PETITION TO THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Petition for Reconsideration of EPA's Partial Disapproval of Washington's Human Health Water Quality Criteria and Implementation Tools submitted by the State of Washington on August 1, 2016, and Repeal of the Final Rule Revision of Certain Federal Water Quality Standards Applicable to Washington, 81 Fed. Reg 85,417 (Nov. 28, 2016)	Submitted February 21, 2017 to the Administrator and Acting Assistant Administrator of the Office of Water, U.S. Environmental Protection Agency

Northwest Pulp & Paper Association, American Forest and Paper Association, Association of Washington Business, Greater Spokane Incorporated, Treated Wood Council, Western Wood Preservers Institute, Utility Water Act Group and Washington Farm Bureau submit this petition to the Administrator of the U.S. Environmental Protection Agency ("EPA") under 5 U.S.C. § 553(e) for the following actions: reconsideration and approval of the State of Washington Human Health Water Quality Criteria and Implementation Tools submitted to the EPA on August 1, 2016, and either repeal or withdrawal of the Revisions of Certain Federal Water Quality Standards Applicable to Washington published at 81 Fed. Reg. 85,417-85,437 (Nov. 28, 2016) ("EPA Final Rule").

I. SUMMARY

On November 15, 2016, EPA wrongfully disapproved 143 human health criteria submitted by the State of Washington to EPA on August 1, 2016. EPA is required under section 303(c)(3) of the Clean Water Act ("CWA"), 33 U.S.C. § 1313(c)(3), to approve state water quality standards ("WQS") if they meet the requirements of the CWA. EPA regulations specify that state standards for toxics must be protective of beneficial uses, 40 C.F.R. § 131.11(a)(2), and derived using EPA guidance or other scientifically defensible methods. 40 C.F.R. §131.11(b). In each instance the Washington state-submitted standards are consistent with EPA guidance and the best available science, and therefore comply with the CWA. In disapproving those standards, EPA improperly usurped the primary role of the state to make risk management decisions for human health water quality criteria as well as EPA's own long-standing guidance.

EPA has imposed on the people of the state of Washington arbitrary and capricious human health water quality criteria that will likely be devastating to our local communities and businesses. EPA has sought to advanced its own agenda with no basis in and in disregard of the Clean Water Act, EPA's own regulations and guidance, and long established understanding of science and public health.

In pursuit of its political agenda EPA ignored substantial and overwhelming evidence that its final human health criteria afford no benefit to public health over the Washington-submitted standards, while imposing potentially billions of dollars in additional regulatory and compliance expenses. We respectfully request that EPA reconsider the human health water quality criteria adopted by the State of Washington and either repeal or withdraw the EPA Final Rule. As

discussed below, while Petitioners believe that EPA pushed the State of Washington to adopt criteria that are far more stringent than what is required under the CWA, EPA should now respect the state's prerogative under the CWA to make risk management decisions in deriving human health water quality criteria.

II. RECONSIDERATION AND APPROVAL OF WASHINGTON HUMAN HEALTH WATER QUALITY CRITERIA

A. Introduction

The Washington Department of Ecology ("Ecology") submitted the State of Washington Human Health Water Quality Criteria and Implementation Tools to EPA on August 1, 2016. The new and revised WQS were adopted by Ecology on August 1, 2016, and included for the first-time adoption of human health criteria into Washington's WQS. The Ecology submission also included new and revised language on implementation tools: variances, compliance schedules, intake credits, and combined sewer overflow ("CSO") treatment plants. These new and revised criteria and provisions are located in the Water Quality Standards for Surface Waters of the State of Washington (Chapter 173-201A WAC):

Human Health Criteria and Other Narrative Revisions (WAC 173-201A-240)

Variances (WAC 173-201A-420)

Intake Credits (WAC 173-201A-460)

Compliance Schedules (WAC 173-201A-510(4))

Implementation Clarification for Combined Sewer Overflows (CSO) Treatment Plants (WAC 173-201A-510(6))

EPA initially established Washington's human health criteria for toxic pollutants in the 1992 National Toxics Rule ("NTR").[1] Ecology's August 1, 2016 submittal contains 192 new human health criteria for 97 priority pollutants that are applicable to all surface waters of the state. EPA should take action under CWA § 303(c), 33 U.S.C. § 1313(c), to approve the human health criteria submitted by Washington because the criteria are based on sound scientific rationale and protective of applicable designated uses in Washington.

B. EPA is Required to Approve State Water Quality Standards that are Consistent with EPA Guidance and Scientifically Defensible Methods

Congress established a federal-state partnership for implementing the CWA. *PUD No. 1 of Jefferson County v. Washington 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. U.S.*, 505 U.S. 144, 167, 112 S.Ct.

[1] 57 Fed. Reg. 60,848 (Dec. 22, 1992)(00768-847); 40 CFR Part 131.36 (as amended in 1999 for PCBs).

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 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).

C. The State of Washington Used Appropriate Inputs to Derive Its Human Health Water Quality Criteria

EPA's 2000 Human Health Methodology[3] ("2000 Human Health Methodology") provides states with CWA 304(a) Guidance for deriving human health criteria for toxic pollutants. For each input used in the criteria calculation, EPA provides a national recommended value and guidance on specific adjustments that may be necessary to reflect local conditions and protect the most highly exposed populations. As part of evaluating whether Washington's criteria protect the applicable designated uses, EPA should review Washington's selected input values by evaluating the scientific rationale for each input and whether there was Washington-specific information relative to each value that should be considered in the review.

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[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.

[3] EPA. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004 (2000)(00074-0258).

i. Inputs to Washington's Human Health Criteria

1. *Cancer Risk Level*

Ecology derived human health criteria for carcinogens using a chemical-specific cancer risk level of one-in-one million (10^{-6}) as specified in WAC 173-201A-240, except for the chemical-specific risk level for PCBs of 2.3 x 10-^{5}. Ecology's selection of a 10^{-6} cancer risk level and separate chemical specific risk level for PCBs is consistent with the EPA's 2000 Human Health Methodology.[4]

2. *Cancer Slope and Reference Dose*

Ecology used the Cancer Slope Factors ("CFSs") and Reference Dose ("RfDs") that correspond to EPA's most recent 304(a) recommended criteria with two exceptions. For arsenic and 2,3,7,8-TCDD ("dioxin"), the state has used alternative approaches based on scientifically defensible methods that are consistent with the CWA and EPA guidance.

3. *Exposure Assumptions*

a. *Fish Consumption Rate*

Ecology used an FCR of 175 g/day to derive the Washington human health criteria. Ecology describes this decision as a Washington-specific risk management choice to use a value that: (1) is representative of state-specific information; and (2) was determined through a process that included consideration of the EPA guidance and precedent, and input from multiple groups of stakeholders.[5] Specifically, in selecting a FCR of 175 g/day, Ecology stated: "Since Washington has a strong tradition of fish and shellfish harvest and consumption from local waters, and within-state survey information indicates that different groups of people harvest fish both recreationally and for subsistence (Ecology, 2013), *Ecology has made the risk management decision to base the fish consumption rate used in the HHC equation on "highly exposed populations,"* which include, among other groups, the following: tribes, Asian Pacific Islanders (API), recreational and subsistence fishers, immigrant populations."[6]

EPA's 2000 Human Health Methodology recognizes the variability of FCRs among population groups and by geographic region. In employing the 2000 Human Health Methodology to derive criteria, EPA urges states and tribes to use a fish intake level derived from local or regional data instead of the national default recommendation in order to ensure the fish intake level chosen is protective of highly exposed subpopulations. The 2000 Human Health Methodology includes a four-preference hierarchy concerning the use of fish consumption rate

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[4] *Id.*.

[5] Ecology, *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*, at 27 (Aug. 2016); Ecology,.*Fish Consumption Rates Technical Support Document* (Jan. 2013)(05398-5591).

[6] *See* n.5, Ecology Overview, at 28.

data: (1) use of local data; (2) use of data reflecting similar geography/population groups; (3) use of data from national surveys; and (4) use of the EPA's default intake rate.

EPA should defer to the FCR and basis for the value articulated by Ecology. Ecology's approach is consistent with EPA's recommendation to use scientifically sound regional and local fish consumption data. EPA should acknowledge that while some tribes within the state have reportedly viewed 175 g/day as a compromise minimum value for current criteria-setting purposes, only so long as it is coupled with a cancer risk level of 10^{-6} that there is no treaty right or scientific basis for establishing 10^{-6} risk level as a minimum risk level necessary to protect beneficial use of state waters for tribal members.

EPA should accordingly approve of Washington's decision to derive the human health criteria using a FCR of 175 g/day and at the chemical specific cancer risk levels applied by the state, including the chemical specific risk level used for derivation of the state PCB criteria.

b. Drinking Water Intake

Ecology properly derived human health criteria using a drinking water intake rate of 2.4 L/day. In the absence of reliable local or regional data, EPA recommends that states refer to the most current available national data on drinking water intake rates. EPA should approve Ecology's use of a drinking water intake value of 2.4 L/day to derive human health criteria, consistent with EPA's 2015 updated 304(a) recommendations.

c. Body Weight

Ecology properly derived human health criteria using a body weight assumption of 80 kg based on tribal survey data relevant to Washington and EPA's 2011 Exposure Factors Handbook.[7] EPA should approve Ecology's selection of a body weight of 80 kg to derive human health criteria.

d. Bioconcentration Factors/Bioaccumulation Factors

Ecology properly derived human health criteria using Bioconcentration Factors ("BCFs"), including the use of EPA's 1980 guidance to calculate BCFs for 1,1,1-Trichloroethane and 3-Methyl-4-chlorophenol. Ecology concluded that, 1) BCFs are more closely related to water which is regulated under the CWA, 2) BCFs do not include as many inputs and predictions based on national datasets, 3) BCFs have fewer inputs and less uncertainty, and 4) BCFs are acceptable under the CWA for criteria development.[8] Ecology demonstrated that its selection of BCFs to derive human health criteria is scientifically defensible and protective of the applicable designated uses.

To account for bioaccumulation, the EPA 2000 Human Health Methodology recommends use of bioaccumulation factors ("BAFs") that account for uptake of a contaminant

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[7] EPA. *EPA Exposure Factors Handbook*. 2011 ed. (EPA 600/R-090/052F). http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252.

[8] *See* n.5, Ecology Overview, at 56.

from all sources by fish and shellfish, rather than BCFs that only account for uptake from the water column. EPA's 2015 304(a) recommendations replace BCFs with BAFs, where data are available. EPA's national recommended BAFs are not, however, based on publicly available data or translatable to Washington waters without extensive additional information. EPA published supplemental information on development of the national recommended BAFs in January 2016 that is still lacking in sufficient technical and scientific detail for its application to developing human health criteria in Washington.[9]

Ecology explained in its August 2016 submittal to EPA that it made an appropriate risk management decision to "use a BCF-based approach (as per EPA, 1980, and as used in the NTR) for criteria calculation for the following reasons:

- BCFs are more closely related to the specific environmental media (water) that is regulated under the Clean Water Act.
- BCFs do not include as many inputs and predictions that are based on national water, sediment, and biota datasets, while BAFs are dependent on these inputs. The national datasets supporting the BAFs are not necessarily reflective of Washington waters.
- The BCF-based approach includes far fewer input values. Because of this, the BCFs have far fewer sources of directly introduced uncertainty.
- BCFs are acceptable science for purposes of Clean Water Act criteria development. EPA currently uses a combination of BAFs and BCFs to calculate its NRWQC, and used a combination of BAFs and BCFs for its 2015 proposed new regulation for Washington. Therefore, both BAFs and BCFs could represent acceptable science choices for Clean Water Act purposes."[10]

EPA should approve the use of BCFs by Washington to derive the state human health water quality criteria as a scientifically defensible risk management decision for a state developing water quality standards under the CWA.

4. Relative Source Contribution

Ecology appropriately derived human health criteria using a relative source contribution ("RSC") value of 1.0. Ecology stated that this is an appropriate risk management decision due to the limited ability of the CWA to control exposure to pollutant sources outside of its jurisdiction.

EPA recommends an RSC ceiling of 0.8 to ensure protection of individuals whose exposure could be greater than indicated by current data and to account for unknown sources of exposure. In the EPA 2015 updated 304(a) recommendations EPA applied a pollutant-specific RSC value for all non-carcinogens and nonlinear carcinogens.[27] The EPA human health criteria FAQs clarify that, where a state FCR includes freshwater, estuarine, and all marine fish

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[9] USEPA. January 2016. *Development of National Bioaccumulation Factors: Supplemental Information for EPA's 2015 Human Health Criteria Update.* Office of Water, Washington, D.C. EPA 822-R-16-001.

[10] Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment.* August 2016. Ecology Publication no. 16-10-025 at 56. https://fortress.wa.gov/ecy/publications/documents/1610025.pdf;

consumption, states can adjust the RSC upward to reflect that marine exposures are already accounted for in the FCR.[30] In Washington, Ecology used an FCR of 175 g/day that includes all fish and shellfish, including all salmon, restaurant, locally caught, imported, and from other sources. Because the selected FCR includes all marine species, it is appropriate to use an RSC of 1.0 as the FCR already accounts for other potential exposure sources consistent with the logic and procedures used in establishing the national 304(a) criteria recommendations.

Ecology has adequately justified departing from the EPA guidance (to use an RSC between 0.2 and 0.8) when using an RSC value of 1.0 to derive human health criteria for all non-carcinogens and nonlinear carcinogens, and it has adequately explained why it is appropriate to disregard all other routes of exposure, including air, soil, other marine fish and shellfish, non-fish food, etc. Ecology demonstrated how its selection of an RSC value of 1.0 to derive human health criteria is scientifically defensible and protective of the applicable designated uses.

D. EPA Should Approve All of the Washington Human Health Water Quality Criteria

In accordance with 40 CFR 131.11(a), EPA must ensure that new or revised criteria are based on sound scientific rationale and contain sufficient parameters or constituents to protect designated uses. EPA should find that Ecology adopted human health criteria protective of designated uses in all cases and approve the Washington criteria as protective of Washington's designated uses, consistent with CWA requirements and EPA's implementing regulations at 40 CFR 131.11.

i. EPA Approval of 192 New Human Health Criteria

The EPA Action

Based upon the above evaluation and in accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR part 131, EPA should approve the 192 "water + organism" and "organism only" human health criteria identified in Table 1.

The EPA Rationale

EPA should evaluate Washington's criteria values against its 304(a) Guidance and the scientifically defensible methods cited in Ecology's key decision document. EPA should determine that the state human health water quality criteria are protective of Washington's designated uses.

Table 1. Approved Human Health Criteria

			Washington's Criteria	
	Chemical	**CAS Number**	**Water & Organisms (µg/L)**	**Organisms Only (µg/L)**
1	1,1,1-Trichloroethane	71556	47000	160000
2	1,1,2,2-Tetrachloroethane	79345	0.12	0.46

			Washington's Criteria	
	Chemical	**CAS Number**	**Water & Organisms (µg/L)**	**Organisms Only (µg/L)**
3	1,1,2-Trichloroethane	79005	0.44	1.8
4	1,1-Dichloroethylene	75354	1200	4100
5	1,2,4-Trichlorobenzene	120821	0.12	0.14
6	1,2-Dichlorobenzene	95501	2000	2500
7	1,2-Dichloroethane	107062	9.3	120
8	1,2-Dichloropropane	78875	0.71	3.1
9	1,2-Diphenylhydrazine	122667	0.015	0.023
10	1,2-Trans-Dichloroethylene	156605	600	5800
11	1,3-Dichlorobenzene	541731	13	16
12	1,3-Dichloropropene	542756	0.24	2.0
13	1,4-Dichlorobenzene	106467	460	580
14	2,3,7,8-TCDD (Dioxin)	1746016	0.000000013	0.000000014
15	2,4,6-Trichlorophenol	88062	0.25	0.28
16	2,4-Dichlorophenol	120832	25	34
17	2,4-Dimethylphenol	105679	85	97
18	2,4-Dinitrophenol	51285	60	610
19	2,4-Dinitrotoluene	121142	0.039	0.18
20	2-Chloronaphthalene	91587	170	180
21	2-Chlorophenol	95578	15	17
22	2-Methyl-4,6-Dinitrophenol	534521	7.1	25
23	3,3'-Dichlorobenzidine	91941	0.0031	0.0033
24	3-Methyl-4-Chlorophenol	59507	36	36
25	4,4'-DDD	72548	0.000036	0.000036
26	4,4'-DDE	72559	0.000051	0.000051
27	4,4'-DDT	50293	0.000025	0.000025
28	Acenaphthene	83329	110	110
29	Acrolein	107028	1.0	1.1
30	Acrylonitrile	107131	0.019	0.028
31	Aldrin	309002	0.0000057	0.0000058
32	alpha-BHC	319846	0.0005	0.00056
33	alpha-Endosulfan	959988	9.7	10
34	Anthracene	120127	3100	4600
35	Antimony	7440360	12	180
36	Arsenic	7440382	10	10

			Washington's Criteria	
	Chemical	**CAS Number**	**Water & Organisms (µg/L)**	**Organisms Only (µg/L)**
37	Asbestos	1332214	7,000,000 (fibers/L)	
38	Benzene	71432	0.44	1.6
39	Benzidine	92875	0.00002	0.000023
40	Benzo(a) Anthracene	56553	0.014	0.021
41	Benzo(a) Pyrene	50328	0.0014	0.0021
42	Benzo(b) Fluoranthene	205992	0.014	0.021
43	Benzo(k) Fluoranthene	207089	0.014	0.21
44	beta-BHC	319857	0.0018	0.002
45	beta-Endosulfan	33213659	9.7	10
46	Bis(2-Chloroethyl) Ether	111444	0.02	0.06
47	*Bis(2-Chloro-1-Methylethyl) Ether	108601	Not submitted	Not submitted
48	Bis(2-Ethylhexyl) Phthalate	117817	0.23	0.25
49	Bromoform	75252	5.8	27
50	Butylbenzyl Phthalate	85687	0.56	0.58
51	Carbon Tetrachloride	56235	0.2	0.35
52	Chlordane	57749	0.000093	0.000093
53	Chlorobenzene	108907	380	890
54	Chlorodibromomethane	124481	0.65	3
55	Chloroform	67663	260	1200
56	Chrysene	218019	1.4	2.1
57	Copper	7440508	1300	
58	Cyanide	57125	19	270
59	Dibenzo(a,h) Anthracene	53703	0.0014	0.0021
60	Dichlorobromomethane	75274	0.77	3.6
61	Dieldrin	60571	0.0000061	0.0000061
62	Diethyl Phthalate	84662	4200	5000
63	Dimethyl Phthalate	131113	92000	130000
64	Di-n-Butyl Phthalate	84742	450	510
65	Endosulfan Sulfate	1031078	9.7	10
66	Endrin	72208	0.034	0.035
67	Endrin Aldehyde	7421934	0.034	0.035
68	Ethylbenzene	100414	200	270
69	Fluoranthene	206440	16	16

			Washington's Criteria	
	Chemical	**CAS Number**	**Water & Organisms (µg/L)**	**Organisms Only (µg/L)**
70	Fluorene	86737	420	610
71	Gamma-BHC; Lindane	58899	15	17
72	Heptachlor	76448	0.0000099	0.00001
73	Heptachlor Epoxide	1024573	0.0000074	0.0000074
74	Hexachlorobenzene	118741	0.000051	0.000052
75	Hexachlorobutadiene	87683	0.69	4.1
76	Hexachlorocyclopentadiene	77474	150	630
77	Hexachloroethane	67721	0.11	0.13
78	Indeno(1,2,3-cd) Pyrene	193395	0.014	0.021
79	Isophorone	78591	27	110
80	Methyl Bromide	74839	520	2400
81	Methylene Chloride	75092	16	250
82	Methylmercury	22967926	Not submitted	Not submitted
83	Nickel	7440020	150	190
84	Nitrobenzene	98953	55	320
85	N-Nitrosodimethylamine	62759	0.00065	0.34
86	N-Nitrosodi-n-Propylamine	621647	0.0044	0.058
87	N-Nitrosodiphenylamine	86306	062	0.69
88	Pentachlorophenol (PCP)	87865	0.046	0.1
89	Phenol	108952	18000	200000
90	Polychlorinated Biphenyls (PCBs)	PCB	0.00017	0.00017
91	Pyrene	129000	310	460
92	Selenium	7782492	120	480
93	Tetrachloroethylene	127184	4.9	7.1
94	Thallium	7440280	0.24	0.27
95	Toluene	108883	180	410
96	Toxaphene	8001352	0.000032	0.000032
97	Trichloroethylene	79016	0.38	0.86
98	Vinyl Chloride	75014	0.02	0.26
99	Zinc	7440666	2300	2900

ii. EPA Approval of Washington Human Health Criteria for PCBs

Ecology adopted human health criteria for PCBs that are the same as those that were in effect under the NTR (as revised in 1999): 0.00017 µg/L for both the criteria for water & organisms and organisms only. Ecology appropriately considered local and regional data when selecting an FCR of 175 g/day and risk level of 4×10^{-5} for deriving its PCB criteria. This risk level is the same level of risk/hazard used by the Washington Department of Health in developing fish advisories. When Ecology used the 4×10^{-5} cancer risk level along with its other inputs to calculate PCB criteria, the resulting criteria of 0.00029 µg/L were less stringent than the 1999 NTR values. Ecology then made an appropriate risk management decision to adjust the cancer risk level to 2.3×10^{-5} so the criteria adopted by the state would be equivalent to the NTR criteria for PCBs, 0.00017 µg/L.[11]

The EPA Action

Based upon the above evaluation and in accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA should approve Washington's "water + organism" and "organism only" human health criteria for PCBs of 0.00017 µg/L.

The EPA Rationale

EPA should determine that Washington's criteria of 0.00017 µg/L for the protection of human health from exposure to PCBs from the consumption of water and organisms and organisms only are protective of Washington's designated uses and, therefore, comply with CWA § 303(c) and 40 CFR 131.11. Ecology provided adequate supporting information for its chemical specific state risk management decision, which conforms to EPA historic and recent 304(a) Guidance.

Ecology's submittal of human health criteria to EPA includes information regarding both the difficulty in detecting and the ability to treat effluent to remove PCBs. The analytical method required by EPA for compliance purposes (EPA Method 608) does not detect PCBs at the low concentrations in water at which they occur. Because PCBs in the water column are difficult to detect, methods that depend on concentration of PCBs in fish and shellfish tissue are frequently used to assess PCB levels across the state. Aquatic biota accumulate PCBs as part of their exposure to the food web, and the PCBs are often detected in fish and shellfish tissue. The use of fish and shellfish tissue monitoring data are used to support development of Washington Department of Health fish advisories (WDOH, 2014) and Clean Water Act Section 303(d) impaired waters lists (Ecology, 2012). Monitoring information demonstrates that PCBs are widespread in the environment, but have in general been decreasing in concentrations since the 1979 "ban" on use of PCBs was put in place.

PCBs present regulatory challenges for Clean Water Act programs because:

- PCBs were widely used prior to the 1979 "ban".
- PCBs are widespread in the sediments and in biota.

[11] *See* n.5, Ecology Overview, at 67.

- PCBs are long-lasting and bind readily to fats. Because of this they continue to cycle in the environment and in the food web. PCBs readily accumulate in organisms.
- PCBs are transported through the atmosphere.
- Because PCBs are transported along many pathways, and come from many sources associated with human habitation and use, they are found widely in environments that range from pristine to highly developed.
- Treatment plants are most often not designed to remove these chemicals. However, treatment plants that enhance solids removal will also remove PCBs.

These PCB characteristics make them particularly difficult to control, and efforts to address PCBs are multimedia, including contaminated site clean-up, regulation of PCBs in products, and reductions of PCBs from airborne sources. Disposal of PCBs requires specifically designed equipment. Ecology has developed a Chemical Action Plan for PCBs to address additional multimedia approaches to control PCBs entering the environment.[12]

EPA additionally has acknowledged unresolved technical issues associated with deriving human health water quality criteria for PCBs.

On June 29, 2015, EPA issued a final update to its CWA 304(a) Guidance for the protection of public health. PCBs were among the chemicals that EPA did not update due to "outstanding technical issues."[13] The scope of these technical issues is described in statements by EPA justifying its decision not to revise the Toxics Substance Control Act ("TSCA") PCB regulations. Dennis McLerran, in a letter addressed to the Spokane River Regional Toxics Task Force through the Department of Ecology, wrote:

> Revising current regulations to reduce inadvertently generated PCBs presents both policy and scientific challenges. Before proposing more stringent regulations on the inadvertent generation of PCBs in pigments, the EPA would seek to further understand the complexities and contributions of not only pigments, but also other congeners that may be present [in receiving water]….
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> …The aggregation of PCB congeners may in some instances be problematic for risk assessment because the toxicity of different PCB congeners varies and a fixed water quality concentration for total PCBs may not adequately represent the variable toxicity of the various congeners actually present in a particular water 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.[14]

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[12] *See* n.5, Ecology Overview, at 63.

[13] *See* n.129. EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update at 2.

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

EPA affirmed as recently as August 3, 2015, that revising PCB regulations "presents both policy and scientific challenges."[15] This is particularly the case because EPA 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.

These challenges support the state PCB criteria. 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.[16]

For many dischargers in Washington, EPA-allowed PCB concentrations are a significant portion of the PCBs in their effluent. For pulp and paper mills using recycled materials their primary source of PCBs is from EPA-allowed concentrations in inks and dyes. [17] The same is true for wastewater treatment plants. In a 2015 report, Spokane County reported that PCB-11, a PCB congener associated with EPA allowed PCB concentrations, "was measured at relatively high concentrations…in both the influent and effluent."[18] PCB-11 was the "single most abundant congener in the effluent.[19] 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."[20]

Ecology made an appropriate risk management decision specific to PCBs given the ubiquitous presence of PCBs in Washington surface waters in effluent and stormwater, including discharges and fish released from federal and tribal fish hatcheries. Implementing the PCB criteria adopted in the EPA Final Rule would create a regulatory quagmire for the state NPDES and TMDL program.

Most of the state of Washington would likely be listed as impaired for failing to meet the EPA PCB criteria. This is illustrated in the following chart, based on water column data in the Ecology Environmental Information ("EIM") database.[21] This table shows an average of the total PCBs for each monitoring station at the surface and at depth throughout Puget Sound:

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

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

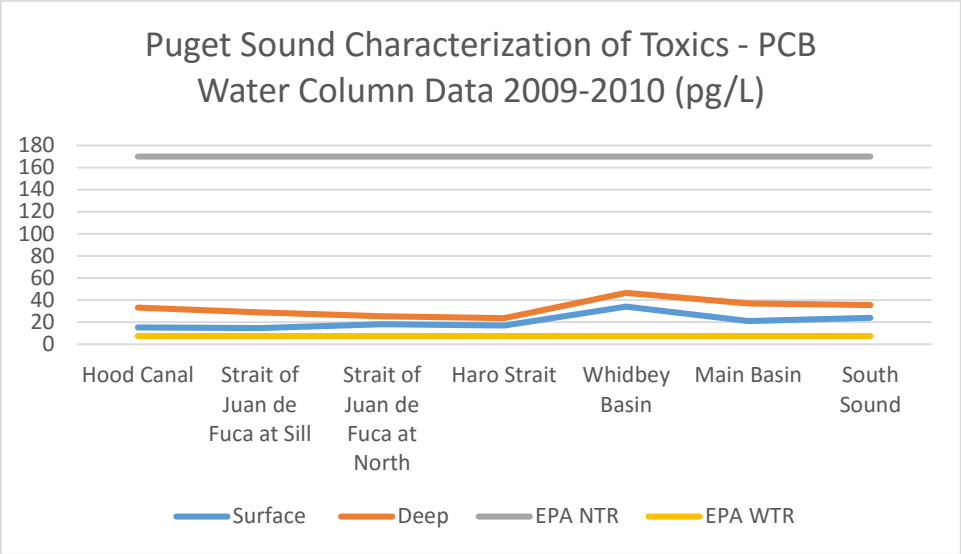
[17] D. Krapas, Slide Show "Dealing with PCBs in the Spokane River" at 3 (October 2, 2012)(06443-6463).

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

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

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

[21] Ecology email (07311) and attached EIM Data for Puget Sound (Dec. 8, 2015)(05987)



Based on this data, all of Puget Sound, Hood Canal and Strait of Juan de Fuca would be subject to listing under the CWA as impaired for failing to meet the EPA Final Rule PCB criteria. Ecology has further documented that wastewater treatment plants in Washington have levels of PCB concentrations that are well above the EPA Final Rule PCB criteria. 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 final EPA criteria.[22]

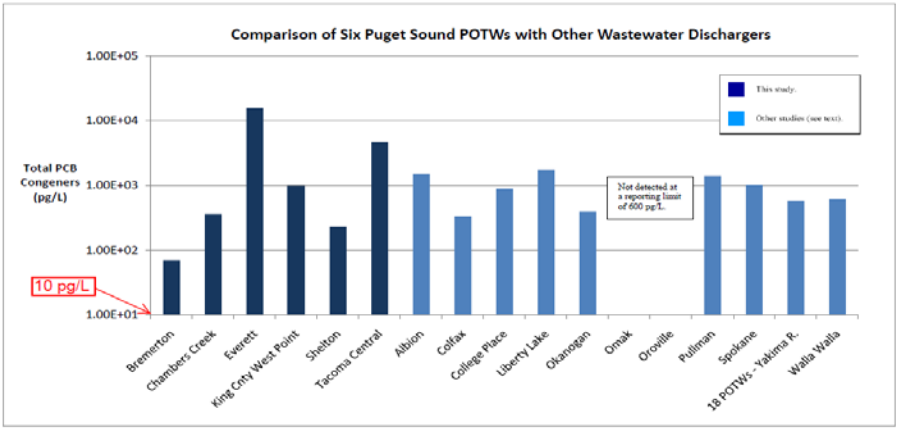


Figure 2. Comparison of Average Total PCB Results among Several POTWs

EPA has previously relied on this effluent data information to perform a narrative reasonable potential analysis for three municipalities on the Spokane River. In the 2012 Fact

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

Sheet for the City of Coeur d'Alene wastewater treatment plant NPDES permit EPA made 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 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.[23]

The Spokane River offers a precedent for how PCBs will be regulated in NPDES permits throughout the state of Washington under the EPA Final Rule PCB criteria. EPA approved water quality standards for the Spokane Tribe of Indians in 2013 that include a PCB criteria of 1.3 pg/L. In litigation regarding the obligation of EPA to develop a PCB TMDL for the Spokane River EPA has represented in federal court that year-round tertiary membrane filtration treatment is an appropriate best management practice for a wastewater treatment plant.[24]

The incremental cost for such treatment including construction costs and operation and maintenance costs range between $75 and $160 million for a 5 mgd plant and net present value unit cost of between $15 and $32 per gallon per day. Attachment C, at ES-3, Table ES-1. EPA previously identified 406 NPDES permits administered by Ecology including 73 "major" permits in its economic impact analysis for the EPA Final Rule. If EPA were to follow the same approach on Puget Sound that it has on the Spokane River, this would amount to a range of compliance costs from nearly $6 billion to over $11 billion for just "major" permits identified by EPA.[25]

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.[26] Ecology has identified hatcheries as a significant source of PCB loading to waters of the state, and has estimated that as much as ten percent of annual PCB loading to Puget Sound is attributable to returning salmon.[27]. 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.[28]

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

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

[25] $75 MM x 73 = $5.5 Billion; $160 MM x 73 = $11.7 Billion.

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

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

[28] *Id.*

Ecology has also acknowledged, in addition to the PCB loading from returning salmon, that PCB contaminated hatchery fish play a significant role in CWA Section 303(d) listings for PCBs.[29] Ecology concluded that hatchery fish "may contribute to impairment and, in some cases, may cause the bulk of impairment."[30] *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.[31] Other researchers have found between 39 and 59 ng/g total PCBs in whole-body juvenile Chinook salmon from six west coast hatcheries.[32] The authors concluded, "contaminated salmon may be a significant source of toxicants in the environment and in the food chain."[33] 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.[34] 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).[35] 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).[36] NOAA Fisheries has also documented the significant PCB concentrations in hatchery fish feed and in hatchery origin fish.[37]

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

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

[30] *Id.* at 30.

[31] *See* n.29.

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

[33] *Id.*

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

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

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

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

fish including 117.4 million Chinook salmon.[38] In 2015, the Northwest Indian Fisheries Commission reported that tribal hatcheries alone released 40 million salmon and steelhead.[39]

The Washington PCB criteria reflect a reasonable state risk management decision that is consistent with EPA 304(a) Guidance. It represents a level of protection that is well within the acceptable range of risk provided for in that guidance, reflects the use of a defensible scientific method by relying on the basis for fish advisories by the state Department of Health, and is a reasoned approach given the technical and scientific issues in developing PCB criteria as well as the potential dislocation of the state water quality program under very stringent PCB criteria.

iii. EPA Approval of Washington Human Health Water Quality Criteria for Arsenic

Ecology adopted human health criteria of 10 µg/L for arsenic for water & organisms and organisms. These criteria are equivalent to the Safe Drinking Water Act ("SDWA") maximum contaminant level ("MCL") that applies in Washington for drinking water protection. Ecology based this decision on scientific information, regulatory precedent by other states and EPA, and high concentrations of naturally occurring arsenic in Washington.[40] Washington's aquatic life water quality standards for arsenic are contained in the state's water quality standards rule for aquatic life criteria (WAC 173-201A-240). Arsenic human health criteria are also contained in the EPA-promulgated NTR. 40 C.F.R. § 131.36.

Arsenic is a naturally occurring element present in the environment in both inorganic and organic forms. Arsenic is present in rocks, soils, and the waters in contact with them, and concentrations in ground waters in the United States generally are highest in the West, with elevated levels also commonly occurring in the Midwest and Northeast. (USGS, 2000). Inorganic forms of arsenic are considered to be the most toxic, and are found in groundwater and surface water, as well as in many foods. A wide variety of adverse health effects, including skin and internal cancers, and cardiovascular and neurological effects, have been attributed to chronic arsenic exposure, primarily from drinking water (NAS, 1999; CTD, 2013).

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.[41] The report recommends that EPA use the Safe Drinking Water Act (SDWA) Maximum Contaminant Levels (MCLs) for arsenic.[42] In the west,

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

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

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

[41] EPA, Arsenic and Fish Consumption, 2-5 9Dec. 3,1997)(05043-5062).

[42] *Id.*, at 1.

where naturally high levels of arsenic in groundwater and geology are prevalent, six states have also adopted the SDWA arsenic MCL as their human health water quality criteria.

Up until 2001, the drinking water MCL for arsenic was 50 µg/L. EPA lowered the arsenic MCL to 10 µg/L in 2001 (EPA, 2001), following an extensive public process. The new standard went into effect for public supplies of drinking water nationwide in 2006. SDWA standards for arsenic in Washington are under the authority of the Washington Department of Health.

EPA is currently in the process of reviewing the toxicity information in the Integrated Risk Information System ("IRIS") related to inorganic arsenic, and plans to submit its next draft to the National Research Council for future peer review (EPA, 2014). Nationwide, nearly half of the states use the SDWA MCL value of 10 µg/L for their arsenic HHC (ODEQ, 2011, P. 19). Use of SDWA regulatory levels as HHC is not unusual for both EPA and states. EPA developed CWA §304(a) national recommended HHC (for freshwater) for asbestos in 1991 and copper in 1998 based on SDWA regulatory levels (EPA 2002). The SDWA-based asbestos criterion (7,000,000 fibers/L) is currently in the NTR, was issued to several states in 1992, and was retained in the 1999 NTR revision; and the copper criterion (1,300 mg/L) was issued by EPA to California in 2000 (40 CFR 131.38 - Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California).

Ecology reasonably determined that it could not calculate arsenic criteria based on cancer without a reliable toxicity factor. EPA agrees that new cancer-based criteria for arsenic cannot be calculated at this time. In a May 6, 2016 filing with the United States District Court for the Western District of Washington, EPA stated that it will withdraw its proposed arsenic criteria for Washington because "extensive additional scientific analysis is necessary before revised criteria" for arsenic can be promulgated. *Puget Soundkeeper Alliance et. al. v. U.S.E.P.A.,* Case No. 2:16-cv-00293-JLR, EPA's Motion for Summary Judgment (May 6, 2016) at 13. As EPA explained in the Declaration of Elizabeth Southerland, Director of the Office of Science and Technology with EPA's Office of Water, "EPA did not update its CWA section 304(a) recommended criteria" for arsenic in 2015, and "EPA recognizes that there is substantial uncertainty surrounding the toxicological assessment of arsenic with respect to human health effects." Declaration of Elizabeth Southerland (May 5, 2016) at 7.

Ecology reasonably determined that use of the EPA cancer potency factor would introduce a significant amount of uncertainty if used to develop HHC for arsenic:

- The inorganic arsenic cancer potency factor has been under reassessment for many years, and a date for finalization is not finalized (EPA, 2014). Newer information from EPA indicates that the CSF for arsenic could be finalized in EPA's IRIS in 2017.
- EPA did not use the 1998 IRIS cancer potency factor in its development of the new Safe Drinking Water Act (SDWA) MCL of 10 ppb promulgated in 2001, nor did they depend on this value in their promulgation of the HHC for the state of California in 2000. In the 2000 California Toxics Rule, EPA expressed their finding of uncertainty around the effects of arsenic, and did not use the newer 1998 cancer potency factor (EPA 2000). EPA used the older cancer potency factor ((1.75 per (mg/kg)/day) derived from the drinking water unit risk (5E-5 per (µg/L)) that was used to calculate

> the NTR arsenic criteria in its 1998 and 2002 national recommended guidance criteria calculations, but not as the basis of new regulations in either the 2000 California Toxics Rule or the new 2001 Safe Drinking Water Act MCL for arsenic.

On June 29, 2015, EPA published an update to the CWA 304(a) human health criteria.[43] The updated criteria did not include new criteria for arsenic. EPA stated in the announcement of the proposed updates in 2014 that the agency did not have the ability to update the arsenic criteria due to "outstanding technical issues."[44]

Nationally, about half of the states have obtained EPA approval for arsenic human health criteria based on the SDWA MCL.[45] EPA should accordingly agree that the Ecology adopted arsenic criteria are protective of public health, consistent with EPA guidance and based on scientifically defensible methods.

III. EPA SHOULD UNDERTAKE RULEMAKING TO WITHDRAW THE FEDERAL HUMAN HEALTH WATER QUALITY CRITERIA FOR WASHINGTON

Undoing EPA's arbitrary and capricious disapproval of the Washington-submitted human health criteria and simultaneous promulgation of substitute criteria is a two-step process. First, as set forth above, EPA should reconsider the August 2016 Washington-submitted standards and approve those standards pursuant to CWA § 303(c)(3), (c)(4). Second, EPA should repeal or withdraw the substitute criteria in the EPA Final Rule.

A. EPA Unlawfully Pre-Determined the Washington Water Quality Standards During the State and Federal Rulemaking Process

The EPA Final Rule expresses what had been a political demand by EPA for human health water quality criteria in the state of Washington since at least 2013. The EPA demands were not based on the CWA, EPA guidance, sound science or applicable law. It was apparent, from the inception of rulemaking in early 2013 by Ecology through publication of EPA's final rule during the last weeks of the previous administration, that EPA had taken a hardened position on two key factors—fish consumption rates and acceptable risk levels. Throughout this process, EPA refused to engage in any discussion on the merits or basis for its demands. The background information provided in the proposed and final rule Federal Register notices continued these obfuscations and in several cases, misrepresented the cited references and basis for the rule. Bereft of any basis under the CWA, its regulations and guidance, EPA pursued a post-hoc rationalization using a new, invented and ever-changing interpretation of Indian tribal treaty rights.

In a recent meeting of the Spokane River Regional Toxics Task Force on January 25, 2017, attended by EPA officials Christine Psyk, Angela Chung, Matthew Szelag, Lucy Edmundson and Brian Nickel, Angela Chung admitted that the final rule was based on EPA's

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[43] *See* n.128. EPA, Final Updated Ambient Water Quality Criteria at 36987.

[44] *See* n.129. EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update.

[45] *See* n.5. Ecology Overview, at 44 (00050).

interpretation of treaty fishing rights. The EPA-interpreted "rights" are not rights contained in any underlying treaty. The EPA Final Rule is not even based on the treaty rights as described in the proposed rule, but rather on an entirely new interpretation of treaty rights set forth, for the first time, in the final rule. As EPA admitted in its response to comments on the proposed rule, EPA's position on the treaty law has "evolved."[46] The evolution here was in fact a quest to find some justification for a political decision that had been made by EPA years ago.

The EPA disapproval of the Washington human health water quality criteria represents a fundamental departure from the basis and authority for EPA review of state water quality standards. 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 how EPA usurped the role of the State of Washington in developing water quality standards:

> [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.[47]

EPA drew a line in the sand on these issues with the regulated community in Washington at a meeting on April 9, 2013. That meeting took place in the offices of EPA Region 10 in Seattle, Washington and was attended by then EPA Regional Administrator Dennis McLerran and Daniel Opalski, as the Director of the Region 10 Office of Water and Watersheds, representatives of Northwest Pulp & Paper Association, the Association of Washington Business, the Association of Washington Cities, the City of Everett, Weyerhaeuser and Inland Empire Paper Company. Mr. McLerran opened the meeting by stating that the criteria in Washington should be based on a 175 grams per day (g/day) fish consumption rate and risk policy of one in one million (1×10^{-6} or 10^{-6}). Mr. McLerran explained, exhibiting ignorance of the basis for water quality standards, that this was so because "everyone should be protected to the same level."[48] It is in fact impossible to protect every consumer to the same risk level as there will always be, in the case of fish consumption, a range of consumption rates and therefore

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[46] A. Chung, pers communication to Spokane River Regional Toxics Task Force (Jan. 25, 2017).

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

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

a range of risks. Mr. McLerran further stated, with no basis under the CWA, that there had to be regional, meaning EPA regional, consistency on the toxic criteria. Mr. McLerran further stated that he was otherwise unwilling to discuss these factors with the regulated community.

EPA was 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 five years. The origins and basis for the one in one million risk policy were the subjects of several emails to EPA regional staff in January and February 2013.[49] 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.[50] 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 human health criteria in Washington to vary from national guidance.

Ecology specifically raised the risk policy issue to EPA national and regional staff at a meeting on March 20, 2013. The regional staff included Lisa Macchio, Mary Lou Soscia, Matthew Szelag, Lon Kissinger and Angela Chung.[51] 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?
>
> Angela Chung: EPA can't answer that now.[52]

Ecology raised this issue with EPA staff again in emails and meetings in October and November 2013.[53] 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.[54] EPA staff were present for the meeting but made no comment on national 304(a) 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.

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

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

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

[52] *Id.*

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

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

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, with yet again profound ignorance of the EPA principles for environmental justice, that "175 grams a day at 10^{-6} is a baseline for environmental justice."[55] Mr. McLerran falsely 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?**[56]

Mr. Opalski responded to this email and confirmed that there is no such statement. In an email dated March 11, 2014, he conceded: "Regarding the environmental justice concern, you are right that there isn't anything that will/does call out particular risk levels."[57]

EPA Region 10 provided an additional comment on the Washington proposal in a letter dated July 1, 2014. This letter was in response to two letters from Washington State Senator Doug Ericksen. Sen. Ericksen, in his first letter on April 3, 2014, asked EPA Regional Administrator Dennis McLerran, "I specifically would like to know what your agency considers to be an appropriate cancer risk level for the state of Washington."[58] Three weeks later Mr. McLerran responded with a letter that was not responsive to this question.[59] 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."[60] Sen. Ericksen requested an answer to his question and rephrased it as follows:

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

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

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

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

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

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

(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?[61]

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.[62] Mr. McLerran and EPA refused to answer the basic question of whether there is a threshold cancer risk level for deriving human health criteria.

By the summer of 2014 it was clear that EPA was struggling to find some post-hoc rationalization for its demands. In some instances EPA 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."[63] 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 explanations for the basis of the EPA proposed and final rule.[64]

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. In that letter, EPA asserted an entirely new basis for EPA's demands, stating that a one in one million risk level applied to tribal consumption rates is a "compromise position" of Washington tribes.[65] 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, an attorney in the Region 10 Office of Regional Counsel, 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

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[61] *Id.*

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

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

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

[65] *Id*.

position of the tribes."[66] At most some tribal representatives have demanded a 10^{-6} risk level but there is no evidence that any tribal representative has offered any scientific research or data to support what is a significant change in the risk policy applied in Washington.

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 specific risk level to tribal consumption rates. EPA had never 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 specific 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?[67]

This becomes one of the central questions in the EPA rule—what exactly is the legal and scientific connection between a tribal treaty right and the use of a specific risk level as a factor in the equation that derives water quality criteria. Consistent with its 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.[68] 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."[69] Christine Psyk, Associate Director for Region 10, responded that "**EPA would not because that requirement does not appear in EPA regulations or guidance.**"[70]

It is not surprising that Ecology's subsequent July 2015 draft responses to comments on the proposed Washington State rule concluded that there is no legal basis for requiring criteria based on tribal consumption rates using a 10^{-6} risk level.[71]

EPA's proposed and final rule exemplify its continued failure to provide a sound scientific rationale for its demands regarding risk policy and the fish consumption rate. In the EPA Final Rule the agency abandoned the treaty rights "analysis" contained in the proposed rule

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

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

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

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

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

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

and replaced it with a new and non-existent "treaty-reserved subsistence fishing right" in an effort to support its arbitrary and politically based human health criteria.

B. Tribal Treaty Rights Do Not Support EPA's Final Rule

Three key decisions drive EPA's preferred human health criteria. EPA (1) treats the Indian tribal population as the "target general population", (2) adopts a cancer risk level of 10^{-6} to be applied to that newly defined "target general population", and (3) uses a fish consumption rate based on unsuppressed fish consumption. These decisions are based not on sound scientific rationale, as required by the CWA, but rather on EPA's own novel and expansive interpretation of tribal treaty fishing rights. In its proposed rule, EPA presented no legal analysis whatsoever to support its interpretation of the treaties. In its Final Rule, EPA invents a new and non-existent "treaty-reserved subsistence fishing right" as support for its interpretation. In fact, the federal courts have never interpreted the treaty reserved fishing right as a right to take and consume fish at a subsistence rate, and 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.[72]

EPA's proposed rule did not cite to any legal authority supporting its reading of tribal fishing rights[1]. Moreover, EPA's stated interpretation of the treaty rights, and its reliance on those "rights" in deriving human health criteria, was described in the proposed rule using ambiguous and inconsistent language suggesting that EPA itself was unsure of exactly what "rights" it was talking about, and giving the public little idea as to how EPA had used the "rights" as the basis for its decision-making. EPA alternately described its preferred criteria as necessary "to effectuate" treaty rights (80 Fed Reg. at 55,068 (§ IV.C.b)); and then to "effectuate and harmonize" such rights (*Id.* at 55,067 (§IV.A.)). At one point EPA stated that the treaty rights merely "informed" EPA's decisions (*Id.*. at 55,066 (§ III.A)) at other times that EPA had "considered" treaty rights (*Id*. at 55,067 (§ IV.A); 55,068 § IV.C.b)). More than once EPA described its chosen human health criteria as based on what the treaties "could" require: "[W]here tribal treaty or other reserved fishing rights apply, selecting a FCR that reflects unsuppressed fish consumption *could be necessary in order to satisfy such rights*" (*Id.* at 55,066 (§ II.B.c)); "Independently, the treaties themselves *could require higher levels of protection*. The treaties themselves *could be interpreted to require a certain level of risk*; e.g. a *de minimis* level of risk that would most reasonably approximate conditions at the time the treaties were signed and the fishing rights were reserved" (emphasis added). *Id*. at 55,068 (§ IV.C.b)).

Perhaps unsurprisingly, given the number of comments pointing out the lack of any legal basis for EPA's stated treaty rights position, EPA in the Final Rule has now discovered a new legal theory which supposedly supported its reading of the treaties all along. Gone from the Final Rule is the proposed rule's ambiguous language about what the treaties "could" require;

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[72] At the time of EPA's proposed rule, the only indication from EPA as to the legal basis for its treaty rights position came in response to an email request by the Department of Ecology for "a legal opinion or rationale on how risk level and treaty tribal rights are connected, and why 10^{-6} is looked upon by EPA as fulfilling the rights, and 10^{-5} is not." EPA staff directed Ecology to EPA's disapproval of the Maine water quality standards and associated documents, including the Maine Tribal Fishing Rights Letter. *See* n.68. EPA FOIA Response. Although not referenced in the proposed rule, the Maine Tribal Fishing Rights is referenced in the Final Rule. 81 Fed. Reg. at 85,423 n. 39.

somewhere between the proposed and final rule EPA has decided exactly what the treaties require. The right described as a "tribal reserved fishing right" in the proposed rule is now styled as a "treaty-reserved subsistence right" in the Final Rule. Whereas the word "subsistence" appears only twice in the proposed rule, it appears sixty times in the Final Rule, as EPA states for the first time that "[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." (81 Fed Reg. at 85,423 (§ III.B.b). However, the relevant case law—including that cited by EPA in the Final Rule—do not support EPA's position, and in fact say just the opposite. The treaties only reserve to the Indian tribes the right to a fair share of the available fish.

i. There is no "treaty-reserved subsistence right" to take 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, as long as that regulation is non-discriminatory and for conservation purposes. *Puyallup Tribe v. Dep't of Game of Washington*, 391 U.S. 392, 398 (1968); *United States v. Oregon*, 657 F.2d 1009, 1016-17 (1981). Although treaties are to be interpreted liberally in favor of the Indians, it has long been the law that Indian treaties "cannot be re-written or expanded beyond their clear terms to remedy a claimed injustice or to achieve the asserted understanding of the parties." *Choctaw Nation of Indians v. United States*, 318 U.S. 423, 432 (1943); *See also Gros Ventre Tribe v. United States*, 469 F.3d 801, 813 (9th Cir. 2006) ("Whatever duty exists at law today must be expressly set forth in statutes or treaties.").

The treaties at issue here were negotiated by territorial Governor Isaac Stevens in 1854 and 1855 with several northwest Indian tribes, for the principal purpose of extinguishing Indian claims to land in what is now Washington State. *Washington v. Washington State Commercial Passenger Fishing Vessel Ass'n* (*"Fishing Vessel"*), 443 U.S. 658, 661-62 (1979). A critical component of the Stevens Treaties was the reserved "right of taking fish, at all usual and accustomed grounds and stations. . . in common with all citizens of the Territory." Federal courts began to recognize and interpret this treaty right as early as 1905. *See United States v. Winans*, 198 U.S. 371 (1905). 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 available fish as a *ceiling*, which could be reduced if circumstances changed and a lesser quantity of fish was sufficient to meet the tribes' "moderate living" needs. *Id*. at 685-89.

The underpinning of EPA's entire 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. *U.S. v. Washington*, 759 F.2d 1353, 1358-59 (9th Cir. 1985). There is simply no basis in law for EPA's extraordinary assertion that the treaties require that Washington's human health criteria be based on a subsistence level of fish consumption "regardless of whether such consumption is occurring today." 81 Fed. Reg. 85,425 (§ III.B.e). [73]

1. EPA's treaty rights theory is not supported by any subsidiary environmental right

In a footnote to the Final Rule, EPA makes another argument not contained in its proposed rule, appearing to read the treaty right to a share of available fish as containing 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 actions that will harm fish runs.

The issue of whether the treaty right to take fish includes an implied "environmental" right has been addressed in two lines of cases. In Phase II of *U.S. v. Washington*, the Ninth Circuit overturned a district court decision and held that in *Fishing Vessel* the Supreme Court "did not adopt a comprehensive environmental servitude." *U.S. v. Washington*, 694 F.2d 1374, 1381 (1982). That decision was later vacated on procedural grounds. *U.S. v. Washington*, 759

[73] 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 (07312-7348); Idaho Human Health Criteria Update Justification and Compliance with Clean Water Act (December 2016) at 11. 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.

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,* 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 of Washington to refrain from building or operating culverts that hinder fish passage and thus decrease the number of fish available for tribal harvest. *U.S. v. Washington*, No. CV 70-9213, 2007 WL 2437166 (2007). After a bench trial the Court issued a permanent injunction directing the state to correct the barrier culverts. *U.S. v. Washington*, No. CV 70-9213, 2013 WL 1334391 (2013). The district court emphasized that the state's duty not to block fish passage "is not a broad 'environmental servitude' or the imposition of an affirmative duty to take all possible steps to protect fish runs. . . but rather a narrow directive to refrain from impeding fish runs in one specific manner." *U.S. v. Washington*, No. CV 70-9213, 2007 WL 2437166 at *10 (2007); *U.S. v. Washington*, No. 70-9213, 2013 WL 1334391 at *24 (2013) ("it is a narrow and specific treaty-based duty that attaches when the State elects to block rather than bridge a salmon-bearing stream with a roadbed"). The Ninth Circuit Court of Appeals' recent affirmance of the district court decision was similarly narrowly based on the lower court's factual findings that the consequence of the state's building and maintaining the barrier culverts 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. *U.S. v. Washington*, 827 F.3d 836, 853 (9th Cir. 2016).[74]

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

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[74] Although EPA suggests in the 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 in that case. 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 *USA v. State of Washington*, Case No. 13-35474 (9th Cir., Oct. 16 2015) at 16 (6964-6985).

quality, those populations are already protected by Washington's EPA-approved aquatic life criteria.[75] *See* WAC 173-201A-200, 210, 240.

ii. EPA has no authority to interpret tribal treaties

In its Final Rule EPA cites for the first time to CWA § 511(a)(3), suggesting that this section of the Clean Water Act obligates it to "consider" tribal treaties to ensure that EPA's actions are "in harmony" and "do not conflict" with such treaties. This provision of the Clean Water act simply states that the CWA should not be construed as "affecting or impairing the provisions of any treaty of the United States." 33 U.S.C. § 1371(a)(3). This savings clause clarifies that the CWA does not overrule or take precedence over treaties. It does not give EPA unfettered discretion to invent a "treaty-reserved subsistence right" and then assert that only its preferred human health criteria is "in harmony" with that "right."

It is particularly remarkable that EPA would base its derivation of Washington's human health criteria on its interpretation of Indian treaty language because EPA has no authority to interpret Indian treaties. EPA's interpretation of the CWA, a statute which it administers, may under certain circumstances be entitled to deference pursuant to *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S. Ct. 2778 (1984). But EPA's interpretation of Indian treaties is not entitled to deference. *See Maine v. Johnson*, 498 F.3d 37, 45 (1st Cir. 2007). A precondition to deference under *Chevron* is a congressional delegation of administrative authority. *Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 649-50 (1990). EPA has not been delegated the authority to interpret Indian treaties. *Maine*, 498 F.3d at 45. To the contrary, the federal courts have sole jurisdiction over questions of treaty-guaranteed rights. *See* 28 U.S.C. § 1362; *Confederated Salish and Kootenai Tribes of Flathead Reservation, Montana v. Flathead Irr. & Power Project*, 16 F. Supp. 1292, 1295 (D. Mont. 1985). Moreover, to the extent that EPA is relying upon the Department of Interior Solicitor General's interpretation of the Stevens treaties in the Maine Tribal Fishing Rights letter, that interpretation is similarly not entitled to deference. *Cherokee Nation of Oklahoma v. Norton*, 389 F.3d 1074, 1078-79 (10th Cir. 2004) (Department of Interior's position based solely on its analysis of Indian treaties and agreements was not afforded any deference "because Congress did not give [the Department] the discretion to administer those treaties and agreements").

C. EPA Has Violated APA Notice and Comment Rulemaking Requirements Requiring Reference to Legal Authority

As outlined above, EPA's interpretation of treaty rights contained in the proposed rule *cited to no legal authority whatsoever*. Without any disclosure in the proposed rule of what legal authority EPA was purporting to rely upon, commenters on the treaty rights portions of the proposed rule were left to guess, and comment accordingly. Although it was not referenced in the proposed rule, some commenters were aware of the Maine Treaty Rights Letter from the Solicitor General and EPA's reliance on that letter in its disapproval of Maine's Water Quality Standards. However, as explained above, the treaty rights interpretation set out by EPA in the final rule is a completely new analysis, not contained in the proposed rule, and not set forth in the

[75] Notably, EPA is deferring action on WAC 173-201A-510(4)(a)(i), Washington's newly adopted compliance schedule for aquatic life uses, stating that it must first complete an Endangered Species Act consultation.

Solicitor General's letter. Not only was EPA's invention of a new "treaty-reserved subsistence fishing right" in the final rule not put forth in the proposed rule, the word "subsistence" barely even appeared in the proposed rule. Similarly, EPA's new reliance in the final rule on CWA § 511 as providing it with the authority to interpret a tribal treaty right and engraft that right onto the Clean Water Act was not put forth in the proposed rule – CWA § 511 was never mentioned in the proposed rule.

Federal agencies must conduct rulemaking in accordance with the Administrative Procedures Act, which requires public notice of a rule and a meaningful opportunity for public comment on those changes. 5 U.S.C. § 553(b), (c). The notice of proposed rulemaking must include a "reference to the legal authority under which the rule is proposed." 5 U.S.C. § 553(b)(2). Such reference "must be sufficiently precise to appraise interested persons of the agency's legal authority to issue the proposed rule." *Louisiana Forestry Association, Inc. v. Solis*, 889 F. Supp. 2d 711, 732 (E.D. Pa. 2012) (citing Attorney General's Manual on the Administrative Procedure Act 29 (1947)). The required specification of legal authority must also be done "with *particularity*." *Global Van Lines, Inc. v. I.C.C.*, 714 F.2d 1290, 1298 (5th Cir. 1983) (emphasis in original). Because legal authority for EPA's treaty rights statements did not appear in the proposed rule, and because the legal theory put forth its final rule had never previously been disclosed, affected stakeholders were given no opportunity in the rule-making process to present legal analysis challenging that theory. EPA's Final Rule therefore violated the APA.[76]

D. Just as with Trust Responsibilities to the Tribes, Compliance with the CWA is Sufficient to Meet Tribal Treaty Rights

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

> There is a "distinctive obligation of trust incumbent upon the Government in its dealings with [Indian tribes]." *Gros Ventre Tribe v. United States*, 469 F.3d 801, 810 (9th Cir. 2006) (quoting *United States v. Mitchell*, 463 U.S. 206, 225 (1983)). However, "[w]ithout an unambiguous provision by Congress that clearly outlines a federal trust responsibility, courts must appreciate that whatever fiduciary obligation otherwise exists, it is a limited one only." *Shoshone-Bannock Tribes v. Reno*, 56 F.3d 1476, 1482 (D.C. Cir. 1995). While that general trust relationship allows the federal government to consider and act in the tribes' interests in taking

[76] EPA's newly discovered "treaty reserved subsistence fishing right" and its reliance on CWA § 511 also "raise novel legal or policy issues arising out of legal mandates" and thus render the Final Rule a significant regulatory action requiring full OMB review. *See infra*, at 63.

> 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.[77]

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

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

E. Executive Orders and EPA Policies Regarding Consultation and Coordination with Tribes Do Not Support EPA's Final Rule

EPA repeatedly refers in both the proposed and Final Rule to its consultation with Indian tribes as justification for the selection of an unsuppressed FCR of 175 g/day and a cancer risk level of 10^{-6}.[78] In fact, EPA admits that it had insufficient evidence of unsuppressed FCR for the

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

[78] *See* EPA Proposed Rule, 80 Fed. Reg. 55,066 (§ 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. 55,067 (§ 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. 55,068 (§ IV.C.b) ("EPA considers 10^{-6} to be sufficiently protective, and the tribes have supported this during consultation"); 80 Fed. Reg. at 55,074 (§ VI.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}. . . ."). *See also* n.64, at 5

tribes, and lacking such data, allowed the tribes to dictate both the FCR and the cancer risk level.[79] EPA thus relies on its obligation to consult and coordinate with Indian tribes—and the tribes' preferences as to the FCR 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.[80] *See* EPA Policy for the Administration of Environmental Programs on Indian Reservations" Memorandum on Government-to-Government Relations with Native American Tribal Governments, 59 Fed. Reg. 22,951 (Apr. 29, 1994) ("1994 Presidential Memorandum"). This Presidential Memorandum was followed by Executive Order 13084 "Consultation and Coordination with Indian Tribal Governments", 63 Fed. Reg. 27655 (May 14, 1998) (references tribal treaty rights in introduction and §§ 2, 5), which was replaced two years later with Executive Order 13175 "Consultation and Coordination with Indian Tribal Governments", 65 Fed. Reg. 67349 (Nov. 6, 2000) (references tribal treaty rights in §§ 2(a), 2(b), 3(a), 5(d)).

In 2009 President Obama issued a Presidential Memorandum on Tribal Consultation, 74 Fed. Reg. 57881 (Nov. 5, 2009) ("2009 Presidential Memorandum"); directing that all executive departments and agencies 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.[81]

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

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("[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). *See* EPA Final Rule, 81 Fed. Reg.t 85,426 (§ 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. 85,426 (§ III.C.a) ("The Washington tribes have generally agreed that 175 g/day is acceptable for deriving protective criteria at this time. . . ."); 81 Fed. Reg. 85,427 (§ III.C.b) ("Throughout tribal consultation, the tribes generally supported 175 g/day as an acceptable FCR . . . when accompanied by other protective input paramaters. . ."); 81 Fed Reg. 85,435 (§ 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}. . . .").

[79] *Id.*

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

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

any right, benefit, or trust responsibility, substantive or procedural, enforceable at law by a party against the United States, its agencies, or any person." 1994 Presidential Memorandum; Exec. Order No. 13084 § 7; Exec. Order No. 13175 § 10; 2009 Presidential Memorandum. They are "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; "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. Presidential executive orders cannot impose legal requirements on the executive branch that are inconsistent with a statute—such as the CWA—duly enacted by Congress. *United States v. Rhode Island Dep't of Corr.*, 81 F. Supp. 3d 182, 188 (D.R.I. 2015) (*citing Chamber of Commerce of U.S. v. Reich*, 74 F.3d 1322, 1332-34 (D.C. Cir. 1996)); *Utah Ass'n of Counties v. Bush*, 316 F. Supp. 2d 1172, 1184 (D. Utah 2004).

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

Executive orders, presidential memoranda and EPA policies simply do not allow tribes to dictate the appropriate cancer risk level and FCR. EPA has been clear in its proposed and final rules that it has allowed the tribes to do exactly that. The tribes "repeatedly asked" and "consistently emphasized" that the HHC "should be derived" using at least a minimum FCR of 175 g/day and a cancer risk level of 10^{-6}, "which the tribes have generally viewed as a compromise minimum value in tribal consultation."[82] Under the CWA EPA must base WQS on sound scientific rationale—not on what the tribes express as their preference during the consultation process. Choosing to use a FCR of 175 g/day and a cancer risk level of 10^{-6} because

[82] *See* n.78.

the tribes "consistently emphasized" in meetings that EPA "should" do so violates the CWA and its implementing regulations.

F. There is no Basis in EPA Policy for the Risk Policy used by EPA in the Final Rule

In its rulemaking, EPA misrepresented the Washington risk policy as setting a risk level for human health criteria applicable to all consumers at a level of one in one million. Prior to August 1, 2016, under WAC 173-201A-240(5) Ecology applied the one in one million (or 1×10^{-6}) risk level to the per capita consumption rate of the general population and not to more highly exposed subpopulations. EPA established this as a matter of law in *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995).[83]

EPA fails to acknowledge or disclose that Ecology has interpreted and publicly stated that its risk policy for human health criteria in the state Water Quality Standards, WAC 173-201A-240(6), is intended to apply to the per capita consumption rate of the general population.[84] EPA also misrepresents that EPA and not Washington set the risk level for application of the NTR in Washington. Through the NTR process, EPA offered states the option of human health criteria calculated based on either a 10^{-6} or 10^{-5} risk level for the general population. Washington opted to use a 10^{-6} risk level.[85] In the context of the NTR, however, this risk level is applicable to the per capita consumption rate of the general population on the assumption that NTR criteria are protective of higher consuming subpopulations at a 10^{-4} risk level, and is consistent with long-standing EPA policy.

EPA and Washington have never assumed that the 10^{-6} risk policy set forth in WAC 173-201A-240(6) would apply to all consumers of fish. Otherwise, Washington would not have adopted, nor would EPA have approved, coverage under the NTR where the criteria are based on a range of acceptable risk levels from 10^{-6} to 10^{-4}.[86] EPA described this in its brief in the *Dioxin* case as a choice "to provide a high level of protection for the average population in order to provide what they [Washington and other states] deem adequate protection for more sensitive populations."[87]

The scope and intent of the 10^{-6} risk policy in WAC 173-201A-240(6) was a central issue in a challenge to a dioxin water quality improvement plan or Total Maximum Daily Load ("TMDL") allocation developed by EPA for the Columbia River. The dioxin TMDL was based on the same assumptions for the dioxin criterion in the NTR, including a FCR of 6.5 g/day. The TMDL was challenged in federal court on the basis of evidence that actual FCRs on the

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

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

[85] NTR, 57 Fed. Reg. 60,848-01, 60868 (00768-847); 40 C.F.R. §131.36(b)(14)(iii)(00848-0860).

[86] WAC 173-201A-240(6). EPA's "policy in the NTR [is] to select the risk level that reflect[s] the policies or preferences of CWA programs in the affected States." 65 Fed. Reg. 31,682, 31,699 (May 18, 2000)(00861-0898).

[87] *See* n.83. EPA, Brief for the Defendant-Appellees.

Columbia River for recreational fishers and Tribes was as high as 150 grams per day. The challengers contended that EPA should have applied WAC 173-201A-240(6) to derive a water quality criterion for dioxin that would protect all fish consumers to a level of 10^{-6} based on the higher FCR. In *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995), the court concluded that Washington did not intend to mandate a 10^{-6} risk level for every fish consumer. The Ninth Circuit held that "the one-in-a-million risk level mandated by the state water quality standards for the general population does not necessarily reflect state legislative intent to provide the highest level of protection for *all* subpopulations but could reasonably be construed to allow for lower yet adequate protection of specific subpopulations." 57 F.3d at 1524 (emphasis in original).[88]

In *Dioxin/Organochlorine Center*, EPA successfully argued that the mere fact that actual fish consumption in Washington is greater than the FCR in the TMDL (the same as the NTR) does not mean that the national criteria violate the state risk policy to protect human health under WAC 173-201A-240(6). EPA argued that the FCR and risk levels in the federal criteria are based on consumption of maximally contaminated fish, and are not intended to reflect actual consumption rates.[89] EPA also argued that the 6.5 grams per day fish consumption rate was not intended to accurately represent total consumption of fish, but instead the ingestion rate of a given contaminant.[90] According to EPA, the fish consumption rate used in the NTR was "intended to represent only a subset of total fish consumption."[91] The FCR is the assumed amount of "maximum residue fish" consumed.[92] EPA further asserted that consuming anadromous fish, like salmon, is unlikely to cause ingestion of contaminants at a rate equal to consuming maximum residue fish.[93] EPA explained: "[T]he <u>total</u> fish consumption rate of various individuals is not determinative; the central question is whether the actual rate of ingestion [of a contaminant] is greater than that assumed by EPA."[94]

To understand Washington's prior risk policy, one must take into consideration the timing and sequence of the state's adoption of its risk policy and when the state was formally subject to the NTR. The risk policy, WAC 173-201A-240(5), was promulgated as a state regulation in October 1992.[95] The promulgation of the regulation referencing the NTR was included with revisions to the state Water Quality Standards, WAC 173-201A-240(6), five years

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

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

[90] *See* n.83. EPA, Brief for the Defendant-Appellees.

[91] *See* n.83. EPA, Brief for the Defendant-Appellees at 44 (00954).

[92] *Id.*

[93] 16 F.3d at 1403; *see also* n.23. EPA, Brief for the Defendant-Appellees at 44 (00954).

[94] *See* n.83. EPA, Brief for the Defendant-Appellees at 45 (00955); EPA's water quality criteria guidance includes a margin of safety for water consumption. 65 Fed. Reg. 31,682, 31693 (May 18, 2000) (00861-0898).

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

later in November 1997.[96] In addition to the fact that the NTR does not extend the 10^{-6} risk level to all consumers, there is the intervening ruling in *Dioxin/Organochlorine Center* that the state policy does not reflect any intent to protect high consumers to the 10^{-6} risk level. A basic rule of statutory construction provides that the failure to amend an act following a judicial construction indicates approval of the construction.[97] Thus, if Ecology believed that the risk policy was intended to more broadly apply in Washington it would have amended the regulation prior to incorporating a reference to the NTR in the state Water Quality Standards. [98]

The EPA final rule is based on a misrepresentation that state risk policy requires all consumers to be protected to a risk level of 10^{-6}. EPA ignored the chemical specific risk level and accompanying risk management decision made for the state PCB criteria. EPA improperly replaced and usurped a state risk management decision.

G. EPA Mispresents its Policy and Guidance on Risk Factors used to Derive Human Health Water Quality Criteria

In its draft and final rule the EPA misrepresented its guidance and supporting science for deriving human health water quality criteria. EPA failed 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}. [99] The 2000 Human Health Methodology is clear that EPA deems both 10^{-6} and 10^{-5} risk levels as acceptable for the general population, [100] 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."[101] "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."[102]

EPA 304(a) Guidance addresses the need to consider carefully the impact of criteria on sensitive and subsistence populations. This guidance is reflected in the preference for local data

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

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

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

[99] *See* n.1. NTR at 60,855.

[100] EPA asked states covered by the NTR to tell EPA if they preferred the human health criteria for the state be applied at a risk level of 10^{-5}. *See* n.25. NTR at 60,864. In general, the NTR established AWQC for states based on a 10^{-6} risk level. *Id*. at 60,860. 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*.

[101] *See* n.1. NTR at 60,855; *see also* 65 FR 31,682, 31,699 (May 18, 2000) (00861-0898).

[102] *See* n.3, EPA, 2000 Methodology for Human Health, at 1-12 (00074-0258); *see also* n.1, NTR at 60,848, 60,863 (describing 10^{-5} level as "adequately protective").

over EPA default values for fish consumption rates.[103] That does not mean, however, that a 10^{-6} risk level becomes a baseline for all population exposures. The EPA guidance directs that more specific information on consumption rates should be used to ensure that the criteria are within the protective range of EPA risk policy guidance:

> EPA understands that fish consumption rates vary considerably, especially among subsistence populations, and it is such great variation among these population groups that may make either 10^{-6} or 10^{-5} protective of those groups at a 10^{-4} risk level. Therefore, depending on the consumption patterns in a given State or Tribal jurisdiction, a 10^{-6} or 10^{-5} risk level could be appropriate. In cases where fish consumption among highly exposed population groups is of a magnitude that a 10^{-4} risk level would be exceeded, a more protective risk level should be chosen.[104]

As seen in the above quoted passage from the 2000 Human Health Methodology, consumption patterns among subsistence populations and within a given tribal jurisdiction were considered in the methodology, despite EPA's assertions to the contrary.

Moreover, EPA has updated and amended this guidance numerous times since its publication in 2002 as documented on the EPA web site.[105] 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.[106]

H. EPA Misrepresented Scientific Research in its Draft Rule

The EPA Final Rule failed to acknowledge that its rationale for the proposed Washington human health criteria based on the claim that "EPA often uses 10^{-6} as a *de minimis* risk level" misrepresents what EPA has long considered *de minimis* in deriving risk based criteria. EPA, across its environmental programs, the FDA and other federal agencies have consistently deemed 10^{-4} as a *de minimis* risk level when applied to a highly exposed subpopulation. EPA has provided no explanation or justification why this long-standing national consensus is no longer applicable as a matter of science and public health to deriving water quality standards in Washington.

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

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[103] *See* n.3, EPA 2000 Methodology for Human Health , at 1-12, 4-25.

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

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

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

and a level of risk that is acceptable and insignificant for setting human health standards, including water quality standards.

In support of its rationale EPA cited one scientific study in the proposed rule 80 Fed. Reg. 55,068 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 EPA's implication that EPA considers a 10^{-6} risk level to be a bright line standard for *de minimis* risk. The authors in fact state, "As a point of comparison, The U.S. EPA has defined 1 in 1,000,000 excess cancer risk as a *de minimis* risk level for cancer (Caldwell et al. 1998; Clean Air Act Amendments 1990; Fiori and Meyeroff, 2002; U.S. EPA 1991), **although regulatory actions are sometimes limited to instances where risk exceeds 1 in 100,000**." (Emphasis added.)

"Fiori and Meyeroff, 2002[107]," 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).[108]

The "EPA 1991" references in both articles are the same, the draft NTR.[109] 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.[110] Consistent with this guidance, EPA elected to use a "relatively stringent" cancer risk level of 10^{-6} as applied to the general population and deemed that protective of "subsistence fishermen" who are more exposed than the general population.[111] 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."[112]

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

[108] *Id.* at 210.

[109] 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. 58,420 (Nov. 19, 1991) (06471-6529).

[110] *Id.* at 58,434.

[111] *Id.* at 58,435.

[112] *Id.*

EPA 304(a) 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.[113]

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

The EPA Final Rule additionally fails to acknowledge that the federal government has repeatedly deemed a 10^{-4} risk level to result in a *de minimis* risk when applied to more exposed subpopulations in deriving human health criteria under the CWA. EPA likewise failed to acknowledge that across EPA and FDA programs exposures at the level of risk between 10^{-6} and 10^{-4} are deemed acceptable because they represent an insignificant and essentially zero increased risk of cancer.[115]

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[113] *See* n.3, EPA, 2000 Human Health Methodology at 2-7 (00113).

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

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

"*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."[116] EPA appears to be reversing decades of scientific research and sound public policy by implying that highly exposed populations will not be as well protected if their exposure risk is at a risk level of 10^{-4}. On the contrary, it has been well understood prior to today that "if only a small population would be at greatest risk, the expected number of excess cancers corresponding to individual risks at the *de minimis* level of 10^{-4} would still be zero."[117] 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}.[118] 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.[119] A survey of these decisions concluded that "for small-population effects, regulatory action was never taken for individual risk levels below 10^{-4}.[120]

The national policy on acceptable risk is based on an extended scientific evaluation and has withstood legal challenges.[121] 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}.[122] 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."[123]

A long line of EPA decisions affirm the existing risk policy in human health criteria approvals for states on the Great Lakes[124], the California Toxic Rule, 40 C.F.R. § 131.38, and the state of Oregon human health criteria. The 2011 Technical Support Document for the Oregon criteria unequivocally states:

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

[117] 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).

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

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

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

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

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

[123] *See* n.3, EPA, 2000 Human Health Methodology at 2-6 (00112); *see also* Attachment A at 13-14.

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

> EPA has identified a risk level range of 1 x 10^{-6} (1:1,000,000) to 1 x 10^{-5} (1:100,000) to be an acceptable risk management goal for the general population….
>
> EPA's 2000 Methodology states that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sport fishers or subsistence fishers) does not exceed the 10^{-4} risk policy.[125]

Under the EPA risk policy, compared to the current state risk policy, the general population consumption rate results in criteria that will be protective to a level more stringent than 10^{-7}. The 100th percentile of tribal consumption will be protected to 10^{-5}. Ecology concluded that the mean consumption rate for the general population in Washington is 18.8 g/day including all fish.[126] 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 304(a) Guidance would be fully protective of tribal consumption without this dramatic change in risk policy. If EPA used 17.5 g/day as the consumption rate for the general population in Washington, at a risk level of 10^{-6}, the resulting criteria would be protective to a consumption rate of 175 g/day at a 10^{-5} risk level and for a consumption rate of 1,750 g/day at a risk of 10^{-4}. The Washington Office of Financial Management estimates that there are 104,000 American Indian and Alaska natives in Washington.[127] If EPA followed established guidance and science and applied a 10^{-6} risk level to the general population the resulting exposures at risk levels of 10^{-5} and 10^{-4} would not predict a single excess cancer risk for this population—a result that is more stringent than EPA guidance which calls for no excess cancer risk at the median consumption rate for high consuming populations at 10^{-4}.

ARCADIS, Summary of Health Risk Assessment Decisions in Environmental Regulations (March 6, 2015), Attachment A, explains in detail why tribal consumers would have the equivalent of a zero-increased risk of cancer if EPA complied with its own guidance in setting criteria based on the general population consumption rate. The risk of cancer from all causes far outweighs the possible risk of cancer from exposure to chemicals in the environment. *Id.* at 2. To add some meaning to these risks, the excess cancer risk that may occur as a result of exposure to a carcinogen in the environment in Washington on an annual basis is 0.54% while the lifetime risk of cancer based on a risk level of 10^{-4} used to set water quality criteria is

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

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

[127] *Id.* at 18.

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 9-21. It is inexplicable why EPA is proposing to ignore and in some sense misrepresent the best available science and policy in risk management.

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

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

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

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

Before today EPA has never wavered on the risk management guidance that evolved prior to and since the adoption of the NTR in 1992. In June 2015 EPA published final updated ambient water quality criteria for the protection of public health in accordance with section 304(a)(1) of the Clean Water Act.[128] 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 Methodology. [129] 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."[130]

There is no basis for the 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. 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.

I. THE EPA FINAL RULE IS NOT CONSISTENT WITH THE EPA ENVIRONMENTAL JUSTICE GUIDANCE

The EPA final rule is inconsistent with the EPA guidance on environmental justice EPA guidance on environmental justice, including consideration of tribal consumption rates, in fact supports the human health criteria submitted by Washington to EPA.

In May 2015 EPA published formal guidance on considering environmental justice in agency actions, including rulemaking.[131] 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 the agency will determine whether there is a disproportionate impact from an agency action:

> It is important to note that the role of the analyst is to assess and present differences in anticipated impacts across population groups of concern to the

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

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

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

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

> 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.[132]

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

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

> Commentators argued that a 15 gram per day assumption in the methodology would not adequately protect populations that consume greater than this amount (e.g. low-income minority anglers and Native Americans). And that such an approach therefore would be inconsistent with Executive Order 12898 regarding environmental justice (February 16, 1994, 59 Fed. Reg. 7629). **EPA believes that the human health criteria methodology, including the fish consumption rate, will provide adequate health protection for the public, including more highly exposed sub-populations.** In carrying out our regulatory actions under a variety of statutory authorities, including the CWA, EPA has generally viewed an upper bound incremental cancer risk in the range of 10^{-4} to 10^{-6} as adequately protective of public health. As discussed above, the human health criteria methodology is based on a risk level of 10^{-5}. Therefore, if fish are contaminated at the level permitted by the criteria derived under the final Guidance, individuals eating up to 10 times (i.e., 150 grams per day) the assumed fish consumption rate would still be protected to 10^{-4} risk level.[133]

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.

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

[133] *See* n.124, EPA, Final Water Quality Guidelines for the Great Lakes System at 15 (emphasis added)(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.[134]

There is no question that the 2015 guidance on environmental justice fully reflects the consideration of tribal consumption rates and concerns about the EPA trust and treaty obligations. EPA failed to explain how it is possible for its 304(a) Guidance on risk levels to be consistent with environmental justice but not consistent with a newly invented interpretation of tribal treaty rights.

J. EPA Used a Fish Consumption Rate that is Not Supported by Available Technical Information

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

EPA is required under the EPA-approved state risk policy to use a fish consumption rate that is less than 19 g/day. Ecology documented 18.8 g/day as the average consumption rate for consumers only for the general population in Washington.[135] Ecology has not provided a consumption rate that reflects both consumers and non-consumers but it must be substantially

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

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

lower than 18.8 g/day given that Ecology estimated that between 25% and 70% of the general population in the state of Washington do not eat fish.[136]

The FCR used by EPA in the rule exceeds that used by any state to derive human health criteria, with the exception of the Oregon human health criteria adopted in 2012.[137] EPA guidance recommends for exposure to carcinogens that states use an FCR that protects the 90th percentile consumption of the general population while ensuring that subsistence fishers are protected at their average intake rate. EPA guidance recommends a default fish intake rate of 17.5 grams a day to protect the general population.[138] 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."[139]

The rationale for this guidance is to ensure that human health criteria are protective within a broad range of consumption rates in a state from the general population at the 90th to the 99th percentile rates of consumption. EPA guidance describes the use of the general population consumption of 17.5 grams a day at the 90th percentile as a baseline to ensure protection of the 99th percentile of the general population and average consumption rate for more exposed populations including subsistence fishers.[140] 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."[141] The fish consumption rate of 175 grams a day used by Ecology is ten times the 90th percentile consumption rate established by EPA guidance for the general population. 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 FCR for its criteria using the same consumption studies relied on by EPA in the final rule 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

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[136] *See* n.5. Ecology, Fish Consumption Rate Technical Support Document Version 2.0.

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

[138] *See* n.5. Ecology, Overview at 15 (00021).

[139] *See* n.3. EPA, 2000 Human Health Methodology at 4-27 (00186).

[140] *See* n.1064. 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).

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

the rates documented in the Puget Sound studies (to protect at least 90% of fish consumers in Oregon).[142]

The following table from an Ecology technical support document developed for the state rulemaking summarizes the consumption rates from Tribal studies. The 175 grams per day FCR used by EPA exceeds the median (50th percentile) for all Tribes and the 90th percentile for all Tribes with the exception of the Tulalips, 206 g/day, and the Suquamish, 489 g/day. The Suquamish consumption rate shown in this table is heavily influenced by high consumption rates reported by a few individuals. In other studies, such as the Tulalip study, similar high rates were excluded from the analysis as "outliers."[143] 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."[144]

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

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

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

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.[145] This analysis calculated the median Tribal consumption rate to be 127.2 g/day for all fish.[146]

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

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

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

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

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

ARCADIS also developed a composite distribution of Washington Tribal consumption rates based on the TSD data.[147] That distribution calculates the median 90th and 95th percentiles for Tribal consumption rates to be 55.05, 137.77 and 178.69 grams per day.[148]

The Clean Water Act and EPA regulations require human health water quality criteria to protect exposures that may result from pollutants in state waters. EPA guidance accordingly does not require human health criteria to regulate pollutant levels in marine fish that do not accumulate pollutants in waters of the United States within the jurisdiction of a state. The default value of 17.5 grams a day in EPA guidance thus reflects freshwater/estuarine fish and shellfish only.[149] The range of consumption rates in the 2000 EPA guidance similarly do not include marine fish.[150]

Salmon, as a marine species, should accordingly be excluded from the consumption rate used to derive Washington's criteria. The data on fish tissue samples from salmon in Puget Sound indicates that the predominant fraction of PCBs detected is accumulated while the fish are in the ocean-phase of their life cycle.[151] Including all salmon in the FCR is not likely to benefit public health for contaminants that are accumulated in marine waters beyond the jurisdiction of the state.[152] 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.[153]

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.[154] The ARCADIS analysis independently calculated the "non-salmon" median consumption rate for Washington Tribes at 29.73 g/day.[155] Even if consumption rates are

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

[148] *Id.*

[149] *See* n.3. EPA, 2000 Human Health Methodology at 4-25 (EPA default fish consumption rates represent the ingestion of "freshwater and estuarine fish")(00184).

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

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

[152] *Id.*

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

[154] *See* n.145. Polissar and Hippe, Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes at 2 (00633).

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

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.[156] The ARCADIS analysis calculated a Washington tribal consumption rate with apportioned salmon at a median rate of consumption to be 37.78 g/day and of 122.63 g/day at the 95th percentile.[157]

EPA improperly bases its criteria on what are alleged to be "suppressed" fish consumption rates for northwest tribal members. 80 Fed. Reg. 55,068. It is impossible to comment on this basis for the rule as EPA does not cite to a single study, document or statistic of any kind to support its contention other than "consultation with Washington tribes and Columbia River basin tribes." *Id.* Reliance on meetings that are closed to the public and on propositions for which there is no documentation or scientific analysis is a facial violation of CWA and APA requirements to provide a scientific basis for proposed standards and an opportunity for public participation.

The only regulatory authority cited in this section of the Federal Register notice for the draft rule is a cross-reference to section II.B.c in the same notice that includes a representation that EPA "generally" recommends "selecting a FCR that reflects consumption that is not suppressed by fish availability or concerns about the safety of available fish." 80 Fed. Reg. 55,065. The sole authority for this proposition is a "Frequently Asked Questions" document that EPA posted online in January 2013. *See* 80 Fed. Reg. 55,065, n. 15. EPA has conceded that this posting was done improperly and previously assured state regulators that the document would be withdrawn.[158] EPA has also conceded that it is not sure how suppression should be factored into criteria.[159]

It is difficult to fathom how EPA "generally" recommends consideration for suppressed consumption rates when until December 2016 there was no guidance on how EPA and the states are supposed to factor this into developing water quality criteria.[160] EPA has long advised states to use data to develop criteria (with a preference for local or regional data over national data).[161] EPA is now asserting that it is permissible for it to consider unknown impacts on consumption rates for which there is no data.

EPA does not reference any evidence to support its 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 rule docket posted by EPA to support such a contention. EPA

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[156] *See* n.145. Polissar and Hippe, Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes at 2 (00633).

[157] *See* n.155.

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

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

[160] *See* n.64. EPA, Comment on Ecology Draft Rule.

[161] *See* n.3. EPA, 2000 Human Health Methodology at 2-2 (00108).

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.[162]

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

Even if it was appropriate to factor availability of fish in consideration of consumption rates, EPA has failed to cite to any evidence that there is a lack of availability of fish that would drive suppression. There is no documentation for example that tribal members lack access to fish. On the contrary, the tribal consumption studies document that at most two individual tribal members eat as much as 1600 g/day of fish.[163] This is nearly twice the historic rate of consumption used in deriving the Spokane Tribe of Indians human health criteria.[164]

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.[165] By 2012, the Columbia River Inter-Tribal Fish Commission was claiming that the 95th percentile of tribal members were consuming 175 g/day.[166] 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 FCR 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.[167] This indicates that consumption rates used in setting criteria are

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

[163] *See* n.64. EPA, Comment on Ecology Draft Rule; *see also* n.104. Polissar and Hippe, Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes.

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

[165] *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.").

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

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

adjusting with increasing consumption rates. This is illustrated in the following figure from the Idaho negotiated rulemaking process:[168]

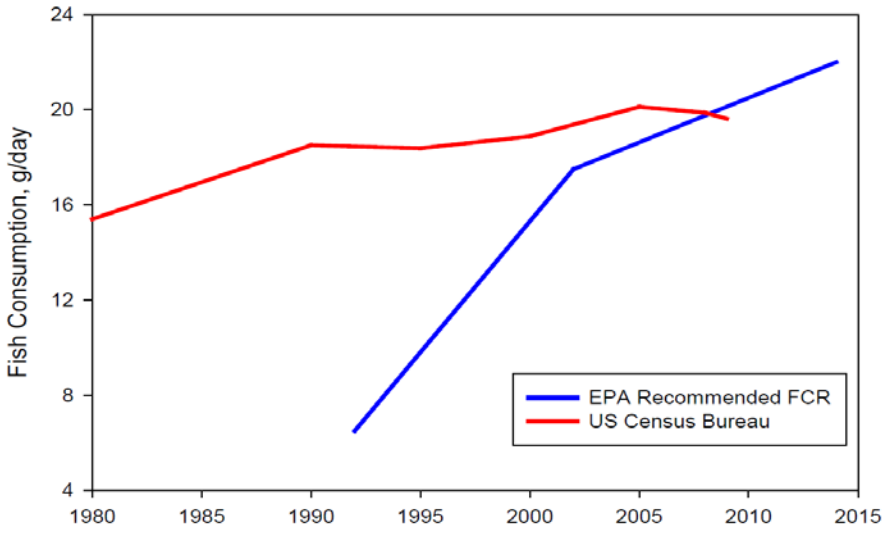

Figure 4. Per capita consumption of fish in the United States and EPA-recommended fish consumption rate (FCR), 1980–2014.

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

K. Compliance with Downstream Water Quality Standards is not a Basis for the Proposed Rule

EPA has improperly relied on the need to protect downstream water quality standards as a basis for its demands that the state of Washington use a high tribal consumption rate and 10^{-6} risk policy. This was declared by Mr. McLerran in his meeting with Mr. Opalski and the regulated community in April 2013.[169] It was echoed by EPA staff at meetings with state officials.[170] 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).[171] EPA repeats these post-hoc rationalizations in the Federal Register notice.

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[168] *See* n.162. Idaho Department of Environmental Quality, Considerations in Deciding Which Fish to Include in Idaho's Fish Consumption Rate: Policy Summary at 7.

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

[170] *See* n.63. C. Niemi, Handwritten Notes and A. Chung, Pers. Communication, NWPPA Annual Meeting (June 6, 2013).

[171] *See* n.62. D. McLerran, Letter.

80 Fed. Reg. at 55068 ("Use of [175 g/day] should thus help provide for the attainment of and maintenance of downstream WQS in Oregon.")

EPA regulations, 40 C.F.R. § 131.10(b), do not require upstream states to adopt the same water quality standards as downstream states. EPA issued a Frequently Asked Questions document in June 2014 that allows the state to comply with this provision in EPA regulations by adopting a narrative provision in its water quality standards that discharges from the state will not cause or contribute to a violation of applicable downstream state water quality standards.[172] 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).

Ecology considered and applied the Oregon human health criteria in NPDES permits recently issued on the Columbia River.[173] 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.[174] Ecology has made the same consideration of the downstream Spokane Tribe of Indians criteria in developing a PCB TMDL on the Spokane River.[175] 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.[176] 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

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

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

[174] *See* n.172. EPA, Protection of Downstream Waters FAQ.

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

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

> standards of downstream waters." 40 C.F.R. §131.10(b). **The regulations do not compel states to adopt the same criteria and uses, nor do they suggest that this is the only way a state can meet these requirements. The water quality program is structured to provide states with flexibility to determine the best way to meet their obligations under § 131.10(b).**

(Emphasis added.)[177]

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.[178]

EPA Region 10 has advised Washington and Idaho to consider EPA decisions on other state water quality standards in the state risk management decisions.[179] EPA should do the same with respect to its 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.

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[177] *Id.* at 4.

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

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

L. The Relative Source Contribution value used by EPA is arbitrary and capricious

The Relative Source Contribution ("RSC") is a factor in the derivation of criteria representing the portion of exposure to a contaminant that is attributable to sources regulated by the CWA.[180] It is arbitrary and capricious for EPA to use a RSC factor of less than 1.0 in deriving human health criteria where EPA is simultaneously using a fish consumption rate that includes all fish whether or not that fish is purchased from a store or a marine fish that does not accumulate pollutants in waters regulated by the state's water quality standards. By using an FCR 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**.[181]

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."[182]

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

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[180] *See* n.5. Ecology, Overview at 21 (00027).

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

[182] *See* n.3. EPA, 2000 Human Health Methodology at 1-11 (00103). *See* D. Essig, Email to C. Niemi (September 6, 2012)(06685-6688).

to a lower or fractional RSC.[183] EPA Region 10 has urged Northwest states to consider EPA action on water quality standards for other states.[184] EPA Region 10 has further endorsed the Oregon approach as "the right outcome."[185]

This endorsement is also set forth in a letter dated September 5, 2014, from EPA to the state of Idaho.[186] 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."[187] 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.[188]

There is significant difference between risk assessment in other programs such as the Safe Drinking Water Act and Superfund Cleanup Program.[189] The SDWA uses an RSC of 20% and 80% of exposure but does so in terms of goals, not water quality criteria.[190] The SDWA is using this range of RSC for establishing Maximum Contaminant Level Goals that are not by definition regulatory limits.[191] 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 failed to 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 an RSC value of less than 1.0.

EPA acknowledged in its final rule that the RSC values in its proposed rule effectively double counted the fish consumption by using a RSC values less than 1.0. Instead of correcting this error, EPA improperly cited entirely new data and previously undisclosed analysis to adjust the RSC values in its final rule.

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

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

[185] *See* n.51. C. Niemi, Handwritten Notes. ("Dennis thinks the Oregon outcome is the right outcome.")

[186] *See* n.184.

[187] *Id.* at 2.

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

[189] *See* n.5. Ecology, Overview at 22.

[190] *Id.*

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

M. The PCB Criteria Adopted by the EPA are Not Based on Substantial Evidence and are Arbitrary and Capricious

EPA failed in its final rule to explain how it has resolved technical issues associated with deriving human health water quality criteria for PCBs and how EPA reconciles the technical difficulties that it has acknowledged in revising PCB standards under the Toxics Substance Control Act ("TSCA"). EPA also failed to justify overly stringent water quality criteria for PCBs while simultaneously authorizing 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 the Department of Ecology, wrote:

> Revising current regulations to reduce inadvertently generated PCBs presents both policy and scientific challenges. Before proposing more stringent regulations on the inadvertent generation of PCBs in pigments, the EPA would seek to further understand the complexities and contributions of not only pigments, but also other congeners that be present [in receiving water]….
>
> …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 does not have the ability to revise the PCB NTR criteria applicable to Washington. EPA affirmed as recently as August 3, 2015, that revising PCB regulations "presents both policy and scientific challenges."[194]

EPA should withdraw the final PCB criteria as the uncertainties described above have not been addressed or resolved in the final rule. 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

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[192] *See* n.129. EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update at 2.

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

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

quality criteria and then propose revised criteria for Washington that will be potentially devastating to Washington industries, local governments and continued hatchery operations.

EPA cannot justify the final criteria in light of the ongoing release of PCBs into the environment through its TSCA regulations. The TSCA regulations allow PCB concentrations up to 50 ppm in manufactured products. 40 C.F.R. §§ 761.3 and 761.20. This amounts to the equivalent of 50 million pg/L allowed under TSCA compared to the EPA proposed PCB water quality criteria in Washington at 7.3 pg/L. EPA has offered no explanation as to why 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.[195]

EPA established PCB criteria that will be impossible to meet in many circumstances due to the ongoing release of PCBs that EPA authorizes as adequately protective under TSCA. A recent study in Washington documented the ubiquitous presence of low PCB levels in manufactured products including paints, used motor oil, road striping, dust suppressants, antifreeze, hydro-seed materials, packaging, toothpaste, hand soap, laundry soap and shampoo.[196]

N. The proposed Methylmercury Criterion is Arbitrary and Capricious and Not Supported by Substantial Evidence

EPA should have deferred action on a methylmercury criterion (MeHg) for the state of Washington. EPA adopted 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.[197] EPA acknowledged unresolved technical issues and delayed action on updating this value in the 2015 recommended updated human health water quality criteria.[198] EPA failed to acknowledge the 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. [199] 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.

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[195] *See* n.1. NTR at 60848-01, 60868.

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

[197] *See* n.5. Ecology, Overview at 50 (00056).

[198] *See* n.128. EPA, Final Updated Ambient Water Quality Criteria for the Protection of Public Health and *see* n.84. EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update.

[199] *See* n.5. Ecology, Overview at 49 (00055).

Ecology has previously identified to EPA the numerous technical difficulties it will have in implementing the EPA tissue based criterion.[200] 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.[201]

Ecology has explained to EPA that the EPA guidance on implementing the 2001 criterion does not address these outstanding issues.[202] EPA has not responded to these concerns or explained in the final rule how the state and regulated community in Washington can feasibly implement the proposed methylmercury criteria. EPA should accordingly withdraw the MeHg criterion and take no further action on establishing a MeHg criterion for Washington until the recognized technical issues with the outdated 2001 criterion are resolved.

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

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. EPA's FCR 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

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[200] *See* n.5. Ecology Overview at 50

[201] *See* n.5. Ecology Overview.

[202] *Id.*

this value based on a Faroes Island study. [203] Island residents consumed both fish and pilot whales, and subtle effects were observed in some children. In addition to mercury, the pilot whales contained elevated levels of PCBs and other chlorinated, recalcitrant pollutants. These confounders were not appropriately considered in establishing the mercury reference dose. The most comprehensive study on potential health effects of mercury in children is the Seychelles Island study.[204] 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 MeHg fish tissue criterion is well below observed concentrations of mercury in several fish species collected in Washington waters as documented in various studies.[205] For example, the median concentration of mercury in 97 fish samples collected and analyzed in 2004 and 2005 was 0.154 mg/kg (wet weight), five times the proposed MeHg criterion. A study conducted by USGS in Franklin D. Roosevelt Lake and the upper Columbia River basin reported the mean and minimum mercury concentrations in walleye, smallmouth bass, and rainbow trout, all of which were four to five times higher than EPA's proposed criterion.[206] 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.[207] 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 final criterion 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.

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

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

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

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

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

> 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. [208]

EPA failed to evaluate the voluminous information regarding the health benefits of consuming fish. The 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, assuming that they exist at all.

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.[209] Recent reports have explained the mechanisms of this protective effect.[210] When the molecular? or molar? ratio of selenium to mercury in fish tissue exceeds 1.0 in freshwater and marine fish, a protective effect can be assumed.[211] EPA should evaluate the selenium/mercury molecular 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.

O. 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.

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

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

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

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

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.

EPA has failed to provide adequate information 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. Absent such information, EPA should withdraw the final rule relying on BAF values.

P. EPA's Economic Impact Analysis Fails to Include an Adequate Assessment of Compliance with the Final PCB Criteria

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

The draft economic impact analysis did not address PCBs on the pretext that there is no water column data in Washington indicating ambient PCB concentrations below the NTR but above the proposed PCB criteria. In section 4.1.2 in the draft economic impact analysis EPA represents that it evaluated discharge monitoring and permit application data and "ambient pollutant concentrations from the Environmental Information Management (EIM) database." In section 5.1 of the draft analysis EPA represents that it evaluated "potential incremental impairment" based on available EIM data. EPA purports in footnote 17 of the document to

exclude all "U" data for non-detected results or results that could not be used but "kept" "J" data where an analyte is positively identified and the reported result is an estimate.

It is inexplicable, given these parameters, how EPA represented in Exhibit 5-1 in the draft economic impact analysis that there is no PCB water column in the EIM database that is either unqualified or J qualified. In fact, there is substantial PCB water column data for Puget Sound and the major tributaries to Puget Sound. This data was collected by or for Ecology relatively recently in 2009 and 2010.[212] This report has been reviewed and that data in the report has been included in the EIM database.[213] 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.[214] This includes PCB water column data for total congeners collected at each of these sites.[215] All of the total congener data is either unqualified or J qualified. This data should have been identified and listed in Exhibit 5-1 in the economic impact analysis.

EPA failed to adequately acknowledge in the final rule 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. See Table 1, *supra*, at XX. Without citing this data the final economic analysis estimates that there would be at least 25 additional water body segments listed as impaired for PCBs in Washington.[216] EPA failed to consider, however, available data documenting that dischargers are potentially going to cause or contribute to a violation of its proposed PCB criteria. EPA appears to have conveniently placed blinders on its review by relying on discharge monitoring data knowing that such data, if collected, is based on an EPA test method with detection levels that are above even the NTR criteria. In doing so EPA ignored data from Ecology on wastewater treatment plants that document levels of PCB concentrations that are well above the proposed PCB criteria. In fact, every wastewater treatment plant sampled by Ecology (which includes two of the specific facilities evaluated by EPA in the economic impact analysis), with the exception of two facilities with reporting levels of 600 pg/L, were well above the proposed criteria.[217] *See* Table 2, *supra at XX*.

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

[213] 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).

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

[215] *Id.*

[216] EPA, Economic Analysis for Water Quality Standards Applicable to the State of Washington (Oct. 21, 2016).

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

The failure of EPA to consider this data is inexcusable where EPA has relied on this information to perform a narrative reasonable potential analysis for three municipalities on the Spokane River.[218]

The economic impact analysis for PCBs should have also considered stormwater. EPA excluded stormwater from the analysis by failing to identify PCB data in Table 5-1. PCB concentrations are present in stormwater monitoring in the City of Spokane and Western Washington.[219] The median concentration for PCBs in Western Washington stormwater is 0.011 µg/L. The analysis should include some assessment of the economic impact of managing stormwater discharges.

EPA should have also addressed the economic impact of proposed PCB criteria on the continued operations of tribal and federal fish hatcheries. EPA should have explained 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. EPA provided no explanation as to how hatcheries can be allowed to continue operations knowing that they are a significant source of PCBs in waters that will be considered impaired for PCBs under the final criteria. EPA is the NPDES permit authority for these facilities and should have fully accounted for the economic impact of its final criteria on their continued operations.

The economic impact analysis should also include an assessment of the impact from potential section 303(d) PCB listings based on fish tissue. The economic impact analysis acknowledges that fish tissue data can be a basis for listing under the Ecology Policy 1-11. EPA offers no explanation as to why it failed to consider PCB fish tissue data that is available in the EIM database. This is particularly relevant as Washington is the only state in EPA Region 10 to use fish tissue data as a basis for 303(d) listings. EPA Region 10 has been adamant with the Ecology that it not revise this policy to remove consideration of fish tissue.[220]

EPA should withdraw the final rule based on the inadequate economic impact analysis and provided additional opportunity for public comment on the revised economic impact analysis.

Q. The Final 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

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

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

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

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. The agency makes the initial determination of what regulatory actions may be significant, but 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).[221]

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.[222]

Here, EPA determined that neither its proposed nor final rules were a "significant regulatory action" under E.O. 12866 and were "therefore, not subject to review under Executive Orders 12866 and 13563." 80 Fed. Reg. 55,073 § VI.A; 81 Fed. Reg. 85,417, 92,466 § V.A. The sole basis given by EPA for this determination was the statement that "the proposed rule does not

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[221] 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).

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

establish any requirements directly applicable to regulated entities or other sources of toxic pollutants." *Id*.

EPA should withdraw the rule on the basis that it was not properly considered a significant regulatory action based on the rule's economic impacts. EPA's focus on the "directly applicable" costs of the Rule is inconsistent with E.O. 12866. E.O. 12866 contains no requirement that 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. This is evident in E.O. 12866's directive that agencies "assess *all* costs and benefits of available regulatory alternatives, including the alternative of not regulating." (Emphasis added).

EPA's determination is also inconsistent with characterization of rules adopting water quality criteria for other states. In December 2016 EPA described as "significant regulatory action" its rule adopting water quality standards for certain waters under the state of Maine's jurisdiction. 81 Fed. Reg. 92,466, 92,486. EPA's standards for these waters involve fewer criteria, lower estimated compliance costs, and fewer affected facilities than Washington's rule. The discrepancy in treatment suggests that rather than actually assessing whether the rule falls within the definition of "significant regulatory action." EPA 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.

Moreover, EPA's characterization of the rule as not establishing "directly applicable" requirements is misleading. There is nothing permissive about a state's obligation under the CWA to ensure its NPDES permits include limitations on discharges necessary to comply with the standards in the final rule. *See, e.g.*, 81 Fed. Reg. 85,417, 85,434 §V.C. EPA acknowledges that NPDES-permitted facilities for which the revised human health criteria are more stringent than applicable aquatic life criteria face new compliance costs. *Id*. at § VI. Far from speculative, EPA identified a subset of point source facilities for which it could reasonably estimate the costs of complying with the final rule. 81 Fed. Reg. 85,417, 85,433 §IV.A. Moreover, Ecology has notified some permittees that it intends to translate the rule's criteria into enforceable NPDES permit limits.

The rule does constitute an economically significant regulatory action requiring economic analyses by OIRA. A cost analysis prepared in 2013 by HDR Engineering estimated the cost of compliance by regulated industries and local governments with Oregon's water quality standards that are consistent with the EPA Final Rule in a range of $5 billion dollars to $11 billion dollars for just the 73 "major" NPDES permits out of 409 NDPES permits administered by Ecology. This does include the 18 general permits administered by Ecology or federal individual and general NPDES permits administered by EPA in Washington.[223] 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

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

as contributing up to 10% of the PCB loadings associated with hatcheries.[224] In 2006 Ecology published a report documenting the PCB loadings associated with hatcheries.[225] As illustrated by Ecology's section 401 certification for the Leavenworth Federal Fish Hatchery, this is a statewide problem.[226] EPA's rule could very well have the unintended consequence of shutting down these very fish hatcheries.

The "economic analysis" that EPA had prepared by Abt Associates "in the spirit" of E.O. 12866 is no substitute for the full economic analyses required by OIRA.[227] As but one example, E.O. 12866 requires a cost benefit analysis of feasible alternatives to a proposed rule—such as the water quality standards proposed by Ecology—and an explanation of why EPA's 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.[228] 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.[229] The agency must also consider the option of deferring to regulation at the State or local level and assess whether federal regulation is the best solution. *Id*. at 6. Finally, the agency should conduct both a benefit-cost analysis and cost-effectiveness analysis. The Abt Associates "economic analysis" does not examine any alternatives to EPA's 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.

In addition to economic costs, the rule should have been identified as significant based on its novel legal and policy issues. A "significant regulatory action" includes any regulatory action that raises "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 explained above, EPA's derivation of human health criteria for Washington is based on novel legal interpretations of treaty rights that are unsupported by case or statutory law. Moreover, the Rule raises novel policy issues insofar as EPA's methods for deriving the criteria are inconsistent with EPA policy.

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[224] Ecology, Control of Toxic Chemicals in Puget Sound, Assessment of Selected Toxic Chemicals in the Puget Sound Basin, 2007-2011.

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

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

[227] Abt Associates, Economic Analysis for the Revision of Certain Federal Water Quality Criteria Applicable to Washington (August 17, 2015).

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

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

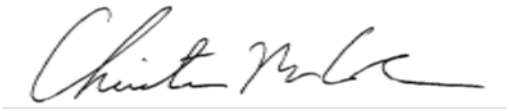
Based on the novel legal and policy issues involved, EPA should have notified OIRA and OMB that this rule involved a potentially significant regulatory action.

EPA should repeal or withdraw the EPA Final Rule based on the failure of the agency to comply with E.O. 12866 and 13563.

IV. CONCLUSION

For the reasons described above, Petitioners request that EPA reconsider the State of Washington's Human Health Water Quality Standards and Implementation Tools, submitted to EPA on August 1, 2016; and repeal or withdraw the Final Rule Revision of Certain Federal Water Quality Standards Applicable to Washington, 81 Fed. Reg. 85,417 (Nov. 28, 2016).

Dated this 21st day of February, 2017.



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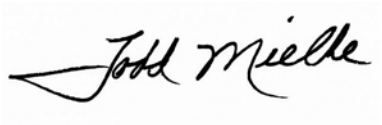

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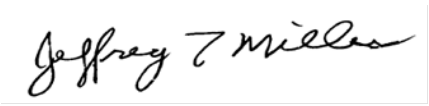

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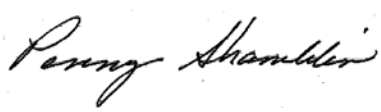

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