ORAL ARGUMENT NOT YET SCHEDULED

No. 24-1188 (consolidated with Nos. 24-1191, 24-1192)

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN WATER WORKS ASSOCIATION, et al.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,

Respondents,

CONCERNED CITIZENS OF WMEL WATER AUTHORITY GRASSROOTS, et al.,

Respondent-Intervenors.

On Petition for Review of Final Action by the
United States Environmental Protection Agency —
89 Fed. Reg. 32,532 (April 26, 2024)

OPENING BRIEF OF PETITIONERS AMERICAN WATER WORKS ASSOCIATION AND ASSOCIATION OF METROPOLITAN WATER AGENCIES

(Names and addresses of counsel appear inside cover.)

Dated: October 7, 2024

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), Petitioners American Water Works Association and Association of Metropolitan Water Agencies submit this certificate as to parties, rulings, and related cases.

A. PARTIES AND AMICI

The Petitioners are American Water Works Association and Association of Metropolitan Water Agencies (No. 24-1188); National Association of Manufacturers and American Chemistry Council (No. 24-1191); and The Chemours Company FC, LLC (No. 24-1192).

The Respondents are the United States Environmental Protection Agency and Michael S. Regan, Administrator of the United States Environmental Protection Agency.

The Intervenors are the Natural Resources Defense Council, Buxmont Coalition for Safe Water, Clean Cape Fear, Clean Haw River, Concerned Citizens of WMEL Water Authority Grassroots, Environmental Justice Task Force, Fight for Zero, Merrimack Citizens for Clean Water, and Newburgh Clean Water Project.

The State of Connecticut has notified the Court of its intention to participate as *amicus* curiae. At this time, counsel is unaware of any other party that has moved to participate as *amicus curiae*.

B. RULINGS UNDER REVIEW

The consolidated petitions for review challenge the Environmental Protection Agency's final rule titled "PFAS National Primary Drinking Water Regulation," 89 Fed. Reg. 32,532 (April 26, 2024).

C. RELATED CASES

This case has been consolidated with the following petitions for review of the same EPA final rule: *National Association of Manufacturers, et al. v. EPA, et al.* (No. 24-1191), and *The Chemours Company FC, LLC v. EPA, et al.* (No. 24-1192). At this time, counsel is unaware of any other related cases within the meaning of Circuit Rule 28(a)(1)(C).

/s/ Corinne V. Snow
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Counsel for American Water Works Association and Association of Metropolitan Water Agencies

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Petitioners American Water Works Association and Association of Metropolitan Water Agencies, through undersigned counsel, certify as follows:

The American Water Works Association is a non-governmental corporation with no parent corporation and no publicly held company holding 10% or more of its stock. The American Water Works Association is a corporation organized and existing under the laws of the State of Illinois. The American Water Works Association is an international, nonprofit, scientific and educational society dedicated to assuring the effective management of water. Founded in 1881, the Association is the largest organization of water supply professionals in the world. The Association's membership includes more than 4,000 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation's wastewater. The Association's 50,000-plus total membership represents the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water, our most important resource. The American Water Works Association unites the diverse water community to advance public health, safety, the economy, and the environment.

Association of Metropolitan Water Agencies is a non-governmental corporation with no parent corporation and no publicly held company holding 10% or more of its stock. The Association of Metropolitan Water Agencies is a corporation organized under the laws of the District of Columbia. The Association of Metropolitan Water Agencies is a nonprofit tax-exempt trade association representing approximately 180 of the largest publicly owned drinking water systems in the United States. The Association of Metropolitan Water Agencies' members provide more than 160 million people across the country with safe drinking water. The Association of Metropolitan Water Agencies' members include municipal agencies and special purpose districts and commissions serving customers on either a local or regional basis. Some are wholesalers providing water to other utilities, some serve end-use customers directly, and some do both. The Association's members are responsible for constructing and operating water treatment systems necessary to ensure compliance with National Primary Drinking Water Regulations promulgated pursuant to the Safe Drinking Water Act.

/s/ Corinne V. Snow
Corinne V. Snow

Counsel for American Water Works Association and Association of Metropolitan Water Agencies

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GLOSSARY

Act	Safe Drinking Water Act, 42 U.S.C. § 300f *et seq.*
AMWA	Association of Metropolitan Water Agencies
AWWA	American Water Works Association
Board	U.S. Environmental Protection Agency's Science Advisory Board
Determination to Regulate or **Determination**	A final determination to regulate a contaminant pursuant to 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I)
EPA or **the Agency**	U.S. Environmental Protection Agency
Goal	Maximum Contaminant Level Goal
HFPO–DA	Hexafluoropropylene oxide dimer acid
Index PFAS	PFHxS, PFNA, PFBS, and HFPO–DA
Level	Maximum Contaminant Level
List	Contaminant Candidate List
ng/L	Nanograms per liter
PFAS	Per- and polyfluoroalkyl substances
PFBS	Perfluorobutane sulfonic acid
PFHxS	Perfluorohexane sulfonic acid
PFNA	Perfluorononanoic acid
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctane sulfonic acid

ppt	Parts per trillion
Preliminary Determination	A preliminary determination to regulate a contaminant pursuant to 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I)
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 5	Fifth Unregulated Contaminant Monitoring Rule
Water Associations	AMWA and AWWA

INTRODUCTION

Respondent Environmental Protection Agency ("EPA" or the "Agency") finalized what promises to be the most expensive Safe Drinking Water Act ("Act") regulations ever visited on U.S. water systems in a single rulemaking that includes determinations to regulate and national primary drinking water regulations for six per- and polyfluoroalkyl substances ("PFAS"): perfluorooctanoic acid ("PFOA"); perfluorooctane sulfonic acid ("PFOS"); perfluorohexane sulfonic acid ("PFHxS"); perfluorononanoic acid ("PFNA"); perfluorobutane sulfonic acid ("PFBS"); and hexafluoropropylene oxide dimer acid ("HFPO–DA").

In doing so, EPA flouted the Act's carefully prescribed risk evaluation and standard setting process. EPA instead invented an unprecedented and atextual process designed with speed in mind. To hasten the timeline for PFHxS, PFNA, PFBS, and HFPO–DA (collectively the "Index PFAS"), EPA truncated the multistep process prescribed by Congress and pressed forward without nationally representative occurrence data, relying instead on piecemeal local data contrary to past practice.[1] Furthermore, EPA made novel use of a "hazard index" to regulate combinations of Index PFAS as a "mixture" based on a convoluted formula rather than individual limits for each contaminant.

[1] "Occurrence" refers to the detection of a contaminant above a certain minimum concentration.

Petitioners American Water Works Association ("AWWA") and Association of Metropolitan Water Agencies ("AMWA") (together, "Water Associations") support EPA's efforts to develop national primary drinking water regulations for PFOA and PFOS that cost-effectively protect public health. This rule, however, is neither feasible nor cost-effective, as required by the Act, and creates significant risks for water system compliance and water affordability.

The themes of EPA's rulemaking are apparent—hastiness, novelty, and inadequate data. In its rush to promulgate this rule, EPA violated the Act and the Administrative Procedure Act. While the substance of this rulemaking may be technical, the errors are abundant, clear, and grounded in statutory text. This Court should therefore vacate the rule and remand, so that EPA can undertake the data-driven and science-based regulatory process required by the Act.

JURISDICTIONAL STATEMENT

Water Associations seek review of EPA's final action, "PFAS National Primary Drinking Water Regulation," 89 Fed. Reg. 32,532 (April 26, 2024) (the "Rule"). Joint Appendix ("JA") __-__. This Court has jurisdiction to review the challenged action. 42 U.S.C. § 300j-7(a) [42 U.S.C. § 300j-7, ADD-26-ADD-27]. Water Associations timely filed their petition on June 7, 2024—within 45 days of the Rule's publication in the *Federal Register*. *Id.*

STATEMENT OF THE ISSUES

Whether EPA violated the Act or Administrative Procedure Act by:

- Issuing proposed regulations for Index PFAS before making final determinations to regulate those PFAS;
- Using a "hazard index" as a national primary drinking water regulation for mixtures of two or more Index PFAS;
- Determining that inadequate occurrence data for Index PFAS demonstrated their occurrence (or substantial likelihood of occurrence) in drinking water with a frequency and at levels of public health concern to justify determinations to regulate HFPO-DA and PFNA, individually, and mixtures of two or more Index PFAS; and
- Promulgating regulations that are not cost-effective or feasible and based on a flawed cost benefit analysis.

STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in a separate addendum.

STATEMENT OF THE CASE

A. PFAS

PFAS are a large and diverse class of thousands of synthetic chemicals that have been used in a wide range of products across a variety of consumer and industrial applications. Each PFAS chemical has distinct characteristics, including

different uses, levels of presence in the environment, and potential health impacts. Some, such as PFOA and PFOS, have been studied in greater depth than others, and their production has largely been phased out and replaced by other PFAS, such as PFHxS, HFPO-DA, and PFBS. *See* U.S. Dep't of Health and Human Servs., *Toxicological Profile for Perfluoroalkyls* at 3 (2021), EPA-HQ-OW-2022-0114-0066, JA__; 89 Fed. Reg. at 32,536, JA__. In 2021, EPA committed to an ambitious agenda to "immediately" address PFAS under multiple authorities, including the Act. 89 Fed. Reg. at 32,538, JA__.

The same characteristics that make PFAS desirable for many applications also presents a challenge for water systems to remove them from drinking water supplies, as water systems have only a limited set of treatment options available—e.g., granular activated carbon, anion exchange, reverse osmosis, and nanofiltration. *Id.* at 32,624-25, JA__-__. These technologies require significant capital, operating, and maintenance costs. They also pose risk trade-offs from downstream water quality, treatment byproducts, and environmental burdens. *See* AWWA Comment at 6-7, 29, EPA-HQ-OW-2022-0114-1759, JA__-__, __. Other alternatives can pose significant issues, and most systems will rely on installing new treatment facilities. *Id.* at 30-33, JA__-__. Importantly, because most water systems depend on revenue from water ratepayers, the costs of regulation are largely borne by the systems' customers.

B. Legal Background

The Act applies generally to "each public water system in each State" and authorizes EPA to regulate certain contaminants in drinking water. 42 U.S.C. § 300g [42 U.S.C. § 300g, ADD-5-ADD-7]. The Act prescribes a unique regulatory process, mandating that EPA carefully consider the best available science; information on the occurrence of contaminants in drinking water; the feasibility of regulation; the costs of compliance; and the potential for meaningful health benefits. This multistep process allows for ample public engagement and minimizes the risk of "locking-in" regulations that are impractical for water systems, or pose excessive water affordability challenges for consumers. The Act also recognizes that not all contaminants pose a risk to public health at all occurrence levels, and that not all contaminants warrant national regulation at a particular stringency.

The current statutory structure results from Congressional dissatisfaction with the previous approach: Prior to 1996, the Act required EPA to set standards for 25 additional contaminants every 3 years. 42 U.S.C. § 300g-1(b)(3)(A), (C) (1986) [42 U.S.C. § 300g-1 (1986), ADD18-ADD-21]. That approach "provoked more critical comment than virtually any other element of environmental law," and led to "arbitrary Federal law imposing burdens on consumers and the taxpayers . . . with no rational relationship to the public benefits that might be realized" because some contaminants

> occur so infrequently in public water systems that the costs of monitoring (for a substance not present) far outweigh any health benefit that could be realized at the few systems that may detect the contaminant. In other cases, the available science is so uncertain that standards incorporate extravagant margins of safety (30,000-fold for one contaminant) making it impossible to assert that expenditures to implement the regulation are a public health necessity.

S. Rep. No. 104-169, at 12-13 (1995); *see* H.R. Rep. No. 104-632, at 10 (1996) (approach "dilutes limited resources on lower priority contaminants, and as a consequence may hinder more rapid progress on high priority contaminants." (quoting EPA Assistant Administrator Robert Perciasepe)). The burdens of ill-advised regulation that "provide[d] only marginal increases in [public] health protection at significant costs," especially where there was "much uncertainty concerning both the occurrence and real threat to public health of many contaminants," ultimately fell to customers because compliance costs are directly passed on through rates. H.R. Rep. No. 104-632 at 9 (quoting Ronald Dungan, President of the National Association of Water Companies).

Congress responded with the current sequential, six-step regulatory process. *First*, EPA publishes a draft Contaminant Candidate List ("List") of unregulated contaminants that are known or anticipated to occur in public water systems every 5 years. 42 U.S.C. § 300g-1(b)(1)(B)(i) [42 U.S.C. § 300g-1, ADD-8-ADD-17]. *Second*, EPA finalizes the List after notice and comment. *Id.* § 300g-1(b)(1)(B)(i)(I).

Third, every 5 years EPA determines whether to regulate at least 5 contaminants identified on the List. *Id.* § 300g-1(b)(1)(B)(ii)(I). Importantly, EPA must initially publish a "notice of the ***preliminary* determination**" of whether to regulate a contaminant, accompanied by an "opportunity for public comment." *Id.* (emphasis added). To support these efforts, every 5 years EPA issues a list of up to 30 unregulated contaminants for public water systems to monitor through an Unregulated Contaminant Monitoring Rule ("UCMR"), which creates a nationally representative dataset on the occurrence of unregulated contaminants in drinking water supplies. *See id.* §§ 300j-4(a)(2) [§ 300j-4, ADD-22-ADD-25], 300g-1(b)(1)(B)(ii)(II), 300j-4(g).

Fourth, EPA issues a **Determination to Regulate** (or "**Determination**") if three statutory criteria are met:

> (i) the contaminant may have an adverse effect on the health of persons;
>
> (ii) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and
>
> (iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

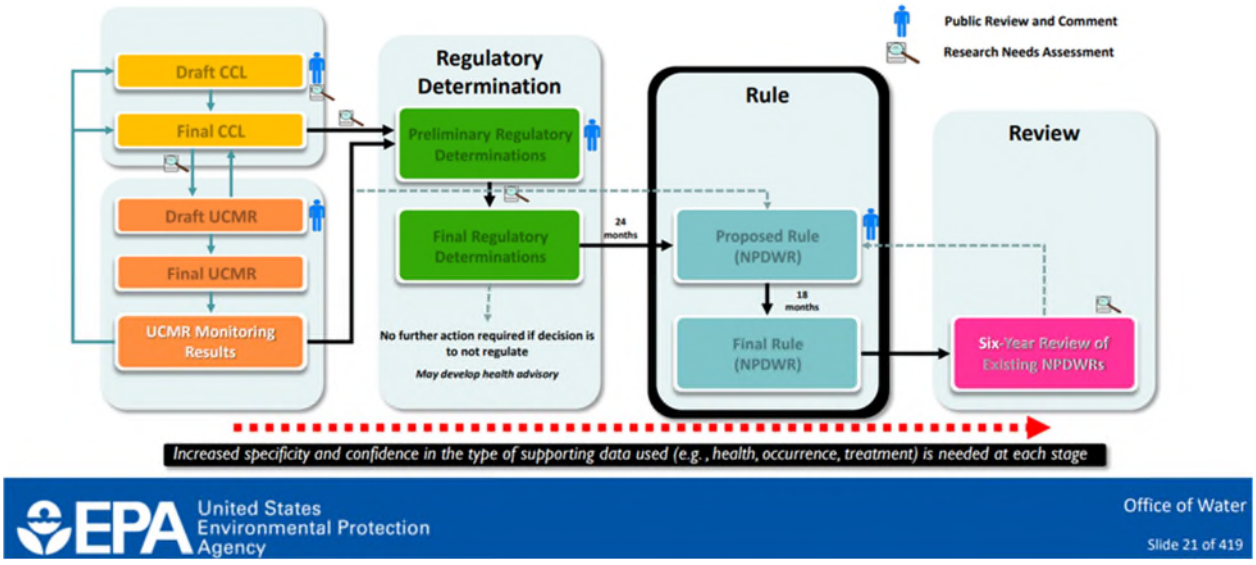
Id. § 300g-1(b)(1)(A)(i)-iii; *id.* § 300g-1(b)(1)(B)(ii)(II). The Determination must also be based on "the best available public health information," including occurrence data of the contaminant in drinking water. *Id.* § 300g-1(b)(1)(B)(ii)(II).

Fifth, if EPA issues a Determination to Regulate, the Agency shall publish a maximum contaminant level goal ("Goal")" for that contaminant. *Id.* § 300g-1(b)(1)(E); *see id.* § 300g-1(b)(1)(A). Goals are non-enforceable and identify the level of a contaminant at which point "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." *Id.* § 300g-1(b)(4)(A). Along with a Goal, EPA must promulgate a "national primary drinking water regulation." *Id.* § 300g-1(b)(1)(E). This often takes the form of a maximum contaminant level ("Level"). The alternative is a "treatment technique," 42 U.S.C. § 300g-1(b)(7)(A), which is not at issue in this case. While the Goal is aspirational, the Level is legally enforceable. EPA must propose the Goal and Level "not later than 24 months after" the Determination to Regulate and may publish the proposed regulation concurrent with the Determination to Regulate. *Id.* § 300g-1(b)(1)(E). The final Goal and Level must come "within 18 months" of proposal, although EPA may extend that deadline. *Id.* EPA must base its actions on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices," as well as "data collected by accepted methods or best available methods." *Id.* § 300g-1(b)(3)(A).

When proposing a Level, EPA must "publish, seek public comment on, and use" a Health Risk Reduction and Cost Analysis for the proposed Level and each alternative Level that EPA is considering. *Id.* § 300g-1(b)(3)(C)(i). This analysis

considers "[q]uantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record." *Id.* § 300g-1(b)(3)(C)(i)(I)-(II). EPA must also consider "[q]uantifiable and nonquantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the [Level]" (e.g., monitoring costs, treatment costs), as well as "[t]he incremental costs and benefits associated with each alternative maximum contaminant level considered." *Id.* § 300g-1(b)(3)(C)(i)(III)-(IV). EPA must also determine "whether the benefits of the [Level] justify, or do not justify, the costs." *Id.* § 300g-1(b)(4)(C). And a Level "shall not be more stringent than is feasible." *Id.* § 300g-1(b)(5)(B). *Sixth*, EPA issues a final regulation.

EPA has repeatedly used this graphic to describe the process:



EPA, *Discuss Potential Approaches to the Sixth Unregulated Contaminant Monitoring Rule* (UCMR 6) at 12 (2024) [hereinafter *EPA UCMR 6 Presentation*],

https://www.epa.gov/system/files/documents/2024-05/public-webinar-development-proposed-ucmr-6.pdf.

The Act's multistep process, and EPA's careful consideration of the best available science, data and costs, is essential because once issued, EPA cannot withdraw a Determination to Regulate. *See Nat. Res. Def. Council v. Regan*, 67 F.4th 397, 401, 402 (D.C. Cir. 2023). And once promulgated, any future regulatory revisions must "maintain, or provide greater, protection of the health of persons." 42 U.S.C. § 300g-1(b)(9); *see Regan*, 67 F.4th at 399. The Act thus limits EPA's ability to revisit regulatory actions—e.g., Determinations to Regulate low-occurrence contaminants, or regulations that are too stringent and costly. In such instances, customers could bare rate increases disproportionate to potential public health benefits, while water systems could be prevented from better allocating resources towards activities that provide greater public health benefits.

C. The Rulemaking

EPA initially followed the Act's six-step process: EPA proposed and then included PFOA and PFOS in the third and fourth Lists (Steps 1-2). *See* 74 Fed. Reg. 51,850, 51,852 (Oct. 8, 2009), JA__; 81 Fed. Reg. 81,099, 81,107 (Nov. 17, 2016), JA__. EPA then collected nationally representative data on the occurrence of PFOA and PFOS, as well as PFHxS, PFNA, and PFBS, in drinking water as part of the third UCMR ("UCMR 3"). *See* 77 Fed. Reg. 26,072 (May 2, 2012), JA__. Next, EPA

issued Preliminary Determinations to regulate PFOA and PFOS (Step 3), *see* 85 Fed. Reg. 14,098 (Mar. 10, 2020), JA__, and after public comment, issued Determinations to Regulate (Step 4), *see* 86 Fed. Reg. 12,272, 12,275 (Mar. 3, 2021), JA__.

In 2021 EPA published the fifth UCMR ("UCMR 5") to collect nationally representative occurrence data, including for all 6 PFAS. *See* 86 Fed. Reg. 73,131, 73,148, 73,155-56 (Dec. 27, 2021), JA__, __-__. UCMR 5 is more representative of systems nationally than UCMR 3, with more than twice as many systems monitoring at lower reporting thresholds. *Compare* 77 Fed. Reg. at 26,090, 26,099, JA__, __ (Exhibit 9 and Table 1), *with* 86 Fed. Reg. at 73,148, 73,155-56, JA__, __-__ (Exhibit 6 and Table 1). UCMR 5 is scheduled for completion in December 2025 and EPA has already started to receive preliminary results.

In March 2023, EPA proposed the Rule (Step 5): For each of PFOA and PFOS, EPA proposed Goals of zero and enforceable Levels at 4.0 parts per trillion ("ppt").[2] 88 Fed. Reg. 18,638, 18,639, 18,666-68 (Mar. 29, 2023), JA__,___. 4.0 ppt is "the lowest concentration that [the two contaminants] can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating

[2] For drinking water rulemakings, including the one here, ppt and nanograms per liter ("ng/L") are often used interchangeably.

conditions." *Id.* at 18,666, JA __. EPA also requested comment on alternative Levels of 5.0 and 10.0 ppt. *Id.* at 18,670, JA__.

In the same proposal, EPA made stark departures from the Act's stepwise process and analytical requirements: EPA published Preliminary Determinations (Step 3) to regulate Index PFAS as individual contaminants, as well as mixtures of two or more of the four contaminants. *Id.* at 18,641, JA__. In support of those Preliminary Determinations, EPA relied upon occurrence data from UCMR 3, which did not include HFPO-DA, and non-targeted (i.e., not site-specific, or limited to areas of known or potential contamination) occurrence data from 11 states, which EPA acknowledged "var[ied] in terms of quantity and coverage." *Id.* at 18,648-49, JA__-__.

EPA concurrently proposed a novel use of a "hazard index," setting a value of 1.0 (unitless) as the Goal and Level for Index PFAS, individually and as mixtures of two or more contaminants (Step 5). *Id.* at 18,641-42, 18,663-66, JA __-__, __-__. EPA previously used the hazard index to investigate and compare the relative potential health risks of chemical mixtures at contaminated sites under the Superfund program. *Id.* at 18,669, JA__; *infra* Section II.B. As proposed by EPA in 2023, the hazard index is the sum of four "hazard quotients," which are ratios between the measured concentration of an Index PFAS in a water sample and its "health-based water concentration" (i.e., the level below which adverse health effects are not likely

to occur). *Id.* at 18,639, 18,665, JA__, __. EPA proposed health-based water concentrations for PFHxS (9.0 ppt), HFPO-DA (10 ppt), PFNA (10 ppt), and PFBS (2000 ppt). *Id.* at 18,641-42, JA__-__. Water Associations extensively commented that the proposal violated the Act. *See generally* AWWA Comment, JA__; AMWA Comment, EPA-HQ-OW-2022-0114-1738, JA__.

D. The Rule

EPA issued the Rule (Step 6). For PFOA and PFOS, EPA finalized Goals of zero and Levels of 4.0 ppt—by far the most costly Level considered by EPA: At 4.0 ppt, EPA's expected annualized quantified costs (at a 2% discount rate) are about $1.537 billion . *See* 89 Fed. Reg. at 32,535, 32,710-12, JA__, __-__ (Tables 69, 70, and 71).

EPA also finalized Determinations to Regulate PFHxS, PFNA, and HFPO-DA individually. *Id.* at 32,535, JA__.[3] For each, EPA promulgated individual Goals and Levels of 10 ppt. *Id.* Additionally, EPA finalized a Determination to Regulate mixtures of any two or more Index PFAS, and promulgated a Goal and Level based on a hazard index value of 1 (unitless). *Id.*

[3] EPA deferred making a determination to regulate PFBS on an individual basis. 89 Fed. Reg. at 32,535, JA__. EPA's justification for deferral (insufficient occurrence information) would apply equally to HFPO-DA and PFNA.

For Index PFAS, EPA relied on UCMR 3 occurrence data and piecemeal, non-targeted (i.e., not site-specific, or limited to areas of known or potential contamination) occurrence data from a limited number of states, having "supplemented the data" between the proposed and final Rule. *Id.* at 32,553-55, JA__-__. EPA asserted this was the "best available occurrence data" and declined to wait for nationally representative occurrence data from UCMR 5—while also noting that the individual states used reporting thresholds that were "not defined consistently across all states." *Id.* at 32,553, 32,554-55, JA__, __-__.

EPA also finalized monitoring, reporting, and public notification requirements, which will require public water systems to monitor for all six PFAS in perpetuity, even if none of the substances has ever been detected in a system's source water. *Id.* at 32,535, JA__.

SUMMARY OF ARGUMENT

I. EPA violated the Act by proposing regulations for Index PFAS **before** issuing a Determination to Regulate those PFAS. That action was contrary to the plain language of the Act and represents an unreasoned and unacknowledged departure from decades of prior policy.

II. EPA's use of the "hazard index" value of 1 (unitless) as a Level for Index PFAS was arbitrary and contrary to the Act. A Level refers to a fixed, clearly defined threshold, not a convoluted equation where compliance hinges upon

fluctuations in the relative concentrations of four different contaminants. EPA's use of the hazard index is contrary to agency guidance and science, because its underlying inputs are based upon a mixture of chemicals with disparate adverse health effects.

III. EPA arbitrarily determined that HFPO-DA, PFNA, and Index PFAS (as mixtures) have a "substantial likelihood" of occurrence "in public water systems with a frequency and at levels of public health concern." 42 U.S.C. § 300g-1(b)(1)(A)(ii). EPA did not wait for nationally representative UCMR 5 data and instead relied upon a limited patchwork of state-level data. That data does not show those substances and mixtures occur at frequencies and levels of public health concern.

IV. EPA's defective analysis drastically underestimated the Rule's costs. Even EPA's own erroneous analysis demonstrates that it should have set the Levels for PFOA and PFOS at 10.0 ppt rather than 4.0 ppt.

STANDING

Water Associations' standing is self-evident because their public water system members are "directly regulated by the rule and ha[ve]been injured by it." *Advocs. for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 41 F.4th 586, 594 (D.C. Cir. 2022). Water Associations' public water system members are objects of the Rule, and subject to the Rule's requirements. *See* 89 Fed. Reg. at 32,534-35,

JA__-__; 42 U.S.C. § 300g (coverage of the Act); *e.g.*, Hedges Decl. ¶9, Standing Addendum ("SA") -64; Granger Decl. ¶10, SA-42-43; Gross Decl. ¶8, SA-57.

Water Associations' members satisfy the requirements for Article III standing. *See Advocs. for Highway and Auto Safety*, 41 F.4th at 593-94. The challenged actions give rise to "concrete, particularized pocketbook injur[ies]" for Water Associations' members. *Maine Lobstermen's Ass'n v. Nat'l Marine Fisheries Serv.*, 70 F.4th 582, 592 (D.C. Cir. 2023);*See* 89 Fed. Reg. at 32,653-63, JA__-__ (estimating costs); EPA, *Economic Analysis for the Final Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation* at C-1 to C-33 (2024) [hereinafter *Economic Analysis*], EPA-HQ-OW-2022-0114-3084 and 2085, JA__-__. Even for systems that do not have any of the regulated PFAS above the applicable Levels, the Rule's initial and long-term compliance monitoring requirements will impose water sampling and lab testing costs. 89 Fed. Reg. at 32,660-63, JA__-__; Gross Decl. ¶¶9-12, SA-57-59; Rechtin Decl. ¶¶9-15, SA-73-76; Braker Decl. ¶¶12-18, SA-33-37. Members would not face some or all of those costs if the Rule is vacated in part or in full. *See* Granger Decl. ¶¶6, 12-13, SA-41, 43-44.

Water Associations' challenge is germane to their respective purposes, and there is no reason individual members must participate in it. *See Maine Lobersterman's Ass'n*, 70 F.4th at 593; *Comm. for Effective Cellular Rules v. FCC*,

53 F.3d 1309, 1315 (D.C. Cir. 1995). By challenging the Rule, Water Associations serve their organizational purposes of ensuring that drinking water regulations are feasible, cost-effective, and consistent with the Act. *See* Mehan Decl. ¶6, SA-3; Dobbins Decl. ¶4, SA-12.

STANDARD OF REVIEW

This Court holds unlawful and sets aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A), ADD-1. "[T]he overarching question" is whether the agency's "decisionmaking was reasoned, principled, and based upon the record," *Env't Def. Fund v. FERC*, 2 F.4th 953, 967-68 (D.C. Cir. 2021) (internal quotation marks omitted); *see Bluewater Network v. EPA*, 370 F.3d 1, 22 (D.C. Cir. 2004) (deference to agency findings "only if [the agency] has adequately explained the basis" for it).

On questions of statutory interpretation, EPA is no longer entitled to deference, and this Court "must apply what [it] regard[s] as the statute's 'best' reading." *U.S. Sugar Corp. v. EPA*, 113 F.4th 984, 991 (D.C. Cir. 2024) (citing *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266 (2024)). The interpretive inquiry "begin[s] with the text," and focuses on "the ordinary meaning of [the statute's] key terms." *Pac. Gas & Elec. Co. v. FERC*, 113 F.4th 943, 948 (D.C. Cir. 2024) (citations omitted).

ARGUMENT

I. EPA Violated the Act by Issuing Proposed Regulations for Index PFAS Before Making Final Determinations to Regulate Those PFAS.

The Act mandates a sequential, six-step process for regulation. For the first time ever, EPA departed from that process. EPA instead used a four-step process for regulating the Index PFAS based on its new interpretation of the term "determination to regulate." When mapped onto the statutory structure, EPA's actions look like this:

Step		Statutory Citation	PFAS Rulemaking
1	Draft List	42 U.S.C. § 300g-1(b)(1)(B)(i)(I).	**PFOA/PFOS: 2008**. 73 Fed. Reg. 9628 (Feb. 21, 2008), JA__. **Index PFAS: 2021**. 86 Fed. Reg. 37,948, 37,952 (July 19, 2021), JA__.
2	Final List	42 U.S.C. § 300g-1(b)(1)(B)(i)(I).	**PFOA/PFOS: 2009/2016**. 74 Fed. Reg. 51,850, 51,852, JA__; 81 Fed. Reg. 81,099, 81,107, JA__. **Index PFAS: 2022**. 87 Fed. Reg. 68,060, 68,062 (Nov. 14, 2022), JA__.
3	Preliminary Determination to Regulate	EPA makes a "preliminary determination . . . of whether or not to regulate such contaminants" subject to notice and comment 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I).	**PFOA/PFOS: 2020**. 85 Fed. Reg. at 14,100, JA__. **Index PFAS: 2023**. 88 Fed. Reg. at 18,641-42, JA__-__ (combined with Step 5).

4	Determination to Regulate	After notice-and-comment on the Preliminary Determination, EPA "make[s] determinations of whether or not to regulate." 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I).	**PFOA/PFOS: 2022**. 86 Fed. Reg. at 12,273, JA__. **Index PFAS: 2024**. 89 Fed. Reg. at 32,535, JA__ (combined with Step 6).
5	Proposed Regulation	For each contaminant EPA determines to regulate, EPA shall propose the Goal and regulation not later than 24 months after the Determination to Regulate. 42 U.S.C. § 300g-1(b)(1)(E).	**All: 2023**. 88 Fed. Reg. at 18,641-42, JA__-__.
6	Final Regulation	EPA shall publish a Level, Goal, and promulgate a regulation within 18 months after the proposal 42 U.S.C. § 300g-1(b)(1)(E).	**All: 2024**. 89 Fed. Reg. at 32,535, JA__.
	UCMR data	42 U.S.C. §§ 300g-1(b)(1)(B)(ii)(II), 300j-4(a)(2), 300j-4(g).	**UCMR 3: 2012** (PFOA, PFOS, PFHxS, PFNA, and PFBS). 77 Fed. Reg. at 26,075, JA__. **UCMR 5: 2021** (All 6 PFAS). 86 Fed. Reg. at 73,148, 73,155-56, JA__, __-__.

The question here is whether it was lawful for EPA to issue proposed regulations for Index PFAS (Step 5) **before** it issued its Determinations to Regulate (Step 4). The answer is no: The best reading of the Act is that a proposed regulation may be issued either concurrently with or after the Determination to Regulate, but not before. EPA's current position, concocted for the one-off purpose of "accelerating" this rulemaking, departs from the Agency's prior interpretations without reasoned explanation or even acknowledgement. What few arguments offered in support of its novel approach are unpersuasive.

A. Under the plain language of the Act, EPA may not issue a proposed rule before issuing a final Determination.

"In addressing a question of statutory interpretation, we begin with the text." *City of Clarksville v. FERC*, 888 F.3d 477, 482 (D.C. Cir. 2018). Here, the dispute turns largely on the meaning of Section 1412(b)(1)(E), reproduced below, broken out into its four key clauses:

> **[1]** For each contaminant that the Administrator determines to regulate under subparagraph (B),[4] the Administrator shall publish [Goals] and promulgate, by rule, national primary drinking water regulations under this subsection.

[4] "Subparagraph (B)" provides that EPA will "make determinations of whether or not to regulate" contaminants "after notice of the preliminary determination and opportunity for public comment." 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I).

> **[2]** The Administrator shall propose the [Goal] and national primary drinking water regulation for a contaminant not later than 24 months after the determination to regulate under subparagraph (B), and
>
> **[3]** may publish such proposed regulation concurrent with the determination to regulate.
>
> **[4]** The Administrator shall publish a [Goal] and promulgate a national primary drinking water regulation within 18 months after the proposal thereof.

42 U.S.C. § 300g-1(b)(1)(E).

EPA's theory hinges on a puzzling and ever-shifting interpretation of Clause 3. Before this rulemaking, EPA had always interpreted the phrase "determination to regulate" to be just that: the **final** Determination to Regulate (Step 4). *See infra* Section I.B. But here, EPA debuted the argument that "the reference to 'determination to regulate' in Section 1412(b)(1)(E) [is] referring to the **regulatory process** in 1412(b)(1)(B)(ii) that begins with a preliminary determination"—*i.e.*, that "determination to regulate" means the whole "rulemaking process[]" including both the Preliminary Determination and the final Determination. 88 Fed. Reg. at 18,644, JA__ (emphasis added). Then, EPA shifted its position again, and now "interpret[s] 'determination to regulate' in the phrase 'may publish such proposed regulation concurrent with the determination to regulation' in [Clause 3] to be a **preliminary determination**." 89 Fed. Reg. at 32,541, JA__ (emphasis added). In short, EPA first viewed the phrase "determination to regulate" to mean just that—the final Determination to Regulate, then said that phrase meant the whole

"regulatory process," and then said it meant the Preliminary Determination. Based on its third interpretation, EPA argued that Clause 3 authorizes EPA to issue a proposed regulation concurrently with a "determination to regulate" (in its view, a Preliminary Determination), which means that the proposed regulation (Step 5) can come before the Determination to Regulate (Step 4). *Id.* at 32,541-42, JA__-__. There is little to recommend EPA's view.

1. EPA must publish the Determination to Regulate before the proposed regulation.

Clause 1 provides that EPA "shall publish" a proposed regulation for contaminants that "the Administrator determines to regulate." The phrase "determines to regulate" must mean the final Determination to Regulate. The word "determination" itself means "a **final** decision by a court or administrative agency,"[5] The Determination to Regulate is the only Agency decision that is "final" or fixed. By contrast, a Preliminary Determination is non-final and can be withdrawn. *See Regan*, 67 F.4th at 398. Because the phrase "determines to regulate" in Clause 1 means the Determination to Regulate, and because Clause 1 provides that a proposed regulation shall be published only for those contaminants EPA has "determine[d] to

[5] *Black's Law Dictionary* 564 (11th ed. 2019) (emphasis added); *accord Webster's New International Dictionary* 616 (3d ed. 1971) ("determination" means "the settling and ending of a controversy" or "the act of deciding definitely and firmly"; "determine" means to "fix conclusively"); *Webster's New College Dictionary* 308 (2d ed. 1995) ("determine" means to "end or decide by final . . . action").

regulate," it follows that a proposed regulation *cannot* be issued before making a Determination to Regulate.

Moreover, interpreting the phrase "determines to regulate" in Clause 1 to mean the Preliminary Determination would create absurd results, as it would **obligate** EPA to issue a proposed regulation whenever it makes a Preliminary Determination. EPA plainly does not read the statute to create that obligation; indeed, in every past instance of regulation under the Act, EPA has **not** issued a proposed regulation together with its Preliminary Determination.

That reading is confirmed by Clauses 2 and 3. Clause 2 requires EPA to issue a proposed regulation "not later than 24 months **after the determination to regulate**." EPA appears to agree that this use of the term "determination to regulate" refers to the Determination to Regulate; no other reading is plausible, because no "determination to regulate" is made unless and until the final Determination is issued. Clause 3 then clarifies that EPA may issue a proposed regulation "concurrent with the determination to regulate." Thus, Clauses 2 and 3 work together to specify that the proposed regulation can be issued either "concurrent" with or "after" the Determination to Regulate—but not before.

EPA ignores that Congress elsewhere explicitly used "preliminary" when it meant to refer to a Preliminary Determination, and yet did not do so in Clause 3. *See* 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I) (EPA makes Determination to Regulate "after

notice of the **preliminary determination** and opportunity for public comment" (emphasis added)). Conversely, when Congress intended to refer to the final Determination to Regulate, it repeatedly used that exact phase. *See id.* § 300g-1(b)(1)(B)(ii)(II), (III). Indeed, EPA would have this Court believe that Congress intended the phrase "determination to regulate" in Clause 3 to mean the Preliminary Determination, even though Congress did not use the word "preliminary" in Clause 3 but did elsewhere in the same sub-section. That is not how statutory interpretation works. *See Romag Fasteners, Inc. v. Fossil, Inc.*, 590 U.S. 212, 215 (2020); *Salinas v. U.S. R.R. Ret. Bd.*, 592 U.S. 188, 196 (2021); *United States v. Bowser*, 964 F.3d 26, 31 (D.C. Cir. 2020).

EPA's theory would also require this Court to conclude that Congress meant the phrase "determination to regulate" to mean two different things in the same sentence of the same statute. EPA agrees that the phrase "determination to regulate" in Clause 2 means the final Determination. And rightly so: Read in context, that phrase could not possibly mean anything else. *See supra* note 5. *See Atl. Cleaners & Dyers v. United States*, 286 U.S. 427, 433 (1932) (observing "natural presumption that identical words used in different parts of the same act are intended to have the same meaning"); *Judge Rotenberg Educ. Ctr., Inc. v. DEA*, 3 F.4th 390, 398 (D.C. Cir. 2021) (similar).

Were that not enough, this Court itself recently and repeatedly confirmed Water Associations' reading of the statute in its May 2023 opinion concerning regulation of perchlorate. *See Regan*, 67 F.4th at 402 ("[T]he preliminary determination precedes the notice and comment period. Once that period ends, the agency makes its regulatory determination, and that determination is final."); *see also id.* at 398, 399, 400, 403 (using "final determination" and "regulatory determination" interchangeably). More importantly, this Court held that the "**final determination to regulate perchlorate . . . started a clock . . . to propose regulations** within twenty-four months"—not the **Preliminary** Determination, as EPA contends here. *Id.* at 398. The opinion also clarified that EPA may only issue a proposed regulation "**after** determining the statutory criteria" in § 300g-1(b)(1)(A)(iii) "are met." *Id.* at 399 (emphasis added). That too confirms Water Associations' interpretation, because EPA does not determine whether the criteria of § 300g-1(b)(1)(A)(iii) "are met" until it makes the Determination—indeed, determining whether those criteria "are met" is the whole point of allowing comment on the Preliminary Determination. 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II).

B. EPA's new interpretation rests on an unreasoned and unacknowledged departure from decades of prior policy.

The Rule adopts several interpretations of the Act that contradict the Agency's public statements dating back more than a decade. That is a paradigmatic example

of arbitrary action. *See Northpoint Tech., Ltd. v. FCC*, 412 F.3d 145, 156 (D.C. Cir. 2005); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

EPA has undertaken multiple processes to regulate contaminants since the Act was amended. Until this proceeding, it had **never** issued a proposed regulation before making a Determination to Regulate and had always regarded the Determination to Regulate as the trigger for the 24-month window to issue a proposed rule. The preambles to the rulemaking documents confirm that—before this case—EPA's view was that the Determination to Regulate must precede the proposed regulation. For example, the preamble to EPA's Final Determination 4 stated that, "[i]f **after** considering public comment on a preliminary determination, the Agency **makes a determination to regulate** a contaminant, EPA will **initiate** the process to propose and promulgate" a regulation. 86 Fed. Reg. at 12,273 (emphasis added). This confirms that EPA does not "make[] a determination to regulate" until "after" the comment period on the Preliminary Determination, and that EPA in turn does not "initiate" rulemaking until after the Determination to Regulate.

Similarly, the preamble to EPA's Preliminary Determination 3 described the regulatory process in this way:

> If after the public comment period [on the Preliminary Determination], the agency answers 'yes' to all three statutory criteria, the agency **then** makes a 'positive' final determination that regulation is necessary and

> **proceeds to develop** [a Goal] and [regulation] [i.e., a proposed regulation].

79 Fed. Reg. 62,716, 62,727 (Oct. 20, 2014). For more than a decade, EPA has thus understood that the Agency cannot "proceed to develop" a proposed regulation until after a "final determination" is made.

EPA has also issued numerous guidance documents which contravene its position in the Rule. EPA's website provides this summary:

> EPA first publishes a preliminary regulatory determination . . . and provides an opportunity for public comment. After review and consideration of public comment, EPA publishes a final [Federal Register] notice with the regulatory determination decisions. If EPA makes a decision to regulate a particular contaminant, the Agency **starts** the rulemaking process . . . .

EPA, *How EPA Regulates Drinking Water Contaminants* (Nov. 2, 2023), https://perma.cc/W7R3-FS2D (accessed Sept. 24, 2024) (emphasis added). Helpful graphics provided by the Agency reaffirm this process. *See, e.g.*, EPA, *Understanding How EPA Develops New Drinking Water Regulations*, https://www.epa.gov/system/files/images/2024-01/epa-regulate_drinking_water_contaminants-final-508.png; *EPA UCMR 6 Presentation*, *supra* p. 9. Outside the context of this litigation, EPA clearly believes the "regulatory determination decision[]" to be the Step 5 Determination to Regulate, and that EPA understands that Determination as being the event that "**starts** the rulemaking process."

C. EPA's defense of its novel approach is unpersuasive.

EPA attempted to justify its novel reading of the Act by presenting four arguments. Each is confusing. None is persuasive.

First, EPA claimed that "Congress's use of the phrase 'determination to regulate' . . . in SDWA is not consistent." 89 Fed. Reg. at 32,541, JA__. But EPA has never identified any part of the Act that uses the phrase "determination to regulate" to mean anything **other than** the final Determination. EPA claims that the phrase "determination for a contaminant" as used in Section 1412(b)(1)(B)(iii) of the Act is supposedly a clear reference to a Preliminary Determination. *See id*. To state the obvious, the phrase "determination for a **contaminant**" is not the same as the phrase "determination to **regulate**." The former refers to the decision to list a contaminant from the List in the Preliminary Determination, whereas the latter refers to the agency's final decision on whether to pursue regulation.

Second, EPA advances a curious interpretation of Section 1412(b)(1)(E), which provides that EPA "shall propose the [proposed regulation] not later than 24 months after the determination to regulate." 42 U.S.C. § 300g-1(b)(1)(E). According to EPA, this language creates a deadline requiring EPA to issue a proposed regulation "not later" than two years after the final Determination, but does not "preclude the EPA from issuing a proposed rule at any time prior to the expiration of the 24 months after a final regulatory determination, including issuing the

proposed rule on the same day as the preliminary regulatory determination." 89 Fed. Reg. at 32,541, JA__. This reading of the Act is the exact inverse of what EPA has previously told the public. *See supra* Section I.B. EPA's reading violates also the rule against superfluities: The phrase "determination to regulate" in Clause 3 must mean the final Determination. If that is so, then the phrase "not later than 24 months after the determination to regulate" as used in Clause 2 cannot mean that EPA may publish the proposed rule at any time before the date that is 24 months after the final Determination. Otherwise Clause 3 would be superfluous, because Clause 2 would already have authorized EPA to publish the proposed regulation contemporaneously with the final Determination. The better reading is that Clause 2 allows EPA to publish the proposed regulation "**after** the determination to regulate" (i.e., the Determination), and that Clause 2 allows EPA to publish the Proposed Regulation "concurrent with the determination to regulate" (again, the Determination).[6]

Moreover, EPA errs by reading Clause 2 in a vacuum. EPA ignores the first sentence of Clause 2, which states that "the Administrator shall publish" a proposed

[6] According to EPA, interpreting the phrase "concurrent with the determination to regulate" in Clause 3 to refer only to the Determination would render that phrase a "nullity," because Clause 2 already "expressly acknowledges that the EPA may issue a proposed rule concurrent with a final determination." 89 Fed. Reg. at 32,541, JA__. Not so. Clause 2 does not "expressly acknowledge" that the proposed regulation and Determination would be concurrent; only Clause 3 makes that clarification, and that is its independent utility. *See BFP v. Resolution Tr. Corp.*, 511 U.S. 531, 543 n.7 (1994) ("It is no superfluity for Congress to clarify what had been at best unclear.").

regulation "**[f]or each contaminant that the Administrator determines to regulate**." 42 U.S.C. § 300g-1(b)(1)(E) (emphasis added). Because the Administrator does not "determine[] to regulate" until a Determination to Regulate is issued, the proposed regulation cannot precede that Determination.

Third, EPA contends that requiring the Agency to issue a Determination to Regulate before a proposed regulation would "hinder Congress's goal" of "accelerat[ing] EPA action under SDWA." 89 Fed. Reg. at 32,541, JA__. But this Court must credit the "enacted statutory text" EPA's "curated account[] of a law's purposes." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2291 n.6 (2024) (Gorsuch, J., concurring) (internal brackets and quotation marks omitted). Appeals to "statutory purpose" are no substitute for the standard "interpretive toolkit." *Id*. at 2271 (majority op.). And Congress specifically added mechanisms to the Act that allow EPA to regulate expeditiously on matters that presented "urgent threats to public health." 42 U.S.C. § 300g-1(b)(1)(D). EPA should not be permitted to invent a new, atextual process to "accelerate" a rule when the agency elected to ignore the separate, textual process for accelerated rulemaking that Congress actually crafted.

Indeed, as amended in 1996, the Act walked back Congress's prior approach of requiring EPA to move forward with regulation for 25 contaminants every 3 years, and replaced that system with the multistep process described on pages 5-12 above.

The amended statute evinces a methodical, deliberative approach from end-to-end—not an overriding concern with "acceleration."

Fourth, EPA argues that allowing "concurrent" comment on the Preliminary Determination and the proposed regulation, instead of two separate comment periods, somehow "enhances . . . the deliberative stepwise process provided in the statute." 89 Fed. Reg. at 32,541, JA__. But the fact of matter is that the Act prescribes two comment periods,[7] and gives no indication that they could be combined. Wedding the two comment periods into one had the practical effect of giving the public only 60 days to comment on two complex issues, instead of the two 60-day comment periods to which they were entitled.[8]

EPA contends that "it is not clear what further benefit would be provided by two separate public comment periods" given that the information provided in a separate comment period on a proposed rule "cannot be used to undo a final

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[7] *Cf.* 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I); *id.* § 300g-1(b)(1)(E).

[8] In the Rule's preamble, EPA suggest that combining the comment periods meant that commenters had "more information to evaluate the preliminary regulatory determinations"—i.e., that they were able to review on the record for the Preliminary Determination, but also on the "full rulemaking record . . . that supports the proposed [regulation]." 89 Fed. Reg. at 32,542, JA__. That argument overlooks the fact that the decision of whether or not to regulate and the decision of how to shape a proposed regulation rest on very different criteria. *Compare* 42 U.S.C. §§ 300g-1(b)(1)(A)(i)-(iii), (B)(ii)(II), *with id.* § 300g-1(b)(4)(C). EPA itself has previously confirmed that the "regulatory determination process is distinct from the more detailed analyses needed to develop a national primary drinking water regulation." 79 Fed. Reg. at 62,727.

regulatory determination." 89 Fed. Reg. at 32,542, JA__. That argument is a straw man as there must be separate comment periods on the *Preliminary* Determination and the proposed regulation, not that there cannot be a combined comment period on the proposed regulation and the final Determination. In any case, the fact that a Determination to Regulate cannot be withdrawn strengthens Water Associations' argument. Congress knew that the Act contains two separate "points of no return": A Determination cannot be withdrawn once made (*see Regan*, 67 F.4th at 402), and a regulation cannot be weakened once promulgated (the "anti-backsliding" provision at 42 U.S.C. § 300g-1(b)(9)). That the Act includes these one-way ratchets makes it critical that EPA conduct a complete process **before** those points of no return are reached.

* * *

No matter the potential expediencies, EPA's approach of concurrently issuing Preliminary Determinations to regulate alongside proposed regulations for the Index PFAS was contrary to the language of the Act, EPA precedent, and the purpose of the overall statutory scheme. These portions of the Rule should therefore be vacated and remanded to EPA.

II. EPA's Use of the Hazard Index as an Enforceable Level for Mixtures of Two or More Index PFAS Violated the Act and Was Arbitrary and Capricious.

For each regulated contaminant, the Act gives EPA only two options for the form of regulation: a Level or, if certain conditions are met, a treatment technique. *See* 42 U.S.C. § 300g-1(b)(1)(E), (b)(7)(A).

Here, EPA invented a third approach: For the first time ever, EPA promulgated a novel "hazard index" value of 1 (unitless) as the applicable "Level" for mixtures of two or more Index PFAS. 89 Fed. Reg. at 32,535, JA__. For the Rule, EPA derived a hazard index equation that sums together the "hazard quotients" (i.e., ratios meant to characterize a constituent chemical's relative potential health risk) for each of the four Index PFAS, according to their "health-based water concentrations" (i.e., the level below which adverse health effects are not likely to occur). *Id.* at 32,533, JA__. EPA conceded in the proposed Rule that "this is the first use of a[] [hazard index] approach for a [] National Primary Drinking Water Regulation." 88 Fed. Reg. at 18,669, JA__. EPA's novel use of the hazard index as a Level was inappropriate, because the hazard index is not a "Level" under the Act, and hazard indices are designed as risk screening/comparison tools, not the bases for regulation. The Index PFAS "Levels" should therefore be vacated.

A. The hazard index is not a Level.

A Level is "the maximum permissible **level of a contaminant** in water which is delivered to any user of a public water system." 42 U.S.C. § 300f(3) [42 U.S.C. § 300f, ADD-2-ADD-4] (emphasis added). "Level," as ordinarily understood, means "[r]elative position or rank on a scale" or "[a] **relative degree, as of** achievement, intensity, or **concentration**." The American Heritage College Dictionary 779 (3d ed. 1993) (emphasis added). In the context of the Act, "maximum . . . level of a contaminant" has long meant a fixed number, usually expressed in terms like ppt (or parts per billion, per million, etc.) or milligrams per liter (or ng/L, etc.). *See, e.g.*, 40 C.F.R. § 141.61(a), (c) [40 C.F.R. § 141.61, ADD-28-ADD-34] (expressing Levels for volatile organic contaminants and synthetic organic contaminants, except for PFAS, in terms of milligrams per liter); *see also* S. Rep. No. 104-169 at 3 ("Generally, the standards are stated as concentrations of particular contaminants in the water (in parts per million or parts per billion) as delivered to the tap of the consumer."). In total, there are 72 Levels that regulate contaminants in drinking water, and **all** are expressed and described as a concentration level. EPA has done so even when *combining* individual contaminants, like radionuclides. *See* 40 C.F.R. § 141.66(b), (c) [40 C.F.R. § 141.66, ADD-35-ADD-40] (Levels in terms of picocuries per liter). Levels, as long understood this way, make it relatively simple for a water system to maintain

compliance; the system only needs to monitor a contaminant's concentration in its water source against the contaminant's fixed concentration level in the regulation.

The hazard index is fundamentally different. The hazard index is the sum of four different ratios (called "hazard quotients") and depends on the relative occurrence of four different contaminants in a sample of drinking water. A sum of those calculations greater than 1 (unitless) constitutes an exceedance of the Level. The hazard-index equation, reproduced below, bears no resemblance to the concentration-based levels that EPA has, until now, used under the Act:

$$HI\ MCL = \left(\frac{[HFPO\text{-}DA_{water} ng/L]}{[10\ ng/L]}\right) + \left(\frac{[PFBS_{water} ng/L]}{[2000\ ng/L]}\right) + \left(\frac{[PFNA_{water} ng/L]}{[10\ ng/L]}\right) + \left(\frac{[PFHxS_{water} ng/L]}{[10\ ng/L]}\right) = 1$$

89 Fed. Reg. at 32,533, JA__.

EPA thus impermissibly substituted a mathematical equation for a maximum contaminant *level*. EPA's principal justification for using the hazard index as a Level is that the Act does not "dictate that the [Level] take a particular form," so long as it "establishes a maximum permissible level of a contaminant in water" and is capable of being "validated." EPA, *Responses to Public Comments on Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation Rulemaking* at 5-390 (2024) [hereinafter *Responses to Public Comments*], EPA-HQ-OW-2022-0114-3077, JA__; *see* 89 Fed. Reg. at 32,563, JA__. But this assertion of

virtually limitless flexibility proves too much. The hazard index-approach represents a series of ratios, not a "maximum level" for each constituent contaminant. Nor does it lend itself to easy validation, as a water system's compliance hinges upon fluctuations in the relative concentrations of four different contaminants. While EPA justifies using the hazard index to address the co-occurrence of Index PFAS and their "dose-additive" adverse health effects from co-exposure to those same PFAS, *see id.* at 32,539, 32,543, JA__, __, the structure of the hazard index means that for a particular sample, a violation of the Level could result if only *one* of the Index PFAS (i.e., PFHxS, PFNA, or HFPO-DA) is above its health-based water concentration, while the others are just above the detection limit. In that situation, a water system would be out of compliance with individual Level for that PFAS **and** the hazard index Level, despite the almost near absence of any theoretical "dose-additive" adverse health effects. That outcome is absurd.

B. The hazard index is not appropriate for regulating "mixtures" of Index PFAS.

EPA's use of the hazard index as a Level is arbitrary and capricious, counter to sound scientific principles, and does not conform with EPA's longstanding risk assessment practices. EPA has previously used a "general hazard index" approach, as a preliminary *screening* tool to evaluate the potential comparative risk between Superfund sites. *See id*. at 32,550, 32,569, JA__, __. But EPA has also cautioned

against the use of the hazard index beyond such screening where, as here, the substances induce different adverse health effects and endpoints.[9]

Here, the hazard index relies upon "health-based water concentrations," which EPA identified as the levels below which lifetime adverse health effects are not expected and allow for a margin of safety. *Id.* at 32,544, JA__. Each Index PFAS's health-based water concentration is based on a different particular health effect and endpoint. For HFPO-DA, the value is based on liver effects in adult mice. *Id.* For PFHxS, the value is based on thyroid effects in adult rats. *Id.* For PFNA and PFBS, both values are based on effects on offspring of exposed mice, although looking at different endpoints—bodyweight for PFNA and thyroid hormone levels for PFBS. *Id.* at 32,544-45, JA__-__. EPA thus derived health-based water concentrations based on disparate responses and adverse health effects.

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[9] *See* EPA, *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* at A-25 (2000) [hereinafter 2000 *Supplementary Guidance*], EPA-HQ-OW-2022-0114-0075, JA__ (cautioning that "the act of combining all compounds, even if they induce dissimilar effects, is a **screening procedure and not the preferred procedure in developing a hazard index**" (emphasis added)); EPA, *Guidelines for the Health Risk Assessment of Chemical Mixtures* at 26 (1986), EPA-HQ-OW-2022-0114-0068, JA__ (similar); EPA, *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A)* at 8-14 (1989), EPA-HQ-OW-2022-0114-0891, JA__ ("[A]pplication of the hazard index equation to a number of compounds that are not expected to induce the same type of effects or that do not act by the same mechanism could overestimate the potential for effects, **although such an approach is appropriate at a screening level**." (emphasis added)).

EPA's use of the general hazard index as an enforceable Level was therefore contrary to the prevailing view of a recently convened panel of independent experts, which explained that for purposes of assessing dose additivity, "PFAS groupings should be based only on common toxic [modes of action] and/or target organs," such that "[o]nly those PFAS that affect the same target organ/tissue/system should be grouped and assessed for dose additive or response additive approaches." J.K. Anderson et al., *Grouping of PFAS for Human Health Risk Assessment: Findings from an Independent Panel of Experts*, 134 Regulatory Toxicology and Pharmacology 105226, at 5 (Oct. 2022), https://tinyurl.com/35kb39cu.[10]

EPA asserted that the dose additivity assumptions underlying its hazard-index approach "can [] be based on 'toxicological similarity, but for specific conditions (endpoint, route, duration),'" and that it has "flexibility in the level of biological organization at which similarity among mixture components can be determined." 89 Fed. Reg. at 32,569, JA__ (quoting 2000 *Supplementary Guidance* at 29, JA__). But here there is **no** similar endpoint, target organ, and adverse health effects.

EPA's approach was also contrary to the recommendations of its Science Advisory Board ("Board"), which reviewed aspects of EPA's approach to PFAS mixtures as part of this rulemaking. *Id.* at 32,542, 32,568, JA__, __; EPA,

[10] *See* 3M Comment at 23, EPA-HQ-OW-2022-0114-1774, JA__; American Chemistry Council Comment at 36, EPA-HQ-OW-2022-0114-1841, JA__.

Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) at 6-8 (2024) [hereinafter *Framework for Estimating*], EPA-HQ-OW-2022-0114-3088, JA__-__. The Board explained that where different effects and endpoints are being considered, the hazard index is most appropriate for screening and identifying areas for further evaluation:

> In general, the screening level Hazard Index (HI) approach, in which Reference Values (RfVs) for the mixture components are used **regardless of the effect on which the RfVs are based**, is appropriate for **initial screening of whether exposure to a mixture of PFAS poses a potential risk that should be further evaluated**.

EPA, SAB, *Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS, Final Report* at 91 (2022), EPA-HQ-OW-2022-0114-3724, JA__ (emphases added). As the Board explained, EPA's hazard-index approach, which the Agency finalized as Levels, is actually fit for "initial screening" to determine whether there are potential risks that should be "further evaluated."

Moreover, Index PFAS are not "mixtures" as the term is generally understood. Here, EPA treats the mere fact that Index PFAS may co-occur as a justification to treat them as mixtures. But this argument proves too much: a similar argument could be made to justify any number of combinations of contaminants that happen to reside in the same source water. Rather than making an individualized assessment of the contaminant's health impacts, EPA could end-run the Act's statutory criteria by

using a hazard index to amalgamate the disparate health impacts of each substance to justify regulation. And common sense requires that a mixture must have "components and respective portions [that] exist in approximately the same pattern," 89 Fed. Reg. 32,542, JA__, whereas EPA's approach allows for infinite combinations of the Index PFAS. *Cf.* EPA, *Guidelines for Health Risk Assessment of Chemical Mixtures* (1986) https://www.epa.gov/sites/default/files/2014-11/documents/chem_mix_1986.pdf.

EPA failed to adequately justify its decision to use the hazard index as enforceable "Levels"; the hazard index Levels should be vacated.

III. EPA's Determinations to Regulate HFPO-DA, PFNA, and Mixtures of Two or More Index PFAS Were Unreasonable and Should Be Vacated.

EPA cannot regulate a contaminant under the Act unless "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems **with a frequency and at levels of public health concern**." 42 U.S.C. § 300g-1(b)(1)(A)(ii) (emphasis added). EPA concluded that this criterion was satisfied for HFPO-DA and PFNA, individually, and for mixtures of two or more Index PFAS based on its "evaluation of the best available occurrence information." 89 Fed. Reg. at 32,552, JA__. That "best available occurrence information," consisted of disparate occurrence data from a limited subset of states, rather than the nationally representative data upon which EPA typically relies. Worse, the occurrence information fails to justify EPA's determinations that HFPO-

DA, PFNA, or mixtures of two or more Index PFAS have a substantial likelihood of occurring in public water systems with a frequency and at levels of public health concern to warrant national regulation. Those determinations should be vacated.

A. EPA arbitrarily relied upon limited, piecemeal state-level occurrence information to reach Determinations to Regulate HFPO-DA, PFNA, and mixtures of two or more Index PFAS.

EPA's findings must "be based on the best available public health information, including the occurrence data base established under [Section 1445(g) of the Act]." 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II); *cf. Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290 (D.C. Cir. 2000) (finding similar "best available" requirement in the Act "unequivocal[]"). That "occurrence data base" refers to the UCMR program, *see supra* p. 7, which generates a nationally representative dataset of the occurrence of unregulated contaminants in drinking water.

"Nationally representative occurrence data are the primary source of the drinking water occurrence data" for the Act's principal standard-setting provision, ensuring that EPA does not prematurely move forward with **nationally applicable** regulation, when state regulations would be more appropriate to address localized problems. *See* EPA, *Protocol for Regulatory Determination 3* at 20 (2014), EPA-HQ-OW-2022-0114-3613, JA__. The Act created the UCMR program to gather this

national-level data according to uniform procedures and minimum reporting levels,[11] which produces more comparable data.

Indeed, EPA has previously determined *not* to regulate a contaminant (Acanthamoeba) where there was "no national monitoring data." *See* 68 Fed. Reg. 42,898, 42,903 (July 18, 2003). EPA has also declined to make a Determination (positive or negative) because of "[o]ccurence data gaps (no nationally representative finished water data or sufficient other finished water data)." 85 Fed. Reg. at 14,105, JA__; *accord* 79 Fed. Reg. at 62,725.

Here, there is the notable absence of decision-useful national occurrence data for Index PFAS. While UCMR 3 provided occurrence data for PFHxS, PFNA, and PFBS, the data were gathered using minimum reporting levels disconnected from (and often much higher than) the health reference levels[12] used for this Rule to gauge the effects of exposure to those contaminants. *Compare* 89 Fed. Reg. at 32,544-45, JA__ (health reference levels of 10ng/L for PFHxS and PFNA, and 2000 ng/L for PFBS), *with* 77 Fed. Reg. at 26,099, JA__ (minimum reporting levels of 30 ng/L for

[11] A minimum reporting level reflects the minimum quantitation level that a laboratory can consistently achieve. 89 Fed. Reg. at 32,574, JA__.

[12] A health reference level is "the level below which adverse health effects over a lifetime of exposure are not expected to occur, including for sensitive populations and life stages, and allows for an adequate margin of safety." 89 Fed. Reg. at 32,544, JA__.

PFHxS, 20 ng/L for PFNA, and 90 ng/L for PFBS). This necessarily limits the data's utility in evaluating whether these PFAS are occurring at a level of **public health concern**.

EPA has previously asserted that in the absence of "nationally representative occurrence data," "[s]tate-level finished water monitoring data" *may* be sufficient to evaluate the statutory criteria and support determinations to regulate. *See* EPA, *Protocol for Regulatory Determination 3* at 20-21. But while that may sometimes be the case, it was not true here due to the significant limitations in the state data. Specifically, EPA heavily relied upon "non-targeted" occurrence data (i.e., not site-specific, or limited to areas of known or potential contamination) from 19 states. 89 Fed. Reg. at 32,553, JA__. Nineteen states plainly do not present a national cross-section. Worse, the state-level data suffers from several flaws: the selected states used varying reporting levels to gather their data, while for some states, there was even variance *within* the reported data, attributable to the particular laboratory or laboratories analyzing the data. *See* EPA, *Per- and Polyfluoroalkyl Substances (PFAS) Occurrence and Contaminant Background Support Document for the Final PFAS National Primary Drinking Water Regulation* at 134, 168, 200 (2024) [hereinafter *Occurrence Support Document*], EPA-HQ-OW-2022-0114-3086, JA__, __, __.

For HFPO-DA two states did not have publicly available reporting levels. Other states used extremely wide ranges of reporting levels that extended well beyond EPA's health reference level and the "practical quantitation level," meaning the lowest concentration that can be reliably measured in a laboratory. *See Occurrence Support Document* at 200, 202-03, JA__, __-__; *see* 89 Fed. Reg. at 32,555, JA__ (using occurrence data from those four states). Similar problems abound for the remaining Index PFAS. *See Occurrence Support Document* at 134-39, 168-73, A-10 to A-15, JA__-__, __-__, __-__.

In sum, the patchwork "best available" occurrence data that EPA compiled to assess the "substantial likelihood" criterion suffered from acute data quality problems, and could not form a reasoned basis for EPA's Determinations.

B. The available occurrence information did not demonstrate that HFPO-DA, PFNA, or mixtures of two or more Index PFAS have a substantial likelihood of occurring in public water systems with a frequency and at levels of public health concern.

The "best available" occurrence information upon which EPA relies—again, neither nationally representative nor otherwise reliable—does *not* support the determinations that HFPO-DA, PFNA, or mixtures of two or more Index PFAS, have a substantial likelihood of occurring in public water systems with a frequency and at levels of public health concern.

At the outset, EPA asserts that there is not "a simple threshold of public health concern for all contaminants the agency considers for regulation under [the Act]."

89 Fed. Reg. at 32,552, JA__. But the statutory language "substantial likelihood" of occurrence, 42 U.S.C. § 300g-1(b)(1)(A)(ii), must provide some threshold standard for EPA to meet, and against which courts can review. *Cf. Bluewater Network*, 370 F.3d at 21 (agency must be able to explain "how it arrived at the specific standards adopted"). "Substantial," means "[c]onsiderable in importance, value, degree, amount, or extent." *Substantial*, The American Heritage College Dictionary 1354 (3d ed. 1993); *accord Life Techs. Corp. v. Promega Corp*., 580 U.S. 140, 146 (2017) ("substantial portion" may "refer to an important portion or to a large portion"). This ordinary meaning is supplemented by statutory context, *see Blackmon-Malloy v. U.S. Capitol Police Bd.*, 575 F.3d 699, 708 (D.C. Cir. 2009), which is chiefly aimed at determining whether "**national** primary drinking water regulations" are necessary. *See* 42 U.S.C. § 300g-1(a) (emphasis added). Thus, the likelihood of occurrence must be considerable in nature, and national in scope.

EPA has previously *declined* to regulate contaminants, including those with significant potential public health effects, occurring above their respective health reference levels (or above one half of those levels) in less than 0.1% of water systems.[13] This aligns with EPA protocol, which inquires into how many systems

[13] *See* 86 Fed. Reg. at 12,275 (declining to regulate nitrobenzene and RDX; each occurring above its cancer health reference level (or above one-half of the level) in only 0.05% and 0.07%, respectively, of public water systems); 81 Fed. Reg. 13, 16

have detections above the applicable health reference level (or above one half of that level). *See* EPA, *Protocol for Regulatory Determination 3* at 26-27, JA__-__. It is also important to ask whether occurrence is truly national, or reflective or regional patterns best addressed through state regulation.

As explained below, the occurrence information EPA relied on did not support Determinations to Regulate HFPO-DA, PFNA, and mixtures of two or more Index PFAS on a national level. *See Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014) (vacating action that relied on "unsubstantiated conclusion[s]"); *see also Motor Vehicles Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (action is arbitrary and capricious if agency "offered an explanation for its decision that runs counter to the evidence before the agency").

1. HFPO-DA

While HFPO-DA was included in UCMR 5, those monitoring efforts are still ongoing and EPA declined to rely on the preliminary results. 89 Fed. Reg. at 32,557, JA__. Instead, EPA principally relied upon state-level occurrence data from 16 states. *Id.* Even assuming that this state-level occurrence data was an adequate substitute for national data, *see supra* Section III.A, the data does not come close to showing occurrence in water systems **with a frequency and at levels of public**

(Jan. 4, 2016) (same for terbufos sulfone, found to occur above its health reference level (or above one-half of the level) in only 0.02% of public water systems).

health concern: only 10 of the 16 states identified detections of HFPO-DA in their water systems. *Id.* And there were either no or very few detections exceeding the HFPO-DA health reference level identified by EPA (10 ng/L). *Id.* at 32,544, 32,557, JA__, __. Of the 10 states with detections, 7 states reported *no* water system as having a detection above 10 ng/L,[14] while 2 states reported very few—Michigan (3 of 2,508 systems monitored, or 0.12%) and Ohio (1 of 1,479 systems, or 0.07%). *See Occurrence Support Document* at 211-13, JA__-__. Most of the state-level occurrence data therefore does not indicate occurrence with a frequency and at levels of public health concern, relative to the applicable health reference level. In fact, the available data aligns more closely with those instances where EPA has declined to make a positive Determination to Regulate. *See supra* n.13.

For Kentucky, EPA reports that 2 of the 74 systems monitored (or 2.7%) had detections of HFPO-DA above the health reference level of 10 ng/L. *See Occurrence Support Document* at 211, JA__. But 74 systems represent only a fraction of Kentucky's 435 public water systems.[15] More importantly, 10 of the 11 Kentucky water systems with HFPO-DA detections draw water from the Ohio River; those

[14] For Alabama, EPA acknowledged that "only detections were reported and there was no information on the total number of samples collected to determine percent detection." 89 Fed. Reg. at 32,553, JA__.

[15] *See* Kentucky Energy and Environment Cabinet, Division of Water, *Drinking Water*, https://tinyurl.com/ykjpxvks (last visited Sept. 21, 2024).

systems may have been impacted by discharges of HFPO-DA from the Washington Works PFAS manufacturing plant. *See* AWWA Comment at 15-16, JA__-__. Kentucky's Division of Water observed the same geographic concentration of systems. *See* Kentucky Dep't for Env't Prot., *Evaluation of Kentucky Community Drinking Water for Per- and Poly-Fluoroalkyl Substances* at 20 (2019), EPA-HQ-OW-2022-0114-0431, JA__ ("All of the detections [at water treatment plants using surface water] of [HFPO-DA] occurred at [plants] using the Ohio River and Ohio River Alluvium as sources."). EPA's response to this point is bare, citing only "disagree[ment]" with the argument that "the state monitoring results demonstrate this is a local or regional issue only, given the documented drinking water occurrence both for detections at any concentrations and at levels above the [health reference level] in 13 and 5 states, respectively." *Responses to Public Comments* at 3-42, JA__. But the limited state-level data does not demonstrate that the HFPO-DA occurs in drinking water with a frequency and at levels of public health concern at the **national** scale.

2. PFNA

For PFNA, the problems are similar, and the available occurrence data does not support the finding that PFNA is known to occur (or has a substantial likelihood of occurring) in drinking water with a frequency and at levels of public health concern. 42 U.S.C. § 300g-1(b)(1)(A)(ii).

UCMR 3 indicated that PFNA was detected in approximately 0.28% of water systems across only 7 states at a minimum reporting level of 20 ng/L, or twice the heath reference level of 10 ng/L used in the Rule. *See* 89 Fed. Reg. at 32,544, 32,556, JA__, __. The UCMR 3 data for PFNA thus tells little about the extent to which PFNA occurs with a frequency and **at levels of public health concern**. EPA acknowledged as much by asserting that it "expects there is even greater occurrence and exposed population in the range between 10 and 20 ng/L." *Id.* at 32,556, JA__. But EPA did not present additional nationally representative data to support that claim. The Act calls for the "best **available**" occurrence information. 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II) (emphasis added). Rather than speculating, EPA could have used UCMR 5 information for PFNA (and the other regulated PFAS), which uses a lower reporting level of 4.0 ng/L. *See* 89 Fed. Reg. at 32,600, JA__. Instead, EPA decided to rush to regulate based, in part, on speculation. *See Int'l Union, United Mine Workers v. MSHA*, 626 F.3d 84, 93 (D.C. Cir. 2010) (rejecting a "conclusory statement" that was "unsupported by the rulemaking record"); *Leather Indus. of Am., Inc. v. EPA*, 40 F.3d 392, 403 (D.C. Cir. 1994) (similar).

As with HFPO-DA, EPA relied on limited state-level PFNA occurrence data—the sum of which does not support EPA's conclusion that PFNA warrants *national* regulation. Of the 16 states that EPA reported as having detections of PFNA, 8 states—Colorado (non-targeted data), Illinois, Indiana, Kentucky,

Maryland, Massachusetts, South Carolina, and Wisconsin—reported **no** water system as having a detection above the health reference level of 10 ng/L. *Occurrence Support Document* at 180-83, JA__-__. Two states reported detections above 10 ng/L in less than 0.1% of systems: Michigan (1 of 2,508 monitored systems, or 0.04%) and Ohio (1 of 1,479 monitored systems, or 0.07%). *Id.* at 182, JA__.[16] Thus, for more than half of the already limited number of states comprising EPA's dataset, PFNA did not occur in water systems with a frequency and at levels of public health concern, relative to the applicable health reference level, and instead more closely aligns with those instances where EPA has declined to make a positive Determination to Regulate. *See supra* note 13. The information also undermines EPA's speculation that PFNA has some materially greater degree of occurrence at levels between 10 and 20 ng/L. *See* 89 Fed. Reg. at 32,556, JA__.

While the remaining states reported a relatively higher number of water systems with detections above 10 ng/L, *Occurrence Support Document* at 181-83, JA__-__, those datapoints actually evince a more regionalized concern in the northeastern United States, where many states have existing PFNA regulations. *See* N.H. Code Admin. R. Env-Dw 705.06(b), ADD-41 (11 ppt); N.J. Admin. Code

[16] Alabama had 1 water system with a detection of PFNA above 10 ng/L, *Occurrence Support Document* at 180, JA__, but the utility of Alabama's occurrence data is questionable, *see supra* n.14.

§ 7:10-5.2(a)(5)(i), ADD-44 (13 ppt); Vt. Code R. 12-037-001 n. (f), (g), ADD-81 (20 ppt, for combination of PFNA and other PFAS). Those datapoints should not form the basis for **national** regulation of PFNA.

Moreover, EPA acknowledges that PFNA "has generally been phased out in the U.S.," and that its use would likely only result from "legacy stocks" or imported products. 89 Fed. Reg. at 32,556, JA__. Those findings—in combination with the lack of occurrence data showing occurrence in public water systems with a frequency and at levels of public health concern—cannot support EPA's conclusion that "there is a substantial likelihood that environmental contamination of sources of drinking water will continue." *Id.* at 32,556, JA__.

3. Index PFAS

For its Determination to Regulate mixtures of two or more Index PFAS, the key problem is that EPA relied on mere detections of Index PFAS (i.e., the reported absence or presence), irrespective of their concentrations. But without comparison to concentrations or the PFAS chemicals' health reference levels, mere detection tells very little about whether mixtures of two or more Index PFAS occur in public water systems with a frequency and **at levels of public health concern**, the necessary inquiry under the Act. *See* 42 U.S.C. § 300g-1(b)(1)(A)(ii).

EPA's rationale for regulating mixtures of two or more of Index PFAS is that "all available UCMR 3 and state occurrence data demonstrates that there is

substantial likelihood that combinations . . . co-occur or will co-occur at a frequency and level of public health concern." 89 Fed. Reg. at 32,557, JA__. To make that case, EPA goes through a complicated "groupwise and pairwise" statistical analysis of UCMR 3 and state-level detection information (from 18 states) for the Index PFAS. *Id.* at 32,558, 32,589-93, JA__, __-__. An underlying flaw, however, is that EPA used the mere detection (i.e., the reported presence or absence) of an Index PFAS in a water sample, without accounting for its concentration. This is apparent from EPA's supporting documentation, which explains that "the **reported absence or presence of chemicals** were used to conduct categorical analyses," and "continuous approaches relying on **relationships between chemical concentrations were not used**." *Occurrence Support Document* at 236, JA__ (emphases added). EPA thus largely evades the necessary inquiry of whether two or more Index PFAS co-occur in relation to their health reference levels. *See* EPA, *Protocol for Regulatory Determination 3* at 26-27, JA__-__. Instead, EPA treats occurrence at frequencies and levels of public health concern simply as a function of mere presence, which does not align with the statutory criteria. *See* 89 Fed. Reg. at 32,552-53, JA__-__.

EPA supplemented its approach by pointing to state-level occurrence data showing samples exceeding a hazard index value of 1 (unitless), which EPA interprets as "demonstrat[ing] [the] prevalence of [the Index PFAS] at levels of

concern." *Id.* at 32,594-96, JA__-__. But as explained above, *supra* Section II.B, the hazard index is ill-suited for regulatory purposes or to predict adverse health effects, as opposed to initial screening to set further evaluation goals. Exceedances of the hazard index therefore do not inform whether a particular mixture of PFAS occurs at a level of public health concern. EPA's justification in this respect does not advance the ball.

IV. Based on a Fatally Flawed Cost Analysis, the Rule Arbitrarily Regulates at Levels that Impose Significant Additional Costs Without Commensurate Health Benefits and Are Not Feasible.

The Act recognizes that public health risk reductions in drinking water necessarily require consideration of costs and the downstream consequences on water affordability. This is because increased compliance costs for water systems are largely borne by water users, presenting very real health and economic concerns for lower income Americans.

A. The Rule should be remanded to EPA to cure the serious deficiencies in its cost analysis.

The Act requires "a determination as to whether the benefits of the [Level] justify, or do not justify, the costs." 42 U.S.C. § 300g-1(b)(4)(C). And a Level "shall not be more stringent than is feasible." *Id.* § 300g-1(b)(5)(B)(ii). "[T]he term 'feasible' means feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost

into consideration)." *Id.* § 300g-1(b)(4)(D). Without a reliable assessment of both the costs and benefits of the Rule, EPA therefore could not appropriately set Levels as required by the Act.

EPA's cost estimates significantly underestimate the quantifiable costs of compliance "likely to occur solely as a result of compliance." 42 U.S.C. § 300g-1(b)(3)(C)(i)(III). AWWA provided EPA with a cost modeling report ("Black & Veatch Study"), which estimated the range of capital and operating costs attributable to PFOA and PFOS Levels and found that the national annualized costs would be $2.45 billion —**significantly** higher than EPA's initial costs estimate of $0.772 billion. *See* AWWA Comment at 24-35. JA__-__. AWWA also compiled more than 100 case studies of **actual** water systems that had detected and treated, or developed costs estimates to treat, PFAS contamination ("Case Study"). *See id.* at App. D, JA__-__. AWWA's comparison showed that EPA's modeling underestimated costs by a factor of 3.17 (based on the Black & Veatch Study) or 330% (based on the Case Study). *See id.* at 26, Table A-5, JA__-__. To the extent EPA considered any real-world data, it relied on older studies that do not account for inflation or the additional costs from simultaneous compliance by thousands of systems. *See Responses to Public Comments* at 3706 (citing Eric Forrester & Christy Bostardi, *PFAS Treatment: GAC vs. IX* (2019)), JA__. As a result, EPA's Health Risk Reduction

and Cost Analysis cannot provide an adequate basis to conclude that the Rule's benefits justify its costs. The Rule must therefore be vacated and remanded.

B. The incremental costs of the Rule's Levels are unsupported.

Even under EPA's flawed analysis, it cannot justify the incremental costs of the Rule's Levels. The Act requires EPA's Health Risk Reduction and Cost Analysis to analyze the incremental costs and benefits of each Level considered. *See* 42 U.S.C. § 300g-1(b)(3)(C)(IV). Here, EPA selected the most costly regulatory alternative for PFOA and PFOS (4.0 ppt) after considering Levels of 4.0, 5.0 ppt and 10.0 ppt. 89 Fed. Reg. at 32,634, JA__. By EPA's own estimates (assuming a 2% discount rate), the expected costs of implementation increase 208% when the Levels decrease from 10.0 ppt to 4.0 ppt, with an incremental **negative** benefit of $159.49 million annually. *See* 89 Fed. Reg. at 32,710-12, JA__-__; AWWA Comment at 42-43, JA__-__; *Economic Analysis* at 7-1 to 7-4 (Tables 7-1, 7-2, 7-3, 7-4), JA__-__.

This is because many systems would not be required to construct PFAS treatment facilities to comply with a 10.0 ppt Level, but will need to do so at a 4.0 ppt Level. AWWA Comment at 42, JA__. As Water Associations made clear, regulating PFOA and PFOS at 10.0 ppt would allow EPA to address the systems presenting the highest potential for health risk without incurring the same nationwide costs: EPA estimated that while 10.0 ppt Levels would cost $500 million annually, the annual public health benefits would exceed $665 million annually—a net benefit of $165

million annually (33% of the costs). By contrast, the annual costs for PFOA and PFOS Levels at 4.0 ppt were estimated to be $1.54 billion with only $5.7 million annual net benefit. *See* 89 Fed. Reg. at 32,710, 32,712, JA__, __. Regulating at 4.0 ppt thus reduce the annual net benefit by 96.% nationally, as it requires systems with Levels between 4.0 and 10.0 to install treatment facilities at a cost that exceeds potential health benefits, and increases the ongoing costs of treatment. *See* AMWA Comment at 23, JA__. Yet EPA somehow found it reasonable to ratchet up implementation costs (above anything seen before under the Act), even as the expected net benefits significantly decreased.

While the Act allows for the consideration of nonquantifiable benefits, here roughly 20% for 4.0 ppt PFOA/PFOS and more than 75% of the benefits for the Index PFAS would need to come from such nonquantifiable benefits to justify the costs. In addition, the analysis submitted by AWWA demonstrates that there are minimal incremental benefit to including regulation of the Index PFAS, *see* AWWA Comment at 42, JA__, while AMWA's analysis indicates that those same PFAS can drive significant compliance costs for some systems, *see* AMWA Comment at 36-38, JA__-__.

EPA selected the regulatory alternative that imposes the most costs and produces the least net benefits. That is not reasoned decision-making, nor in keeping with EPA past practice, where it has not set Levels below a point where there is

marginal benefit. *See, e.g.*, 66 Fed. Reg. 6976 (Jan 22, 2021). It is also counter to congressional intent, as the 1996 amendments sought to avoid precisely the type of regulations here—those that "impos[e] burdens on consumers and the taxpayers of other governments with no rational relationship to the public benefits that might be realized." S. Rep. No. 104-169, at 13. The outcome is particularly problematic because small systems serving less than 10,000 persons will face the most significant costs on a per-household basis. Water Associations' affordability analyses suggest that the costs to implement these treatment facilities will range from hundreds to thousands of dollars annually for individual households, significantly exceeding affordable margins for household expenditures for drinking water. *See* AWWA Comment at 41, 44, JA__, __; AMWA Comment at 32-34, JA__-__.

CONCLUSION

For the foregoing reasons, the Court should grant the petition for review, vacate the Rule, and remand to EPA.

Date: October 7, 2024

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CERTIFICATE OF COMPLIANCE

1. This Opening Brief of Petitioners American Water Works Association and Association of Metropolitan Water Agencies complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) and the Court's order of September 3, 2024. It contains 12,906 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1).

2. This Opening Brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6), because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

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CERTIFICATE OF SERVICE

Pursuant to Rule 25 of the Federal Rules of Appellate Procedure, I hereby certify that, on October 7, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the U.S. Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system, and served copies of the foregoing via the Court's CM/ECF system on all ECF-registered counsel.

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