IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF WASHINGTON BUSI-NESS, NORTHWEST PULP & PAPER AS-SOCIATION, AMERICAN FOREST & PA-PER ASSOCIATION, GREATER SPOKANE, INC., and FOOD NORTHWEST,

Plaintiffs,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and

MICHAEL S. REGAN, in his official capacity as Administrator of the U.S. Environmental Protection agency,

Defendants.

Civil Action No. 23-cv-3605

COMPLAINT

Plaintiffs Association of Washington Business, Northwest Pulp & Paper Association, American Forest & Paper Association, Greater Spokane, Inc., and Food Northwest hereby allege as follows:

I. Introduction

1. This is a challenge to a final rule promulgated by the U.S. Environmental Protection Agency (EPA) imposing water quality standards (WQS) on the State of Washington that are so stringent that compliance cannot even be measured, much less achieved. EPA arrived at these impossible standards by populating the variables in the relevant standards-setting formula with values that are unscientific, conflict with EPA guidance, and have no basis in real-world data. Among other errors, EPA treated a small and speculative subpopulation of tribal subsistence fishers as the "general population," even though its own guidance distinguishes between the

general population and highly exposed subpopulations when calculating these standards. To justify that assumption, EPA purported to give effect to tribal treaties that EPA has no reason—or legal authority—to interpret. EPA compounded that error by relying on an assumption about that subpopulation's rate of fish consumption that the agency admits is inconsistent with present-day realities. And EPA substituted its own preferences for Washington's in selecting an acceptable cancer risk level for certain chemicals—even though Washington's policy choice was fully consistent with EPA's guidance. In adopting these flawed inputs, EPA reversed its own prior determination—made just a few years earlier—that these inputs were unlawful and based on improper, nonscientific concerns involving tribal rights. EPA cited no new scientific evidence to justify its about face. In the end, EPA's arbitrary assumptions produced absurd standards that fall below even background levels of the relevant pollutants in many water bodies, rendering Washington's communities and businesses powerless to comply. EPA added insult to injury by justifying the rule in part using a flawed economic analysis that purported to find the standards are cost-free. Because reasoned decisionmaking requires far more than that, this Court should vacate the 2022 rule.

2. The Clean Water Act (CWA) "anticipates a partnership between the States and the Federal Government, animated by a shared objective: 'to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." *Arkansas v. Oklahoma*, 503 U.S. 91, 101 (1992) (quoting 33 U.S.C. § 1251(a)). This "program of cooperative federalism," *New York v. United States*, 505 U.S. 144, 167 (1992) (citation omitted), tasks the States with developing water quality standards and the EPA with issuing guidance and reviewing state standards for consistency with the CWA and its implementing regulations. If EPA determines that a State's

standards are inconsistent with the CWA, it must conduct its own analysis and promulgate federal standards that comply with the statute's requirements.

- 3. In August 2016, the State of Washington submitted a set of water quality standards to EPA after an extensive process of scientific analysis and public input. Washington used a "fish consumption rate" higher than EPA's national recommendation and pollutant-specific "cancer risk levels" within the recommended range set out in EPA's longstanding guidance. After analyzing these inputs, Washington developed target concentrations for the pollutants at issue.
- 4. In November 2016, EPA partially disapproved Washington's water quality standards. EPA based this decision not on reasonable interpretations of the CWA or its implementing regulations, however, but on a novel legal theory with sweeping implications: That EPA had the authority to interpret treaties between the United States and tribes located in Washington, and that "harmonizing" its interpretation of those treaties with the CWA required EPA to reject some of Washington's standards.
- 5. Pursuant to this theory, EPA treated "tribal subsistence fishers" as the "target general population" rather than as a highly exposed subpopulation; required a more stringent "cancer risk level" for a key pollutant than the State deemed appropriate; and imposed federal water quality standards that were as much as 25 times more stringent than the State's. In fact, EPA's standards for polychlorinated biphenyls (PCBs) were so stringent that modern technology cannot even detect the pollutant at EPA's selected level.
- 6. In 2019, after receiving a petition for reconsideration by a coalition of Washington businesses and others (some of which are Plaintiffs here), EPA revisited its decision and reversed course, approving the State of Washington's August 2016 proposed standards, finding them to be scientifically sound and protective of human health and the environment, and withdrawing the

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November 2016 federal standards that EPA had imposed on the State. EPA acknowledged that its prior tribal rights theory had no basis in the CWA or EPA regulations, and reaffirmed its position that States have primary responsibility to make risk-management decisions in setting water quality standards.

- 7. In 2022, however, EPA reversed its reversal, returning to and relying on much of the same discredited rationale of the November 2016 EPA rule and re-imposing the federal standards on Washington, claiming that the State's standards were not based on sound science. In reality, EPA's 2022 decision relied on its unsupported and unlawful tribal-rights rationale. Despite commenters' identification of the serious flaws with EPA's approach in a round of notice and comment, EPA offered no further justification for its asserted tribal-rights authority, and did not explain adequately why EPA's rejection of that authority in 2019 was no longer correct. In support of its impossibly stringent 2022 standards, EPA offered an economic analysis asserting that the 2022 rule imposed *no costs* on regulated parties, including small entities, because the State's role in complying with the federal standards through the permitting process made estimating those costs "highly speculative."
- 8. In reality, EPA's 2022 rule imminently threatens severe injuries to regulated parties in Washington—including many of Plaintiffs' members—by imposing pollutant concentration thresholds that are unduly burdensome and, by all accounts, impossible to measure and achieve using available detection and treatment technologies. As a direct result of EPA's unlawful action, Plaintiffs' members will incur billions of dollars in additional compliance costs, and endure regulatory uncertainty that disrupts their investment-backed reliance on EPA's longstanding prior policies.

- 9. As alleged in greater detail below, EPA's 2022 rule is unlawful for a number of independent reasons.
- decision is arbitrary and capricious and violates the Administrative Procedure Act (APA). Less than three years after expressly disclaiming the tribal-rights rationale for selecting a high consumption subpopulation as a target general population, an unreasonably high fish consumption rate, and a more stringent cancer risk level, EPA's 2022 rule changed tack by finding that the 2019 standards were not based on sound science and, relying on this baseless rationale, imposed unduly stringent, and unnecessary, federal standards. In doing so, EPA failed to explain or demonstrate why the 2019 rule was not based on sound science or was not sufficiently protective of human health and the environment; despite bald assertions to the contrary, EPA's 2022 rule still relies on its groundless tribal-rights rationale. Agencies may abandon prior positions and adopt new ones so long as the change is "reasonable and reasonably explained." *Biden v. Texas*, 142 S. Ct. 2528, 2543 (2022). Because EPA's 2022 rule is neither, it violates the APA.
- 11. Second, EPA's 2022 rule violates the APA by relying on a risk analysis that departs from the agency's own longstanding guidance. Rather than analyze risk based on Washington's population, EPA considered tribal subsistence fishers as the target general population in setting the federal standards—an analytical choice with no basis in law that does not reflect population realities and has no relation to the sound science requirement that EPA purported to apply in disapproving Washington's standards. Based on this improper assumption, EPA then triple-counted the need to protect its chosen target general population by: (1) failing to consider that anadromous fish such as salmon have lower pollutant concentrations than freshwater or estuarine fish; (2) setting an unsupported and unreasonably high fish-consumption rate of 175 g/day; and

- (3) choosing a more stringent cancer-risk level than even that recommended by EPA's guidance—which remains in force.
- 12. Third, EPA's 2022 rule further violates the APA by imposing a target concentration level for PCBs that is unmeasurable and unworkable. As EPA was forced to admit, its PCB limit of 7 parts per quadrillion (or 0.00007 micrograms per liter) is so low that modern technology literally cannot detect or measure the pollutant at EPA's selected concentration. Background PCB levels in many Washington waters already exceed this standard. Yet EPA expects regulated parties to comply with this limit through as-yet-unknown technologies at enormous expense. That is arbitrary and capricious, and it violates the APA.
- and implausible conclusion that its impossible target level for PCBs imposes *no costs* on regulated parties, despite receiving ample evidence to the contrary from those parties. For an administrative agency to estimate unduly low costs is one thing; but to say a regulation imposes no costs at all is astounding. Despite proceeding to impose the federal standards for PCBs and scores of other pollutants, EPA asserted that the costs of that approach were too "speculative" to evaluate before forcing Washington and regulated parties to comply. But Washington regulators are already compelling the City of Spokane to comply, generating costs of around \$19 million per gram of PCB removal. Further, contrary to EPA's view, EPA should consider costs when setting water quality standards under these circumstances. EPA's mistaken legal premise is itself reason to vacate and remand. And when an agency performs a cost-benefit analysis, that analysis must be reasonable. EPA's is not, and that violates the APA.
- 14. *Fifth*, EPA's 2022 rule is unreasonable in light of the Regulatory Flexibility Act (RFA) for much the same reasons. Like its decision not to assess costs at all, EPA failed to perform

any regulatory flexibility analysis. It failed to do so despite the rule's evident impact on small entities, instead certifying that costs would flow not from the 2022 rule but from Washington's permitting decisions. But it is the 2022 rule that overrode the 2019 standards, forcing regulated parties, including small entities, to comply with an impossibly low limit, and EPA was required to consider economic impacts on small entities when issuing its federal standards. That failure undermined the notice and comment process, and it is arbitrary and capricious.

- 15. Sixth, EPA's 2022 rule exceeds the agency's statutory authority under the CWA. States retain primacy in developing water quality standards, with EPA authorized to step in only when "necessary." Given Washington's protective standard and sound scientific basis for those standards under longstanding regulatory guidance, imposing federal criteria was unnecessary. Moreover, EPA's claimed authority to interpret tribal treaties with the United States and to use its own interpretation to impose more stringent requirements on the States has no basis in the CWA, its implementing regulations, or longstanding EPA policy. Recognizing this fact, EPA only *later* issued a proposed rule to codify its supposed tribal-rights authority into law. But that approach is neither required, nor authorized, by the CWA.
- 16. For these reasons and more, the Court should vacate EPA's unlawful 2022 rule and allow Washington's water quality standards to go into effect by operation of law.

II. Parties

17. Plaintiff Association of Washington Business (AWB) is a non-profit association headquartered in Olympia, Washington, that represents nearly 7,000 businesses with over 700,000 employees, approximately one-quarter of Washington's workforce. 90% of its members are small businesses employing fewer than 100 people, and many of its members are subject to CWA National Pollutant Discharge Elimination System (NPDES) permitting requirements administered by the Washington Department of Ecology (Ecology) under EPA supervision. AWB represents

its members' interests on state and federal policy issues, including environmental stewardship, water resources, climate change, and land use, as a key part of its mission. As relevant here, AWB and its members directly participated in the formulation of the human health criteria developed by Ecology and disapproved by EPA, and AWB commented extensively on the EPA rulemaking challenged in this case to urge adoption of a more reasonable standard.

- 18. Plaintiff Northwest Pulp & Paper Association (NWPPA) is a trade association headquartered in Olympia, Washington, that represents 12 members in the paper products industry employing over 10,000 people at pulp and paper mills in Washington, Oregon, and Idaho. Many of its members are subject to CWA NPDES permitting requirements administered by Ecology under EPA supervision. NWPPA represents its members' interests on legislative and regulatory issues at the federal and state level, including environmental policy, as a key part of its mission. As relevant here, NWPPA and its members actively participated in Ecology's development of the human health criteria disapproved by EPA, including through the Governor's Informal Advisory Group, and commented extensively on the EPA rulemaking challenged in this case to urge adoption of a more reasonable standard.
- 19. Plaintiff American Forest & Paper Association (AF&PA) is a trade association headquartered in Washington, D.C., that represents member companies that make about 87% of the pulp, paper, paper-based packaging, and tissue products made in the United States, including in Washington. The forest products industry accounts for approximately 5% of the total U.S. manufacturing GDP, manufactures about \$350 billion in products annually and employs about 925,000 people. AF&PA membership includes small businesses employing fewer than 100 people, and several AF&PA members are subject to CWA NPDES permitting requirements administered by Ecology under EPA supervision. AF&PA represents its members' interests on

legislative and regulatory issues at the federal and state level, including environmental and energy policy, as a key part of its mission. As relevant here, AF&PA and its members commented extensively on the EPA rulemaking challenged in this case to urge adoption of a more reasonable standard.

- 20. Plaintiff Greater Spokane, Inc., is a non-profit corporation headquartered in Spokane, Washington, that represents hundreds of businesses in the greater Spokane area. Many of its members are small businesses employing fewer than 100 people, and many are subject to CWA NPDES permitting requirements administered by Ecology under EPA supervision. Greater Spokane represents its members' interests on legislative and regulatory issues at the federal and state level, including environmental policy, as a key part of its mission. As relevant here, Greater Spokane and its members commented extensively on the EPA rulemaking challenged in this case to urge adoption of a more reasonable standard.
- 21. Plaintiff Food Northwest is a trade association headquartered in Portland, Oregon, that represents over 350 members in the food-processing industry located in Washington, Oregon, and Idaho. Many of its members are small businesses employing fewer than 100 people, and many are subject to CWA NPDES permitting requirements administered by Ecology under EPA supervision. Food Northwest represents its members' interests on legislative and regulatory issues at the federal and state level, including environmental policy, as a key part of its mission. Food Northwest's members will be required to expend millions of dollars in an effort to comply with the challenged rule, which sets an impossibly high standard.
- 22. Defendant U.S. Environmental Protection Agency is an executive department of the United States.

23. Defendant Michael S. Regan is the Administrator of the U.S. Environmental Protection Agency and the official charged by statute with administering the CWA. *See* 33 U.S.C. §§ 1313, 1361. Defendant Regan is named in his official capacity only.

III. Jurisdiction and Venue

- 24. This action arises under the CWA, 33 U.S.C. §§ 1311 *et seq.*, the APA, 5 U.S.C. §§ 500 *et seq.*, the RFA, 5 U.S.C. §§ 601 *et seq.*, and EPA rules and regulations.
 - 25. This Court therefore has jurisdiction under 28 U.S.C. § 1331.
- 26. Plaintiffs have associational standing to bring this suit on behalf of individual members who have standing because their members' individual participation is not required and because the issues in this case are germane to Plaintiffs' organizational missions. Plaintiffs' individual members include holders of and applicants for NPDES permits issued by Ecology under EPA supervision, are subject to CWA permitting requirements and the unlawful water quality standards imposed by the challenged EPA rule, and will, as a result of the challenged EPA rule, incur additional compliance costs, bear additional fees and expenses associated with applications for permits and variance development that would otherwise have been unnecessary, and endure regulatory uncertainty that disrupts their investment-backed reliance on EPA's prior policies.
- 27. Venue is proper in this district under 28 U.S.C. § 1391(e) because Defendants EPA and Regan reside in this judicial district, and no real property is involved in this action.

IV. Allegations

A. The CWA

- 28. The Clean Water Act requires States to adopt water quality standards regulating discharges of pollutants into navigable waters.
- 29. Water quality standards incorporate the "designated uses" for the water body at issue (e.g., supporting aquatic life or recreational use) and the "water quality criteria" necessary to

protect those uses, which are typically specified as the maximum concentration of a pollutant that may be present in the water. 33 U.S.C. § 1313(c)(2)(A); see also 40 C.F.R. §§ 131.3(b), 131.11(a).

- 30. Water quality criteria include human health criteria representing specific levels of chemicals or conditions in a water body that are not expected to cause adverse effects to human health. Such criteria "must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use." 40 C.F.R. § 131.11(a)(1).
- 31. States must periodically submit proposed water quality standards to EPA for review and approval. 33 U.S.C. § 1313(c).
- 32. To guide States in promulgating such standards, EPA publishes criteria recommendations for States to consider when adopting water quality criteria for particular pollutants based on "the latest scientific knowledge." 33 U.S.C. § 1314(a). Among other pollutants, EPA has published criteria recommendations for PCBs.
- 33. States may, but are not required to, adopt criteria recommendations identical to EPA's federal criteria. They also may adopt criteria modified to reflect site-specific conditions, or other scientifically defensible methods. 40 C.F.R. § 131.11(b)(1).
- 34. This case principally concerns Washington's water quality standards for PCBs—"a group of man-made organic chemicals consisting of carbon, hydrogen and chlorine atoms." EPA, Learn About Polychlorinated Biphenyls (Apr. 12, 2023), https://www.epa.gov/pcbs/learn-about-polychlorinated-biphenyls. For much of the twentieth century, PCBs were used in hundreds of industrial and commercial applications, including in electrical equipment, as plasticizers in paints, plastics, and rubber products, and in pigments, dyes, and carbonless copy paper. *Id*.
- 35. In 1979, Congress banned PCBs in the Toxic Substances Control Act (TSCA). While no longer commercially produced in the United States, however, PCBs may still be present

in products and materials—including in common items like electrical equipment, cable insulation, caulking, and floor finish—that were produced before the 1979 PCB ban. PCBs remain present in air, water, and soil.

- 36. PCBs have been well studied for both their carcinogenic and non-carcinogenic effects. EPA has never recommended that States adopt a water quality criteria permitting zero PCBs, rejecting that level as "not . . . attainable." EPA, Ambient Water Quality Criteria for Polychlorinated Biphenyls vii (Oct. 1980), https://www.epa.gov/sites/default/files/2019-03/documents/ambient-wqc-polychlorinatedbiphenyls-1980.pdf.
- 37. In 2000, EPA published guidance—"EPA's Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health" (2000 Methodology)—that "is used in the development of EPA's recommended criteria and offered as guidance for states and tribes in developing their own criteria." EPA, Human Health Water Quality Criteria and Methods for Toxics (Oct. 2, 2023), https://epa.gov/wqc/human-health-water-quality-criteria-and-methods-toxics. The 2000 Methodology recommends specific inputs to the formulas used in determining human health criteria for particular pollutants.
- 38. Those inputs include the cancer risks associated with the presence of a particular pollutant in surface water. In evaluating carcinogenic effects, EPA recommends a formula with, as relevant here, two major sub-inputs: (1) cancer risk level (CRL), an excess lifetime cancer risk in the population used to derive an acceptable concentration of a pollutant in water; and (2) fish-consumption rate (FCR), a measure of the amount of fish consumed by the target general population on average per day over a lifetime. EPA also considers as other sub-inputs exposure through the ingestion of contaminated surface water and a relative source contribution—the percentage of a reference dose (the amount of a chemical that a person can ingest every day for a lifetime that is

not anticipated to cause harmful noncancer health effects) to be attributed to ambient water and freshwater and estuarine fish consumption. EPA, Water Quality Standards Handbook, Chapter 3, § 3.3.1 (2014), http://www.epa.gov/wqs-tech/water-quality-standards-handbook.

- 39. The 2000 Methodology provides that human health criteria "based on a 10⁻⁵ [cancer] risk level"—*i.e.*, the acceptable pollutant concentration should reflect a probability of no more than one additional case of cancer in a population of one hundred thousand—"are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sportfishers or subsistence fishers) does not exceed the 10⁻⁴ level." 2000 Methodology 1-12.
- 40. The 2000 Methodology further specifies that "[t]he default fish consumption value for the general adult population . . . is 17.5 grams/day, which represents an estimate of the 90th percentile consumption rate for the U.S. adult population," and is a default value "chosen to be protective of the majority of the general population." 2000 Methodology 1-12.
- 41. The 2000 Methodology acknowledged, however, that these choices were not entirely scientific decisions. While "[s]ome decisions" for relevant inputs to the human health criteria formula "are more grounded in science," EPA explained, "others are more obviously *risk management* decisions (such as the determination of default fish consumption rates and cancer risk levels)." 2000 Methodology 2-4 (emphasis added).
- 42. States are required to propose water quality standards pursuant to 33 U.S.C. § 1313(c)(1).
- 43. If EPA determines that a State's proposed standards satisfy the CWA's requirements, "such standard[s] shall thereafter be the water quality standard[s] for the applicable waters of that State." 33 U.S.C. § 1313(c)(3).

- 44. The CWA thus gives States primary responsibility for establishing water quality standards and regulating their waters, and EPA may step in only if it determines that a State's water quality standards are inconsistent with the Act. 33 U.S.C. § 1313(c)(3).
- 45. If a State fails to adopt standards that meet the Clean Water Act's requirements and EPA "determines that a revised or new standard is necessary to meet the requirements" of the Act, EPA must "promptly prepare and publish proposed regulations setting forth a revised or new water quality standard." 33 U.S.C. § 1313(c)(4)(B). EPA's federal standards must be "in accordance with the applicable requirements" of the Act and, as with all agency action subject to the APA, must involve reasonable analysis, arrive at a reasonable result, and be reasonably explained. *Id.* § 1313(b)(1); *Biden*, 142 S. Ct. at 2543.
- 46. Whether ultimately adopted as state or federal standards, approved water quality standards are used to set effluent limits in the permits that dischargers must obtain to discharge pollutants from a point source into waters covered by the CWA. 33 U.S.C. § 1342; *see* 40 C.F.R. § 122.44(d)(1).
- 47. Under regulations issued by EPA, States may also seek a variance from approved water quality standards—the so-called "base" water quality standards—if compliance with such standards is shown to be infeasible. *See* 40 C.F.R. § 131.14. But EPA and States with delegated authority rarely grant variances. Indeed, Washington State has never been granted a variance. EPA may approve a variance only if the State can demonstrate that compliance with the base water quality standards is not feasible for one of several enumerated reasons. *Id.* §§ 131.10(g), 131.14(b)(2)(i)(A). Moreover, "new sources are ineligible for variances from performance standards," which are "potentially available" only "to existing sources." *Nat. Res. Def. Council, Inc. v. EPA*, 822 F.2d 104, 112 (D.C. Cir. 1987). Even once granted, a variance provides only

a narrow, time-limited exemption from the base water quality standards, applicable to specific pollutants and to specific dischargers or a particular water body. 40 C.F.R. §§ 131.3(o), 131.14(a).

B. Washington's 2016 Water Quality Standards

- 48. In 2015, EPA determined that updated human health criteria (HHC) were "necessary" to protect Washington residents and invoked its authority to establish new federal water quality standards. 80 Fed. Reg. 55,063, 55,066 (Sept. 14, 2015). EPA proposed criteria for 99 CWA-listed toxic pollutants, including PCBs. *Id.* at 55,067. The agency calculated these standards using an FCR of 175 g/day and a CRL of 10⁻⁶ for all chemicals, including PCBs. *Id.* at 55,067–68. This FCR far surpassed the 2000 Methodology's FCR of 17.5 g/day; EPA adopted this higher value because it stated that 175 g/day reflected the "95th percentile consumption rate of surveyed tribal members." *Id.* at 55,067. EPA's chosen CRL of 10⁻⁶ was an order of magnitude more stringent than the 2000 Methodology's CRL for PCBs; EPA adopted this more stringent value only by mischaracterizing its own Methodology as requiring it. *Compare* 81 Fed. Reg. 85,417, 85,420 & n.10 (Nov. 28, 2016) ("Criteria based on a 10⁻⁵ risk level are acceptable "), *with id.* at 85,427 ("EPA issued its 2000 Methodology, which states that when promulgating water quality criteria for states and tribes, EPA intends to use the 10⁻⁶ cancer risk level, which reflects an appropriate risk for the general population.").
- 49. In August 2016, before EPA finalized its proposed federal standards, Washington adopted its own HHC following, in EPA's words, "an extensive public process." *Toxic Substances—WAC 173-201A-240*, Wash. State Legislature (2019), https://apps.leg.wa.gov/wac/default.aspx?cite=173-201a-240; 87 Fed. Reg. 69,183, 69,187 (Nov. 18, 2022). In all, the State's Department of Ecology promulgated 188 new criteria. The State used its discretion to make risk management decisions for its waters by incorporating several of EPA's proposed inputs, including

the unusually high FCR and CRL, while using a different CRL level of 10⁻⁵ for PCBs. *Toxic Substances—WAC 173-201A-240, supra*, at tbl. 240 & nn.B, E.

- 50. In 2016, EPA approved 45 and disapproved 143 of Washington's HHC, finding they were not adequately supported by sound science. 81 Fed. Reg. at 85,419. Specifically, EPA rejected the State's PCB standards because it erroneously concluded that any CRL below 10⁻⁶ for that chemical would be insufficiently protective. When paired with the State's inflated fish consumption rate, these inputs produced a remarkably low (and therefore stringent) PCB target level (7 parts per quadrillion, or 7 x 10⁻⁶ micrograms per liter). *Id.* at 85,431.
- 51. EPA's November 2016 rule acknowledged that its 2000 Methodology authorizes a 1.0 x 10⁻⁵ CRL (close to, and in reality, due to the theoretical nature of these values, indistinguishable from the value Washington had used, 2.3 x 10⁻⁵), as long as "more highly exposed subgroups"—like "subsistence fishers"—were protected at a 10⁻⁴ CRL. 81 Fed. Reg. at 85,420 & n.10. But the agency moved the goalposts, defining "tribal subsistence fishers" as the "target general population" and combining it with a 10⁻⁶ CRL. To exacerbate its error, EPA not only identified the wrong group as the "general population" (it is a gross misuse of the terms of the CWA to designate an extremely small subpopulation as the "general population"), but also used an inflated estimation of that population's fish consumption rate. *Id.*; *id.* at 85,424. In promulgating the 2022 rule, EPA "appl[ied] the same rationale here as the agency articulated . . . in the 2016 federal rule." 87 Fed. Reg. 19,046, 19,054 (Apr. 1, 2022) (noting this point in connection with selection of FCR); id. at 19,055 (noting that selected CRL "is protective of tribal members exercising their legal right to harvest and consume fish and shellfish at subsistence levels"). This definitional shift effectively protects the actual general population of Washington at a 10⁻⁸ risk level—one additional case of cancer in a population of one hundred million. Nw. Pulp & Paper

Ass'n Comment Letter on EPA Proposed Human Health Water Quality Criteria for Washington 23, Dkt. No. 2015-1089 (Apr. 1, 2022). There is absolutely no basis under the CWA for EPA to impose on a State a rule with such a risk level; the CWA gives States and tribes discretion whether to adopt such an extremely conservative (and likely unprecedented) standard. 81 Fed. Reg. at 85,420.

- 52. EPA's only explanation for its change in position is that the 2000 Methodology did not "speak to or envision the unique situation of setting WQS [water quality standards] that cover areas where tribes have treaty-reserved rights to practice subsistence fishing"—even though the Methodology used the phrase "subsistence fishers." 81 Fed. Reg. at 85,424–25. While purporting to disapprove Washington's standards for scientific reasons, EPA in fact predominantly relied on a tribal-rights theory that has no basis in applicable regulations or EPA's longstanding Methodology and is not a scientific consideration.
- 53. Both the CRL and high FCR rested on EPA's assumption of authority to "harmonize treaty-reserved fishing rights with the CWA." 81 Fed. Reg. at 85,424. The agency decided that even though "[t]he CWA generally assigns to a state the responsibility of determining the designated uses of its waters . . . , through treaties, tribes reserved specific fishing rights . . . including the right to take fish from such waters for their subsistence." *Id.* EPA then construed this "subsistence fishing" right to require that the agency treat tribes as the "target general population." *Id.*
- 54. According to the U.S. Census Bureau, 1.6% of Washington state's population were American Indian and Alaska Native in 2020. *Race and Ethnicity*, U.S. Census Bureau (2023), https://data.census.gov/profile/Washington?g=040XX00US53#race-and-ethnicity. Not all of these individuals are tribal members, and even fewer fish for subsistence. Moreover, a substantial

number of tribal members who do fish for subsistence likely live on tribal reservation land and fish in whole or in part in tribal reservation waters, which expressly are *not* governed by EPA's WQS or Washington's HHC. *See* 81 Fed. Reg. at 85,422 & n.27 ("This rule applies to waters under the State of Washington's jurisdiction, and not to waters within Indian country"). Thus, EPA's rule applied to all waters in the State and the entire population of Washington—even though likely less than 1% of the population consumes the amount of fish on which the fish consumption rate was based.

55. Shortly after its promulgation, a coalition of Washington businesses and others petitioned EPA to reconsider the 2016 rule. Compl. Ex. 1, Pet. for Rulemaking, *Washington v. EPA*, No. 2:19-cv-00884-RAJ (W.D. Wash. June 6, 2019). The petitioners urged that EPA change course for three reasons: (1) The CWA required EPA to approve state standards that met statutory requirements, as Washington's did, "improperly usurp[ing] the primary role of the state to make risk management decisions"; (2) EPA's new standards were arbitrary and capricious because they would "devastat[e the State's] local communities and businesses"; and (3) the federal criteria offered "no benefit to public health over the Washington-submitted standards." *Id.* at 2–3.

C. EPA's Reconsideration

- 56. In 2019, EPA approved all but two of Washington's HHC after determining that its partial disapproval had improperly infringed on Washington's authority under the CWA to make its own risk-management decisions based in sound science. Letter from Chris Hladick, Regional Administrator, EPA Region 10, to Maia Bellon, Director, Wash. Dep't of Ecology 8 (May 10, 2019), https://www.epa.gov/sites/default/files/2019-05/documents/wawqsletter_td_dated_may_2019.pdf ("EPA Approval").
- 57. Applying the 2000 Methodology, EPA determined that Washington's cancer risk level of 2.3 x 10⁻⁵ for PCBs satisfied CWA requirements, was based on sound science, and was

protective of the general population and high-consuming subpopulations. EPA Approval at 21. EPA confirmed that the CWA does not require States to meet or exceed each of EPA's recommended criteria so long as the submission's risk-management decisions are "based on sound science and the resulting criteria protect the designated uses," consistent with the 2000 Methodology. *Id.* at 24.

- EPA policy by requiring Washington as a matter of sound science to treat tribal subsistence fishers as the "target general population." EPA Approval at 21–23. As EPA explained, it was "improper and unnecessary" under the CWA and existing regulations to purportedly "harmonize" tribal treaty rights with the CWA under a new theory not found in the statute or EPA regulations. *Id.* at 22–24. EPA further explained that the partial disapproval had relied on an interpretation of treaty rights that "was not consistent with Washington's interpretation of its designed use[s]." *Id.* at 22.
- 59. In 2020, EPA allowed Washington's approved HHC to go into effect by finalizing its withdrawal of the relevant federal WQS for Washington through notice-and-comment rulemaking. 85 Fed. Reg. 28,494 (May 13, 2020). EPA restated its longstanding position that "EPA prefers that states maintain primary responsibility and establish their own WQS in keeping with the text and structure of the CWA." *Id.* at 28,495. EPA explained that because Washington's HHC satisfied all statutory requirements, "the cooperative federalism structure of the CWA" required the agency "to withdraw the federal WQS to enable the EPA-approved state WQS to become the applicable WQS for CWA purposes." *Id.* at 28,496.
- 60. In doing so, EPA affirmed its view that "Washington's HHC are based on sound science and are protective of Washington's designated uses." 85 Fed. Reg. at 28,496. EPA noted in response to comments that "some of Washington's HHC are less stringent than the federal HHC,

and some are more stringent." *Id.* As EPA explained, the CWA entitled Washington to make such risk-management decisions because its inputs for doing so were based on sound science. *Id.*

D. EPA's 2022 Rule

- 61. In 2022, following a change in administration, EPA again reversed its position and proposed to determine that Washington's HHC were not based on sound science and therefore not protective of the designated uses in Washington. 87 Fed. Reg. at 19,051. EPA finalized that determination several months later and imposed federal WQS for Washington nearly identical to those promulgated in EPA's November 2016 rule. 87 Fed. Reg. at 69,183. EPA again noted that federal WQS for Washington do not apply to "waters within Indian country." *Id.* at 69,188 & n.52.
- 62. In the 2022 rule, EPA purported to rely on science but in fact relied on the same rationale used in the 2016 rule to arrive at the same analytical inputs and similar federal WQS. 87 Fed. Reg. at 69,188–89. Without addressing the contrary findings in the agency's 2020 rule and 2019 approval, EPA once again determined that "tribal subsistence fishers" *must* be treated as the "target general population" when setting the fish consumption rate and cancer risk level in States with tribal reserved treaty rights. 87 Fed. Reg. at 19,054–55 (applying "same rationale" to determine fish consumption rate as 2016 Rule, and emphasizing that as "in EPA's 2016 final rule," "EPA's selection of a 10-6 CRL is protective of tribal members exercising their legal right to harvest and consume fish and shellfish at subsistence levels"); *see also* 87 Fed. Reg. at 69,188–90. Specifically, EPA again adopted a 10-6 CRL for PCBs and a 175 g/day fish consumption rate. 87 Fed. Reg. at 69,188–90.
- 63. Relying on these inputs, EPA finalized the extraordinarily low target level for PCBs of 7 parts per quadrillion (0.000007 micrograms per liter). 87 Fed. Reg. at 69,193. Despite insisting that this target level was required by the CWA, EPA acknowledged that the existing detection limit for PCBs under EPA-approved testing methodologies is 170 parts per quadrillion

(0.00017 micrograms per liter), almost 25-times higher than EPA's target level for PCB concentrations. *Id.* at 69,195. Nevertheless, EPA asserted that "it is important that WQS reflect the necessary level of protection regardless of contemporary limitations of analytical methods." *Id.* at 69,196.

- 64. EPA also relied on an economic analysis that estimated the 2022 rule would impose no costs at all on permitholders and only \$100,000 to \$182,000 in administrative costs on the State. 87 Fed. Reg. at 69,195–96. EPA found that it would be "highly speculative to attempt to estimate potential costs" because, for example, the PCB target level is well below existing detection capabilities. *Id.* at 69,195.
- 65. Finally, EPA certified that the 2022 rule "will not have a significant economic impact on a substantial number of small entities under the [Regulatory Flexibility Act]." 87 Fed. Reg. at 69,196. EPA asserted that it was not required to conduct a regulatory flexibility analysis because "the State will have a number of choices associated with permit writing" while implementing the federal WQS. *Id*.

Count One (All Defendants):

EPA's Unjustified Change In Position Violates The APA.

- 66. Plaintiffs incorporate by reference the allegations above.
- 67. Abruptly reversing longstanding policy by disapproving the 2019 standards (which were based on the State of Washington's August 2016 proposed standards) and enacting the 2022 rule based in part on the purportedly scientific need to protect tribal subsistence fishers as the "target general population," EPA changed its position without adequate justification and without considering the reasonable, investment-backed reliance of regulated parties in the State. EPA again failed to offer any valid reason why the sound science standard or any applicable statutory

or regulatory requirements mandated its disapproval and imposition of infinitesimally low values for the federal standards. That unexplained departure is arbitrary and capricious and warrants vacatur of the 2022 rule.

- 68. The CWA and its implementing regulations enumerate specific requirements for state criteria, including the use of sound science. *See* 33 U.S.C. § 1313; 40 C.F.R. §§ 131.1 *et seq*. None requires, or even mentions, any role for tribal reserved rights in determining the "target general population," fish consumption rate, and cancer risk level in setting and reviewing WQS. EPA has since admitted in a proposed rule that "EPA's existing WQS regulation" and applicable guidance "do[] not . . . explicitly address how WQS must protect tribal reserved rights." 87 Fed. Reg. 74,361, 74,365 (Dec. 5, 2022).
- 69. As recently as 2019, EPA has explained to States and regulated parties that "[t]he existence of tribal treaties with reserved fishing rights does not grant the EPA authority to recharacterize a state's designated uses or otherwise skew the federal-state balance of the CWA towards the federal government" and that "[n]othing in the CWA or the EPA's regulations and guidance, including the 2000 Methodology, requires a state to set a FCR based on an estimate of unsuppressed consumption." EPA Approval of the State of Idaho's New/Revised Human Health Water Quality Criteria for Toxics and Other Water Quality Standards Provisions 12, 27 (Apr. 4, 2019), https://www.epa.gov/sites/default/files/2019-04/documents/04042019_cover_letter_approval_of_deq_human_health_criteria_signed.pdf.
- 70. In 2019 and 2020, EPA reiterated the same view in its decisions approving Washington's August 2016 WQS and withdrawing EPA's November 2016 WQS and explained that "EPA prefers that states maintain primary responsibility and establish their own WQS in keeping with the text and structure of the CWA." 85 Fed. Reg. at 28,495.

- 71. EPA failed to adequately justify or explain its change in position when superseding the existing, 2019 standards with new federal standards, noting only that it was returning in part to the rationale of EPA's November 2016 WQS and that, without explaining why, the agency preferred chemical-specific cancer risk levels to be consistent across pollutants. 87 Fed. Reg. at 69,189. There is no basis in the CWA or implementing regulations to require States to adopt the same cancer risk level for all human health criteria.
- 72. Tellingly, EPA did not even mention the contrary policy that EPA itself adopted in 2019 and 2020 (which correctly applied EPA's longstanding approach) regarding the role of reserved tribal fishing rights in setting WQS, let alone justify its new policy based on the text, structure, and regulatory history of the CWA in light of the extensive contrary reasoning in its 2019 and 2020 decisions and many prior decisions approving water quality standards in Washington and other States without application of its novel tribal-treaty approach. Instead, EPA purported to rely on a sound-science rationale, although its reversal was based on its novel and unsupported tribal-rights rationale. And when, as here, an agency repeatedly changes its interpretation of a statute, its interpretation should receive little (if any) deference. *See INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987).
- 73. Moreover, EPA completely failed to acknowledge the reliance interests of States and regulated parties. Instead, as alleged herein, EPA unreasonably asserted that costs to regulated parties would be zero and estimated an absurdly low cost to Washington in implementing the new federal WQS at between \$100,000 and \$182,000. 87 Fed. Reg. at 69,195–96.

Count Two (All Defendants):

EPA's Risk Analysis Violates The APA.

74. Plaintiffs incorporate by reference the allegations above.

- 75. EPA relied on a risk analysis to promulgate the 2022 rule that is arbitrary, capricious, and otherwise unlawful in multiple ways in violation of the APA. 5 U.S.C. § 706(2).
- 76. First, as it did in its November 2016 rule, EPA began its analysis with the insupportable conclusion that hypothetical tribal subsistence fishers consuming fish at a speculative "unsuppressed" rate must be considered the "target general population for protection, rather than a subpopulation," for "the purposes of setting risk levels to protect the subsistence fishing use." 81 Fed. Reg. at 85,424 (emphasis added); 87 Fed. Reg. at 69,189 ("EPA is applying the same rationale here as the agency articulated to support its use of those inputs in the 2016 Federal rule. . . . As noted in EPA's 2016 final rule for Washington, several tribes in Washington have treaty-reserved rights to fish on waters throughout the State." (footnote omitted)). EPA's choice of FCR for that population necessarily—and unjustifiably—presupposes an "unsuppressed" rate because EPA selected a value well above the 90th percentile of consumption in its survey data. And EPA failed to adequately justify that choice based on sound science, instead merely piggybacking off the "FCR . . . that Washington used in 2016 and that EPA used in its 2016 federal rule." EPA Response to Public Comments, Restoring Protective Human Health Criteria in Washington 50, Dkt. No. EPA-HQ-OW-2015-0174 (2022).
- 77. EPA's position relies on an erroneous understanding of federal duties imposed by reserved tribal rights and is based on speculation, not science or EPA's expertise as an environmental regulator. Specifically, EPA exceeded its authority under the CWA by purporting to interpret the Stevens-Palmer Treaties with the Washington Tribes to impose affirmative obligations on the United States to guarantee "water quality sufficient under the CWA to ensure that tribal members can safely eat the fish for their own subsistence." 81 Fed. Reg. at 85,423.

- 78. Nothing in the CWA delegates to EPA the authority to interpret treaties between the United States and Indian Tribes, much less to use such treaties to impose affirmative environmental obligations on States and regulated parties. EPA invokes its authority to make an Administrator's Determination, 33 U.S.C. § 1313(c)(4)(B), but that provision is limited to a determination that water quality standards are "not consistent with the applicable requirements of this Act"—not with treaties, id. § 1313(a)(1)–(3) (emphasis added).
- 79. EPA points to no other treaty text or statutory provision that is sufficiently clear to support EPA's expansive claim of authority to impose billions of dollars of costs on regulated parties. *See West Virginia v. EPA*, 142 S. Ct. 2587, 2604 (2022) (Congress must have clearly authorized rule that would, among other things, "entail billions of dollars in compliance costs"). The provision that the CWA "not be construed as . . . affecting or impairing the provisions of any treaty of the United States," for example, is not a grant of authority at all; it is merely a rule of construction. 81 Fed. Reg. at 85,422 & n.31 (quoting 33 U.S.C. § 1371(a)). And nothing in that ancillary provision or elsewhere suggests that the treaties may be used as the basis for EPA to set impossible-to-attain water quality standards.
- 80. Even assuming EPA could interpret the scope of obligations imposed by treaty, it clearly erred in interpreting the Stevens-Palmer Treaties as imposing affirmative regulatory obligations under the CWA. "Whether the Government has expressly accepted such obligations 'must train on specific rights-creating or duty-imposing' language in a treaty, statute, or regulation." *Arizona v. Navajo Nation*, 143 S. Ct. 1804, 1813 (2023) (quoting *United States v. Navajo Nation*, 537 U.S. 488, 506 (2003)). By its plain terms, language in the Stevens-Palmer Treaties reserving rights "of taking fish at usual and accustomed places, in common with all citizens of the Territory" does not impose a duty on EPA to supplant state water quality standards

in order to treat tribal subsistence fishers as the "target general population." *See id.* at 1814 (similar language did not impose affirmative duties with respect to providing water to the Navajo Nation).

- 81. Moreover, EPA's attempt to "harmonize" its interpretation of the Stevens-Palmer Treaties with the CWA falls well outside the agency's expertise and is not entitled to deference. 81 Fed. Reg. at 85,423 & n.39. EPA cites no statutory authority or established practice authorizing the agency to interpret tribal reserved rights or to take these rights into account when evaluating WQS submitted by the States. Indeed, EPA has since admitted in a notice of proposed rulemaking that "EPA's existing WQS regulation" and relevant agency guidance on methodologies "do[] not . . . explicitly address how WQS must protect tribal reserved rights." 87 Fed. Reg. at 74,365.
- 82. Perhaps recognizing that this approach is unlawful, EPA contends that it "determined that a 10⁻⁶ CRL was appropriate independent of treaty rights," 87 Fed. Reg. at 69,189, and that it derived its new inputs based instead on a "finding that Washington's criteria are not scientifically sound," EPA 2022 Response to Public Comments, *supra*, at 50. But EPA expressly conceded "that it does not have new data or information suggesting a need to revisit the inputs utilized in the 2016 rule," 87 Fed. Reg. at 69,189, cited no new scientific data to support its return to the rationale for EPA's November 2016 rule, and did not explain how the "science" somehow supported reaching precisely the same number it had previously adopted under a flawed legal rationale. Notwithstanding its reflexive recitation of the sound-science standard, EPA's unsupported tribal-rights rationale was critical to its decision—and it is not a scientific consideration.
- 83. *Second*, EPA adopted a fish consumption rate for its "target general population" of 175 g/day, that is based on an overly conservative assumption that this amount of fish is consumed every day, for seventy years, a three-fold increase from even the 90th percentile fish consumption

rate of 53 g/day. 87 Fed. Reg. at 69,188–89; 81 Fed. Reg. at 85,426–27. Because EPA arrived at this figure based on speculation rather than sound science, its use renders the 2022 rule arbitrary and capricious.

- 84. In selecting its fish consumption rate, EPA relied on "heritage tribal consumption reports" estimating fish consumption rates between 63 and 995 g/day under "traditional tribal practices, prior to contact with European settlers." 81 Fed. Reg. at 85,426 & n.53. These reports are inherently speculative estimates of behavior in the absence of real-world data that cannot take the place of the sound science required by the CWA and its implementing regulations.
- 85. Although purporting to rely on "local and regional FCR surveys," EPA actually disregarded them on the grounds that "[t]here is no local survey of contemporary fish consumption in Washington adjusted specifically to account for suppression, and no survey is a clear representation of current unsuppressed consumption for all tribes in Washington." 81 Fed. Reg. at 85,426. EPA provides no statutory, regulatory, or scientific justification for "adjust[ing]" this undisclosed data to account for "unsuppressed" rates beyond its reliance on speculative "heritage" data. Ultimately, EPA in part defers selection of its fish consumption rate to the Washington tribes, which "have generally agreed that 175 g/day is acceptable for deriving protective criteria at this time." *Id.* That subdelegation is not authorized by statute or regulation and fails to reflect "sound science."
- 86. In addition, EPA points to Oregon's approved fish consumption rate of 175 g/day as supporting the same rate for the general population in Washington without explaining why one State's choice would be required for setting federal standards in another. EPA's reliance on 40 C.F.R. § 131.10(b) similarly is misplaced, as that provision does not require either EPA or upstream States to adopt the same or even more stringent water quality standards as downstream

States. EPA also fails to mention, or take into account, that Idaho's more recently approved WQS used a fish consumption rate of 66.5 g/day for the general population. *See* EPA Idaho Approval, *supra*, at 28. And EPA's allusion to "maintaining consistency between the fish consumption values in this rule with Washington's other HHC that are not affected by the rule," EPA 2022 Response to Comments, *supra*, at 26—without any explanation for why such consistency is important enough to override EPA's obligation to base its FCR on sound science—also fails to provide an adequate basis for EPA's decision.

- 87. Third, EPA assumed without justification that anadromous fish species, including salmon, which spend most of their life cycle in non-nearshore ocean waters, have the same pollutant concentrations "as those in inland and nearshore fish." 87 Fed. Reg. at 69,190. EPA failed to consider in setting the FCR that anadromous fish have significantly lower pollutant concentrations than fish that spend the entirety of their life cycles in inland and nearshore waters. The failure to consider this aspect of the problem is material because, as repeatedly emphasized in the sources cited by EPA, salmon are the primary traditional fish food source of tribes in the Pacific Northwest. See Washington v. Wash. State Com. Passenger Fishing Vessel Ass'n, 443 U.S. 658, 663 (1979).
- 88. Fourth, EPA failed to explain why it did not use the National Cancer Institute (NCI) method (or EPA's simplified variant of the same method)—a sounder method than EPA's chosen approach—for estimating the FCR. EPA, National Health and Nutrition Examination Survey 21–22 (Apr. 2014), https://19january2017snapshot.epa.gov/sites/production/files/2015-01/documents/fish-consumption-rates-2014.pdf. These methods account for the reality that most people do not eat the same amount of fish every day over their entire lives. Id. If EPA chose not to adjust the numbers this way, as it has acknowledged that it should, the agency should have justified that

choice. It failed to do so. *See id.*; 87 Fed. Reg. at 69,185–86 (discussing the FCR data from 2003 through 2010 without discussing the newer NCI methodology in EPA's FCR publication in 2014); 81 Fed. Reg. at 85,426 (same); EPA Response to Public Comments, *Restoring Protective Human Health Criteria in Washington* 159–60, Dkt. No. 2015-0174-0427 (2016) (explaining the FCR calculation without mentioning the NCI method); *id.* at 145–46, 149–52 (same); *id.* at 174 (acknowledging a commenter's suggestion that EPA use the NCI method to process the fish consumption data). Using the NCI method would have lowered the FCR for the 2022 rule. Nw. Pulp & Paper Ass'n Comment Letter, *supra*, at 21–22.

- 89. *Fifth*, EPA triple-counted its unwarranted assumptions by selecting an irrational chemical-specific CRL of 1 x 10⁻⁶ for PCBs based on the purported need to protect reserved tribal fishing rights, although that consideration was already reflected in the selection of subsistence fishing communities as the "target general population" and the adoption of an inflated, counterfactual FCR. 87 Fed. Reg. at 69,189; 81 Fed. Reg. at 85,427. EPA offers no scientifically defensible rationale for overriding Washington's CRL of 2.3 x 10⁻⁵ for PCBs—a level deemed sufficient in EPA's own 2000 Methodology—and instead relies on the unreasonable and erroneous tribal-reserved-rights rationale described above. EPA's efforts to disclaim reliance on this rationale are incompatible with what it actually did in the 2022 rule.
- 90. EPA asserted that Washington's selected CRL was not sound because it purportedly failed to account for carcinogenic health effects. But consistent with the 2000 Methodology, Washington's CRL is protective of the general population's consumption rates within a range of risk factors from 10⁻⁶ and 10⁻⁵, while protecting tribal consumption rates at better than 10⁻⁴. EPA points to no *science* mandating a 10⁻⁶ CRL—and it has no authority to second-guess Washington's

risk-management decision. *See* 2000 Methodology 2-4 (describing choice of CRL within range as principally a risk-management decision).

91. EPA's unscientific and *ultra vires* rationale is arbitrary and capricious.

Count Three (All Defendants):

EPA's Unreasonable PCB Standard Violates The APA.

- 92. Plaintiffs incorporate by reference the allegations above.
- 93. EPA admits that the 2022 rule's 7 parts-per-quadrillion (ppq) limit is neither measurable nor attainable with current technology.
- 94. *First*, EPA lacks any tools to measure whether 7 ppq of PCBs exist in a given water sample. As the agency admits, "EPA has completed a multi-laboratory validation of a new analytical method for PCBs (method 1628) that has an average analytical quantitation limit for each PCB congener of approximately 2,000 [ppq], which is a substantial improvement over the current regulatory method, but still well above either the criterion currently in place or EPA's criterion." 87 Fed. Reg. at 69,195–96. EPA has not even hinted that its standard would be measurable with any technology lurking on the horizon, much less any existing pilot projects.
- 95. Second, the standard is unachievable, even with cost-prohibitive control technology. Washington acknowledged in a public presentation that currently installed municipal-treatment systems cannot achieve 7 ppq of PCBs, even with advanced methods like reverse osmosis, activated carbon, or advanced oxidation. Workshop on PCB Variances for Spokane River Dischargers 83 (Nov. 14, 2019), https://www.ezview.wa.gov/Portals/_1962/Documents/SpokaneRiverCleanWater/VarianceWorkshop_All.pdf. According to a study conducted by AWB, even the highest-performing treatment systems in Washington can reduce PCBs only to 100 ppq. Nw. Pulp & Paper Ass'n Comment Letter, supra, Attach. C at 36.

96. Third, EPA has not justified its 7 ppg standard in the face of its own chemical regulations. EPA's rules under TSCA allow PCB concentrations of up to 50 ppm in manufactured goods, recycled fluids and used oils, and other items. 40 C.F.R. § 761.20; id. § 761.3 ("Excluded PCB products," subsections (1)–(4)). It is arbitrary and capricious to allow 50,000,000,000 ppg concentrations in products in commerce, while requiring other regulated entities to limit PCBs to an infinitesimal 7 ppq level. The inconsistency between these two regulations creates arbitrary and capricious burdens on CWA-regulated entities as compared to TSCA-regulated ones. EPA proffered two reasons for this discrepancy: (1) that TSCA regulations are based on the levels required for chemicals in products instead of surface water that the CWA regulates; and (2) EPA's interpretation that it cannot consider costs in setting CWA water quality standards. EPA 2016 Response Letter, supra, at 106; EPA 2022 Response to Public Comments, supra, at 109 & n.255. But those explanations do not excuse the agency's failure to grapple with TSCA's effects on PCBs in the environment and the burden that EPA shifts to CWA sources to reduce PCB concentrations below background levels. And EPA's understanding of its duty to consider costs under the CWA is mistaken: EPA *must* consider costs in setting water quality standards.

Count Four (All Defendants):

EPA's Failure To Consider Costs Violates The APA.

- 97. Plaintiffs incorporate by reference the allegations above.
- 98. EPA has broad discretion to weigh costs and benefits in implementing its regulatory statutes, and it generally must do so unless the statutory text precludes it. *See Michigan v. EPA*, 576 U.S. 743, 752 (2015). Here, nothing in the Clean Water Act's open-ended directive that the Administrator determine that a new federal standard must be "necessary" to meet the requirements of the Act forecloses consideration of costs and benefits in setting water quality standards. To the

contrary, because such costs affect whether a new standard is "necessary," ignoring compliance costs would be arbitrary and capricious.

- 99. EPA, however, proceeded on the mistaken legal premise that it could *not* consider such costs in setting water quality standards. EPA 2022 Response to Public Comments, *supra*, at 109 & n.255 (explaining that costs cannot be considered in the "development of water quality criteria such as HHC under the CWA"). Even if the CWA does not require it, EPA at minimum has *discretion* to consider costs. But EPA's mistaken premise led it to ignore costs altogether—or at least to arbitrarily zero them out.
- 100. Agency action that "stands on a faulty legal premise" is arbitrary and capricious. *Prill v. NLRB*, 755 F.2d 941, 948 (D.C. Cir. 1985). When an agency erroneously disclaims discretion that it possesses, vacatur and remand is required so that the agency may consider whether and how to exercise that discretion.
- 101. EPA's standards are especially arbitrary and capricious in light of the enormous costs EPA's criteria would impose on regulated entities. EPA's failure to consider the costs involved blinded the agency to an important aspect of the problem.

Count Five (All Defendants):

EPA's Unreasonable Economic Analysis Violates The APA.

- 102. Plaintiffs incorporate by reference the allegations above.
- 103. To the extent EPA did conduct and rely upon an economic analysis, EPA's economic analysis is arbitrary and capricious under the APA. 5 U.S.C. § 706(2).
- 104. When an agency conducts and relies upon an economic analysis in promulgating a rule, the APA requires that the analysis be reasonable and reasonably explained.

- 105. EPA conducted an economic analysis in setting Washington's standards. *See* 87 Fed. Reg. at 69,194–96. To the extent EPA relied on this analysis in determining that its proposed standards are "necessary" to meet the Clean Water Act's requirements, EPA's analysis is neither reasonable nor reasonably explained.
- explained that it did so not because there are no such costs, but because EPA believed it would be too "speculative" to estimate the costs of developing new technologies to measure pollutants at lower levels, even below current levels of detection, or for major facilities to change facility operations and practices to comply with EPA's new standards. The APA does not permit EPA to treat such costs as nonexistent, or to refuse to make any effort to quantify them, merely because the costs present some uncertainty or cannot be precisely quantified.
- 107. EPA also failed to adequately address commenters' specific cost estimates. Commenters explained that the rule would impose enormous compliance costs, providing specific estimates, and that the standards are unattainable even with cost-prohibitive control technology.
- 108. Available data indicates that large segments of state waters would qualify as impaired under the CWA for failing to meet the PCB criteria, based on EPA's 2022 standards, and almost every publicly owned wastewater treatment plant in Washington and other dischargers would therefore need to adopt tertiary membrane filtration treatment or other tertiary treatment technology to address PCBs. Notwithstanding this, there are no known combinations of treatments that would actually achieve EPA's PCB criteria.
- 109. One commenter estimated that the incremental cost for such treatment, including construction costs and operation and maintenance costs, would be between \$53 and \$82 million for a plant that processes 500,000 gallons of wastewater per day, with a net present value unit cost

of between \$106 and \$262 per gallon per day. This will amount to a range of compliance costs from nearly \$6 billion to over \$11 billion just for the major permits identified by EPA. Another commenter estimated costs of a similar magnitude. EPA ignored substantial record evidence by failing to explain why these cost estimates were wrong and by failing to consider the cost implications of lower analytic limits.

- 110. Pursuant to EPA's 2022 rule, Washington Department of Ecology is already compelling the City of Spokane to spend funds to use a more rigorous testing method to address PCB levels (Method 1668) that purports to accurately measure PCBs in the low parts per quadrillion range. An expansion of the City's wastewater treatment plants to add additional tertiary treatment to address PCBs, the City estimates, would cost \$19 million per gram of additional PCB removal.
- 111. In the face of these crippling compliance costs, EPA's estimate of zero compliance costs is arbitrary and capricious and is evidence that the agency failed to apprehend important aspects of the problem it attempted to address.

Count Six (All Defendants):

EPA's Regulatory Flexibility Act Certification Violates The APA.

- 112. Plaintiffs incorporate by reference the allegations above.
- 113. Many of Plaintiffs' members are "small entit[ies]," including "small business[es]" as defined in the RFA and incorporated regulatory definitions promulgated by the Small Business Administration. 5 U.S.C. § 601(3), (6); *see also* 15 U.S.C. § 632(a); 13 C.F.R. § 121.201.
- 114. EPA was required by law to promulgate the 2022 rule through notice-and-comment rulemaking under the APA. *See* 5 U.S.C. §§ 553, 603(a), 604(a).
- 115. EPA is a "covered agency" under the RFA subject to additional consultation requirements for engaging in reasoned agency rulemaking. 5 U.S.C. § 609(d)(1).

- 116. EPA failed to ensure participation by small entities, including small businesses and small governmental jurisdictions, in the comment period for the 2022 rule by noting the potential small-entity impacts of the rule in the notice of proposed rulemaking or taking any steps to notify, directly or indirectly, small entities, including small businesses, of the potential impacts of the proposed rule. *See* 5 U.S.C. § 609(a).
- 117. EPA failed to comply with the RFA's requirement that "a covered agency" notify the Small Business Administration and convene a small entity impact review panel prior to publishing the proposed 2022 rule. *See* 5 U.S.C. § 609(b).
- 118. EPA failed to prepare, consider, and publish for comment an initial regulatory flexibility analysis of the compliance costs imposed by the 2022 rule on small businesses and other small entities or of regulatory alternatives that would minimize any significant impact on small entities while achieving the agency's objectives. *See* 5 U.S.C. § 603.
- 119. EPA failed to prepare, consider, or publish a final regulatory flexibility analysis responding to small-business-related and other small-entity-related comments, justifying the choice to finalize the 2022 rule as opposed to regulatory alternatives with lesser impacts on small businesses, and describing the steps the agency has taken or will take to minimize the economic impact of the 2022 rule on small businesses. *See* 5 U.S.C. § 604.
- 120. EPA's purported certification that the 2022 rule "will not have a significant economic impact on a substantial number of small entities" because they are "not directly regulated by this rule," 87 Fed. Reg. at 69,196, is invalid, arbitrary and capricious, contrary to the factual record, and insufficient to evade the agency's reasoned-decisionmaking duties under the APA.
- 121. EPA's purported certification demonstrates that the agency failed to consider the 2022 rule's economic impact on small entities, failed to consider reasonable alternatives that would

have lessened those economic impacts, and failed to explain why the 2022 rule was justified despite those economic impacts, in violation of the APA.

Count Seven (All Defendants):

EPA Exceeded Its Statutory Authority Under The CWA.

- 122. Plaintiffs incorporate by reference the allegations above.
- 123. EPA exceeded its statutory authority under the CWA when it concluded that superseding Washington state's standard was "necessary" to meet the requirements of this chapter. 33 U.S.C. § 1313(c)(4)(B). States retain primacy in developing water quality standards. Federal Water Quality Coalition Comment on EPA's Proposal "Restoring Human Health Criteria in Washington" 3 n.6, Dkt. No. EPA-HQ-OW-2015-0174 (May 31, 2022) (collecting authority).
- 124. The Act's requirements are both procedural and substantive. Procedurally, States must submit timely water quality standards, 33 U.S.C. § 1313(b), after public hearings, *id.* § 1313(c)(1). Substantively, the standards must "consist of the designated uses" for the waters, "water quality criteria" for such uses, and those designations must "protect the public health or welfare, enhance the quality of water . . . tak[e] into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and . . . their use and value for navigation." *Id.* § 1313(c)(2)(A).
- 125. EPA never raised procedural problems with Washington's standard and it acknowledged that Washington's "designated uses" for its waters "include fish and shellfish harvesting." 81 Fed. Reg. at 85,424.
- 126. As a substantive matter, EPA exceeded its statutory authority vis-à-vis tribal treaties. The CWA mandates only that its provisions shall not "affect[] or impair[] the provisions of any treaty of the United States." 33 U.S.C. § 1371(a). From these words, EPA presumes the power to regulate more stringently based on *its own interpretation* of tribal treaties. There are at least

two problems with this approach: EPA assumes interpretive authority over tribal treaties and, based on that, greater regulatory authority for itself. The CWA grants neither. And EPA's power-grab undermines its statutory duty to revise state criteria only when "necessary." *Id.* § 1313(c)(4)(B).

- 127. EPA's revisions are also not "necessary." 33 U.S.C. § 1313(c)(4)(B). EPA contends only that Washington's criteria should be "set at levels that will adequately protect Washington residents, including tribes." 81 Fed. Reg. at 85,417. But Washington's original rule was extremely protective, setting a technology-forcing 170 ppq PCB standard. *Toxic Substances—WAC 173-201A-240*, *supra*.
- 128. EPA used nearly the "same inputs to derive its proposed PCB HHC as Washington used, with the exception of the [CRL]." EPA 2022 Response to Public Comments, *supra*, at 116. But the CRL that EPA used in this rulemaking (10⁻⁶) exceeded its 2000 Methodology (10⁻⁴), which Washington followed. Nw. Pulp & Paper Ass'n Comment Letter, *supra*, at 9. Moreover, States need not even follow every aspect of the 2000 Methodology; it is only guidance and was never promulgated as a rule. Federal Water Quality Coalition Comment, *supra*, at 4. In short, EPA has failed to show that the CWA requires its newly adopted cancer risk level, such that federal standards were "necessary" to displace state standards. EPA's new federal standards are *ultra vires* and defy the CWA's deference to state standards.

Count Eight (All Defendants):

EPA's Failure To Follow Regulations Violates The APA.

- 129. Plaintiffs incorporate by reference the allegations above.
- 130. EPA's water quality standards violate the APA's procedural requirements and well-settled principles of administrative law because they fail to follow EPA's own rules for promulgating such standards.

- 131. Like the Clean Water Act, EPA's implementing regulations authorize EPA to "promulgate a new or revised standard when *necessary* to meet the requirements of the Act." 40 C.F.R. § 131.5(b) (emphasis added). Because no EPA action is "necessary" if existing standards already satisfy the Act's requirements, EPA's authority to promulgate WQS is triggered only if existing state standards are unlawful.
- 132. As relevant here, Washington must have "adopted criteria that protect the designated water uses based on sound scientific rationale," and Washington must have "followed applicable legal procedures for revising or adopting standards." 40 C.F.R. § 131.5(a)(1)–(2), (6). As EPA itself has explained, "[i]f the EPA finds the state WQS are based on sound science and protect the state's designated uses, the CWA requires the EPA to approve those state WQS." 85 Fed. Reg. at 28,495.
- 133. In May 2019, EPA concluded that "Washington's HHC are based on sound science and are protective of Washington's designated uses." 85 Fed. Reg. at 28,496. That determination was based on a finding that Washington's HHC were based on already "conservative inputs," which "appropriately balanced risks and resulted in HHC that are based on sound science and are protective of Washington's designated uses, consistent with the rationale provided in Ecology's submittal." EPA Approval at 18.
- 134. In addition to failing to adequately explain its departure from its prior findings, EPA had no authority to promulgate new regulations. Because the state standards were sufficiently protective, EPA's own regulations forbid it from promulgating more stringent standards.
 - 135. Plaintiffs are therefore entitled to relief under the APA and other applicable law.

Prayer for Relief

- 136. Plaintiffs pray for an order and judgment:
- a. Declaring that EPA violated the APA in finalizing the 2022 rule because its risk analysis, economic analysis, and unattainable PCB water quality standard are arbitrary and capricious; that EPA violated the APA and the CWA by failing to consider costs, to compare the costs to the incremental benefits likely to result, and to consider reasonable alternatives; that EPA violated the APA in finalizing the 2022 rule without analyzing and accounting for its impact on small entities, including small businesses, as required by applicable law, including the APA and RFA; and that EPA exceeded its statutory authority under the CWA and failed to follow its own regulations in disapproving Washington's WQS and promulgating federal WQS based on an invalid tribal reserved rights rationale.
- b. Declaring that any attempt to force Washington to implement or enforce the 2022 rule violates the APA and CWA;
 - c. Vacating and setting aside the 2022 rule;
- d. Issuing all other process necessary and appropriate to postpone further implementation of the 2022 rule pending the conclusion of this case;
- e. Awarding Plaintiffs their reasonable costs, including attorneys' fees, incurred in bringing this action under 28 U.S.C. § 2412 or other applicable law; and
 - f. Granting such other and further relief as this Court deems just and proper.

Dated: December 4, 2023 Respectfully submitted,

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