Northwest Indian Fisheries Commission, Tribal Natural Resources Management, A Report from the Treaty Tribes in Western Washington at 4 (2015)(06530-06545 at 06533).

²¹⁶ EPA, Preliminary Draft NPDES Permit for Federal Aquaculture Facilities and Aquaculture Facilities Located in Indian Country (06216-06319).

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 weight). This value is derived from the outdated basis for the EPA 2001 recommended criteria for methylmercury.²¹⁷ EPA has acknowledged unresolved technical issues and delayed action on updating this value in the 2015 recommended updated human health water quality criteria.²¹⁸ 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.²¹⁹ 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.²²⁰ 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.²²¹

Ecology has explained to EPA that the EPA guidance on implementing the flawed 2001 criterion does not address these outstanding issues.²²² 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.

²¹⁷ Ecology, Overview at 50 (00056).

²¹⁸ EPA, Final Updated Ambient Water Quality Criteria for the Protection of Public Health (04807-04810) and EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update (01772-01774).

²¹⁹ Ecology, Overview at 49 (00055).

²²⁰ Ecology, Overview at 50 (00056).

²²¹ Ecology, Overview (00001-00073).

²²² *Id.*

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.

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, 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.²²³ 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 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.²²⁴ 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.²²⁵ 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

²²³ 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)(07570-07934).

²²⁴ 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)(07349-07355).

²²⁵ 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)(07356-07390).

proposed criterion.²²⁶ The walleye mean and minimum fillet concentration was 0.33 mg/kg and 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.²²⁷ 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.²²⁸

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.²²⁹ Recent reports have explained the mechanisms of this protective effect.²³⁰ When the molar ratio of selenium to mercury in fish tissue exceeds 1.0 in

²²⁶ 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, 1994 USGS Open-File Report 95-195 (1995)(available at <http://pubs.er.usgs.gov/publication/ofr95195>)(07391-07429); 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)(07935-07946).

²²⁷ EPA, Report on the Environment: The National Study of Chemical Residues in Lake Fish Tissue (2009)(EPA-823-R-09-006)(07430-07433).

²²⁸ 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)(07434-07449 at 07434).

²²⁹ Zhang, et al., New Insights into Traditional Health Risk Assessments of Mercury Exposure: Implications for Selenium, 48 *ENVIRONMENTAL SCIENCE & TECHNOLOGY* 1206 (2014)(07947-07953).

²³⁰ Ralston and Raymond, Dietary Selenium's Protective Effects Against Methylmercury Toxicity, 278 *TOXICOLOGY* 112 (2010)(07954-07959).

freshwater and marine fish, a protective effect can be assumed.²³¹ 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.

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.

²³¹ 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)(08531-08537).

The criteria proposal challenges Ecology’s 2016 justification for choosing to use BCFs rather than EPA’s then recently issued, BAFs. In their TSD (Ecology 2016) Ecology presents more than a dozen pages of history on the development of BCFs and BAFs and the science behind their calculation and use when deriving HHC. Ecology did conclude their extensive review with four brief summary points, but EPA’s assertion in the proposed rule that “These justifications are not risk management decisions,” 87 Fed. Reg. at 19053, is incorrect and clearly not reflective of the extensive technical justification used by Ecology in making its decision to use BCFs and not BAFs.

In contrast to the Ecology TSD, the proposed rule is completely lacking any scientific justification for reversing the EPA 2019 determination that the use of BCFs as part of the overall HHC derivation in Washington was adequate. Furthermore, EPA has only attempted to compel the use of BAFs since 2015 and even well after that date has approved state water quality standards that have maintained the use of BCFs.

If EPA is actually concerned about human health criteria based on sound scientific principles, it would defer to the scientific and state-specific determination made by the State of Washington to rely on BCFs.

Comment No. 20: The draft EPA rule is arbitrary and capricious for failing to give meaningful consideration to the large potential costs of the proposed HHWQC.

The U.S. Supreme Court has clarified that EPA has broad discretion to weigh costs and benefits in implementing its regulatory statutes, and failing to do so is arbitrary and capricious unless the statutory text precludes it. *See Michigan v. EPA*, 576 U.S. 743 (2015). The CWA does not relieve EPA from this obligation, and the proposed rule fails to provide meaningful estimates of the costs that would result from the rule—and indeed assigns zero costs to the rule—and likewise does not reasonably compare the costs with the benefits likely to occur nor consider reasonable alternatives.

Comment No. 21: EPA’s Economic Impact Analysis assessment of the potential impact from proposed Arsenic criteria is illusory and contrary to law.

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.²³²

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

²³² *See* Economic Analysis for the Revision of Certain Federal Water Quality Criteria Applicable to Washington referenced at 87 Fed. Reg. 19058, §VI.

Register.²³³ If EPA assumes that an action is required by new arsenic criteria that are based on the same flawed premises as 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.

There is no support 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.²³⁴ 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, 28-29, Table 4-2. 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.

Comment No. 22: EPA’s Economic Impact Analysis fails to include any assessment of compliance with proposed PCB criteria.

EPA continues to erroneously exclude the incremental cost of compliance with its proposed PCB criterion 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. Available data also suggests that essentially every publicly

²³³ Ecology, Overview at 46 (00052). *See also* EPA, Final Updated Ambient Water Quality Criteria for the Protection of Public Health (04807-04810) and EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update (01772-01774).

²³⁴ *Id.*

owned wastewater treatment plant in Washington would have 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 (2022 dollars) cost of \$245 to \$600 million as documented in Attachment C—HDR, Treatment Technology Review and Assessment, at 68, Table 4-7. EPA also needs to acknowledge, as documented in the HDR study, that there are no known combinations of treatment trains that will achieve the EPA PCB criterion. *Id.* at 1. As such, the EPA economic impact analysis must consider the impacts of all available tools that will be required to implement the EPA criterion including variance and use attainability analyses.

The economic impact analysis does not address PCBs on the pretext that (1) there is no NPDES permit monitoring results that indicate a potential to cause or contribute to violations on the PCB criteria, (2) the EPA approved test methods to determine PCB in effluent as low as the proposed federal criterion. This “head in the sand” approach to assessing the potential impact from the EPA PCB criterion ignores available data on PCB concentrations in water column data in Washington indicating ambient PCB concentrations below the current PCB criterion of 170 pg/L but above the EPA proposed PCB criterion of 7 pg/L.

EPA is well aware of PCB water column data in Ecology’s Environmental Information Management (EIM) database that includes 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 2010.²³⁵ This report has been reviewed and that data in the report has been included in the EIM database.²³⁶ 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.²³⁷ This includes PCB water column data for total congeners collected at each of these sites.²³⁸ All of the total congener data is either unqualified or J qualified. This data should have been identified and listed 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 but below the NTR criteria. The following chart, based on water column data in the EIM database,²³⁹ shows an average of the total PCBs for each monitoring station at the surface and at depth:

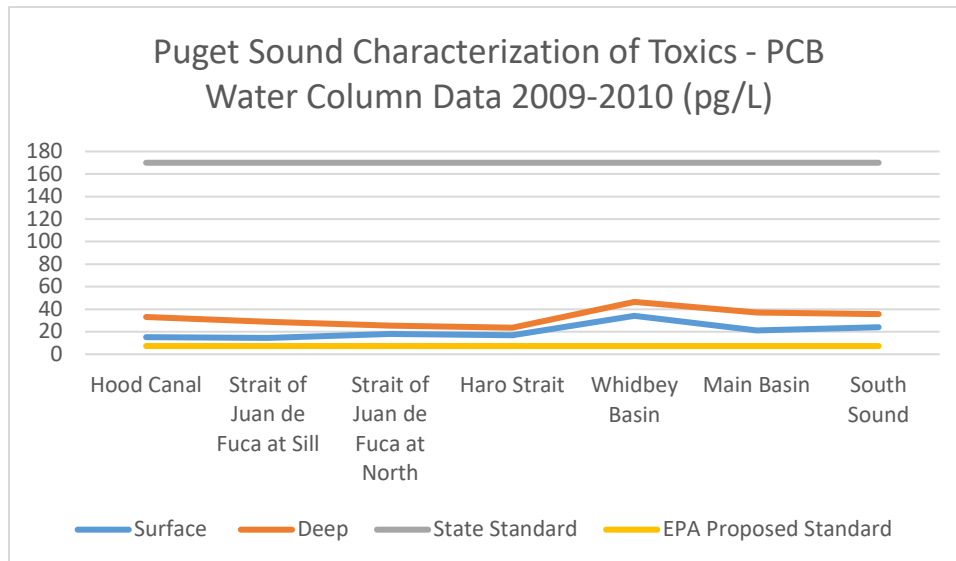
²³⁵ Ecology, Control of Toxic Chemicals in Puget Sound: Characterization of Toxic Chemicals in Puget Sound and Major Tributaries, 2009-10 (January 2011)(available at <https://fortress.wa.gov/ecy/publications/documents/1103008.pdf>)(05155-05395).

²³⁶ 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).

²³⁷ Ecology, Email re download request (07311) and attached EIM Data for Puget Sound (December 8, 2015)(05987). The attached data is limited to water column data for total PCBs.

²³⁸ *Id.*

²³⁹ *Id.*



It is 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 criterion. We have previously provided this data to EPA and EPA, with no explanation, has chosen to continue to ignore it in the current rulemaking. EPA made no response to comments for its final rule in 2016 to this data and it is not addressed in the current rulemaking, or the economic impact analysis filed with the 2022 proposed rule.

EPA is arbitrarily relying on discharge monitoring data knowing that such data, if collected, is based on an EPA test method with detection levels that are above its proposed PCB criterion. 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 criterion. In fact, every wastewater treatment plant sampled by Ecology, with the exception of two facilities with reporting levels of 600 pg/L, were well above the proposed criteria.²⁴⁰

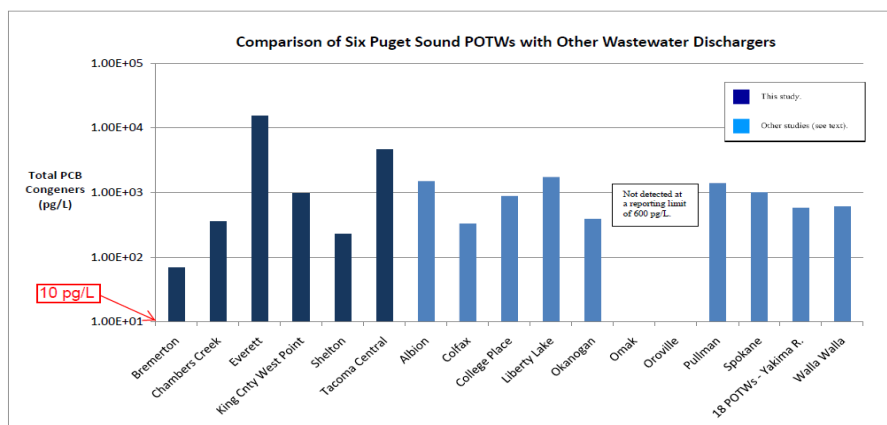


Figure 2. Comparison of Average Total PCB Results among Several POTWs

²⁴⁰ 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)(05746-05986 at 05811).

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.²⁴¹

The Spokane River offers a precedent for how EPA will address low PCB concentrations in NPDES permits throughout the state of Washington under its proposed PCB criterion. 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.²⁴²

EPA misrepresents in its rulemaking that there are no potential economic impacts related to PCB since the approved PCB test method is not sufficiently sensitive to result in compliance costs for permittees.²⁴³ This position is entirely at odds with the position taken by EPA that NPDES permits in Idaho and Washington on the Spokane River specifically require monitoring using unapproved test method 1668C.²⁴⁴ EPA has also insisted that Ecology must use all available data, including data from unapproved test methods to conduct reasonable potential analysis and to derive numeric water quality based effluent limitations. In a NPDES implementation strategy issued by EPA, the agency states:

Monitoring requirements for PCB congeners using Method 1668C can provide quantitative data about the actual PCB loading from point sources. This represents a significant advantage over numeric WQBELs for total PCBs, which, as explained above, currently must be enforced using the far less sensitive approved analytical methods. Therefore, the EPA is recommending that the permits continue to use a BMP approach to PCB control and require the use of EPA method 1668C for monitoring of final effluents for PCB congeners, instead of

²⁴¹ EPA, City of Coeur d'Alene Revised Fact Sheet NPDES Permit No. ID0022853 at 17 (2013)(07468-07569 at 07484).

²⁴² *Sierra Club v. EPA*, Case No.2:11-cv-017959-BJR Doc. No. 129-1, EPA, EPA's Plan for Addressing PCBs in the Spokane River (July 14, 2015)(06320-06350).

²⁴³ 80 Fed. Reg. at 19058.

²⁴⁴ EPA Comment Letter on City of Spokane Draft NPDES Permit, February 28, 2022 (08538-08542).

establishing numeric WQBELs enforced using methods approved under 40 CFR Part 136.

Even if the permitting authority determines that it is appropriate to include numeric WQBELs for PCBs to be enforced using methods approved under 40 CFR 136 in one or more of the subject permits, the EPA nonetheless recommends that the permitting authority include the following BMP requirements and monitoring for PCB congeners using EPA method 1668C in addition to any such numeric WQBELs.²⁴⁵

True to these representations, EPA has directed Ecology to reissue a draft permit to the City of Spokane that proposes to set a ten year compliance schedule to either optimize existing treatment or submit an engineering report to install a treatment system that will achieve the state PCB criterion designed on the basis of data collected using an unapproved test method for PCBs.²⁴⁶ Regardless of whether monitoring using the only approved PCB test will show a violation of the PCB effluent limit, the facility will have to use a more sensitive and unapproved test method for the design and installation of a treatment system. EPA has made clear that the permit should include a reopener clause to adjust the final PCB limit to the EPA proposed criterion when the current rulemaking is complete.²⁴⁷ Contrary to the representations in the current rulemaking, there will be enormous financial impact on public and private permittees in Washington to comply with the proposed PCB criterion.

EPA is also in the process of developing a PCB TMDL for the Spokane River. EPA Region 10 recently made a broad request for PCB data collected using unapproved test method 1668C by the Spokane River Regional Toxics Task Force for the purposes of its TMDL development.²⁴⁸

EPA should also acknowledge that Ecology has codified broad use of unapproved test methods for PCB in its Water Quality Program Permit Writers Manual.²⁴⁹ Ecology has maintained in litigation challenging this action that it has the discretion to require monitoring using unapproved test methods and that it must use such data for all NPDES purposes except for compliance with a numeric effluent limit. *Northwest Pulp & Paper Ass'n v. Dep't of Ecology*, 500 P.3d 231, 239 (2021). Ecology has gone further in 2022 NPDES permitting on the Spokane River to broadly assert that it must require monitoring using the unapproved method whenever it suspects PCB in the effluent at a permitted facility and must use that data to assess the water quality treatment at the facility.²⁵⁰ Regardless of whether PCB is detectable at the Spokane River

²⁴⁵ EPA, EPA's Plan for Addressing PCBs in the Spokane River, July 14, 2015, at 25-26 (06320-06350 at 06344-06345).

²⁴⁶ Ecology, City of Spokane Draft NPDES Permit and Draft Fact Sheet, May 2022 (08543-08722).

²⁴⁷ EPA Comment Letter on City of Spokane Draft NPDES Permit, February 28, 2022 (08538-08542).

²⁴⁸ G. Johnson, EPA Region email to SRRTTF for PCB data, March 29, 2022 (08723).

²⁴⁹ Ecology, Water Quality Program Permit Writer's Manual (Publication no, 92-109)(revised July 2018), Chapter 6, Section 4.5: Polychlorinated Biphenyls (PCBs)(08724-08740).

²⁵⁰ See current NPDES Permits and Fact Sheets for: Kaiser Aluminum Washington, LLC; Inland Empire Paper Company; City of Spokane Riverside Park Water Reclamation Facility and Combined Sewer Overflows (CSOs); Spokane County Regional Water (Division of Utilities); and Liberty Lake Sewer and Water District (08741-09395).

facilities, Ecology has obligated itself and the permittees to ensure that the water quality treatment technology at the facilities must achieve the applicable human health criterion for PCB.

As the information provided above demonstrate, the foundation of EPA's economic impact analysis should be that most state waters will not meet the proposed criteria and that most NPDES wastewater treatment plants will, at a minimum, have to apply tertiary 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 \$53 and \$82 million for a 0.5 MGD plant and net present value unit cost of between \$106 and \$262 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 will amount to a range of compliance costs from nearly \$6 billion to over \$11 billion just for the "major" permits identified by EPA.²⁵¹

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 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 Ecology that the state should not revise this policy to remove consideration of fish tissue in 303(d) listings.²⁵²

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.

²⁵¹ \$75 MM x 73 = \$5.5 Billion; \$160 MM x 73 = \$11.7 Billion.

²⁵² K. Susewind, Email to D. Opalski (March 17, 2014)(04740-04742).

Comment No. 23: 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 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 § 5.²⁵³

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.” 87 Fed. Reg. 19056 § VII. 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 that the state “retains discretion in implementing standards.” 87 Fed. Reg. 1960 § VII.D. 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 the EPA proposed criteria in a range of \$5 billion dollars to \$11 billion dollars for just the 73 “major” NPDES permits out of 409 NPDES permits administered by Ecology. This does not include the 18 general permits administered by Ecology or federal individual and general NPDES permits administered by EPA in Washington.²⁵⁴ 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.²⁵⁵ In 2006 Ecology

²⁵³ 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 (05988-05990); E.O. 13579 76 Fed. Reg. 41,587 (July 11, 2011)(06363-06366). 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)(06351-06354).

²⁵⁴ See Attachment C. HDR, Treatment Technology Review and Assessment for Association of Washington Business, Association of Washington Cities and Washington State Association of Counties (May 24, 2022).

²⁵⁵ Ecology, Control of Toxic Chemicals in Puget Sound, Assessment of Selected Toxic Chemicals in the Puget Sound Basin, 2007-11 (04297-04593), 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)(06618-06684).

published a report documenting the PCB loadings associated with hatcheries.²⁵⁶ As illustrated by Ecology’s section 401 certification for the Leavenworth Federal Fish Hatchery, this is a statewide problem.²⁵⁷ 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 “in the spirit” of E.O. 12866 is no substitute for the full economic analyses required by OIRA.²⁵⁸ 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 adopted by Ecology and approved by EPA—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 2,7-9.²⁵⁹ The analysis “should study alternative levels of stringency to understand more fully the relationship between stringency and the size and 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.²⁶⁰ 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 “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. 24: 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

²⁵⁶ Ecology, Persistent Organic Pollutants in Feed and Rainbow Trout from Selected Trout Hatcheries (04681-04732).

²⁵⁷ Ecology, Final 401 Certification for the Leavenworth National Fish Hatchery, Order No. 7192 (January 7, 2010)(04669).

²⁵⁸ 87 Fed. Reg. at 19058.

²⁵⁹ 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)(04983-05030). *See also* OIRA, Regulatory Impact Analysis: Frequently Asked Questions (FAQs) (February 7, 2011)(05031-05042); OIRA, Regulatory Impact Analysis: A Primer (05139-05154).

²⁶⁰ *Id.* OIRA, Regulatory Impact Analysis: A Primer at 7 (05145); OIRA, Regulatory Impact Analysis: Frequently Asked Questions (FAQs) at 3 (05033).

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 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.²⁶¹ *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. 87 Fed. Reg. 19060 § VII.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

²⁶¹ 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 (November 2008) (06047-06106); Attachment C at 45-46.

criteria for Washington. 87 Fed. Reg. 19051 § IV. Yet EPA also acknowledges that Washington’s existing human health criteria were promulgated by EPA—not Washington—in the NTR. 87 Fed. Reg. 19050 § III. EPA did so pursuant to a 1992 determination of necessity. NTR, 57 Fed. Reg. 60848, 60856-60860, 60868.

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. Wash. Dep’t of Ecology*, 511 U.S. 700, 704 (1994); *Pronsolino v. Nastri*, 291 F.3d 1123, 1127 (9th Cir. 2002); *Natural Res. Def. 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.

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* 87 Fed. Reg. 19060 § VII.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. 25: 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 subject to Executive Order 12866, because it is not a significant regulatory action under Executive Order 12866." 87 Fed. Reg. 19060 § VII.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.²⁶² 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.

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²⁶² See Attachment C at 61, Table 4-5.