

BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:)	
)	R25-1
SDWA UPDATE, USEPA AMENDMENTS)	(Identical-in-Substance
(January 1, 2024, through June 30, 2024))	Rulemaking- Public Water Supply)
)	
SWDA UPDATE, USEPA AMENDMENTS)	R25-9
(July 1, 2024, through December 31, 2024))	(Identical-in-Substance
)	Rulemaking- Public Water Supply)
)	(Consolidated)
To: See attached service list.		

NOTICE OF ELECTRONIC FILING

PLEASE TAKE NOTICE that I have today filed with the Office of the Clerk of the Pollution Control Board comments on behalf of the Illinois Environmental Protection Agency, a copy of which is herewith served upon you.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

Dated: January 8, 2026

Kaitlyn Hutchison
Division of Legal Counsel
Illinois Environmental Protection Agency
2520 W. Iles Ave.
P.O. Box 19276
Springfield, IL 62794-9276
(217) 524-4648
kaitlyn.hutchison@illinois.gov

BY: /s/Kaitlyn Hutchison
Kaitlyn Hutchison

THIS FILING IS SUBMITTED ELECTRONICALLY

SERVICE LIST

USEPA REGION 5

Stacy Meyers
Daniel Leonard
Robert Peachey
Ralph H. Metcalfe Federal Building
77 West Jackson Blvd.
Chicago, Illinois, 60604
meyers.stacy@epa.gov
leonard.daniel@epa.gov
peachey.robert@epa.gov

ILLINOIS POLLUTION CONTROL BOARD

Don Brown, Clerk
Joan Beacom, Hearing Officer
60 E. Van Buren St. Ste. 630
Chicago, Illinois, 60605
Don.Brown@illinois.gov
Joan.beacom2@illinois.gov

ILLINOIS DEPT. OF NATURAL RESOURCES

Renee Snow
One Natural Resources Way
Springfield, Illinois, 62702
renee.snow@illinois.gov

DEPT. OF COMMERCE AND ECONOMIC OPPORTUNITY

Jonathan Eastvold
Small Business Office
500 East Monroe St.
Springfield, Illinois, 62701
Jonathan.eastvold@illinois.gov

JOINT COMMITTEE ON ADMINISTRATIVE RULES

Wm. G. Stratton Office Building
Room 700
Springfield, Illinois, 62706
jcar@ilga.gov

BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:)	
)	R25-1
SDWA UPDATE, USEPA AMENDMENTS)	(Identical-in-Substance
(January 1, 2024, through June 30, 2024))	Rulemaking- Public Water Supply)
)	
SWDA UPDATE, USEPA AMENDMENTS)	R25-9
(July 1, 2024, through December 31, 2024))	(Identical-in-Substance
)	Rulemaking- Public Water Supply)
)	(Consolidated)

ILLINOIS ENVIRONMENTAL PROTECTION AGENCY’S PUBLIC COMMENT

NOW COMES the Illinois Environmental Protection Agency (“Agency”), by and through one of its attorneys, and submits its comments in support of the identical-in-substance amendments proposed by the Illinois Pollution Control Board (“Board”):

The Board in its October 2, 2025 order has proposed important and overdue updates to the State’s drinking water quality standards. The Board requested public comments on four specific issues. This comment addresses those four issues, along with additional comments that have been submitted to the Board. In short, the Board should move forward and adopt the proposed amendments, taking into account the proposed revisions submitted by the United States Environmental Protection Agency (“USEPA”) Region V along with other revisions detailed below. These amendments must be adopted now for State drinking water quality regulations to be as stringent as federal regulations, a necessary predicate to the State maintaining primacy to enforce and implement the Safe Drinking Water Act (“SDWA”) in Illinois. While some commenters have suggested the Board decline to adopt some portions of the currently effective federal regulations, these arguments rest on speculation as to future events and disregard the Board’s statutory mandate. Moreover, they ignore the compelling public health bases for regulating per- and polyfluoroalkyl substances (“PFAS”) and lead and copper service lines that underlie the federal regulations.

I. Responses to the Board's Requests for Comments

The Agency responds as follows to the four issues identified in the Board's October 2, 2025 order:

1. "[W]hether the proposed amendments ensure that Illinois' primary drinking water regulations remain consistent with the [National Primary Drinking Water Regulations]."

Response: If the Board incorporates the revisions proposed by USEPA in its January 6, 2026 comments and the additional revisions in Section II, below, the proposed amendments appear to the Agency to be consistent with the NPDWRs.

2. "[T]he incorporation of the USEPA alternative equivalent methods into the Illinois regulations."

Response: The Agency has the following comments:

- a. SM 3111 B (93) – this is not the 19th edition. The 19th edition date is (89).
- b. SM 3111 B (99) - remove 20th edition from this method.
- c. SM 3111 D (89) - this is not the 19th edition. The 19th edition date is (93)
- d. SM 3113 B (10) – add the word “and before “24th editions.”
- e. SM 2500-Mg B (97) – add a comma after “23rd”
- f. SM 2500-Mg E (91) – this is not the 19th edition. The 19th edition date is (90).
- g. SM 4110 B (91) – this is not the 19th edition. The 19th edition date is (90)
- h. SM 4500-CN- C (99) – the 20th edition is not (99). The 20th edition date is (97).
- i. SM 4500-CN-E (99) – the 23rd and 24th editions are not (99). Both 23rd and 24th editions are (16).
- j. SM 4500-H+B (00) – the 24th edition is not (00). The 24th edition is (21).

Should create a new entry for the 24th edition

k. SM 5310 B (92) – the 19th edition is not (92), it is (90)

l. SM 5310 C (92) - the 19th edition is not (92), it is (90)

m. SM 5310 D (92) - the 19th edition is not (92), it is (90)

n. SM 7500-Ra E – the 22nd edition includes SM 7500-Ra sections B, C, D, approved in 2001 (01). Section E was approved in 2007 (07). Add 22nd edition to SM 7500-Ra E (07) and remove SM 7500-Ra E (01).

o. SM 9221 A (93) – the 18th edition is not (93), it is (91).

p. SM 9221 B (93) – the 18th edition is not (93), it is (91).

q. SM 9221 C (93) - the 18th edition is not (93), it is (91).

r. SM 9221 E (93) - the 18th edition is not (93), it is (91).

s. Changes needed in 611.720 Board Note: SM 7110 D is only in the 24th edition.

3. “[T]he thirty-day post adoption effective date.”

Response: The Agency does not see any issue with the thirty-day post adoption effective date proposed by the Board.

4. “USEPA’s plans to rescind current PFAS regulations.”

Response: The Agency agrees with the Board’s observation that current USEPA efforts to vacate four of six PFAS standards that it promulgated in 2024 are not based on “evidence of reduced risk to human health or scientifically based reasoning for the delay and removal of the 2024 PFAS regulations.” Oct. 2, 2025 Order at 15. As discussed in greater detail below, USEPA has asked the United States Court of Appeals for the D.C. Circuit to vacate four of its six PFAS standards based solely on a procedural argument USEPA itself had earlier rejected, and that the Illinois Attorney General has described in an amicus brief as “confused.”¹ While the federal courts will ultimately decide

¹ See Ex. A, Amicus Curiae Brief at 24.

this legal argument, the fact remains that the contested PFAS standards (along with the other amendments proposed to be adopted) are still valid federal regulations that the Board must adopt to comply with the Act and allow the State to retain SDWA primacy. *See* 40 C.F.R. Part 141 Subpart Z (PFAS NPWDR). Moreover, all current federal PFAS regulations are supported by strong evidence of risks to human health.

On December 7, 2021, the Agency proposed the regulation of six PFAS in the State's groundwater: perfluorooctanoic acid ("PFOA"), perfluorooctanesulfonic acid ("PFOS"), perfluorobutanesulfonic acid ("PFBS"), perfluorohexanesulfonic acid ("PFHxS"), perfluorononanoic acid ("PFNA"), and hexafluoropropylene oxide dimer acid ("HFPO-DA"), in 35 Ill. Adm. Code Part 620. On March 20, 2025, the Board adopted numeric groundwater quality standards for the six proposed PFAS.

The adopted Part 620 Class I potable resource numeric groundwater quality standards reflect USEPA's final rule published in the Federal Register on April 26, 2024, for the PFAS National Primary Drinking Water Regulation ("PFAS NPDWR"). In March 2023, USEPA proposed the rule and requested comments for regulating PFAS in drinking water. The proposed rule included three components:

- Proposed Maximum Contaminant Level Goals ("MCLGs") and Maximum Contaminant Levels ("MCLs") for PFOA and PFOS;
- A preliminary determination to regulate PFHxS, PFNA, PFBS, and HFPO-DA;
- Proposed individual MCLGs and MCLs for PFHxS, PFNA, PFBS, and HFPO-DA, and an MCLG and MCL hazard index ("HI") formulation for PFHxS, PFNA, PFBS, and HFPO-DA to account for cumulative effects for the similar-acting substances.

The PFAS NPDWR final rule established non-enforceable MCLGs for all six proposed PFAS and enforceable MCLs for five of the six proposed PFAS. USEPA did not include an individual PFBS

MCL in its final determination. The final determination also included a hazard index MCLG and MCL to account for cumulative adverse effects due to mixtures in drinking water of two or more of the following PFAS: PFHxS, PFNA, HFPO-DA, and PFBS. Part 620 requires an MCL, or an MCLG if an MCL is not finalized, to be listed as a numerical groundwater quality standard. If neither an MCL nor MCLG is available, health-based standards are calculated with the methods provided at Subpart F and Appendix A of Part 620. Part 620 also includes provisions for calculating a hazard index for similar-acting substances with cumulative effects. The Board adopted the Part 620 standards to mirror the federal MCLs.

USEPA's hazard index calculation to account for cumulative effects from similar-acting substances is the same hazard index calculation located at Section 620. Appendix B. USEPA's PFAS NPDWR hazard index calculation for mixtures of PFHxS, PFNA, HFPO-DA, and PFBS utilize health-based water concentrations ("HBWCs") for determining compliance with a hazard index of 1. The HBWCs for PFHxS, PFNA, and HFPO-DA are the individual MCLs for the substances, as the MCLs for these substances are health-based levels. The HWBC for PFBS is 2,000 ng/L.

Shortly after the adoption of the MCLGs and MCLs, representatives from the manufacturing and utility industries filed appeals of the PFAS MCLs and hazard index to prevent the MCLs from taking effect. In December 2024, USEPA filed its response, arguing it had met all requirements of the SDWA in its issuance of its PFAS MCLGs and MCLs, including its determination to regulate PFHxS, PFNA, HFPO-DA, PFBS, and the setting of MCLGs and MCLs at the same time.²

In September 2025, USEPA filed a motion to partially vacate the PFAS NPDWR, specifically individual MCLGs and MCLs for PFHxS, PFNA, and HFPO-DA, and the regulation of PFAS mixtures with the hazard index calculation.³ USEPA also stated in its motion its intent to defend the PFOA and

² See Ex. B, USEPA Response Br.

³ See Ex. C, USEPA Mot.

PFOS portions of the rule. The basis of USEPA's September 2025 motion is an interpretation of the SDWA that it had previously rejected, which is that USEPA must publish and seek comment on a preliminary regulatory determination before proposing a NPDWR that set MCLGs and MCLs, not at the same time. Less than a year earlier, USEPA in its December 2024 response brief had described this argument as reflecting a "fundamental misunderstanding of the Congressional intent" for SDWA.⁴ The motion offered no scientifically based evidence that the subject PFAS do not create a risk for adverse effects on the human population when ingested via drinking water. The D.C. Circuit has not yet taken any action on USEPA's motion or the appeal as a whole.

The SDWA requires three criteria to be met in determining whether to regulate a substance:

1. The substance is found to have an adverse effect on human health;
2. The substance is known to occur, or there is a substantial likelihood the substance will occur, in public water systems (PWS) with frequency and at levels of public health concern; and
3. In the sole judgment of the administrator, regulation of the substance presents an opportunity for reductions in health risks by PWS users.⁵

Despite USEPA's newly discovered arguments, all three criteria were met in USEPA's promulgation of the PFAS NPDWR.

Perfluorohexane sulfonic acid (PFHxS)

USEPA promulgated an MCLG and MCL for PFHxS as an individual substance and a HBWC as a substance included in the MCLG and MCL hazard index calculation. USEPA's HBWC/MCLG/MCL was based on the best available public health information at the time of USEPA's proposal and request for comments in March 2023. USEPA utilized toxicological data from Centers for

⁴ Ex. B, USEPA Response Br., at 35.

⁵ 42 U.S.C. §300g-1(b).

Disease Control and Prevention's Agency for Toxic Substances and Disease Registry's, "Final Toxicological Profile for Perfluoroalkyls," (ATSDR, 2021). ATSDR set an intermediate (subchronic) minimal risk level ("MRL") for PFHxS at 0.00002 (2E-05) mg/kg-day based on adverse effects to the thyroid in animal studies. USEPA converted the intermediate MRL to a chronic MRL by applying an uncertainty factor (UF) of 10 to the subchronic toxicity value for a chronic toxicity value of 0.000002 (2E-06) mg/kg-day to develop its drinking water value of 10 ng/L. ATSDR is an accepted USEPA source in its hierarchy for assigning toxicity values and MRLs are equivalent to oral reference doses ("RfDs").

Since USEPA's March 2023 PFAS NPDWR proposal, USEPA's Integrated Risk Information System ("IRIS"), USEPA's Tier 1 source for toxicological data, issued its Final Report of its "Toxicological Review of Perfluorohexanesulfonic Acid (PFHxS) and Related Salts," in January 2025. In the January 2025 document, IRIS set its chronic RfD at 0.0000000004 (4E-10) mg/kg-day based on the adverse effect of a decreased immune response to vaccines in a human study of children. The updated toxicity value of 4E-10 mg/kg-day calculated with the same drinking water intake rate and relative source contribution results in the following HBWC:

$$HBWC \left(\frac{mg}{L} \right) = \frac{RfD \cdot RSC}{DWI_{BW-adj}}$$

Where,

Oral Reference Dose (RfD) = 0.0000000004 mg/kg-day

Relative Source Contribution (RSC) = 20% or 0.2

Body Weight-Adjusted Drinking Water Intake (DWI_{BW-adj}) = 0.034 L/kg-day

HBWC = 0.000000002 mg/L (0.002 ng/L), a concentration less than the PQL of 3.0 ng/L.

Therefore, the PFAS NPDWR PFHxS MCL of 10 ng/L is set higher than updated toxicity data from USEPA's primary toxicity source would support. The Agency also notes IRIS developed an updated RfD of 0.0000002 (2E-07) mg/kg-day for adverse effects to the thyroid based on updated animal studies. In other words, the updated RfD is more stringent than the RfD utilized for calculating the PFHxS HBWC/MCLG/MCL, resulting in a health-based value of 0.000001 mg/L (1 ng/L), also less than the PFHxS PQL.

USEPA also adequately justified the occurrence of PFHxS in the public drinking water supply nationwide in its PFAS NPDWR. The Agency's PFAS Statewide Investigation Network for Community Water Supply (CWS) sampling provides prevalence and occurrence information in PFHxS in Illinois public water supplies.⁶ PFHxS was the fourth most commonly detected PFAS in drinking water found during the Illinois CWS sampling initiative. PFAS are commonly detected in water together. Both USEPA and the Agency's sampling have confirmed the presence of PFHxS in samples with detections of other hazard index PFAS.

Perfluorononanoic Acid (PFNA)

Like for PFHxS, USEPA promulgated an MCLG and MCL for PFNA as an individual substance and a HBWC as a substance included in the MCLG and MCL hazard index calculation. USEPA's HBWC/MCLG/MCL was also based on the best available science and public health information at the time of USEPA's proposal and request for comments in March 2023. USEPA utilized the same ATSDR toxicological report, "Final Toxicological Profile for Perfluoroalkyls," (ATSDR, 2021) to calculate a PFNA HBWC/MCLG/MCL. ATSDR set an intermediate (subchronic) minimal risk level ("MRL") for PFNA at 0.000003 (3E-06) mg/kg-day based on decreased body weight

⁶ Additional information concerning the Agency's statewide investigation is available at <https://epa.illinois.gov/topics/water-quality/pfas/pfas-statewide-investigation-network.html>.

and developmental delays in the offspring of mice administered PFNA. As the ATSDR PFNA intermediate MRL is calculated using a pharmacokinetic model instead of a benchmark dose, an uncertainty factor is not required to convert a subchronic MRL to a chronic MRL; therefore, 0.000003 mg/kg-day is the appropriate chronic toxicological value for use in calculating an HBWC/MCLG/MCL. Again, ATSDR is an accepted USEPA source in its hierarchy for assigning toxicity values and MRLs are equivalent to oral reference doses (“RfDs”).

Media reports state IRIS completed its PFNA toxicological review in April 2025; however, it has not been finalized or published. The draft report indicates more stringent toxicity values than found in the ATSDR report and that those values are derived from human studies. A review of the draft PFNA toxicological report indicates the new data could support a lowered PFNA HBWC/MCLG/MCL. The draft PFNA toxicological report is available at: <https://www.epa.gov/iris>.

PFNA was confirmed in only one public water supply during the Agency’s CWS sampling initiative; however, subsequent monitoring of finished water in public water supplies has shown detections of PFNA in additional public water supplies. In some cases, sampling confirmed the presence of PFNA with detections of other hazard index PFAS.

Hexafluoropropylene Oxide Dimer Acid (HFPO-DA)

USEPA promulgated an MCLG and MCL for HFPO-DA as an individual substance and a HBWC as a substance included in the MCLG and MCL hazard index calculation. USEPA’s HBWC/MCLG/MCL was based on the best available public health information at the time of USEPA’s proposal and request for comments in March 2023. USEPA utilized toxicological data developed by USEPA’s Office of Water in its Human Health Toxicity Assessment, published October 2021, and its Drinking Water Health Advisory, published in June 2022. USEPA Office of Water developed an RfD of 0.000003 (3E-06) mg/kg-day for chronic exposures for adverse effects to the liver from animal studies. No updated toxicological information is available from USEPA’s toxicity hierarchy. The Agency did not detect

HFPO-DA during its statewide PFAS sampling initiative, but, as discussed below, HFPO-DA is a more recently developed “replacement” PFAS.

Perfluorobutane Sulfonic Acid (PFBS)

USEPA deferred the final regulatory determination to regulate PFBS as an individual chemical; however, it developed a HBWC of 2,000 ng/L to be used in the hazard index MCL for evaluating cumulative effects of similar-acting substances. Its HBWC is based on the best available public health information at the time of USEPA’s proposal and request for comments in March 2023. USEPA utilized an oral reference dose of 0.0003 (3E-04) mg/kg-day developed as a USEPA provisional peer-reviewed toxicity value (“PPRTV”), published April 2021. USEPA also utilized that toxicity value when issuing its PFBS Drinking Water Health Advisory, published June 2022. The PPRTV was based on adverse effects to the thyroid in newborn mice.

PFBS was a commonly found PFAS during the Agency’s sampling initiative, detected at 88 sample locations. Sampling also confirmed the presence of PFBS with other hazard index PFAS.

As demonstrated above, PFAS cause adverse effects in humans. At present, the list of harms from PFAS includes liver, immunological, developmental (in-utero and ex-utero), thyroid, and reproductive effects; and kidney, testicular, pancreatic, and liver cancers. Toxicological research of PFAS analytes continues to identify adverse effects at lower levels of exposure.

The PFAS class of chemicals may now include more than 12,000 substances and is expected to increase. USEPA-approved analytical methods for PFAS in drinking water encompass only 29 PFAS analytes. The PFAS NPDWR regulates only five PFAS individually and includes a sixth PFAS as part of the hazard index MCL.

PFNA is a long chain carbon perfluoroalkyl with restricted use in consumer products. PFHxS, HFPO-DA, and PFBS are replacement substances for legacy PFAS (PFOA and PFOS) being phased out. As replacements are still in use, it is expected that an increase in the presence of replacement

PFAS will increase while legacy PFAS eventually decrease in water. It is important to regulate these substances to prevent the risk of further harm to the public. Although Illinois is showing lower incidences of occurrence when compared to some other states, PFAS and particularly some mixtures of the NPDWR hazard index MCL have contaminated Illinois public water supplies. At present, the PFAS NWDPR is a final and enforceable federal regulation. *See* USEPA's motion to vacate the PFHxS, PFNA, and HFPO-DA individual MCLs and the hazard index MCL with PFBS is based on a procedural concern, with no discussion or dissention regarding USEPA's methods for determining the drinking water values.

No one can say at this time when or how the federal courts ultimately will resolve USEPA's motion to vacate four of its six standards for PFAS. Without the proposed amendments, though, it is certain Illinois will have no enforceable drinking water MCLs to compel public water supplies to remove PFAS from their drinking water. The longer it takes to enact MCLs, the longer Illinois residents will be exposed to contaminated drinking water. As PFAS have low clearance rates from the body, PFAS will continue to build up within the body, increasing the risks for adverse effects.

In order to comply with the Agency's SDWA program primacy requirements, the Agency must enforce the regulations as they are currently, which require PFAS sampling starting in the second quarter of 2026. Under the primacy program requirements, the Illinois regulations cannot be less stringent than the federal regulations. Under Section 7.2(b) of the Act, 415 ILCS 5/7.2(b), identical-in-substance rulemakings should be completed within one year after the adoption of the corresponding federal rule. After adopting an identical-in-substance rule, if the Board finds that an amendment is needed, the Board shall initiate a new rulemaking to propose that amendment. The Board has already postponed adoption of the rules beyond the typical timeline; no more delay is warranted. Any future adjustments to the federal regulations—whether by judicial action or notice-and-comment rulemaking—can be addressed in future Board rulemakings, as is deemed appropriate at that time.

After adoption of these proposed rules, the Board should carefully consider any request to weaken the rules, though. As the Board notes in the October 2, 2025, Order, there have not been any additional information on the health impacts of PFAS. USEPA's "PFAS National Primary Drinking Water Regulation" fact sheet points out that "PFAS exposure over a long period of time can cause cancer and other serious illnesses...exposure during critical life stages such as pregnancy or early childhood can also result in adverse health impacts."⁷ USEPA has stated that its PFAS limits will reduce tens of thousands of illnesses or deaths related to PFAS and will reduce exposure for approximately 100 million Americans.⁸ Any efforts to weaken these protections should be carefully scrutinized.

In March 2025, the Board adopted a final rule (R22-18) to establish Part 620 Class I potable resource numerical groundwater quality standards, set at the same levels as listed the PFAS NPDWR. The protection of groundwater as a potable resource, as in Part 620, is intended to protect the public from adverse effects to human health from ingesting contaminated groundwater. The protection of public drinking water supplies is equally important for the same reason, to prevent adverse health effects resulting from drinking contaminated water. The Agency respectfully requests the proposed amendments, including all PFAS standards, be adopted at this time.⁹

⁷United States Environmental Protection Agency, *PFAS National Primary Drinking Water Regulation* [Fact Sheet], EPA.gov, April 9, 2024, [pfas-ndpwr_fact-sheet_general_4.9.24v1.pdf](https://www.epa.gov/pfas-ndpwr/pfas-national-primary-drinking-water-regulation), at 1.

⁸ *Id.* at 2.

⁹ General references for response number 4 are as follows:

Agency for Toxic Substances & Disease Registry (ATSDR). 2021. Toxicological Profile for Perfluoroalkyls. <https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf>

ProPublica. 2025. Scientists Completed a Toxicity Report on This Forever Chemical. The EPA Hasn't Released It. <https://www.propublica.org/article/epa-pfna-forever-chemical-report>

U.S. EPA (United States Environmental Protection Agency) Integrated Risk Information System (IRIS). 2025. IRIS Toxicological Review of Perfluorohexanesulfonic Acid (PFHxS, CASRN 335-46-4) and Related Salts. EPA/635/R-25/012Fa. <https://iris.epa.gov/static/pdfs/0705tr.pdf>

U.S. EPA (United States Environmental Protection Agency) Office of Solid Waste and Emergency Response (OSWER). 2013. Tier 3 Toxicity Value White Paper. OSWER Document Number 9285.7-86. <https://www.epa.gov/sites/production/files/2015-11/documents/tier3-toxicityvalue-whitepaper.pdf>

II. Proposed Revisions

The Agency agrees with comments filed by U.S. EPA on January 6, 2026, and suggests the following minor revisions to the proposed amendments:

- a. In section 611.7903(a)- references to 311.611(c) should instead read 611.311(c).
- b. In section 611.881(d)- a semicolon should be added after “(except for PFAS)”.
- c. In section 611.882(a)- reference to “in this subpart G” should instead read “in this subpart U” and a semi-colon should replace the colon after the word “parties”.
- d. In section 611.833(c)(1)(C)- a comma should be added after the word “physical”.
- e. In section 611.883(d)(3)(A)- “No data older than 5 years need by included.” should instead read “No data older than 5 years need be included.”
- f. In section 611.883(d)(3)(B)- reference to 40 CFR 141.553(d)(3)(ii) should instead read 40 CFR 141.153(d)(3)(ii).
- g. In section 611.883(d)(4)(E)- there is a reference to 611.211(b) but 611.211(b) does not exist.
- h. In section 811.833(f)- remove either the word “any” or “of” from the sentence that includes “the report must note any of specific violations...”
- i. In section 611.885(b)- a semicolon should be added between “customers” and “using an opt in notification”
- j. In section 611.885(g)- the phrase “may waive the requirement of subsection (a) for a CWS serving fewer than 10,000 persons” is repeated twice.

k. In section 611.885(g)(2)- the federal regulation states 500 or fewer, not fewer than 500.

III. Responses to Other Public Comments Received by the Board

a. On November 7, 2025, the Illinois Municipal League filed public comments stating that current 10-year timeline in the federal Lead and Copper Rule Improvements (“LCRI”) regulation is impossible to comply with due to various issues. The comments state that Illinois already has laws mandating lead service line replacement that were negotiated between the legislature and stakeholders.

Response: As stated above, in order for Illinois to have primacy over the LCRI program, the Illinois regulations have to be as stringent as the federal regulations. Additionally, even if the Board were not to adopt the LCRI regulations, stakeholders in Illinois would still be required to meet the federal regulations.

b. On November 19, 2025, the Illinois Environmental Regulatory Group (“IERG”) filed public comments stating that, because USEPA has stated its intent to roll back PFAS regulations, the Board should not adopt the rules, because it risks no longer aligning with federal law.

Response: As stated above, the Board has the ability to amend regulations if and when changes in the federal regulations occur, as the Board deems appropriate at that time. But IERG’s argument rests on speculation as to what might occur in the future. As to the present, it is without debate that Illinois regulations are less stringent than federal law, and the Act requires the Board to correct that. Indeed, USEPA Region 5 itself filed comments on January 6, 2026, with concerns that the proposed language is not as stringent as the existing federal regulations. There were no comments from USEPA about federal regulations that might be in place in the future. USEPA Region 5’s comments support the position that the Board’s

regulations should be as stringent as the current federal regulations.

c. On December 12, 2025, the City of Springfield, Office of Public Utilities d/b/s City Water, Light, and Power (“CWLP”) submitted public comments stating that the Board should postpone adoption of the proposed PFAS regulations due to USEPA’s intent to roll back the federal regulations, specifically citing as well to USEPA’s motion to vacate pending before the D.C. Circuit. CWLP’s comments also argue that the LCRI regulations should not be adopted now because of challenges to the LCRI federal rules.

Response: As stated in previous responses, the Board always has the option to amend regulations if federal regulations do in fact change. This proposed rulemaking has been delayed longer than is generally required under the Act already, though. Illinois risks not being able to meet important primacy deadlines if the rulemaking is delayed any longer. Illinois may lose important federal funding if the State loses primacy over these regulations. Federal courts will do their job of deciding whether to countenance USEPA’s new legal arguments concerning its PFAS standards, or other challenges to the federal regulations that underlie these amendments; in the meantime, the Board should do its job of adopting State regulations as stringent as the current federal regulations.

d. On December 30, 2025, the City of Rockford filed public comments stating that the LCRI regulations will not be possible to meet under current staffing and funding conditions.

Response: As stated above, whether or not the Board adopts the proposed amendments will not affect whether the City of Rockford, and other stakeholders in Illinois, have to meet the federal LCRI rules. Also, the Agency has low-interest loan opportunities (including principal forgiveness loans) in place to help alleviate funding concerns for replacing lead and copper pipes. The Agency will continue to marshal all available funding

opportunities to support compliance with drinking water requirements.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

Dated: January 8, 2026
Kaitlyn Hutchison
Division of Legal Counsel
Illinois Environmental Protection Agency
2520 W. Iles Ave
P.O. Box 19276
Springfield, IL 62794-9276
(217) 524-4648
kaitlyn.hutchison@illinois.gov

BY: /s/Kaitlyn Hutchison
Kaitlyn Hutchison

CERTIFICATE OF SERVICE

I, the undersigned, on affirmation certify the following:

That I have electronically served the attached **NOTICE OF FILING and ILLINOIS ENVIRONMENTAL PROTECTION AGENCY'S COMMENTS** by e-mail upon the following

USEPA REGION 5

Stacy Meyers
Daniel Leonard
Robert Peachey
Ralph H. Metcalfe Federal Building
77 West Jackson Blvd.
Chicago, Illinois, 60604
meyers.stacy@epa.gov
leonard.daniel@epa.gov
peachey.robert@epa.gov

ILLINOIS POLLUTION CONTROL BOARD

Don Brown, Clerk
Joan Beacom, Hearing Officer
60 E. Van Buren St. Ste. 630
Chicago, Illinois, 60605
Don.Brown@illinois.gov
Joan.beacom2@illinois.gov

ILLINOIS DEPT. OF NATURAL RESOURCES

Renee Snow
One Natural Resources Way
Springfield, Illinois, 62702
renee.snow@illinois.gov

DEPT. OF COMMERCE AND ECONOMIC OPPORTUNITY

Jonathan Eastvold
Small Business Office
500 East Monroe St.
Springfield, Illinois, 62701
Jonathan.eastvold@illinois.gov

JOINT COMMITTEE ON
ADMINISTRATIVE RULES
Wm. G. Stratton Office Building
Room 700
Springfield, Illinois, 62706
jcar@ilga.gov

That my e-mail address is kaitlyn.hutchison@illinois.gov.

That the e-mail transmission took place before 4:30 p.m. on the date of January 8, 2026.

Kaitlyn Hutchison
Division of Legal Counsel
Illinois Environmental Protection Agency
2520 W. Iles Ave
P.O. Box 19276
Springfield, IL 62794-9276
(217) 524-4648
kaitlyn.hutchison@illinois.gov

BY: /s/Kaitlyn Hutchison
Kaitlyn Hutchison

EXHIBIT A

ORAL ARGUMENT NOT YET SCHEDULED

Case No. 24-1188 (and consolidated cases)

**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.

On Petition for Review of Final Action of the
United States Environmental Protection Agency

**AMICUS CURIAE BRIEF FOR CONNECTICUT, CALIFORNIA,
NEW JERSEY, ARIZONA, COLORADO, DELAWARE, DISTRICT OF
COLUMBIA, HAWAII, ILLINOIS, MARYLAND, MASSACHUSETTS,
MICHIGAN, MINNESOTA, NEW YORK, NORTH CAROLINA, OREGON,
RHODE ISLAND, AND WISCONSIN IN SUPPORT OF RESPONDENT**

(Names and addresses of counsel appear inside cover.)

Date: January 17, 2025

WILLIAM M. TONG
Attorney General of Connecticut
MICHAEL K. SKOLD
Solicitor General
MATTHEW I. LEVINE
Deputy Associate Attorney General
CHRISTOPHER PATRICK KELLY
Assistant Attorney General
165 Capitol Avenue
Hartford, CT 06106
860-808-5250
christopher.kelly@ct.gov

MATTHEW J. PLATKIN
Attorney General of New Jersey
NATHANIEL LEVY
ZACH LAWRENCE
SYDNEY BYERS
Deputy Attorneys General
Hughes Justice Complex
25 Market Street
Trenton, NJ 08625
609-292-1539
zach.lawrence@law.njoag.gov

ROB BONTA
Attorney General of California
MICHAEL MONGAN
Solicitor General
JEREMY BROWN
Supervising Deputy Attorney General
TATIANA GAUR
TAYLOR WETZEL
JINA KIM
BRENDAN HUGHES
Deputy Attorneys General
600 West Broadway, Suite 1800
San Diego, CA 92101
619-738-9339
brendan.hughes@doj.ca.gov

(Additional counsel listed on signature page.)

**CERTIFICATE AS TO PARTIES, RULINGS,
AND RELATED CASES**

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel of record certifies as follows:

A. Parties and Amici

Except for the following, all parties, intervenors, and amici appearing in this Court are listed in the Brief of American Water Works Association and Association of Metropolitan Water Agencies (ECF 2078734) at page i; and in the Brief of National Association of Manufacturers, American Chemistry Council, and the Chemours Company FC, LLC (ECF 2078734) at page iii.

Amicus curiae in support of Petitioners is the Chamber of Commerce of the United States of America.

Amici curiae in support of Respondents are States of New Jersey, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maryland, Michigan, Minnesota, New Jersey, New York, North Carolina, Oregon, Rhode Island, and Wisconsin, Commonwealth of Massachusetts, District of Columbia, Center for Environmental Health, Cape Fear River Watch, Toxic Free North Carolina, Harper Peterson, Michael Watters, and an unidentified “group of interested scientists.”

B. Rulings Under Review

The agency action under review is a rule entitled “PFAS National Primary Drinking Water Regulation,” 89 Fed. Reg. 32,532 (April 26, 2024).

C. Related Cases

The above-captioned case (No. 24-1188) has been consolidated with two additional petitions for review, *National Ass’n of Manufacturers, et al. v. EPA, et al.* (No. 24-1191) and *The Chemours Co. FC, LLC v. EPA, et al.* (No. 24-1192). The rule at issue has not been previously reviewed in this or any other court and there are no related cases within the meaning of Circuit Rule 28(a)(1)(C).

/s/ Christopher Patrick Kelly
Christopher Patrick Kelly

TABLE OF CONTENTS

Certificate as to Parties, Rulings, and Related Cases i
 Table of Contents iii
 Table of Authorities iv
 Glossary..... ix
 Interests of *Amici Curiae* 1
 Statutes and Regulations 4
 Statement of the Case..... 4
 Summary of the Argument..... 4
 Argument..... 5
 I. The Rule Advances the Act’s Public Health Mandate and its Cooperative
 Federalism Framework. 5
 II. The Index PFAS, Individually and as Mixtures, are Contaminants of Public
 Health Concern. 11
 III. The Hazard Index is an Appropriate and Reasonable Tool that is Necessary
 Under the Safe Drinking Water Act. 15
 A. The Hazard Index is an Established and Practical Means to Evaluate
 Contaminant Levels and Risk. 15
 B. The Hazard Index Is the Most Practical Means to Prevent Dose-Additive
 Harms from PFAS Mixtures. 19
 IV. EPA Complied with the Procedural Requirements of the Act..... 22
 A. EPA Can Propose National Primary Drinking Water Regulations in
 Parallel with Determinations to Regulate. 23
 B. EPA’s Economic Analysis and Determination Complied with the
 Requirements of the Act..... 26
 Conclusion 28

TABLE OF AUTHORITIES

CASES

Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA,
 846 F.3d 492 (2d Cir. 2017)24

Chlorine Chemistry Council v. EPA,
 206 F.3d 1286 (D.C. Cir. 2000).....13

City of Portland v. EPA,
 507 F.3d 706 (D.C. Cir. 2007).....27

City of Waukesha v. EPA,
 320 F.3d 228 (D.C. Cir. 2003).....21

Envtl. Def. v. Duke Energy Corp.,
 549 U.S. 561 (2007)24

New State Ice Co. v. Liebmann,
 285 U.S. 262 (1932)2

NRDC v. Regan,
 67 F.4th 397 (D.C. Cir. 2023)8, 12

United States Sugar Corp. v. EPA,
 113 F.4th 984 (D.C. Cir. 2024)24

STATUTES

(Maine) Resolves 2021, ch. 8218

42 U.S.C. § 300g-1.....1

42 U.S.C. § 300g-1(b)(1)(A)..... 4, 7, 11, 19, 26

42 U.S.C. § 300g-1(b)(1)(A)(ii).....12

42 U.S.C. § 300g-1(b)(1)(B)(i).....7

42 U.S.C. § 300g-1(b)(1)(B)(ii).....12

42 U.S.C. § 300g-1(b)(1)(B)(ii)(I).....7
42 U.S.C. § 300g-1(b)(1)(B)(ii)(II).....7
42 U.S.C. § 300g-1(b)(1)(E)..... 23, 26
42 U.S.C. § 300g-1(b)(3)(A).....8
42 U.S.C. § 300g-1(b)(3)(C).....26
42 U.S.C. § 300g-1(b)(4)5, 8
42 U.S.C. § 300g-1(b)(4)(A)..... 5, 8, 16, 20, 21, 22, 26
42 U.S.C. § 300g-1(b)(4)(B)..... 5, 8, 22, 27
42 U.S.C. § 300g-1(b)(4)(D).....26
42 U.S.C. § 300g-1(b)(6)(A).....27
42 U.S.C. § 300g-2.....4
42 U.S.C. § 300g-2(a)3
42 U.S.C. § 300g-4(e)28
42 U.S.C. § 300g-5.....28
42 U.S.C. § 300j-7(a)25
42 U.S.C. § 300g-1(b)(10)28
Or. Rev. Stat. 468A.335, 468A.33718

REGULATIONS

22 Cal. Code Regs. 68400.5.....17
6 Colo. Code Regs. 1007-3, sec. 264.342.....18

Mich. Admin. Code R. 325.10604g.....11

Minn. Admin. R. 4717.7810 to 4717.7900.....18

Or. Admin. R. ch. 340, div. 245.....18

The Massachusetts Drinking Water Regulations, 310 CMR, § 22.00.....18

Water Supply Rule, 12 Code Vt. R. § 12-030-003.....18

OTHER AUTHORITIES

42 U.S.C. § 300g-1(b)(1)(B)(iii).....24

47 Fed. Reg. 31,180 (Jul. 16, 1982).....17

49 New Jersey Reporter 2361(a) (Aug. 7, 2017).....10

50 New Jersey Reporter 1939(a) (Sept. 4, 2018).....10

51 New Jersey Reporter 437(a) (Apr. 1, 2019).....10

54 New Jersey Reporter 1165(b) (June 1, 2020)10

89 Fed. Reg. 32,532 (Apr. 26, 2024) 1, 3, 8, 9, 13, 14, 15, 16, 19, 20, 25, 28

Agency for Toxic Substances and Disease Registry, *Fast Facts: PFAS in the U.S. Population* (Nov. 12, 2024).....7

Cal. Water Code, § 106.3.....9

California Department of Toxic Substances Control, *DTSC Toxicity Criteria Rule for Human Health Risk Assessments* (Jan. 2025).....17

California State Water Resources Control Board, Division of Drinking Water, Process Memo 97-005-R2020, *Revised Guidance for Direct Domestic Use of Extremely Impaired Sources* (1997).....17

California State Water Resources Control Board, *PFAS DDW General Orders* (Mar. 11, 2024).....14

California State Water Resources Control Board, *PFAS: Per- and Polyfluoroalkyl Substances* (Oct. 9, 2024)..... 10, 15

California State Water Resources Control Board, *Water System Administrators: Community and Program Info* (July 16, 2024)28

Connecticut Department of Public Health, *Per- and Polyfluoroalkyl Substances (PFAS) – Information for Public Water Systems* (Jan. 2025)14

Environmental Council of the States, Sarah Grace Hughes, *Processes & Considerations for Setting State PFAS Standards* (March 2023).....5

EPA, *Basic Information about Your Drinking Water* (Nov. 7, 2024).....7

EPA, *EPA’s Per- and Polyfluoroalkyl Substances (PFAS) Action Plan* (Feb. 2019)6, 7

EPA, *Hazard Ranking System (HRS)* (Oct. 9, 2024).....17

EPA, *Per- and Polyfluoroalkyl Substances (PFAS) Occurrence and Contaminant Background Support Document for the Final PFAS National Primary Drinking Water Regulation* (Apr. 2024).....11

EPA, Science Advisory Board, *Review of EPA’s Analyses to Support EPA’s National Primary Drinking Water Rulemaking for PFAS, Final Report* (2022)..... 17, 19

EPA, *SDWIS Federal Reports Search* (2025)3

Minnesota Department of Health, *Evaluating Concurrent Exposures to Multiple Chemicals* (Oct. 3, 2022).....18

New Jersey Department of Environmental Protection, Division of Science and Research, *Per- and Polyfluoroalkyl Substances (PFAS) Research* (Dec. 18, 2024).....10

New Jersey Department of Environmental Protection, Drinking Water Quality Institute, *Appendix A: Health-Based Maximum Contaminant Level Support Document: Perfluorooctane Sulfonate (PFOS)* (June 2018)5

New Jersey Department of Environmental Protection, Drinking Water Quality Institute, *Review of Interim USEPA Health Advisories for PFOA and PFOS and Other Relevant Information* (June 12, 2023).....6

New Jersey Department of Environmental Protection, *Per- and PolyFluoroalkyl Substances (PFAS)* (Apr. 16, 2024)10

New Jersey Department of Environmental Protection, Sandra Goodrow and Gloria B. Post, *Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* (Aug. 16, 2021).....7

New Jersey Department of Health, *Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* (Apr. 2024)6

Pelch, K. et al., *PFAS-Tox Database* (2021)1

Price, P.S. *The Hazard index at thirty-seven: New science new insights*, 34 *Toxicology* 100388 (June 2023).....16

GLOSSARY

EPA	United States Environmental Protection Agency
Goal	Maximum Contaminant Level Goal
HBWC	Health-Based Water Concentration
HFPO-DA	Hexafluoropropylene Oxide Dimer Acid
Index PFAS	HFPO-DA, PFBS, PFHxS, and PFNA
PFAS	Per- and Polyfluoroalkyl Substances
PFBS	Perfluorobutane Sulfonic Acid
PFHxS	Perfluorohexane Sulfonic Acid
PFNA	Perfluorononanoic Acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane Sulfonic Acid
Rule	PFAS National Primary Drinking Water Regulation
SDWA	Safe Drinking Water Act
Standard	Maximum Contaminant Level
UCMR	Unregulated Contaminant Monitoring Rule

INTERESTS OF *AMICI CURIAE*

State Amici—Connecticut, California, New Jersey, Arizona, Colorado, Delaware, District of Columbia, Hawaii, Illinois, Maryland, Massachusetts, Michigan, Minnesota, New York, North Carolina, Oregon, Rhode Island, and Wisconsin—submit this brief in support of Respondent the U.S. Environmental Protection Agency (“EPA”) and its rule establishing nationwide drinking water standards for certain per- and polyfluoroalkyl substances (“PFAS”) under Section 1412 of the Safe Drinking Water Act, 42 U.S.C. § 300g-1 (“SDWA” or the “Act”). *See* 89 Fed. Reg. 32,532 (Apr. 26, 2024) (the “Rule”).¹

State Amici have powerful interests in protecting their residents from the harms of PFAS exposure through drinking water. The presence of PFAS in drinking water is an established threat to public health and safety. A growing body of research shows that most, if not all, PFAS are highly toxic to humans and animals, with even minimal exposures over time associated with deleterious effects to human health.² They also resist degradation in the environment and are accordingly known as “forever chemicals.” These toxins were used for decades in myriad industrial and military settings, along with airports and fire departments,

¹ The PFAS included in the Rule are Perfluorooctanoic Acid (“PFOA”), Perfluorooctane Sulfonic Acid (“PFOS”), Hexafluoropropylene Oxide Dimer Acid (“HFPO-DA”), Perfluorobutane Sulfonic Acid (“PFBS”), Perfluorohexane Sulfonic Acid (“PFHxS”), and Perfluorononanoic Acid (“PFNA”).

² *See, e.g.*, Pelch, K. et al., *PFAS-Tox Database* (last visited Jan. 16, 2025), <https://pfastoxdatabase.org> (“Health Outcomes” tab).

and remain in countless consumer products, from infant car seats and strollers to non-stick cookware and food packaging. As a result, dangerous and highly mobile PFAS have contaminated numerous drinking water sources throughout the State Amici jurisdictions and the bodies of our residents—where they accumulate and persist. Several State Amici have repeatedly urged Congress and EPA to take prompt and aggressive actions to respond to the national PFAS crisis.³ Finally, EPA has acted by issuing this Rule.

The Rule supports those compelling state interests.⁴ While some State Amici already regulate some PFAS contaminants in drinking water under state law, the Rule establishes a federal baseline. This is a particularly important public health measure for jurisdictions without existing regulations, as it will mark the first set of legal protections their residents receive from the harms of particular PFAS present in drinking water. For those States that already regulate PFAS in drinking water, EPA's rule broadly complements and reinforces the various approaches taken by these States and establishes the federal floor above which States may choose to regulate. *Cf. New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932).

In addition, State Amici have a strong interest in seeing the Rule upheld in light of States' significant involvement in the enforcement of the Act and the

³ See, e.g., Comment Letter from State Attorneys General (May 30, 2023), <https://www.regulations.gov/comment/EPA-HQ-OW-2022-0114-1687>.

⁴ State Amici emphasize that no State has challenged the Rule as a petitioner, intervenor, or amicus curiae.

operation of public drinking water systems. Most, but not all, of the State Amici are authorized by EPA to exercise primary enforcement authority over drinking water in their respective jurisdictions, pursuant to 42 U.S.C. § 300g-2(a), and thus have an interest in the law that they enforce. In addition, some State Amici own and operate public water systems that will be subject to the requirements of the Rule. *See* 89 Fed. Reg. 32,535. According to federal data, the State Amici collectively own and operate 2,482 public water systems, of which 353 are subject to the Rule.⁵ Moreover, State Amici provide financial assistance to operators of public water systems which are subject to the Rule to treat PFAS in the water they serve to the public.

As to the statutory and procedural challenges to the Rule in this case, the petitions brought by both the Utility Petitioners and Industry Petitioners should be denied. *See* ECF 2091318 (“EPA Br.”) at i (identifying both sets of petitioners); ECF 2078734 (“Utility Br.”); ECF 2078731 (“Industry Br.”). The Rule is consistent with the purposes of the Act and protects the public from contaminants of concern affecting multiple jurisdictions. Under the Rule, EPA correctly determined, based on the best available science and information, to regulate emerging contaminants across multiple States that qualify as contaminants of public health concern. The Rule also acknowledges the overlapping health

⁵ EPA, *SDWIS Federal Reports Search*, https://sdwis.epa.gov/ords/sfdw_pub/r/sfdw/sdwis_fed_reports_public/200.

concerns presented by these contaminants and implements a hazard index approach to comply with the requirements of the Act. Finally, the Rule complies with the Act's unique procedural requirements for the issuance of nationwide drinking water regulations, including those pertaining to the sequencing of regulatory action as well as the Act's feasibility analysis.

STATUTES AND REGULATIONS

Relevant statutory and regulatory provisions not included with EPA's addendum are contained in the addendum filed with this brief.

STATEMENT OF THE CASE

The statutory and regulatory background is set forth in EPA's Statement of the Case.

SUMMARY OF THE ARGUMENT

I. The Rule serves the public health mandate of the Act by regulating contaminants of concern with substantial evidence of toxicity, which benefits and empowers States to protect drinking water. *See* 42 U.S.C. § 300g-2.

II. EPA's determination that the Index PFAS are substantially likely to occur in public water systems with a frequency and at levels of public health concern is supported by the contemporaneous efforts of state regulators to address the risks from these chemicals. *Id.* § 300g-1(b)(1)(A).

III. The hazard index approach adopted under the Rule has long been used by state and federal environmental regulators to recognize and mitigate the harms of co-occurring contaminants across a variety of environmental media, including to PFAS in drinking water. Petitioners present arguments against the hazard index that are factually inaccurate and contravene the Act's mandate to avoid known or anticipated harm to human health as much as is feasible. *Id.* § 300g-1(b)(4)(A); *Id.* § 300g-1(b)(4)(B).

IV. Petitioners present an interpretation of the Act that hamstring public health regulation with a narrow, less-informed public process and confuses the feasibility analysis required under the Act with a cost-benefit analysis. *Id.* § 300g-1(b)(4). EPA complied with the plain language procedural requirements of the Act.

ARGUMENT

I. The Rule Advances the Act's Public Health Mandate and its Cooperative Federalism Framework.

Drinking water comes from public water systems and private wells, which are fed by surface waters and underground reservoirs that are vulnerable to various contaminants, including PFAS.⁶ PFAS are a class of synthetic organic chemicals that have been used in numerous consumer and industrial products since the

⁶ NJDEP, Drinking Water Quality Institute, *Appendix A: Health-Based Maximum Contaminant Level Support Document: Perfluorooctane Sulfonate (PFOS)* ES-3 (June 2018), <https://www.nj.gov/dep/watersupply/pdf/pfos-recommendation-appendix-a.pdf>.

1940s.⁷ PFAS are characterized in part by their strong carbon-fluoride bonds, which allow many PFAS to persist in the environment for years, decades, or longer.⁸

Research over the past two decades clearly demonstrates PFAS toxicity, and that even miniscule exposures over time are associated with a range of adverse human health effects, including various cancers, liver disease and damage, developmental issues such as low birth weight, hormonal changes, weakened immune system, diabetes, and fertility issues.⁹ Furthermore, oral exposure to certain PFAS are associated with several harmful health effects, including impacts on the liver, thyroid, immune system, pregnancy and fetal development, and cancer.¹⁰ While some types of PFAS (such as PFOA and PFOS) have been phased out of production domestically, they remain in circulation via existing products and newly imported products. *See* EPA Br. 12. Meanwhile, other types of PFAS

⁷ ECOS, Sarah Grace Hughes, *Processes & Considerations for Setting State PFAS Standards* 6 (last updated March 2023), <https://www.ecos.org/wp-content/uploads/2023/03/2023-ECOS-PFAS-Standards-Paper-Update.pdf>; NJDOH, *Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* (last updated Apr. 2024), https://www.nj.gov/health/ceohs/documents/pfas_drinking%20water.pdf.

⁸ EPA, *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan* 9 (Feb. 2019) https://www.epa.gov/sites/default/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf.

⁹ *See* Pelch et al., *supra* note 2.; *see also* NJDEP, Drinking Water Quality Institute, *Review of Interim USEPA Health Advisories for PFOA and PFOS and Other Relevant Information* (June 12, 2023), <https://www.nj.gov/dep/watersupply/pdf/dwqi-health-effects-pfas-report.pdf>.

¹⁰ EPA, *supra* note 8 at 13.

continue to be manufactured, and human exposure to those PFAS is expected to increase over time.¹¹ Currently, PFAS are detectable in the blood of nearly all people in the United States.¹²

The Act governs EPA's process for regulating contaminants of concern in approximately 150,000 public water systems, which supply drinking water to a majority of Americans.¹³ To begin, the Act provides a data-based framework through which EPA can determine to regulate new contaminants. *See* EPA Br. 5. Every five years, EPA must publish a Contaminant Candidate List and must determine whether to regulate no fewer than five listed contaminants. 42 U.S.C. §§ 300g-1(b)(1)(B)(i), (b)(1)(B)(ii)(I). A determination to regulate requires a notice-and-comment rulemaking process and considers public health-focused criteria geared toward seizing "meaningful opportunity for health risk reduction" through regulation. *Id.* § 300g-1(b)(1)(A); *see id.* § 300g-1(b)(1)(B)(ii)(II); EPA Br. 5. The determination to regulate does not consider costs, but rather, the "best available public health information" and EPA's database of occurrences in public

¹¹ *Id.*

¹² Agency for Toxic Substances and Disease Registry, *Fast Facts: PFAS in the U.S. Population* (Nov. 12, 2024), <https://www.atsdr.cdc.gov/pfas/data-research/facts-stats/index.html>; NJDEP, Sandra Goodrow and Gloria B. Post, *Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* (Aug. 16, 2021), <https://dep.nj.gov/wp-content/uploads/dsr/private-well-consortium-pfas-2021.pdf>.

¹³ EPA, *Basic Information about Your Drinking Water* (last updated Nov. 7, 2024), <https://www.epa.gov/ground-water-and-drinking-water/basic-information-about-your-drinking-water>.

water systems. 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II). As this Court recently explained, the “Act frontloads EPA’s discretion” when determining whether to regulate contaminants. *NRDC v. Regan*, 67 F.4th 397, 399 (D.C. Cir. 2023).

After EPA determines to regulate, it must then, with limited exceptions, establish both Maximum Contaminant Level Goals (“Goals”) and Maximum Contaminant Levels (“Standards”). 42 U.S.C. § 300g-1(b)(4). The former must be “set at the level at which 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). The Standards—which are the enforceable drinking water standards—must be set as close to the Goals “as is feasible.” *Id.* § 300g-1(b)(4)(B). While cost considerations factor into the feasibility analysis, the Act does not mandate that a Standard’s benefits outweigh its costs. *See infra* Part IV.B; EPA Br. Part IV.A. In setting those standards, EPA is required to use the “best available, peer-reviewed science” and data collected using the “best available methods.” 42 U.S.C. § 300g-1(b)(3)(A). Certain statutory deadlines also apply to this phase. *See infra* Part IV.A; EPA Br. Part I.B.

Consistent with the Act’s requirements, the Rule advances regulation of multiple PFAS in a number of ways. The Rule finalized drinking water standards for PFOA and PFOS by setting Goals of zero and Standards of 4.0 parts per trillion (“ppt”). 89 Fed. Reg. 32,535. For HFPO-DA, PFHxS, and PFNA, the Rule both

finalized determinations to regulate and established Goals and Standards for each of those contaminants individually. *Id.* Finally, as to HFPO-DA, PFHxS, PFNA, and PFBS (collectively “Index PFAS”), the Rule both finalized a determination to regulate these substances *as a mixture*—where two or more of those contaminants co-occur—and established a Goal and Standard for those mixtures as a hazard index level of 1 (unitless). *Id.*¹⁴

The Rule will protect drinking water in Amici States, which have an integral role under the Act’s cooperative federalist model to ensure safe drinking water for their residents.¹⁵ The landscape of state-level PFAS regulation varies significantly across the country. Laws in some states adopt, but go no further than, federal drinking water regulations for regulated contaminants, leaving PFAS unregulated until EPA acts. Other jurisdictions, such as Wyoming and the District of Columbia, do not have primary enforcement authority under the Act and are directly regulated by the federal government. For residents of those jurisdictions, the Rule is an essential protection from contaminated drinking water. Even States that have adopted monitoring and reporting requirements stand to benefit because the Rule can ease the administrative burden for States that would otherwise set their own

¹⁴ Each aspect of the Rule is severable from the others, and the remainder of the Rule should remain in effect if Petitioners succeed in challenging any portion of it. *See* 89 Fed. Reg. 32,731.

¹⁵ *See, e.g.,* Cal. Water Code, § 106.3 (“[I]t is hereby declared to be the established policy of the state that every human being has the right to safe, clean, affordable, and accessible water.”).

regulations. In California, drinking water regulators have taken concrete steps to quantify PFAS contamination in the state, starting in 2019 with drinking water general monitoring orders, as well as setting nonregulatory notification and response levels for certain PFAS starting in 2020.¹⁶ State regulators may rely on EPA's scientific justification, saving agency resources and easing the burden on state regulators to accomplish this goal when compared to a state-initiated regulation.

The Rule will provide important complementary benefits even for those States that already limit PFAS in drinking water. For instance, New Jersey has maximum contaminant levels for PFOS, PFOA, and PFNA,¹⁷ but not for the other contaminants included in the Rule. New Jersey regulates the former set of compounds because those compounds were disproportionately detected during New Jersey's rulemaking compared to EPA's nationwide occurrence levels.¹⁸ The Rule enhances New Jersey's drinking water protections with the benefit of more

¹⁶ California State Water Resources Control Board, *PFAS: Per- and Polyfluoroalkyl Substances* (last updated Oct. 9, 2024), https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/pfas.html.

¹⁷ See NJDEP, *Per- and PolyFluoroalkyl Substances (PFAS)* (last updated Apr. 16, 2024), <https://dep.nj.gov/pfas/drinking-water/>.

¹⁸ NJDEP, Division of Science and Research, *Per- and Polyfluoroalkyl Substances (PFAS) Research* (last updated Dec. 18, 2024), <https://dep.nj.gov/dsr/pfas/#first>; see 49 N.J.R. 2361(a) (Aug. 7, 2017); 50 N.J.R. 1939(a) (Sept. 4, 2018); 51 N.J.R. 437(a) (Apr. 1, 2019); 54 N.J.R. 1165(b) (June 1, 2020).

recent and comprehensive data.¹⁹ The Rule also establishes more stringent standards for the contaminants New Jersey already regulates, which New Jersey has begun seeking to adopt as its own pursuant to both the Act and state law. The State thus stands to benefit from the Rule's robust protections, as do other States that already regulate PFAS in drinking water.²⁰

II. The Index PFAS, Individually and as Mixtures, are Contaminants of Public Health Concern.

Contrary to Petitioners' arguments, state and federal occurrence data unequivocally demonstrate that the Index PFAS are contaminants of "public health concern" within the meaning of 42 U.S.C. § 300g-1(b)(1)(A).²¹ Consequently, EPA has appropriately determined to regulate them, both individually and as mixtures, and has properly issued national primary drinking water regulations to address them.²²

To make an initial determination on whether to regulate contaminants, EPA is required to consider, among other things, whether those contaminants "occur in

¹⁹ See EPA, *Per- and Polyfluoroalkyl Substances (PFAS) Occurrence and Contaminant Background Support Document for the Final PFAS National Primary Drinking Water Regulation 25-29* (Apr. 2024), EPA-HQ-OW-2022-0114-3086.

²⁰ Some States have regulated some PFAS at concentrations lower than those implemented by the Rule. See, e.g., Mich. Admin. Code R. 325.10604g (setting a maximum contaminant level for PFNA at 6 ppt).

²¹ Petitioners do not contest EPA's threshold determination to regulate PFOA and PFOS in the first instance, which was not part of this Rule. See *infra* Part IV.A (discussing this element of the Act's scheme).

²² The Rule does not regulate PFBS individually, but it is included as part of a mixture under the Hazard Index.

public water systems with a frequency and at levels of public health concern.” *Id.* § 300g-1(b)(1)(A)(ii). Whether a contaminant’s occurrence is “of public health concern” is not defined by the Act, nor has a court defined a standard for meeting that criterion; rather, Congress explicitly authorized the Agency to apply its expertise to protect public health. *See NRDC*, 67 F.4th at 399 (“The Act frontloads EPA’s discretion, allowing the agency to . . . select which of those listed contaminants to consider for regulation, and determine whether the selected contaminants meet the statutory criteria for regulating.”).

Petitioners contest EPA’s determination that the Index PFAS—specifically HFPO-DA, PFNA, and the Index PFAS when co-occurring—occur with a frequency and at levels of public health concern. Utility Br. Part III; Industry Br. Part II.C.1, III.A (asserting specifically that HFPO-DA does not qualify as a public health concern). Most of Petitioners’ arguments fault EPA for using allegedly flawed state monitoring data and for not awaiting additional occurrence data from the Fifth Unregulated Contaminant Monitoring Rule (“UCMR 5”). Utility Br. 42-43; *see, e.g.*, Industry Br. 47.

Both of Petitioners’ criticisms misconstrue EPA’s duty under the Act. First, the Act requires the “best available” data and does not require—or expect—statistical perfection. *See* 42 U.S.C. § 300g-1(b)(1)(B)(ii) (determinations “shall be based on the best *available* public health information” (emphasis added)). Second,

the Act does not require EPA to await future data before regulating. *See Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290-91 (D.C. Cir. 2000) (“EPA cannot reject the ‘best available’ evidence simply because of the possibility of contradiction in the future by evidence unavailable at the time of action—a possibility that will always be present.”).

EPA reasonably exercised its discretion when assessing occurrence data for the Index PFAS and identifying them as contaminants of public health concern. *See* 89 Fed. Reg. 32,555 (“[T]he agency emphasizes that occurrence and co-occurrence of these PFAS is not only at a regional or local level, rather it covers many states throughout the country; therefore, a national level regulation is necessary to ensure all Americans served by PWSs are equally protected.”). EPA’s brief explains in detail how the Agency evaluated the available data and considered the occurrence of HFPO-DA, PFNA, and the Index PFAS. *See* EPA Br. 39-40 (outlining the six factors EPA used when evaluating the available occurrence data). Furthermore, EPA explains that Petitioners have misstated the occurrence data and that the state-provided occurrence data demonstrated frequent co-occurrences of the Index PFAS. *Compare* Industry Br. 40 (“Co-occurrence of even three of the Index [PFAS] is extremely rare”), *with* EPA Br. 59-60 (identifying 1% of sampled water systems with all four Index PFAS and 25.9% of water systems with three Index PFAS).

State Amici concur that these contaminants appear with a frequency, and at levels, that create a public health concern. Occurrence of the Index PFAS is national in scope and each of these contaminants appears within numerous states, including in transboundary waterways. *See, e.g.*, 89 Fed. Reg. 32,557 (noting that available state data showed HFPO-DA detections in 75 systems across 13 states); *see also* Utility Br. 46 (attributing potential HFPO-DA detections to the Ohio River). Many of the State Amici have demonstrated their concern about these contaminants by issuing drinking water testing orders, regulations, and health advisories. For example, the Connecticut Department of Public Health issued advisory health-based “Action Levels” in June 2022 and June 2023 for a total of ten PFAS, including HFPO-DA, PFNA, PFHxS, and PFBS.²³

Since 2019, California has issued several general orders to public water systems to monitor PFAS. The orders have expanded from a focus on at-risk systems to a broader range of systems and require responsive action from systems that exceed the state-set PFAS response levels.²⁴ California established nonregulatory, health-based notification and response levels for PFHxS and PFBS,

²³ Connecticut Department of Public Health, *Per- and Polyfluoroalkyl Substances (PFAS) – Information for Public Water Systems* (last visited Jan. 17, 2025), <https://portal.ct.gov/dph/drinking-water/dws/per--and-polyfluoroalkyl-substances>.

²⁴ *See* California State Water Resources Control Board, *PFAS DDW General Orders* (last updated Mar. 11, 2024), https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/pfas_ddw_general_order/.

which are represented in the Hazard Index. The human health risk assessment, on which the notification and response levels are based, determined that children were the most vulnerable population.²⁵

III. The Hazard Index is an Appropriate and Reasonable Tool that is Necessary Under the Safe Drinking Water Act.

Petitioners erroneously assert that the Rule's hazard index is an unreasonable and illegal form of Standard.²⁶ To the contrary, hazard indices are established and prevalent tools in environmental regulation. Moreover, because EPA identified dose-additive harms from co-occurring contaminants, EPA was obligated to use a hazard index in the Rule.

A. The Hazard Index is an Established and Practical Means to Evaluate Contaminant Levels and Risk.

The Rule establishes a Goal and a Standard for mixtures of the Index PFAS using a hazard index, which creates a level that reflects the measured amount of any of the four Index PFAS in a mixture and the individual toxicity of each. 89 Fed. Reg. 32,568. To calculate the index value of the contaminants, EPA set a “health-based water concentration” (“HBWC”) for each of the Index PFAS, which is a ratio value “set at the level below which adverse effects are not likely to occur and allows for an adequate margin of safety.” 89 Fed. Reg. 32,567-32,568; *see also*

²⁵ California State Water Resources Control Board, *supra* note 17.

²⁶ State Amici concur with EPA's argument that the Standards for PFOA and PFOS are feasible and lawful. EPA Br. Part III.A.

42 U.S.C. § 300g-1(b)(4)(A). The Goal and the Standard are both set at a unitless value of 1 on the hazard index. 89 Fed Reg. 32,532. The hazard index value is calculated by, first, dividing the measured concentration of each of the Index PFAS by its HBWC, which yields the “hazard quotient” for each PFAS in the sample, and then adding the hazard quotients together to determine whether they exceed the unitless value of 1. 89 Fed. Reg. 32,568.

Hazard indices are frequently used in environmental and public health contexts when contaminants that can produce similar “dose addition” effects, or similar health effects, are mixed.²⁷ The intention of the hazard index approach is to ensure that, “if the sum of the [hazard quotients] for an individual is kept below [1], then adverse [noncancer human health] effects are no more likely to occur than if each chemical’s exposure occurred separately.”²⁸ A hazard index can provide greater health protectiveness than individual limits that do not account for the additive and synergistic effects of commingled pollutants, and helps to manage the unique toxicological questions that such pollutants raise.

EPA has most notably used hazard indices in the Superfund program since 1982, evaluating sites under the “Hazard Ranking System” to determine the “potential hazard presented by releases or threatened releases of hazardous

²⁷ See, e.g., Price, P.S. *The Hazard index at thirty-seven: New science new insights*, 34 *Toxicology* 100388 (June 2023),

<https://www.sciencedirect.com/science/article/abs/pii/S2468202023000037>.

²⁸ *Id.*

substances.”²⁹ EPA’s Science Advisory Board considers the longstanding hazard index approach to be “validated” and “a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media.”³⁰

State-level environmental regulators have also adopted hazard indices where authorities must evaluate the human health risk from mixed or potentially mixed contaminants with additive adverse health effects. For example, California uses this approach with respect to remediation of hazardous substances to reduce noncancer risks for future users of contaminated sites.³¹ California also uses a method similar to a hazard index, called an “MCL-equivalent,” to set treatment goals for the direct domestic use of extremely impaired water sources.³² Likewise, Minnesota applies a hazard index approach to remediation of numerous

²⁹ National Oil and Hazardous Substances Contingency Plan, 47 Fed. Reg. 31,180, 31,187 (Jul. 16, 1982); see EPA, *Hazard Ranking System (HRS)* (last updated Oct. 9, 2024), <https://www.epa.gov/superfund/hazard-ranking-system-hrs>.

³⁰ EPA, Science Advisory Board, *Review of EPA’s Analyses to Support EPA’s National Primary Drinking Water Rulemaking for PFAS, Final Report* at 91 (2022), EPA-HQ-OW-2022-0114-3107.

³¹ 22 Cal. Code Regs. 68400.5; see also California Department of Toxic Substances Control, *DTSC Toxicity Criteria Rule for Human Health Risk Assessments* (last visited Jan. 17, 2025), <https://dtsc.ca.gov/toxicity-criteria-rule-for-human-health-risk-assessments-faq/>.

³² See California State Water Resources Control Board, Division of Drinking Water, Process Memo 97-005-R2020, *Revised Guidance for Direct Domestic Use of Extremely Impaired Sources* (1997), https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/docs/process_memo_97-005-r2020_v7.pdf.

contaminants in groundwater.³³ States also frequently use hazard indices to assess risks in air quality and air quality monitoring from industrial facilities burning hazardous waste, such as in Oregon and Colorado.³⁴

Many states have arrived at the same conclusion as EPA that the health risks of PFAS cannot be addressed in isolation, and accordingly now regulate PFAS in drinking water and other media under a hazard index or in summation.³⁵ For example, Wisconsin has developed a health-based hazard index level of one for seventeen types of PFAS, which is used in various regulatory programs that impact groundwater. Maine, Massachusetts, and Vermont have established drinking water standards for sums of PFAS, which include some of those regulated under the Rule: PFOA, PFOS, PFNA, and PFHxS.³⁶ Minnesota has set enforceable Health Risk Limits for individual PFAS contaminants in drinking water and uses a hazard index for mixtures of those contaminants.³⁷

³³ Minn. Admin. R. 4717.7810 to 4717.7900.

³⁴ Or. Rev. Stat. 468A.335, 468A.337, and Or. Admin. R. ch. 340, div. 245; 6 Colo. Code Regs. 1007-3, sec. 264.342.

³⁵ See ECOS, *supra* note 7.

³⁶ (Maine) Resolves 2021, ch. 82; The Massachusetts Drinking Water Regulations, 310 CMR, § 22.00; Water Supply Rule, 12 Code Vt. R. § 12-030-003.

³⁷ Minnesota Department of Health, *Evaluating Concurrent Exposures to Multiple Chemicals* (Oct. 3, 2022), <https://www.health.state.mn.us/communities/environment/risk/guidance/gw/additivity.html>.

B. The Hazard Index Is the Most Practical Means to Prevent Dose-Additive Harms from PFAS Mixtures.

State Amici agree with EPA's sound conclusion that the Hazard Index "is the most practical approach for establishing [a Goal] for PFAS mixtures that meets the statutory requirements outlined in section 1412(b)(1)(A) of SDWA." 89 Fed. Reg. 32,568; *see* 42 U.S.C. § 300g-1(b)(1)(A). Because EPA has identified dose-additive health effects when the Index PFAS are found in combination, EPA *had* to use a hazard index to protect public health to the greatest extent feasible.

EPA's evaluation of the "best available public health information" determined that, not only do the Index PFAS each have an adverse effect on human health, but they also have dose-additive effects that can result in the same adverse health outcomes in combination. 89 Fed. Reg. 32,543; EPA Br. 62 ("[E]xposure to each of the four PFAS leads to endocrine, liver, and kidney toxicity."). The Science Advisory Board supported that conclusion by agreeing with EPA's evaluation of contaminants based upon similar health outcomes and noted that "many PFAS, including the four used in the examples in the draft EPA mixtures document and others, elicit effects on multiple biological pathways that have common adverse outcomes in several biological systems." 89 Fed. Reg. 32,569.³⁸

EPA recognized that promulgating Goals and Standards for individual contaminants would not address the dose-additive effects that may occur when

³⁸ EPA, Science Advisory Board, *supra* note 31 at 91.

those contaminants co-occur at concentrations below their respective Standards. 89 Fed. Reg. 32,543. Having concluded that the Index PFAS have dose-additive effects when in combination, EPA therefore cannot promulgate a Goal to avoid adverse human health effects and allow a margin of safety without the hazard index because promulgating individual Goals for the Index PFAS alone would be insufficient to meet the requirements of the Act. *See* 42 U.S.C. § 300g-1(b)(4)(A). EPA had to use the hazard index to address the relative toxicity and common health risks of these PFAS in order to comply with the plain language and proactive purposes of the Act.

Petitioners object to the hazard index on various grounds. However, Petitioners are incorrect as to each, as explained below.

First, Industry Petitioners object to the hazard index because the Act allegedly only permits regulation of single contaminants in isolation. Industry Br. 31-33. But as explained in EPA's brief, that interpretation contradicts the broad language chosen by Congress, as well as the longstanding interpretation that the Act permits EPA to regulate multiple contaminants together. EPA Br. 28-29 (citing past EPA rulemakings to regulate as groups disinfection byproducts, radionuclides, polychlorinated biphenyls, and asbestos). Furthermore, EPA cannot set appropriate Goals if it may only consider contaminants in isolation and must ignore threats to public health arising from mixtures of contaminants with dose-additive effects. *See*

42 U.S.C. § 300g-1(b)(4)(A). That deleterious outcome would be inconsistent with the requirements of the Act.

Second, Petitioners criticize EPA for using a mathematical equation as a Standard and erroneously characterize all drinking water Standards as “a fixed number” that are “expressed and described as a concentration level.” Utility Br. 34-35. Nothing in the Act supports Petitioners’ arbitrary limitations on Standards. In fact, the use of the hazard index is entirely consistent with the diversity of Standards that EPA has promulgated over decades. Curiously, Utility Petitioners provide their own exception to their mathematical equation argument: EPA regulates sums of radionuclides under the Act, requiring water systems to add together the measured values of individual contaminants. *Id.* at 34; *see also City of Waukesha v. EPA*, 320 F.3d 228, 232 (D.C. Cir. 2003). The 1991 radionuclides regulations address the isotopes radium-226 and radium-228 by combined picocuries/liter, all beta/photon emitters by combined millirems effective dose equivalent, and naturally occurring uranium by micrograms per liter. *City of Waukesha*, 320 F.3d at 231-32. Picocuries measure the rate at which radioactive compounds disintegrate and millirems measure “the dose of radiation an individual receives from a certain type of exposure.” *Id.* at 232, n. 1 and 2. EPA thus has long employed a diversity of Standards that are no less complex than the hazard index.

Third, Petitioners assert that a hazard index approach is only suitable for “screening.” Utility Br. 36-40; Industry Br. 41. But any review of the Act should make clear that “screening”—however Petitioners choose to define it—is exactly what Congress commands the Agency to do. Consider the mandate for Goals, which must be set at the level at which “no known or anticipated adverse effects on [human health] occur *and which allows an adequate margin of safety.*” 42 U.S.C. § 300g-1(b)(4)(A) (emphasis added). Standards are then set as close to that precautionary value as possible. *Id.* § 300g-1(b)(4)(B). The Act is designed to eliminate, to the extent appropriate according to the information available to EPA at that time, any risk to human health. To the extent that Petitioners cite commentary that hazard index screening can identify what contaminants should be further investigated, that commentary serves as no limitation on the ability of EPA to set regulations at this time with the information available to it.

IV. EPA Complied with the Procedural Requirements of the Act.

Under the plain language of the Act, EPA complied with the procedural requirements to issue the Rule. Petitioners misconstrue the statutory language’s procedural requirements with respect to sequencing and incorrectly conflate the Act’s feasibility analysis with a cost-benefit analysis.³⁹

³⁹ State Amici concur with EPA that Petitioners’ other procedural objections to the Rule fail. *See, e.g.,* EPA Br. 72 (explaining that EPA adequately considered

A. EPA Can Propose National Primary Drinking Water Regulations in Parallel with Determinations to Regulate.

Petitioners argue that the Act mandates a strictly sequential process that EPA violated by proposing regulations for the Index PFAS alongside the proposed determination to regulate them. Utility Br. Part I; Industry Br. Part II.B.1. This argument reads new requirements into the Act that are not in the Act's plain language. While the Act establishes a deadline to propose regulations—no later than 24 months after the final determination to regulate—it does not foreclose EPA proposing regulations sooner, including at the same time it renders a preliminary determination to regulate. *See* 42 U.S.C. § 300g-1(b)(1)(E). Petitioners' cramped reading would hamper EPA's ability to implement the Act.

The plain language of the provision at issue permits EPA to propose determinations and regulations in parallel. The provision instructs that EPA “shall propose [Goals and Standards] . . . not later than 24 months after the determination to regulate under subparagraph (B), and *may publish such proposed regulation concurrent with the determination to regulate.*” *Id.* § 300g-1(b)(1)(E) (emphasis added). This provision itself is silent as to whether “determination” means only the *final* determination, as Petitioners claim, or affords EPA latitude to propose standards at the same time *as either the proposed or final* determination, as EPA

alternative standards that were appropriate under the Act); *id.* at 92 (explaining that EPA adequately consulted the Science Advisory Board as required by the Act).

argues. Interpreting this language against the backdrop of the Act's scheme as a whole readily shows that EPA's reading is superior. *See United States Sugar Corp. v. EPA*, 113 F.4th 984, 993 (D.C. Cir. 2024).

The phrase "determination to regulate" does not uniquely refer to the *final* determination. The Act uses "determination to regulate" inconsistently across different provisions, and its meaning in a particular provision must therefore be gleaned from the surrounding words and context of that provision. *Cf. Catskill Mountains Chapter of Trout Unlimited, Inc. v. Env't Prot. Agency*, 846 F.3d 492, 532 (2d Cir. 2017) ("[T]here is no requirement that the same term used in different provisions of the same statute be interpreted identically.") (citing *Env'tl. Def. v. Duke Energy Corp.*, 549 U.S. 561, 574–76 (2007)). For instance, in 42 U.S.C. § 300g-1(b)(1)(B)(iii), the very same phrase can only be read to refer to the *preliminary* determination. *See id.* ("Each document setting forth the determination for a contaminant ... *shall be available for public comment.*"). In contrast to subsection (b)(1)(B)(iii), nothing in subsection (b)(1)(E) tethers the option of "propos[ing] regulation concurrent with the determination to regulate" exclusively to the preliminary or final determination.

Unlike the Petitioners' confused assertion, EPA's reading provides a coherent meaning to subsection (b)(1)(E) as a whole. Interpreting "determination" in subsection (b)(1)(E) to mean "final determination" only, as Petitioners do,

renders the third clause of the paragraph mere surplusage. By expressly adding the option of proposing regulations “concurrent with the determination,” Congress makes clear that EPA need not move in a strict sequence and can instead elect to bundle a preliminary determination together with a proposed standard. *See* EPA Br. 33. If Congress wanted to specify a *single* starting point, as well as an endpoint, for the period in which EPA must propose regulations, it certainly could have as it did elsewhere in the Act. *See* 42 U.S.C. § 300j-7(a) (“shall be filed *within* the 45-day period beginning *on the date of the promulgation* of the regulation”) (emphases added).

Finally, interpreting the Act to permit parallel publishing is consistent with the Act’s purposes. Parallel publishing enables EPA to advance to final rulemaking more quickly and better respond to emerging contaminants of concern that threaten human health. In addition, parallel publishing can yield a greater breadth of public comment at the determination stage than if EPA were to proceed in the four-step sequence Petitioners demand. *See* 89 Fed. Reg. 32,541-32,542. EPA’s process likely yielded a greater amount of public input and data to consider before issuing “final determinations” than if it followed a sequential process. *See id.* Petitioners claim they were entitled to two notice and comment periods instead of one, but do not argue their comments would have materially differed with an additional comment period. Indeed, all Petitioners commented on the combined proposal;

some of them more than once.⁴⁰ This practical reality only further weakens Petitioners' textual argument, and bolsters EPA's.

Petitioners' extratextual limitations undermine the public health goals of the Act. The correct reading of the Act does not insert sequential limitations that are absent from the statutory language. Under the correct reading, a proposed regulation may be issued concurrently with the preliminary determination to regulate, and no later than 24 months after a final determination to regulate. *See* 42 U.S.C. § 300g-1(b)(1)(E).

B. EPA's Economic Analysis and Determination Complied with the Requirements of the Act

Petitioners erroneously contend that the Rule must be vacated due to alleged flaws in EPA's economic analysis. Utility Br. Part IV; Industry Br. 14-23.

Petitioners misunderstand the role of the economic analysis required by 42 U.S.C. § 300g-1(b)(3)(C) specifically and the Act generally. The Act does not permit cost to be a consideration when determining to regulate, *id.* § 300g-1(b)(1)(A), or when establishing Goals. *id.* § 300g-1(b)(4)(A). EPA must *consider* costs as part of the feasibility analysis when setting Standards, but mere consideration of costs is different from the kind of cost-benefit analysis Petitioners demand. *Id.* § 300g-1(b)(4)(D); *see City of Portland v. EPA*, 507 F.3d 706, 712

⁴⁰ *See, e.g.*, Comment Submitted by American Water Works Association (Apr. 5, 2023), EPA-HQ-OW-2022-0114-1465; Comment Submitted by American Water Works Association (June 2, 2023), EPA-HQ-OW-2022-0114-1759.

(D.C. Cir. 2007) (rejecting the conflation of cost-benefit analysis with the Act’s feasibility analysis).

Petitioners appear to argue that any regulation must produce net positive quantifiable benefits over costs. *See, e.g.*, Industry Br. 18 (“EPA’s analysis does not reveal the expected quantifiable net benefit for any one substance taken alone”). On the contrary, the Act does not require benefits to exceed the quantified costs of rules. Instead, Standards are set “as close to the [Goal] as is feasible.” 42 U.S.C. § 300g-1(b)(4)(B).

This Court has already rejected any interpretation that conflates cost with feasibility. *See City of Portland*, 507 F.3d at 712 (“But if ‘feasible’ meant that the technique’s benefits justified its costs, section 300g-1(b)(6)(A) . . . would be surplusage.”). This interpretation of the Act is further evidenced by subsection (b)(6)(A), which gives EPA discretion to set a less stringent Standard than feasible when the benefits of a regulation “would not justify the costs”—but does not require it to do so. 42 U.S.C. § 300g-1(b)(6)(A).

Finally, Petitioners’ substantive criticisms of EPA’s economic analysis do not establish the Agency acted unreasonably. For example, Petitioners allege the Black & Veatch study that American Water Works Association submitted during the comment period demonstrates EPA underestimated costs. Utility Br. 54. But EPA thoroughly engaged with this study in its response to comments and included

three tables critiquing the assumptions made in the study. 89 Fed. Reg. 32,640-32,647. As extensively explained in the Rule, EPA found that numerous faulty assumptions led the study to overestimate the costs of the Rule. *Id.* EPA reasonably considered the study as a submitted comment but was not obligated to adopt its conclusions.

Given their policy interest in ensuring the provision of safe drinking water, and their role in operating their own water systems, Amici States appreciate the practical importance of affordability. Indeed, California already serves as the administrator for numerous financially struggling third-party water utilities and is keenly familiar with the fiscal challenges regulations can impose on such utilities.⁴¹ Although the Act limits cost considerations when promulgating national regulations, it includes tools to mitigate disparate impacts on water systems.⁴² EPA itself has already taken steps to lessen the burden of the Rule by extending the compliance deadline to the maximum allowable five years. *See* 42 U.S.C. § 300g-1(b)(10).

CONCLUSION

For the reasons set forth above, this Court should deny the Petitions.

⁴¹ California State Water Resources Control Board, *Water System Administrators: Community and Program Info* (last updated July 16, 2024), https://www.waterboards.ca.gov/water_issues/programs/hr2w/.

⁴² *See* 42 U.S.C. § 300g-4(e) (providing States with discretion to grant variances to small water systems); 42 U.S.C. § 300g-5 (providing States with discretion to grant water systems additional time to achieve compliance).

Date: January 17, 2025

Respectfully Submitted,

STATE OF CONNECTICUT
WILLIAM M. TONG
Attorney General

STATE OF CALIFORNIA
ROB BONTA
Attorney General

/s/ Christopher Patrick Kelly

MICHAEL MONGAN
Solicitor General
JEREMY BROWN
Supervising Deputy Attorney General
TATIANA GAUR
TAYLOR WETZEL
JINA KIM
BRENDAN HUGHES
Deputy Attorneys General
600 West Broadway, Suite 1800
San Diego, CA 92101
619-738-9339
brendan.hughes@doj.ca.gov

MICHAEL K. SKOLD
Solicitor General
MATTHEW I. LEVINE
Deputy Associate Attorney General
CHRISTOPHER PATRICK KELLY
Assistant Attorney General
165 Capitol Avenue
Hartford, CT 06106
860-808-5250
christopher.kelly@ct.gov

STATE OF NEW JERSEY
MATTHEW J. PLATKIN
Attorney General

NATHANIEL LEVY
ZACH LAWRENCE
SYDNEY BYERS
Deputy Attorneys General
Hughes Justice Complex
25 Market Street
Trenton, NJ 08625
609-292-1539
zach.lawrence@law.njoag.gov

STATE OF ARIZONA
KRIS MAYES
Attorney General

STATE OF COLORADO
PHILIP J. WEISER
Attorney General

STATE OF DELAWARE
KATHLEEN JENNINGS
Attorney General

DISTRICT OF COLUMBIA
BRIAN L. SCHWALB
Attorney General

STATE OF HAWAII
ANNE E. LOPEZ
Attorney General

STATE OF ILLINOIS
KWAME RAOUL
Attorney General

STATE OF MARYLAND
ANTHONY G. BROWN
Attorney General

COMMONWEALTH OF
MASSACHUSETTS
ANDREA JOY CAMPBELL
Attorney General

STATE OF MICHIGAN
DANA NESSEL
Attorney General

STATE OF MINNESOTA
KEITH ELLISON
Attorney General

STATE OF NEW YORK
LETITIA JAMES
Attorney General

STATE OF NORTH CAROLINA
JEFF JACKSON
Attorney General

STATE OF OREGON
DAN RAYFIELD
Attorney General

STATE OF RHODE ISLAND
PETER F. NERONHA
Attorney General

STATE OF WISCONSIN
JOSHUA L. KAUL
Attorney General

CERTIFICATE OF COMPLIANCE

I hereby certify that this document complies with the type-volume limitations of Federal Rules of Appellate Procedure 32(g) and 29(a)(5), as well as Circuit Rule 32(e)(3), because the word count does not exceed the 6,500 words permitted. According to Microsoft Word, the portions of this document not excluded by Federal Rule of Appellate Procedure 32(f) and Circuit Rule 32(e)(1) contain 6,425 words.

I further certify that this brief complies with the typeface requirements of Federal Rules of Appellate Procedure 32(a)(5) and 32(a)(6) because it has been prepared using a proportionally spaced typeface (Times New Roman) in 14-point font.

/s/ Christopher Patrick Kelly
Christopher Patrick Kelly

CERTIFICATE OF SERVICE

I hereby certify that, on January 17, 2025, I electronically filed the foregoing Amicus Brief of the State Amici with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit via the CM/ECF system. Participants in the case who are registered CM/ECF users will be served electronically by that system.

/s/ Christopher Patrick Kelly
Christopher Patrick Kelly

EXHIBIT B

ORAL ARGUMENT NOT YET SCHEDULED

Case No. 24-1188

**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.

On Petition for Review

RESPONDENTS' PROOF BRIEF

Dated: December 23, 2024

TODD KIM

Assistant Attorney General

Of Counsel:

HEIDI NALVEN

U.S. Environmental Protection
Agency
Office of General Counsel

KIMERE J. KIMBALL

ANDREW D. KNUDSEN

U.S. Department of Justice
Env't & Natural Resources Div.
P.O. Box 7611
Washington, DC 20044
(202) 514-2285 (Kimball)
(202) 353-7466 (Knudsen)
Kimere.Kimball@usdoj.gov
Andrew.Knudsen@usdoj.gov

Counsel for Respondents

RESPONDENTS' CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), counsel for Respondents United States Environmental Protection Agency ("EPA") and EPA Administrator Michael S. Regan submit this certificate as to parties, rulings, and related cases.

A. Parties and Amici

The petitioners, respondents, and intervenors in these consolidated cases are set forth in the brief of American Water Works Association and Association of Metropolitan Water Agencies ("Utility Petitioners") (ECF 2078734, "Utility Br."), and in the brief of National Association of Manufacturers, American Chemistry Council, and the Chemours Company FC, LLC ("Industry Petitioners") (ECF 2078734, "Industry Br.").

In addition to those parties listed in Petitioners' briefs, Chamber of Commerce of the United States of America is participating as Amicus Curiae for Petitioners. Additionally, the State of Connecticut, Cape Fear River Watch, Center for Environmental Health, Harper Peterson, Toxic Free North Carolina, and Michael Watters are participating as Amici Curiae for Respondents. In addition, an unidentified "group of interested scientists" is seeking to participate as Amici Curiae for Respondents. (ECF 2089133).

B. Rulings Under Review

The agency action under review is EPA’s rule entitled “PFAS National Primary Drinking Water Regulation,” 89 Fed. Reg. 32532 (April 26, 2024).

C. Related Cases

The above-captioned case (No. 24-1188) has been consolidated with two additional petitions for review, *National Ass’n of Manufacturers, et al. v. EPA, et al.* (No. 24-1191) and *The Chemours Co. FC, LLC v. EPA, et al.* (No. 24-1192). Respondents are not aware of any other related cases within the meaning of Circuit Rule 28(a)(1)(C).

/s/ Kimere J. Kimball
KIMERE J. KIMBALL

Counsel for Respondent

TABLE OF CONTENTS

Respondents' Certificate as to Parties, Rulings, and Related Cases	i
Table of Contents	iii
Table of Authorities	vii
Glossary.....	xiii
Introduction	1
Statement of Jurisdiction.....	3
Statement of the Issues.....	3
Pertinent Statutes and Regulations.....	4
Statement of the Case.....	4
I. The Safe Drinking Water Act.....	4
II. The Regulated PFAS.....	8
A. HFPO-DA	9
1. Health Effects	9
2. Occurrence.....	9
3. Non-Drinking Water Exposure	10
B. PFNA.....	11
1. Health Effects	11
2. Occurrence.....	11
C. Index PFAS Mixtures.....	12
1. Health Effects	12
2. Occurrence.....	13
III. EPA's PFAS Drinking Water Regulation	14
A. Regulatory Determinations for PFOA and PFOS.....	14
B. Science Advisory Board	14
C. Preliminary Regulatory Determinations for Index PFAS and Proposed Goals and Standards for PFOA, PFOS, and Index PFAS.....	16
D. The Final Rule.....	18

Summary of Argument20

Standard of Review23

Argument.....24

 I. The Regulatory Determinations for the Index PFAS Are Lawful and Followed Proper Procedure.....24

 A. EPA Has Authority to Regulate Mixtures of Contaminants.....25

 B. The Act Allows EPA to Propose and Finalize a Standard in Parallel with a Regulatory Determination.....29

 II. The Record Supports EPA’s Determination to Regulate HFPO-DA and PFNA Individually and the Index PFAS Collectively.....38

 A. The Record Supports EPA’s Occurrence Analyses.....38

 1. EPA Properly Considered State Monitoring Data.....41

 2. EPA Reasonably Determined There Is a Substantial Likelihood HFPO-DA Will Occur at Frequencies and Levels of Public Health Concern.....45

 a. Substantial Evidence Supports EPA’s HFPO-DA Occurrence Determination. 45

 b. EPA Properly Limited Its Consideration of the Partial UCMR5 Data..... 48

 3. EPA Reasonably Determined There Is a Substantial Likelihood PFNA Will Occur at Frequencies and Levels of Public Health Concern.....54

 4. EPA Reasonably Determined There Is a Substantial Likelihood Mixtures of the Index PFAS Will Occur at Frequencies and Levels of Public Health Concern.56

 a. EPA Properly Considered Reported Co-Occurrences of Index PFAS. 57

 b. EPA Reasonably Statistically Analyzed Index PFAS Co-Occurrence..... 58

 B. The Record Supports EPA’s Determination that the Index PFAS May Have an Adverse Effect on the Health of Persons.....61

 III. The Rule’s Standards Are Lawful, Reasonable, and Supported by the Record.....65

A. EPA Set the Standards for PFOS and PFOA at the Level That Is as Close to the Goals as Feasible.66

B. EPA Adequately Considered Alternative Standards.72

C. EPA Has Authority to Promulgate Standards in the Form of a Hazard Index.....74

D. The Index PFAS Standard Appropriately Regulates Mixtures of Index PFAS.78

E. The HFPO-DA Individual Standard Is Reasonable and Supported by the Record.81

 1. EPA Reasonably Considered Non-Drinking Water Exposure to HFPO-DA.....81

 2. EPA Reasonably Relied on Rodent Studies Showing HFPO-DA Elicits a Constellation of Adverse Liver Effects Relevant to Humans....84

 3. EPA Reasonably Applied Both Subchronic-to-Chronic and Database Uncertainty Factors of 10.89

F. EPA Satisfied Its Procedural Requirements for Consultation with the Science Advisory Board.92

IV. EPA Appropriately Considered Costs and Benefits in Promulgating the Rule.....95

 A. EPA’s Selection of “Feasible” Standards Does Not Depend on Comparison of Costs and Benefits.....95

 B. The Act Precludes Judicial Review of EPA’s Finding That the Rule’s Benefits Justify Its Costs.....99

 C. EPA Reasonably Determined that the Rule’s Benefits Justify Its Costs.....103

 1. To the Extent the Court May Review EPA’s Assessment of Costs and Benefits, The Scope Is Limited to Arbitrary-and-Capricious Review.103

 2. EPA Properly Based Its Determination on Both the Quantified and Nonquantifiable Costs and Benefits.....105

 3. EPA Was Not Required to Conduct a Stand-Alone Economic Analysis for Each Individual Standard in the Rule.110

 4. EPA Addressed Petitioners’ Specific Concerns with the Economic Analysis in the Record.....114

V. None of Petitioners' Arguments Warrant Vacatur of the Entire Rule.....120
Conclusion122
Certificates of Compliance and Service.....123

TABLE OF AUTHORITIES

CASES

Abbott v. United States,
 562 U.S. 8 (2010).....41

Allied-Signal, Inc. v. U.S. Nuclear Reg. Comm’n,
 988 F.2d 146 (D.C. Cir. 1993).....122

Am. Mining Congress v. EPA,
 907 F.2d 1179 (D.C. Cir. 1990).....23, 24

Am. Textile Mfrs. Inst. v. Donovan,
 452 U.S. 490 (1981).....67

Appalachian Power Co. v. EPA,
 251 F.3d 1026 (D.C. Cir. 2001).....107

Bluewater Network v. EPA,
 370 F.3d 1 (D.C. Cir. 2004).....39

City of Portland v. EPA,
 507 F.3d 706 (D.C. Cir. 2007)..... 66, 67, 74, 96, 98

City of Waukesha v. EPA,
 320 F.3d 228 (D.C. Cir. 2003)..... 23, 36, 37, 76, 94, 113

Coal. for Renewable Nat. Gas v. EPA,
 108 F.4th 846 (D.C. Cir. 2024).....39, 41

Consol. Edison Co. of New York, Inc. v. FERC,
 347 F.3d 964 (D.C. Cir. 2003).....65

Corley v. United States,
 556 U.S. 303 (2009).....26

Del. Dep’t Nat. Res. & Env’t Control v. EPA,
 895 F.3d 90 (D.C. Cir. 2018).....26

Duncan v. Walker,
 533 U.S. 167 (2001).....26

Fed. Trade Comm’n v. Morton Salt Co.,
 334 U.S. 37 (1948).....61

Huntsman Petrochemical LLC v. EPA,
 114 F.4th 727 (D.C. Cir. 2024).....23, 88

Int’l Fabricare Inst. v. EPA,
 972 F.2d 384 (D.C. Cir. 1992)..... 23, 67, 68, 105

Loper Bright Enters. v. Raimondo,
 144 S. Ct. 2244 (2024)..... 24, 25, 28, 39, 74

Michigan v. EPA,
 576 U.S. 743 (2015).....104

Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.,
 463 U.S. 29 (1983)..... 23, 90, 104, 105

Nat’l Ass’n for Surface Finishing v. EPA,
 795 F.3d 1 (D.C. Cir. 2015).....109, 110

NRDC v. EPA,
 529 F.3d 1077 (D.C. Cir. 2008).....52, 109

NRDC v. Regan
 67 F.4th 397 (D.C. Cir. 2023).....32

NYC C.L.A.S.H., Inc. v. Fudge,
 47 F.4th 757 (D.C. Cir. 2022).....82, 85

Sinclar Wyo. Refin. Co. v. EPA,
 101 F.4th 871 (D.C. Cir. 2024).....23, 84, 92

U.S. Sugar Corp. v. EPA,
 113 F.4th 984 (D.C. Cir. 2024).....23

UARG v. EPA,
 573 U.S. 302 (2014).....65

United States v. Am. Trucking Ass’ns,
 310 U.S. 534 (1940).....28

West Virginia v. EPA,
 597 U.S. 697 (2022).....65

STATUTES

5 U.S.C. § 706.....36

5 U.S.C. § 706(2)(A).....23

42 U.S.C. § 300f(1).....6, 113

42 U.S.C. § 300f(3).....6, 75

42 U.S.C. § 300f(6).....25, 26

42 U.S.C. § 300g-1.....50

42 U.S.C. § 300g-1(a)(3)6

42 U.S.C. § 300g-1(b)(1)35, 38, 121

42 U.S.C. § 300g-1(b)(1)(A)-(B).....45

42 U.S.C. § 300g-1(b)(1)(A).....5, 6, 50

42 U.S.C. § 300g-1(b)(1)(A)(i).....61, 63, 64

42 U.S.C. § 300g-1(b)(1)(A)(ii)..... 39, 40, 41, 47, 48

42 U.S.C. § 300g-1(b)(1)(B).....30

42 U.S.C. § 300g-1(b)(1)(B)(i).....5, 35

42 U.S.C. § 300g-1(b)(1)(B)(ii)(I).....5

42 U.S.C. § 300g-1(b)(1)(B)(ii)(II)..... 5, 38, 39, 44, 48, 49, 50, 51

42 U.S.C. § 300g-1(b)(1)(B)(iii).....5, 30, 31, 34

42 U.S.C. § 300g-1(b)(1)(B)(ii)(III)5, 33, 34, 35

42 U.S.C. § 300g-1(b)(1)(E) 14, 29, 30, 32

42 U.S.C. § 300g-1(b)(3)(A).....73, 109

42 U.S.C. § 300g-1(b)(3)(C)..... 7, 73, 112, 113
42 U.S.C. § 300g-1(b)(3)(C)(i)(I)-(II)114
42 U.S.C. § 300g-1(b)(3)(C)(i)(I)-(III)..... 105, 108, 109
42 U.S.C. § 300g-1(b)(3)(C)(i).....113
42 U.S.C. § 300g-1(b)(3)(C)(i)(I).....110
42 U.S.C. § 300g-1(b)(3)(C)(i)(III)72
42 U.S.C. § 300g-1(b)(3)(C)(i)(VII).....109
42 U.S.C. § 300g-1(b)(4)74, 81, 93
42 U.S.C. § 300g-1(b)(4)(A).....6, 74, 104
42 U.S.C. § 300g-1(b)(4)(B)..... 6, 66, 73, 74, 96, 101
42 U.S.C. § 300g-1(b)(4)(C)..... 6, 24, 73, 96, 97, 101, 113
42 U.S.C. § 300g-1(b)(4)(D)..... 66, 67, 69, 96
42 U.S.C. § 300g-1(b)(6)97, 121
42 U.S.C. § 300g-1(b)(6)(A)..... 7, 97, 100, 101
42 U.S.C. § 300g-1(b)(6)(D).....24, 100, 103
42 U.S.C. § 300g-1(b)(7)6
42 U.S.C. § 300g-1(d).....6
42 U.S.C. § 300g-1(e)92, 95
42 U.S.C. § 300i(a)27
42 U.S.C. § 300j-4(g).....5, 44, 48, 49
42 U.S.C. § 300j-4(g)(1)6, 49
42 U.S.C. § 300j-4(g)(3)5
42 U.S.C. § 300j-4(g)(5)49

42 U.S.C. § 300j-4(g)(7)(A)-(B).....52
 42 U.S.C. § 300j-7100
 42 U.S.C. § 300j-7(a)32
 42 U.S.C. § 300j-7(a)(1)3
 42 U.S.C. § 4365(a)93
 Pub. L. No. 115-270 § 2021 (2018), 132 Stat 3765.....52

CODE OF FEDERAL REGULATIONS

40 C.F.R. § 141.2378
 40 C.F.R. § 141.2478
 40 C.F.R. § 141.2678
 40 C.F.R. § 141.64(b)77
 40 C.F.R. § 141.6677
 40 C.F.R. § 141.66(b)76
 40 C.F.R. § 141.66(c).....76
 40 C.F.R. § 141.66(d)76
 40 C.F.R. § 141.13378

FEDERAL REGISTER

44 Fed. Reg. 68624 (Nov. 29, 1979).....29
 51 Fed. Reg. 34836 (Sept. 30, 1986)76
 56 Fed. Reg. 3526 (Jan. 30, 1991)29
 63 Fed. Reg. 69390 (Dec. 16, 1998).....29
 65 Fed. Reg. 76708 (Dec. 7, 2000)..... 29, 77
 66 Fed. Reg. 45676 (Aug. 29, 2001).....93

67 Fed. Reg. 38222 (June 3, 2002)45

68 Fed. Reg. 42898 (July 18, 2003).....45

71 Fed. Reg. 388 (Jan. 4, 2006)29

74 Fed. Reg. 51850 (Oct. 8, 2009).....14

77 Fed. Reg. 26072 (May 2, 2012)29

78 Fed. Reg. 10270 (Feb. 13, 2013)93

85 Fed. Reg. 14098 (Mar. 10, 2020).....14

86 Fed. Reg. 4198 (Jan. 15, 2021)93

86 Fed. Reg. 12272 (Mar. 3, 2021).....14

LEGISLATIVE HISTORY

H.R. Rep. No. 93-1185 (1974),
as reprinted in 1974 U.S.C.C.A.N. 6454.....27, 28, 67

S. Rep. No. 104-169 (1995)..... 67, 99, 101, 102, 104

H.R. Rep. No. 104-632 (1996).....99

OTHER AUTHORITIES

RANDOM HOUSE COLLEGE DICTIONARY
(Laurence Urdang et al. eds., 1973).....25, 75, 80

GLOSSARY

Board	Science Advisory Board
EPA	U.S. Environmental Protection Agency
Goal	Maximum Contaminant Level Goal
HFPO-DA	Hexafluoropropylene oxide dimer acid
Index PFAS	HFPO-DA, PFBS, PFHxS, and PFNA
PFAS	Per- and Polyfluoroalkyl Substances
PFBS	Perfluorobutane Sulfonic Acid
PFHxS	Perfluorohexane Sulfonic Acid
PFNA	Perfluorononanoic Acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane Sulfonic Acid
Standard	Maximum Contaminant Level
SDWA	Safe Drinking Water Act
UCMR	Unregulated Contaminant Monitoring Rule

INTRODUCTION

In the rule challenged here, the U.S. Environmental Protection Agency (“EPA”) took action to safeguard the nation’s drinking water from a class of chemicals so long-lived and persistent in the environment that they are colloquially known as “forever chemicals.” Many of these chemicals, known as per- and polyfluoroalkyl substances (“PFAS”), are known to be dangerous to humans (including children and fetuses); do not break down to become less dangerous over human lifespans; and have widely contaminated the nation’s drinking water supplies. EPA’s action here under the Safe Drinking Water Act (“SDWA” or “Act”) provides much-needed protection from the public health risks of these chemicals.

PFAS persist and accumulate in the environment, meaning that once released, they will remain for decades or even millennia. A large and robust body of scientific evidence indicates PFAS exposure can result in cancer and a broad range of other adverse health effects, including developmental, cardiovascular, liver, kidney, immune, endocrine, metabolic, reproductive, and musculoskeletal effects. Many PFAS have been shown to have the same or similar dose-additive health effects, such that exposure to multiple PFAS together compounds the risk presented. And the best available data demonstrates that these chemicals are

present in many geographically dispersed public water systems at levels of public health concern.

To address the associated public health risks, in this rulemaking EPA has promulgated drinking water standards under the Act applicable to six PFAS.¹ JA-[FR_EPA-HQ-OW-2022-0114-3076_32532] (the “Rule”). The Rule culminates a coordinated years-long research and regulatory process across multiple administrations. It establishes enforceable standards that are estimated to prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses. And the Rule does so at a cost that is lower than its quantified benefits, even before accounting for its substantial nonquantifiable health benefits. JA-[FR_32708].

Petitioners’ arguments challenging the Rule lack merit.² In many of their arguments, Petitioners advance interpretations of EPA’s statutory authority or the role of costs in the Act’s regulatory process that are inconsistent with the statute and with this Court’s precedent. In others, Petitioners second-guess EPA’s

¹ The Rule applies to six PFAS: perfluorooctanoic acid (“PFOA”), perfluorooctane sulfonic acid (“PFOS”), perfluorohexane sulfonic acid (“PFHxS”), perfluorononanoic acid (“PFNA”), hexafluoropropylene oxide dimer acid (“HFPO-DA,” commonly known as GenX Chemicals), and perfluorobutane sulfonic acid (“PFBS”). JA-[FR_32532].

² Petitioners in case number 24-1188 (“Utility Petitioners”) filed one brief, while Petitioners in case numbers 24-1191 and 24-1192 (“Industry Petitioners”) filed a separate brief.

conclusions on scientific issues while misinterpreting or entirely ignoring relevant evidence and explanation in the record. And in still others, Petitioners misstate EPA's past practices under the Act. For all the reasons discussed below, the Court should reject Petitioners' arguments and deny the petitions for review.

STATEMENT OF JURISDICTION

This Court has jurisdiction over the petitions for review under 42 U.S.C. § 300j-7(a)(1).

STATEMENT OF THE ISSUES

1. Whether the Rule's regulatory determinations for PFHxS, PFNA, HFPO-DA, and PFBS (together, the "Index PFAS") are permissible exercises of EPA's statutory authority for which EPA followed the required procedure.
2. Whether the Rule's determinations to regulate the Index PFAS, individually and collectively, are reasonable where:
 - a. EPA considered the best available information on occurrence of these contaminants; and
 - b. EPA supported its findings on the adverse health effects of mixtures of Index PFAS based on the best available, peer-reviewed science.
3. Whether the Rule's national primary drinking water regulations are reasonable where:

- a. EPA addressed Petitioners' comments regarding feasibility of the PFOS and PFOA standards and adequately considered alternatives;
 - b. EPA regulated mixtures of Index PFAS through a hazard index that meets SDWA's definition of a "maximum contaminant level" and appropriately addresses those contaminants' dose-additive effects;
 - c. EPA adequately supported its determination of the safe drinking water level of the Index PFAS collectively and HFPO-DA individually; and
 - d. EPA consulted with its Science Advisory Board on the scientific questions most critical to EPA's proposed Rule.
4. Whether the Court may review EPA's analysis of the Rule's costs and benefits and, if so, whether EPA's determination that the Rule's benefits justify its costs was reasonable.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations not provided in the addendum to Utility Petitioners' Opening Brief are provided in the addendum accompanying this brief.

STATEMENT OF THE CASE

I. The Safe Drinking Water Act

The Safe Drinking Water Act authorizes EPA to promulgate national primary drinking water regulations, which specify enforceable standards limiting contaminants in public water systems.

SDWA provides two processes by which EPA can determine to regulate new contaminants. First, the Act requires EPA to maintain and periodically update a list of contaminants that are candidates for regulation. *Id.* § 300g-1(b)(1)(B)(i). Every five years, EPA must make a determination of whether or not to regulate at least five contaminants on this list. *Id.* § 300g-1(b)(1)(B)(ii)(I). Second, EPA may also make a regulatory determination at any time outside of the candidate listing process. *Id.* § 300g-1(b)(ii)(III). For either approach, EPA must publish a preliminary determination and provide an opportunity for public comment before making its determination. *Id.* § 300g-1(b)(1)(B)(ii)(I), (b)(1)(B)(iii).

EPA determines to regulate a contaminant if three criteria are satisfied:

1. the contaminant may have an adverse effect on the health of persons;
2. 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
3. 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). EPA must make these findings “based on the best available public health information, including the occurrence database established under section 300j-4(g)” of SDWA. *Id.* § 300g-1(b)(1)(B)(ii)(II); *see also id.* § 300j-4(g)(3). The occurrence database consists of “information on the occurrence of

both regulated and unregulated contaminants in public water systems...and reliable information from other public and private sources.” *Id.* § 300j-4(g)(1).

For each contaminant EPA decides to regulate, the agency must publish a maximum contaminant level goal (“Goal”) and promulgate a national primary drinking water regulation for that contaminant through notice-and-comment rulemaking. *Id.* § 300g-1(a)(3), (b)(1)(A), (d). The Goals are non-enforceable public health goals and are set at the level of a contaminant in drinking water below which “no known or anticipated adverse effects on the health of persons occur and which allow[] an adequate margin of safety.” *Id.* § 300g-1(b)(4)(A). The drinking water regulation is enforceable and typically takes the form of a maximum contaminant level (“Standard”) setting the “maximum permissible level of a contaminant in water which is delivered to any user of a public water system.”³ *Id.* § 300f(1), (3). EPA generally must set the Standard “as close to the [Goal] as is feasible.” *Id.* § 300g-1(b)(4)(B). The statute defines “feasible” as “feasible with the use of the best technology, treatment techniques and other means which the Administrator finds...are available (taking cost into consideration).” *Id.* § 300g-1(b)(4)(D).

³ Regulations may also take the form of treatment technique requirements. 42 U.S.C. § 300g-1(b)(7). Because the Rule does not include such requirements, this brief focuses only on “Standards.”

At proposal, EPA must publish a determination as to “whether the benefits of the [Standard] justify, or do not justify, the costs.” *Id.* § 300g-1(b)(4)(C). To inform this determination, SDWA requires EPA to publish a health risk reduction and cost analysis (“Economic Analysis”) along with the proposal setting forth the benefits, costs, and other impacts of the proposed Standards. *Id.* § 300g-

1(b)(3)(C). EPA must analyze:

1. quantifiable and nonquantifiable health risk reduction benefits likely to occur from treatment to comply with the Standard;
2. quantifiable and nonquantifiable health risk reduction benefits likely to occur from reductions of co-occurring contaminants attributable solely to compliance with the Standard;
3. quantifiable and nonquantifiable costs likely to occur solely as a result of compliance with the Standard;
4. incremental costs and benefits associated with any alternative Standards EPA considers;
5. the effects of the contaminant on the general population and more sensitive subgroups within the population;
6. any increased health risk that may occur as a result of compliance; and
7. other “relevant factors,” including the quality and extent of information, uncertainties in the analysis, and the degree and nature of the risk.

Id. § 300g-1(b)(3)(C).

If EPA determines that the benefits of a Standard set as close to the relevant Goal as feasible “would not justify the costs of complying with the [Standard],” it may (at the Administrator’s discretion) adopt a less stringent Standard set at a level

that “maximizes health risk reduction benefits at a cost that is justified by the benefits.” *Id.* § 300g-1(b)(6)(A).

II. The Regulated PFAS

PFAS are a large class of chemically and structurally similar synthetic chemicals, exposure to which can result in a number of significant health effects, including heart attacks, strokes, and cancers. JA-[FR_32536]. Exposure to several different PFAS elicit many of the same harmful health effects, including effects on the liver, hormone levels, kidneys, development and growth, and the immune, nervous, and reproductive systems. JA-[FR_32537]. These chemicals are used across a variety of products for their ability to withstand heat and to repel water and stains, and break down extremely slowly in the environment. JA-[FR_32536].

The Rule individually regulates five PFAS—PFOS, PFOA, PFNA, PFHxS, and HFPO-DA—in drinking water. JA-[FR_32533]. Additionally, because these chemicals occur together (*i.e.*, “co-occur”) and have the same or similar health effects, their individual effects on certain biological systems can add to each other’s health impact (referred to as “dose-additivity”). JA-[FR_32532]. The Rule thus regulates mixtures containing two or more of HFPO-DA, PFNA, PFHxS, and PFBS (collectively, the “Index PFAS”). JA-[FR_32533].

Before issuing the Rule, EPA studied for years the health effects and occurrence of these chemicals in drinking water and in the environment, as well as

technology to remove these chemicals from drinking water. The following summarizes the portion of EPA's extensive research relevant here.

A. HFPO-DA

1. Health Effects

The available scientific HFPO-DA health effects literature demonstrates that exposure elicits adverse health effects on development, the liver and kidney, and the reproductive, immune, and hematological systems. JA-[FR_32544]; JA-[MCLG_EPA-HQ-OW-2022-0114-3078_2-1_to_2-2]. EPA submitted critical components of its analysis of HFPO-DA's health effects for independent peer review three times over six years before setting the Standard; all three panels agreed with EPA's assessments. *See* JA-[HFPO-DA_1st_Peer_Review_USEPA_2018b]; JA-[HFPO-DA_2nd_Peer_Review_EPA-HQ-OW-2022-0114-3618]; JA-[HFPO-DA_TA_EPA-HQ-OW-2022-0114-0102_Appx_D].

2. Occurrence

EPA considered data from 25 state water monitoring programs that monitored for HFPO-DA, and from the Department of Defense and the National Water Information System. JA-[Occurrence_Support_EPA-HQ-OW-2022-0114-3086_205-216]. EPA analyzed the state data both for overall detections and for detections above the health reference level (the concentration below which adverse

health effects are not likely to occur), which EPA has calculated as 10 ng/L for HFPO-DA. JA-[MCLG_2-1]. This data demonstrated that HFPO-DA currently occurs in concentrations above the health reference level in public water systems in five geographically diverse states, and that it is currently detected at lower levels in systems in an additional eight states. JA-[Occurrence_Support_205-216].

HFPO-DA continues to be both produced and used in the United States and is chemically stable and resistant to degradation. JA-[Occurrence_Support_198]; JA-[FR_32557]. EPA thus anticipates that contamination will continue, and may increase, in the future. JA-[FR_32557]. Accordingly, EPA found that there is a substantial likelihood HFPO-DA will occur at frequencies and levels of public health concern. JA-[FR_32557].

3. Non-Drinking Water Exposure

To set a health-protective concentration of HFPO-DA in drinking water, EPA also considered the extent of HFPO-DA exposure that occurs through non-drinking water sources. JA-[MCLG_2-3]. EPA conducted a thorough review of the available scientific studies and data on HFPO-DA exposure from other exposure routes, which demonstrated HFPO-DA's presence in certain foods, soil, sewage sludge, air emissions, rainwater, and indoor dust. JA-[MCLG_A-11_to_A-15]. Because these studies did not allow calculation of the specific amount of HFPO-DA exposure from drinking water versus other media, EPA followed its

standard protocol of attributing 20% of exposure to drinking water and 80% to other sources. JA-[MCLG_2-3, A-15]; JA-[RSC_Guide_EPA-HQ-OW-2022-0114-0882_1-7].

B. PFNA

1. Health Effects

Scientific evidence demonstrates that PFNA exposure, like HFPO-DA exposure, elicits adverse effects on development, reproduction, immune function, and the liver. JA-[FR_32544]; JA-[MCLG_1-7_to_1-10, 2-8].

2. Occurrence

EPA considered a variety of national and state data regarding PFNA in public water systems. JA-[Occurrence_Support_163-93]. EPA analyzed the data both for overall occurrences and for occurrences above the health reference level, which EPA has calculated as 10 ng/L. JA-[MCLG_2-7_to_2-10].

Data from EPA's third cycle of unregulated contaminant monitoring ("UCMR3") reported detections of PFNA at concentrations of 20 ng/L or higher – twice the health reference level. *Id.* Fourteen public water systems across seven states detected PFNA at levels at least twice the health reference level. *Id.*; JA-[FR_32556]. Additionally, data collected from 30 state monitoring programs demonstrate public water systems in 12 states in geographically dispersed areas detected PFNA above the health reference level, and systems in an additional

seven states detected concentrations at lower levels. JA-[Occurrence_Support_180-83]. EPA also considered Department of Defense and National Water Information System testing, which demonstrated, *inter alia*, detections above the health reference level at military bases in South Dakota and Texas. JA-[Occurrence_Support_189-90].

Finally, EPA considered that PFNA is chemically stable and resistant to degradation, making it likely to persist in the environment. JA-[Occurrence_Support_163]. Additionally, although PFNA has largely been phased out of production in the United States, legacy stocks still remain in the United States and may be used in products, and both PFNA and products containing PFNA may to be produced internationally and imported into the United States. JA-[FR_32556]. EPA thus determined that there is a substantial likelihood PFNA will occur at frequencies and levels of public health concern. JA-[FR_32556].

C. Index PFAS Mixtures

1. Health Effects

Scientific evidence demonstrates that exposure to Index PFAS elicit many of the same or similar health effects, including effects on the liver, the kidney, cholesterol, and development, and on the immune, endocrine, and hematologic systems. JA-[FR_32545, 32552]; JA-[MCLG_1-5_to_1-11]; JA-[Framework_EPA-HQ-OW-2022-0114-3088_33-38]. These chemicals are “toxicologically

similar,” meaning that they “elicit the same or similar adverse health effects (but with differing potencies for effect(s))....” JA-[MCLG_1-7]. This toxicological similarity means that the chemicals are expected to act “dose-additively.” JA-[MCLG_1-7]. This means that “individual PFAS, each at doses that are not anticipated to result in adverse health effects, when combined in a mixture may result in adverse health effects.” JA-[MCLG_1-11].

2. Occurrence

EPA analyzed state monitoring data, which demonstrates that two or more Index PFAS occur together at levels above the health reference level in public water systems in at least 21 states. JA-[Occurrence_Support_220-51].

EPA also evaluated state data for co-occurrence using groupwise (comparing PFOA and PFOS with Index PFAS) and pairwise (comparing unique pairs of PFAS) statistical analyses. JA-[Occurrence_Support_220-46]; JA-[FR_32589-596]. The groupwise analysis demonstrated that Index PFAS were more likely to occur when PFOA and/or PFOS were present and also that when Index PFAS were present it was more likely that there would be multiple Index PFAS rather than a single Index PFAS. JA-[Occurrence_Support_240]. The pairwise analysis demonstrated how much more likely one Index PFAS was to occur if a second Index PFAS were present. JA-[Occurrence_Support_242-44]. The odds of detecting one Index PFAS if another was present were between 5.2 and 66.0 times

higher than if the other Index PFAS was not present. JA-[Occurrence_Support_242-44]. EPA thus determined that there is a substantial likelihood the Index PFAS will co-occur at frequencies and levels of public health concern. JA-[FR_32552-53].

III. EPA's PFAS Drinking Water Regulation

A. Regulatory Determinations for PFOA and PFOS

EPA added PFOA and PFOS to its list of candidate contaminants for regulation in 2009. 74 Fed. Reg. 51850 (Oct. 8, 2009). In 2020, EPA published a preliminary determination to regulate these contaminants and solicited public comment. 85 Fed. Reg. 14098 (Mar. 10, 2020). In March 2021, EPA made a final determination to regulate PFOA and PFOS, finding that all three statutory criteria were met for each contaminant. 86 Fed. Reg. 12272 (Mar. 3, 2021). This determination triggered a 24-month deadline for EPA to propose Goals and Standards for PFOS and PFOA. 42 U.S.C. § 300g-1(b)(1)(E).

B. Science Advisory Board

Beginning in December 2021, EPA sought review from its Science Advisory Board ("Board") on four draft documents presenting key scientific issues related to its forthcoming proposed Goals and Standards for PFOS, PFOA, and Index PFAS. JA-[SAB_Report_EPA-HQ-OW-2022-0114-3107_1]. These documents included EPA's proposed framework for estimating noncancer health risks associated with

mixtures of PFAS. JA-[Peer_Review_Draft_Mixture_Framework_EPA-HQ-OW-2022-0114-3619].

With respect to PFAS mixtures, EPA asked the Board for feedback on PFAS dose-additivity. EPA provided an in-depth overview of the scientific literature regarding dose-additivity generally and of PFAS specifically. JA-[Peer_Review_Draft_Mixture_Framework_at_16-26]. EPA sought the Board's input on a tiered process for evaluating PFAS mixtures' health risks whereby PFAS mixtures would first be evaluated using one of several approaches, including a hazard index, and, if risk was indicated, more data-intensive approaches would be followed. JA-[Peer_Review_Draft_Mixture_Framework_at_26-29]. The hazard index approach is "EPA's most commonly used component-based mixture risk assessment method," in which EPA divides the concentration of each contaminant by the contaminant's health reference level, then sums the fractional results and compares that sum to the hazard index health reference level of 1. JA-[Framework_57]; JA-[Occurrence_Support_220].

The Board agreed that many PFAS have common health outcomes and are expected to act dose-additively when present together. JA-[SAB_Report_87, 90]. They noted that PFAS "elicit effects...that have common adverse outcomes in several biological systems (e.g., hepatic, thyroid, lipid synthesis and metabolism, developmental and immune toxicities)." JA-[SAB_Report_87, 90]. The Board

supported EPA's use of a hazard index to evaluate PFAS mixtures, but recommended against the tiered approach. JA-[SAB_Report_91-94].

EPA responded to the Board's recommendations in March 2023 and published a draft framework for public comment along with the proposed Rule. JA-[SAB_Response_EPA-HQ-OW-2022-0114-0043]; JA-[Framework_Public_Comment_Draft_EPA-HQ-OW-2022-0114-0030]. EPA published a finalized framework document along with the final Rule in April 2024. JA-[Framework].

C. Preliminary Regulatory Determinations for Index PFAS and Proposed Goals and Standards for PFOA, PFOS, and Index PFAS

In March 2023, EPA proposed the Rule challenged here. JA-[NPRM_EPA-HQ-OW-2022-0114-0027_18638] ("Proposal"). The Proposal included three primary components: (1) proposed Goals and Standards for PFOA and PFOS; (2) a preliminary determination to regulate the four Index PFAS individually and as a mixture; and (3) a proposed Goal and Standard applicable to the Index PFAS individually and as a mixture. *Id.*

First, for PFOA and PFOS, EPA found that these contaminants are likely human carcinogens and (consistent with its historic practice for such contaminants) proposed to set their Goals at zero. [NPRM_18660, 18663]. EPA proposed to set the Standards at 4.0 ng/L, the lowest concentration at which these contaminants can be reliably quantified, known as the practical-quantitation level.

[NPRM_18666]. EPA identified numerous treatment technologies that are both available and have reliably demonstrated ability to achieve concentrations below the proposed Standards. [NPRM_18668].

Second, EPA made a preliminary determination to regulate the four Index PFAS individually and collectively as a mixture. [NPRM_18645]. Based on the best available public health information, including the information discussed in Pt.II, *supra*, EPA proposed to find that PFHxS, HFPO-DA, PFNA, and PFBS (individually and together in mixtures) satisfied the Act's criteria for regulation. [NPRM_18645-52].

Third, EPA proposed a Goal and Standard for the Index PFAS. EPA proposed to regulate these contaminants in the form of a hazard index to protect against dose-additive risk from combinations of these PFAS. [NPRM_18664]. To account for differences in toxicity among the four Index PFAS, the hazard index approach weights each mixture component using a chemical-specific "health-based water concentration" reflecting the level that is protective of health effects over a lifetime of exposure.⁴ *Id.* Compliance with the hazard index is calculated by dividing each Index PFAS contaminant's measured concentration by its health-based water concentration, then adding the results for the four Index

⁴ EPA proposed health-based water concentrations for PFHxS, HFPO-DA, PFNA, and PFBS of 9.0, 10.0, 10.0, and 2,000.0 ng/L, respectively. [NPRM_18641].

PFAS together. *Id.* at 18665. EPA proposed to set the Goal at 1.0 and to set the Standard at the same level because treatment to the level of the Goal is feasible. [NPRM_18665, 18669]. The Proposal defined a mixture as containing “one or more” of the four Index PFAS, and thus would also regulate each Index PFAS individually if it occurred alone above its health-based water concentration. [NPRM_18638-39]. EPA also solicited comment on whether to promulgate stand-alone Goals and Standards for each of the four Index PFAS individually. [NPRM_18730].

D. The Final Rule

After considering extensive public comments, EPA published the final Rule in April 2024. JA-[FR_32532]. For PFOA and PFOS, the Rule retained the Proposal’s Goals and Standards of zero and 4.0 ng/L, respectively. JA-[FR_32567, 32577]. For the Index PFAS, EPA finalized its preliminary regulatory determinations for PFHxS, HFPO-DA, and PFNA as individual contaminants. JA-[FR_32563]. EPA deferred a final determination for PFBS to continue evaluating it against the criteria for regulation, particularly whether the occurrence information supports regulation of that contaminant individually. JA-[FR_32552]. However, EPA found that there is a substantial likelihood of PFBS co-occurrence in mixtures with the other three Index PFAS with a frequency and at levels of public health concern. Accordingly, EPA finalized its regulatory

determination for mixtures containing two or more Index PFAS (including PFBS). JA-[FR_32557-58].

EPA largely retained the proposed Goal and Standard for mixtures of Index PFAS, but revised the number of significant digits (*i.e.*, from 1.0 to 1) and corrected an error in the health-based water concentration for PFHxS. JA-[FR_32571-72]. EPA promulgated individual Goals and Standards for PFHxS, HFPO-DA, and PFNA that are equivalent to their health-based water concentrations. JA-[FR_32573].

EPA included a revised Economic Analysis in its final Rule that updated the Economic Analysis from its Proposal. JA-[FR_32633-32719]. EPA developed quantified estimates for a limited set of the Rule's health benefits, including reduced birth weight effects, cardiovascular effects and renal cell carcinoma from PFOS and PFOA exposure, as well as health benefits from co-removal of other contaminants. JA-[FR_32715]. Weighing these quantified benefits against costs of compliance associated with PFOS, PFOA, and PFHxS, EPA found net positive national-level benefits of \$760,000 annually. JA-[FR_32708]. Data limitations prevented EPA from quantifying national-level costs of compliance associated with PFNA, HFPO-DA, or PFBS with the same degree of certainty as PFOA, PFOS, and PFHxS. JA-[FR_32713]. But EPA performed a quantitative sensitivity analysis to estimate their cost impact, which indicated that the costs of

treating these contaminants would likely increase the national compliance costs by \$82.4 million, or approximately 5 percent of the Rule's overall quantified costs. JA-[FR_32672]. As required by the Act, EPA also considered the many substantial, nonquantifiable health benefits that are expected to result from compliance with the Rule, including reduced health effects from exposure to PFOS, PFOA, Index PFAS, and other PFAS. JA-[FR_32696-702]. Based on all of the information in its Economic Analysis, EPA reaffirmed its determination made in the Proposal that the benefits of the Rule justify the costs. JA-[FR_32716].

SUMMARY OF ARGUMENT

EPA's regulatory determinations for the Index PFAS (individually and as a mixture) are lawful and were issued in accordance with the statute's procedures. The Act authorizes EPA to regulate "contaminants," a broad term that Congress itself has recognized encompasses groups or mixtures of individual substances. Likewise, the Act permits EPA to propose and finalize the Goal and Standard for a contaminant in parallel with the regulatory determination process, rather than waiting for a final determination. EPA's interpretation is the best reading of the Act because it gives effect to all portions of the statutory text and is consistent with Congressional intent.

EPA's regulatory determinations for the Index PFAS are also reasonable and supported by the administrative record. EPA appropriately relied on occurrence data from robust state datasets, the UCMR3 monitoring cycle (where available), and additional national occurrence database information, which together represent the best available public health information on these contaminants. This data demonstrates that there is a substantial likelihood that HFPO-DA and PFNA will occur both individually and collectively with other Index PFAS at frequencies and levels of public health concern. Moreover, EPA was not required to consider partial data submitted in its ongoing fifth cycle of unregulated contaminant monitoring ("UCMR5") or wait for that monitoring effort to be completed before proceeding, and the preliminary data confirmed EPA's findings of occurrence of these chemicals.

Petitioners' various challenges to the Rule's Standards also lack merit. First, as to PFOS and PFOA, EPA demonstrated in the record that its Standards meet the Act's requirement that they be as close to the Goals as feasible, and Petitioners fail to acknowledge EPA's responses to their narrow objections. EPA also provided a reasoned justification for rejecting Petitioners' suggested alternative Standards. Second, with respect to mixtures of Index PFAS, the Act authorizes EPA to adopt a Standard in the form of a hazard index. The hazard index meets the Act's definition of a "maximum contaminant level," and EPA adequately supported its

decision to use this approach to address the dose-additive effects of Index PFAS. Third, with respect to HFPO-DA individually and the Index PFAS collectively, the Court should reject Petitioners' attempt to second-guess EPA's scientific determinations within its expertise. EPA considered and reasonably addressed each of Petitioners' objections to the scientific inputs of the Index PFAS Standard and the HFPO-DA Standard, and EPA's analyses and conclusions are well-supported by the record.

The Court should also reject Petitioners' challenges to EPA's consideration of costs and benefits in the Rule. The Act and this Court's case law clearly provide that EPA's identification of a Standard at the "feasible" level does not depend on a comparison of costs and benefits. Moreover, the Act does not permit judicial review of EPA's determination as to whether the Rule's benefits justify its costs. To the extent judicial review is available here, EPA reasonably considered all of the relevant factors and responded to Petitioners' comments on the analysis of costs and benefits.

Finally, to the extent the Court finds any of Petitioners' arguments has merit, they cannot justify vacatur of the entire Rule. The Rule's provisions for each contaminant are severable, as are EPA's actions at each step of the regulatory process for each contaminant. Petitioners have not articulated any challenge that would invalidate the Rule in its entirety.

STANDARD OF REVIEW

In reviewing EPA's actions under the Act, this Court follows the Administrative Procedure Act's standard of review. *City of Waukesha v. EPA*, 320 F.3d 228, 247 (D.C. Cir. 2003). Under that standard, the Court evaluates whether EPA's action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992) (quoting 5 U.S.C. § 706(2)(A)).

The Court reviews questions of statutory interpretation *de novo*. *U.S. Sugar Corp. v. EPA*, 113 F.4th 984, 991 (D.C. Cir. 2024). On all other questions, the Court applies a deferential standard of review that assesses whether the agency "entirely failed to consider an important aspect of the problem," "offered an explanation for its decision that runs counter to the evidence before the agency," or failed to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Huntsman Petrochemical LLC v. EPA*, 114 F.4th 727, 735 (D.C. Cir. 2024) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). The Court accords particular deference to EPA's "evaluation of scientific data within its area of expertise." *Id.*; *see also Sinclair Wyo. Refin. Co. v. EPA*, 101 F.4th 871, 883 (D.C. Cir. 2024) (affording particular deference to "matters implicating predictive judgments"); *Am. Mining Congress v. EPA*, 907

F.2d 1179, 1187 (D.C. Cir. 1990) (affording particular deference to “the scientific judgments of the EPA”) (internal citation omitted).

The Act contains special language governing judicial review of EPA’s determination under Section 300g-1(b)(4)(C) as to whether the benefits of a Standard justify or do not justify its costs. 42 U.S.C. § 300g-1(b)(6)(D). Such determinations are reviewable only “as part of a review of a final national primary drinking water regulation that has been promulgated based on the determination.” *Id.* Where such review is available, the scope is limited to arbitrary-and-capricious review. *Id.*

ARGUMENT

I. The Regulatory Determinations for the Index PFAS Are Lawful and Followed Proper Procedure.

Petitioners challenge EPA’s regulatory determinations for the Index PFAS (individually and in a mixture) on both legal and procedural grounds, arguing that the Act does not permit regulation of mixtures and that EPA must finalize the regulatory determination for a contaminant *before* proposing a Goal and Standard. Both arguments lack merit. The Act’s definition of “contaminant” is broad, and the “best reading” of the statute is that it permits EPA to regulate contaminants in a group or mixture. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266 (2024). Likewise, EPA’s interpretation permitting concurrent publication of a

preliminary determination and proposed regulation is the only reading that gives effect to all parts of the Act and to Congress's goals.

A. EPA Has Authority to Regulate Mixtures of Contaminants.

EPA's determination to regulate mixtures of the Index PFAS is consistent with its longstanding interpretation of "contaminant" as including mixtures or groups of individual substances. JA-[FR_32571]. Nothing in the Act confines EPA to "regulat[ing] levels of individual contaminants only, not mixtures of them." *Contra* Industry Br. 31. EPA's interpretation of "contaminant" is the best reading "after applying all relevant interpretive tools," *Loper*, 144 S. Ct. at 2266, including review of the term itself, the statutory context, the legislative history, and EPA's consistent use of its authority to regulate contaminants both individually and collectively.

Congress defined "contaminant" broadly to include "*any* physical, chemical, biological, or radiological substance *or matter* in water." 42 U.S.C. § 300f(6) (emphases added). "Matter" is a broad term that encompasses both pure substances and mixtures or groups of those substances. JA-[FR_32542]; *see* RANDOM HOUSE COLLEGE DICTIONARY 825 (Laurence Urdang et al. eds., 1973) (defining "matter" as "the substance *or substances* of which any physical object consists or is composed" or "a particular *kind* of substance") (emphases added). Industry Petitioners' own brief concedes that a mixture by definition is "*matter*

consisting of two or more components.” Industry Br. 32 (emphasis added). Thus, the mixture of Index PFAS that EPA determined to regulate in this Rule is “matter” that falls within the Act’s definition of “contaminant.”

EPA’s interpretation is the only interpretation that gives the statutory definition’s component terms “substance” and “matter” independent meaning. *See Duncan v. Walker*, 533 U.S. 167, 174 (2001) (stating courts must “give effect, if possible, to every clause and word of a statute”) (cleaned up). Petitioners’ cramped interpretation would render part of the statute “superfluous” by reading out the term “matter” entirely. Industry Br. 32. If “matter” truly encompassed only “*singular* chemical substances,” *id.* at 32-33, then that term would be redundant because it would add nothing to the definition of “contaminant” not covered by “substance.” 42 U.S.C. § 300f(6); *see Del. Dep’t Nat. Res. & Env’t Control v. EPA*, 895 F.3d 90, 99 (D.C. Cir. 2018) (stating Court “strive[s] to construe statutes ‘so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant’) (quoting *Corley v. United States*, 556 U.S. 303, 314 (2009)).

EPA’s interpretation also comports with the rest of the statute, which likewise supports reading “contaminant” to include mixtures or groups of individual substances. JA-[FR_32542]. For example, SDWA’s “emergency powers” provision grants EPA residual authority to take action as necessary

wherever it finds that “*a contaminant* which is present in or is likely to enter a public water system or an underground source of drinking water...may present an imminent and substantial endangerment” to health. 42 U.S.C. § 300i(a) (emphasis added). In enacting this provision, Congress intended to provide EPA with “broad administrative authority” that would be construed “so as to give paramount importance to the objective or protection of the public health.” H.R. Rep. No. 93-1185, at 35 (1974), *as reprinted in* 1974 U.S.C.C.A.N. 6454, 6487-88. EPA’s responses under this authority are often not limited to individual contaminants and must address a mixture, such as a plume of contaminants in groundwater threatening a drinking water intake. Under Petitioners’ reading of “contaminant,” EPA could not invoke this authority where a mixture or group of substances is endangering public health, so long as no individual substance alone presents such endangerment. By contrast, EPA’s reading effectuates Congressional intent by authorizing action under Section 300i wherever a mixture of substances collectively presents imminent and substantial endangerment.

EPA’s interpretation also aligns with the Act’s legislative history, which demonstrates that since the Act’s adoption in 1974, Congress has recognized that EPA may regulate contaminants as groups. *See* JA-[FR_32542]. Noting the tens of thousands of chemical compounds in use, the responsible House Committee acknowledged it would be “impossible for EPA to regulate each of these

contaminants which may be harmful to health on a contaminant-by-contaminant basis.” H.R. Rep. No. 93-1185, at 10, 1974 U.S.C.C.A.N. 6454, 6463. As a result, the Committee anticipated that EPA would “establish primary drinking water regulations for some groups of contaminants,” while also establishing regulations for individual contaminants within those groups as appropriate. *Id.* at 6463-64. By allowing for regulation of contaminants as groups, Congress gave EPA leeway to “assure that the public health will be protected from currently undiscovered, unidentified or under-researched subgroups or specific contaminants within the group.” *Id.* at 6463.

Finally, EPA has consistently used this authority to promulgate Standards that regulate multiple substances collectively. JA-[FR_32543]; *see Loper*, 144 S. Ct. at 2262 (“[I]nterpretations issued contemporaneously with the statute at issue, and which have remained consistent over time, may be especially useful in determining the statute’s meaning.”) (citing *United States v. Am. Trucking Ass’ns*, 310 U.S. 534, 549 (1940)). For example, EPA has adopted Standards collectively regulating such groups as: disinfection byproducts (with subgroups including total trihalomethanes and haloacetic acids); radionuclides (with subgroups including alpha emitters, beta/photon emitters, and combined radium-226 and -228);

polychlorinated biphenyls; and asbestos.⁵ EPA's regulation of mixtures of Index PFAS fits within this longstanding interpretation of the statute.

B. The Act Allows EPA to Propose and Finalize a Standard in Parallel with a Regulatory Determination.

EPA complied with the Act's procedural requirements when it proposed and finalized its regulatory determinations for the Index PFAS concurrently with its Standards and Goals for those contaminants. And even if this Court agrees with Petitioners' contrary interpretation, any error here was harmless, as Petitioners did not suffer any prejudice from EPA's approach.

The Act provides that EPA

[1] shall propose the [Goal] and [Standard] for a contaminant not later than 24 months after the determination to regulate under subparagraph (B), and [2] may publish such proposed regulation *concurrent with the determination to regulate*.

42 U.S.C. § 300g-1(b)(1)(E) (emphasis added). The best reading of this provision is that "determination to regulate" in the second clause refers to EPA's *preliminary* determination, such that EPA may concurrently proceed with a preliminary determination and proposed regulation rather than waiting for a *final* regulatory determination before proposing a Goal and Standard. JA-[FR_32541]. This reading best fits SDWA's text and structure and effectuates Congress's intent to

⁵ 44 Fed. Reg. 68624 (Nov. 29, 1979); 56 Fed. Reg. 3526 (Jan. 30, 1991); 63 Fed. Reg. 69390 (Dec. 16, 1998); 65 Fed. Reg. 76708 (Dec. 7, 2000); 71 Fed. Reg. 388 (Jan. 4, 2006).

propel regulation forward where EPA has evidence that a contaminant warrants regulation.

Although the second clause does not explicitly use the phrase “preliminary determination,” Congress generally used the term “determination to regulate” or simply “determination” in subparagraph (b)(1)(B) without distinguishing between preliminary and final—even where the text demonstrably refers to a preliminary determination. JA-[RTC_EPA-HQ-OW-2022-0114-3077_3-109]. Most notably, subparagraph (b)(1)(B)(iii)—which requires EPA to provide for public comment on “the determination for a contaminant”—uses the term “determination” despite the fact that it plainly refers to comment on a *preliminary* determination to regulate. *Id.* § 300g-1(b)(1)(B)(iii).

Because Congress was inconsistent in its terminology, the meaning of “determination” in any particular part of the Act must be inferred from the surrounding context. Here, the relevant context of subparagraph (b)(1)(E) supports reading SDWA to permit EPA to propose a contaminant’s Goal and Standard concurrently with the *preliminary* determination. Although this reading admittedly results in “determination to regulate” taking a different meaning in the first clause (addressing the *latest* point at which EPA may propose the Goal and Standard) and second clause (addressing the *earliest* point at which EPA may propose them) of this sentence, that result best comports with the Act’s structure and goals.

For one, the rest of the text in this clause indicates Congress intended to allow EPA to align the proposed Goal and Standard with the *public comment process* on a preliminary determination. SDWA’s use of the term “publish” is informative: it identifies the specific action (publication) that EPA may take “concurrent[ly]” for both the regulatory determination and Standard-setting processes. The only other place in the Act where Congress refers to publication of a regulatory determination is in subparagraph (b)(1)(B)(iii), where it clearly refers to publication of a *preliminary* regulatory determination for public comment. 42 U.S.C. § 300g-1(b)(1)(B)(iii). No provision of SDWA refers to publication of a *final* regulatory determination. Thus, Congress must have meant that EPA may “publish” its proposed regulation at the same time that it “publish[es]” a preliminary determination to regulate.

Moreover, EPA’s interpretation is the only one that gives the second clause of this sentence independent meaning. Reading this provision to only allow publication of proposed Goals and Standards alongside a *final* regulatory determination would render it superfluous, because there is nothing else in SDWA or administrative law generally that suggests EPA would otherwise be precluded from doing so. JA-[RTC_3-110]. There is certainly nothing in subparagraph (b)(1)(E)’s deadline provisions implying such a limitation. In particular, SDWA’s requirement to propose regulations “not later than 24 months after” a final

regulatory determination simply establishes when EPA’s deadline begins to run; it does not suggest that EPA may only propose them after that deadline is triggered. 42 U.S.C. § 300g-1(b)(1)(E); JA-[RTC_3-108]. If Congress had wanted to create an exclusive window defining the start and end date for EPA’s proposal of a Goal and Standard, it would have specified that EPA must do so “within” 24 months, as it did for other deadlines in this same section and elsewhere in the Act. JA-[RTC_3-108]; *see* 42 U.S.C. § 300g-1(b)(1)(E) (requiring EPA to promulgate final Goal and Standard “within 18 months after the proposal thereof”); *id.* § 300j-7(a) (requiring petitions for review to be filed “within the 45-day period beginning on the date of the promulgation of the regulation ...”).

This Court’s decision in *NRDC v. Regan* is not to the contrary. Utility Br. 25 (citing 67 F.4th 397 (D.C. Cir. 2023)). The language Petitioners cite from that case only addresses what obligations are triggered once EPA makes a final regulatory determination for a contaminant.⁶ *Id.* *NRDC* never addressed (and had no need to address) at what point EPA may first propose the Goal and Standard for a contaminant.

⁶ *NRDC* did not hold that EPA “may only issue a proposed regulation ‘**after** determining the statutory criteria’” are met. *Contra* Utility Br. 25 (citing *NRDC*, 67 F.4th at 399) (emphasis in original). The Court simply observed that EPA *must* promulgate a *final* Goal and Standard after making that determination. *NRDC*, 67 F.4th at 399.

Additionally, EPA's reading of subparagraph (b)(1)(E) best reflects Congress's goal of accelerating the regulatory process for contaminants that present meaningful public health risks, which is the evident purpose of its allowance for "concurrent" processes. SDWA's 1996 amendments eliminated a previous requirement that EPA regulate 25 additional contaminants every three years, replacing it with the current regulatory determination process. This change reflected Congress's desire for EPA to expeditiously address contaminants that truly warrant regulation, without becoming bogged down in arbitrary quotas and procedural requirements. Moreover, Congress included an explicit provision allowing EPA to initiate regulatory determinations whenever necessary for any contaminant outside of the five-year cycle for its candidate contaminant list, recognizing that EPA may need to act expeditiously to address public health concerns between its periodically scheduled reviews. 42 U.S.C. § 300g-1(b)(1)(B)(ii)(III); JA-[RTC_3-110]. EPA's reading effectuates Congress's intent by allowing the agency to move forward in a "concurrent" manner on both a regulatory determination and a proposed regulation where appropriate. Petitioners' contrary reading transforms this provision into a limit rather than an authorization and would unnecessarily delay EPA's efforts to address public health threats in drinking water, with no apparent benefit.

Petitioners insist that “determination to regulate” must take the same meaning wherever it appears. Industry Br. 35-36; Utility Br. 22-25. But as noted above, Congress itself demonstrably used the shorthand “determination” in reference to both preliminary and final determinations. *See* 42 U.S.C. § 300g-1(b)(1)(B)(iii). Petitioners do not meaningfully engage with this inconsistency; they simply deny it exists.

In particular, Petitioners assert the phrase “determination” in clause (b)(1)(B)(iii) must mean something other than a determination to regulate. Utility Br. 28. But their alternative reading—that it refers to publication of a “decision to list a contaminant from the List in the Preliminary Determination”—makes no sense. Nothing in the Act suggests that EPA’s selection of which candidate contaminants to consider for regulation constitutes a distinct “determination” with its own public comment requirement separate from the preliminary determination to regulate. Moreover, clause (b)(1)(B)(iii) cannot be limited to EPA’s selection of contaminants from its candidate list because it refers to any “determination for a contaminant under clause (ii),” which includes determinations for contaminants *not included* on that list. *See* 42 U.S.C. § 300g-1(b)(1)(B)(ii)(III).

Petitioners cast SDWA’s regulatory process as a set of rigid, stepwise procedures. Utility Br. 6-10, 18-19. But they misstate the statutory requirements: SDWA does not “mandate[] a sequential, six-step process for regulation,” Utility

Br. 18; in fact, the statute clearly provides that the first two “steps” that Petitioners describe are not mandatory. While EPA *may* choose to consider a contaminant for regulation through the candidate listing process in subparagraph (b)(1)(B)(i), the Act also permits EPA at any time to “make a determination to regulate a contaminant that does not appear on” the candidate contaminant list, as it did for the Index PFAS here. 42 U.S.C. § 300g-1(b)(1)(B)(ii)(III); *see also* Industry Br. 34 (describing consultation requirements that apply to development of candidate list, not to regulatory determinations). Petitioners’ mistakes reflect their fundamental misunderstanding of the Congressional goals—namely, a desire to proceed expeditiously toward regulation of contaminants with public health risks—that support EPA’s interpretation.

Petitioners also make much of EPA’s supposed break from “decades of prior policy,” emphasizing that before this Rule EPA “had **never** issued a proposed regulation before making a [final] Determination to Regulate.” Utility Br. 25-26 (emphasis in original). That is true, but EPA has never issued a Goal or Standard for a newly listed contaminant *after* finalizing a determination to regulate either. This Rule is the first time that EPA has promulgated regulations for a new contaminant since enactment of the 1996 amendments creating the regulatory determination process in Section 300g-1(b)(1). Thus, there is no prior rulemaking establishing precedent on this issue from which EPA departs. The agency

statements that Petitioners rely on consist of simplified informational graphics or high-level summaries of the Act’s regulatory process that do not purport to represent EPA’s definitive interpretation of any sequencing requirement in the relevant statutory language.⁷

To the extent this Court agrees with Petitioners’ interpretation of the Act, any procedural violation here was harmless error. Subparagraph (b)(1)(E) governs the *timing* of EPA’s proposed regulations for a contaminant, not its *authority* to propose them. To merit relief from this Court, Petitioners must “show prejudice from an agency procedural violation.” *City of Waukesha*, 320 F.3d at 246 (citing 5 U.S.C. § 706).

Petitioners have failed to establish any harm they suffered from EPA’s decision to propose the Index PFAS Goals and Standards concurrently with the regulatory determination process. At most, Petitioners suggest that they would have benefitted from a longer time to comment on these actions. Utility Br. 31; Industry Br. 37; *see* JA-[NPRM_18638] (providing 60 days for public comment). As an initial matter, Petitioners were not “entitled” to “two 60-day comment periods,” or to a comment period of *any* specific length. Utility Br. 31. The Act does not specify how long EPA must provide for public comments on either a

⁷ Moreover, none of these sources actually states that a final determination “must precede” a proposed regulation. Utility Br. 26.

preliminary regulatory determination or a proposed Goal or Standard. In any event, Petitioners fail to demonstrate that if EPA had proceeded through a bifurcated rulemaking process, they “would have submitted additional, different comments that could have invalidated the rationale for” any portion of the Rule. *City of Waukesha*, 320 F.3d at 246. Petitioners had adequate time to prepare detailed comments with supporting studies addressing all aspects of the Rule, including the regulatory determinations, the proposed Goals and Standards for all of the regulated PFAS, and EPA’s Economic Analysis.

If anything, EPA’s decision to concurrently publish its preliminary regulatory determinations and its proposed regulations for the Index PFAS *promoted* meaningful public comment on those actions by providing Petitioners with much more information to evaluate them. JA-[RTC_3-110]. As a result of this approach, EPA was required to simultaneously publish its Economic Analysis and other record materials supporting the proposed Goals and Standards, including information on risk, cost, occurrence, and benefits that otherwise would not have been available as part of the record for the regulatory determinations. *Id.* Indeed, in this litigation Petitioners are relying on record materials developed for the Goals and Standards to support their challenges to the regulatory determinations. *See* Industry Br. 40.

Accordingly, the Court should reject Petitioners' procedural challenge to the Rule.

II. The Record Supports EPA's Determination to Regulate HFPO-DA and PFNA Individually and the Index PFAS Collectively.

EPA may regulate drinking water contaminants if it determines (1) "there is a substantial *likelihood* that the contaminant *will* occur in public water systems with a frequency and at levels of public health concern" either now or in the future; (2) "the contaminant *may* have an adverse effect on the health of persons;" and (3) "in the sole judgment of [EPA], regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems." 42 U.S.C. § 300g-1(b)(1)(A) (emphases added). In keeping with the health protective nature of the Act, these first two criteria are not onerous. Moreover, in all of these determinations, EPA is to use "the best *available* public health information," underscoring the importance of EPA acting expeditiously to protect human health. *Id.* § 300g-1(b)(1)(B)(ii)(II) (emphasis added).

Here, EPA considered extensive scientific literature, water monitoring data, and statistical analyses to determine to regulate HFPO-DA and PFNA individually, as well as the Index PFAS as a group.

A. The Record Supports EPA's Occurrence Analyses.

EPA used the "best available" data, both national and state, when determining that "there is a substantial likelihood" that PFNA and HFPO-DA

individually⁸ and all Index PFAS collectively “will occur in public water systems at a frequency and at levels of public health concern.” 42 U.S.C. § 300g-1(b)(1)(A)(ii), (B)(ii)(II); JA-[Occurrence_Support_160-258]. The statute mandates only two criteria to find sufficient current or substantially likely future occurrence: (1) a “frequency...of public health concern” and (2) “levels of public health concern.” 42 U.S.C. § 300g-1(b)(1)(A)(ii). The statute has no geographic mandate. Thus, the “best” reading of the “plain text” of the statute is that EPA has discretion to regulate a contaminant anywhere in the United States if the contaminant either does or likely will occur at both frequencies and levels of public health concern. *Loper*, 144 S. Ct. at 2266; *Coal. for Renewable Nat. Gas v. EPA*, 108 F.4th 846, 852-53 (D.C. Cir. 2024).

Guided by this standard, EPA fully explained “how it arrived at” its assessments of public health concern by providing “a reasonable explanation of the specific analysis and evidence upon which the Agency relied...” *Bluewater Network v. EPA*, 370 F.3d 1, 21 (D.C. Cir. 2004); *contra* Utility Br. 45. Pursuant to its longstanding practice, EPA considers several factors when assessing occurrence, including (1) comparing the available occurrence data to the health reference level; (2) the frequency with which the contaminant is found both alone

⁸ Although EPA also fully supported its determination to individually regulate PFOA, PFOS, and PFHxS, no petitioner challenges these determinations. Accordingly, EPA does not discuss them here.

and co-occurring with other contaminants; (3) whether there is a “sustained upward trend” in occurrence; (4) “the geographic distribution (national, regional, or local occurrence)”; (5) the “impacted population, health effect(s), the potency of the contaminant, other possible sources of exposure, and potential impacts on sensitive populations or lifestyles”; and (6) “production and use trends and environmental fate and transport parameters which may indicate that the contaminant would persist and/or would be mobile in water.” JA-[RTC_3-29_to_3-30]; JA-[Reg_Det_Protocol_EPA-HQ-OW-2022-0114-3613_30-31]. EPA provided extensive analysis of these factors for the Index PFAS, both individually and collectively, to determine that the contaminants warrant regulation. JA-[Occurrence_Support_126-258, A-1_to_A-32].

Based solely on the Act’s titling of drinking-water regulations as “national primary drinking water regulations,” Petitioners attempt to rewrite the criteria of a “substantial likelihood that the contaminant will occur in public water systems with a frequency...of public health concern” to add a “national in scope” requirement. 42 U.S.C. § 300g-1(b)(1)(A)(ii); Utility Br. 44-45. Asserting that “considerable” is a synonym, for “substantial,” Petitioners urge that “the likelihood of occurrence must be considerable in nature, and national in scope.” Utility Br. 45. But this strained reading improperly both adds new terms and rearranges the statute’s syntax to create an entirely *different* standard with a nonsensical requirement that

the “likelihood” have a “national scope.” Utility Br. 44-45; *Abbott v. United States*, 562 U.S. 8, 25 (2010) (interpreting statutes to “make[] sense as a matter of syntax”). Because the statutory text imposes no geographic requirement for occurrence, the Court should not accept Petitioners’ atextual interpretation. 42 U.S.C. § 300g-1(b)(1)(A)(ii); *Coal. for Renewable Nat. Gas*, 108 F.4th at 852-53.

1. EPA Properly Considered State Monitoring Data.

When making its regulatory determinations, EPA reasonably relied on a “very large dataset consisting of tens of thousands of samples” from 32 state monitoring programs, “represent[ing] one of the most robust occurrence datasets ever used to inform the development of drinking water regulation of a previously unregulated contaminant.” JA-[FR_32559]. Petitioners fail in their attempts to discount this data based on states’ differing testing criteria and reporting levels and Petitioners’ belief the data was not sufficiently “nationwide.” Utility Br. 43-44; Industry Br. 50-51.

a. With respect to states’ different testing methodologies, EPA carefully assessed the quality of the state data and fully explained the quality-control measures it undertook. JA-[RTC_6-10_to_6-19]; JA-[Occurrence_Support_23-29]. Specifically, EPA ensured that only finished drinking water (i.e., treated drinking water ready to be delivered to consumers) data was used and removed data not representing single types of PFAS. JA-[Occurrence_Support_23-29].

EPA then separated states' data into non-targeted statewide data and data collected from targeted areas where PFAS contamination was expected to have occurred and analyzed these datasets separately to ensure accurate characterization of the data.

JA-[Occurrence_Support_23].

Petitioners argue that states' targeted data should be disregarded as "tainted," Industry Br. 45, 51, but there is nothing inappropriate about this data and ignoring it would arbitrarily exclude relevant information and known exposures to the contaminant. Although testing *only* where a state believes contamination exists may not reveal the full breadth of contamination within a state, it does provide critical information regarding the number of locations with known contamination, the number of people affected, whether the contamination is localized or geographically dispersed, and the levels of contamination in certain areas. This information is highly relevant, and EPA properly considered it.

Additionally, although different states reported occurrences at different thresholds, Utility Br. 43-44; Industry Br. 50, EPA accounted for the specific reporting thresholds of each state's data by analyzing both reported detections and detections above the health reference level. JA-[FR_32554-57]; JA-[Occurrence_Support_200]. While some states' higher reporting thresholds likely undercount the total number of detections in those states, this data still provides useful information on the scale and geographic dispersal of detections. Moreover,

by standardizing analysis through comparison to the health reference level, EPA further ensured that detections monitored at very low thresholds were not given undue weight.

Finally, Petitioners erroneously assert that, because some states reported HFPO-DA levels below the “practical quantitation level” set for this rule (*see* Pt.III.C), those states monitored at levels laboratories cannot accurately test. Utility Br. 44; Industry Br. 50. But the practical-quantitation level is not an assessment of a minimum accurate detection limit; it is a quantitation level that EPA believes can be achieved by “a broad spectrum of capable laboratories across the nation.” JA-[Occurrence_Support_21]; *see also* JA-[RTC_6-13]. In fact, practical-quantitation levels are generally set “*above* the limit of detection,” and for PFAS specifically, all the practical-quantitation levels were set “*well above their limits of detection.*” JA-[FR_32574] (emphasis added). The fact that a state monitoring program used a lower reporting threshold than required in EPA’s nationwide reporting thus does not call any reporting data into question. JA-[RTC_6-13].

b. Petitioners’ concerns that the state data are not part of a nationwide monitoring program are similarly misplaced. Utility Br. 43. SDWA specifically contemplates EPA may consider data sources other than its own nationwide monitoring data. It requires only that EPA must consider “the best available public

health information, *including*”—but not limited to—“[EPA’s nationwide] occurrence database established under 300j-4(g)” of the statute. 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II) (emphasis added).

Here, the state data EPA considered was the “best available public health information” and fully demonstrated that HFPO-DA and PFNA individually and the Index PFAS collectively are present at levels of public health concern across disparate sections of the country. JA-[Occurrence_Support_126-251]; *contra* Utility Br. 43; Industry Br. 50. EPA considered data from 32 states, of which 30 states had data for PFNA and 25 states had data for HFPO-DA. JA-[FR_32554-55]; JA-[Occurrence_Support_23-29, 201-16]. This data came from geographically dispersed states and from both states with concentrated population centers and states that are predominantly rural. JA-[Occurrence_Support_23-29, 201-16]. Although it did not come from every single state, the data was sufficiently robust and representative to warrant EPA’s consideration and reliance. *Id.*; JA-[FR_32553-32560, 32583, 32594-96]; JA-[RTC_6-10].

Additionally, although Petitioners assert that EPA previously declined to regulate a contaminant (*acanthamoeba*) as a drinking water contaminant based on the lack of nationwide data, Utility Br. 42, this is incorrect. EPA declined to regulate *acanthamoeba* through SDWA because the available public health data demonstrated that adverse health effects were not caused by contaminated drinking

water, but instead by “poor hygiene practices among contact lens wearers.” 67 Fed. Reg. 38222, 38232 (June 3, 2002); JA-[RTC_3-38_to_3-39]. EPA’s decision to issue a guidance document on acanthamoeba for contact lens wearers rather than issuing drinking water regulations, thus is entirely distinct from the circumstance presented here. 68 Fed. Reg. 42898, 42903 (July 18, 2003); <https://www.epa.gov/sdwa/danger-using-tap-water-contact-lenses>. Here, EPA reasonably relied on “one of the most robust occurrence datasets ever used to inform development of a drinking water regulation of a previously unregulated contaminant,” JA-[FR_32559], to determine to regulate the Index PFAS.

2. EPA Reasonably Determined There Is a Substantial Likelihood HFPO-DA Will Occur at Frequencies and Levels of Public Health Concern.

EPA properly considered the “best available public health information, including [EPA’s national] occurrence database” to find a substantial likelihood HFPO-DA will occur at frequencies and levels of public health concern. 42 U.S.C. § 300g-1(b)(1)(A)-(B). Additionally, when UCMR5 data became available after the preliminary regulatory determination and was raised in public comments, EPA properly considered the data and determined it confirmed EPA’s prior analysis.

a. Substantial Evidence Supports EPA’s HFPO-DA Occurrence Determination.

To determine that HFPO-DA occurs with a frequency and at levels of public health concern warranting regulation, EPA considered extensive data from 25 state

drinking water monitoring programs and data in its occurrence database from the Department of Defense and National Water Information System. JA-[Occurrence_Support_194-219, 252-58]. This data demonstrates that HFPO-DA currently occurs in concentrations above the health reference level in public water systems in at least five geographically diverse states and is currently detected in eight additional states. JA-[FR_32557]; JA-[Occurrence_Support_205-216]. Additionally, EPA found that, due to the environmental persistence of HFPO-DA, its “continued and increasing presence in consumer products and use,” and the experience gleaned from the extraordinary persistence of other PFAS in the environment, “there is a substantial likelihood HFPO-DA will occur at a frequency and level of public health concern.” JA-[FR_32557]. Despite this evidence, Petitioners incorrectly assert EPA had insufficient data to regulate HFPO-DA.

Industry Petitioners erroneously assert that, if the Court simply disregards the HFPO-DA contamination Petitioner Chemours caused in North Carolina, HFPO-DA rarely occurred elsewhere in the United States. Industry Br. 45, 50-51. Similarly, Utility Petitioners attempt to diminish the significance of HFPO-DA contamination in Kentucky by noting that that contamination *also* may have been caused by Petitioner Chemours’s Washington Works HFPO-DA plant across the state border in West Virginia. Utility Br. 47-48; Industry Br. Add. B14. But neither set of petitioners explains why either EPA or this Court should disregard

significant occurrences of drinking water contamination at levels of public health concern in these states simply because Petitioner Chemours—which still manufactures HFPO-DA at both plants, Industry Br. Add. B14—may have caused the contamination.

Moreover, North Carolina and Kentucky were not the only states with drinking water contaminated by HFPO-DA. JA-[Occurrence_Support_206-213]. Michigan, Ohio, and Virginia also reported public water systems with HFPO-DA contamination above the health reference level; and public water systems in eight additional states, including Vermont, Alabama, and Colorado, detected HFPO-DA at lower levels. JA-[Occurrence_Support_211-213].

Not only do these disparate locations demonstrate HFPO-DA contamination is not limited to a single locality or region, *contra* Utility Br. 48, but Petitioner Chemours does not appear to have facilities in many of these states. *See* <https://www.chemours.com/en/about-chemours/global-reach>. This suggests that contamination comes from more than just Petitioner Chemours's HFPO-DA production facilities, and potentially comes from consumer products containing HFPO-DA. JA-[Occurrence_Support_194]. EPA rested its regulatory determination not only on data demonstrating HFPO-DA's current occurrence, but also on the "substantial likelihood" that the contaminant "*will* occur in public water systems with a frequency and at levels of public health concern" in the future. 42

U.S.C. § 300g-1(b)(1)(A)(ii) (emphasis added). EPA explained that, because HFPO-DA continues to be produced domestically and has a “continued and possibly increasing presence in consumer products and use,” and because it is “very stable chemically” and resistant to degradation, it will continue be present in the environment in increasing amounts. JA-[FR_32557]; JA-[Occurrence_Support_198].

Notably, neither set of Petitioners disputes HFPO-DA’s persistence and accumulation in the environment, or that HFPO-DA continues to enter the environment through both production of the chemical and consumer products containing the chemical. Because the current data demonstrates occurrence at a frequency and level of public health concern, and because the current data represents the nadir of HFPO-DA occurrence, EPA reasonably determined there is a “substantial likelihood [HFPO-DA] *will* occur...at a frequency and at levels of public health concern” in the future. 42 U.S.C. § 300g-1(b)(1)(A)(ii) (emphasis added); JA-[FR_32557].

b. EPA Properly Limited Its Consideration of the Partial UCMR5 Data.

Petitioners incorrectly assert EPA was required to rely on UCMR5 data in making its regulatory determination for HFPO-DA. Industry Br. 44-50. But SDWA requires only that EPA consider the “best available public health information, including the occurrence database established under section 300j-

4(g)....” 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II). Because the UCMR5 data was not “available” data, much less the “best available” data, the Act did not mandate reliance on it. *Id.*

i. At the outset, Petitioners erroneously equate EPA’s “occurrence database” referenced in SDWA with UCMR data. *Compare* Industry Br. 45; Utility Br. 41 *with* 42 U.S.C. § 300j-4(g)(1). The occurrence database is broader than UCMR data; it also includes, for example, Department of Defense and National Water Information System data that EPA explicitly analyzed as part of this rulemaking. *Compare* <https://www.epa.gov/sdwa/national-contaminant-occurrence-database-ncod>; *with* JA-[Occurrence_Support_217-19].

Moreover, at the time of EPA’s preliminary regulatory determination, no UCMR5 data existed, and thus *no* data was “available.” JA-[NPRM_18638]; JA-[Occurrence_Support_252]. Petitioners argue that an entirely different provision of the statute requiring occurrence-database information be made “available to the public in readily accessible form,” 42 U.S.C. § 300j-4(g)(5), transforms the Act’s requirement that EPA use the “best available” data into a requirement to *wait* specifically for UCMR data. Industry Br. 48. But this is inconsistent with the plain text of the statute.

Nothing in the statute requires EPA to include a contaminant in UCMR monitoring prior to regulation, or to await nationally representative UCMR results

for a contaminant before beginning the regulatory process. JA-[RTC_6-68]; 42 U.S.C. § 300g-1. The Act simply states that EPA must consider “the best *available* public health information, *including* the occurrence database....” 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II) (emphases added). Industry Petitioner’s attempt to rewrite the statute to require that EPA consider “the best available...information, including [*UCMR data for the specific contaminant, which must exist in*] the occurrence database” strains the text too far. That no UCMR data for HFPO-DA was present in the database at the time of the proposed regulatory determination does not preclude EPA from evaluating other occurrence information to assess the “substantial likelihood” that a contaminant “will occur...with a frequency and at levels of public health concern.” *Id.* § 300g-1(b)(1)(A).

Consistent with its statutory obligation, EPA considered “the best available public health information, including”—but not limited to—“the occurrence database.” 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II). EPA thus properly considered HFPO-DA data available in the occurrence database—Department of Defense data and National Water Information System data—as well as data from 25 state monitoring programs. JA-[Occurrence_Support_199-219].

ii. Petitioners incorrectly assert EPA should have relied exclusively on the partial UCMR5 data showing very little detection of HFPO-DA in the small number of samples EPA had received by the date of the rulemaking, *instead of* the

substantially more robust state monitoring data that demonstrated HFPO-DA contamination above the health reference level in five states ranging from Michigan to Virginia, and detections as far west as Colorado. Industry Br. 50; JA-[Occurrence_Support_206-210]. Petitioners argue the state monitoring data should be ignored in favor of the partial UCMR5 data because they erroneously claim the state data had fewer samples from fewer public water systems. Industry Br. 50. But the state monitoring data produced over twice as many samples as the partial UCMR5 data had reported—over 35,000 state samples, compared to 16,777 UCMR5 samples available at the time of the final regulatory determination. JA-[Occurrence_Support_205-07, 211-13, 252]. Moreover, the state data monitored nearly three times as many water systems as had been reported in the partial UCMR5 data—over 10,000 water systems in the state monitoring compared to 3,722 reported in the partial UCMR5 data. JA-[Occurrence_Support_205-07, 211-13, 252]. The state data thus was the “best available” data. 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II).

iii. Although Petitioners argue that HFPO-DA should not be regulated because it is largely not present in most of the limited set of UCMR5 samples available, Industry Br. 46, this partial data provides no conclusion regarding the potential occurrence or lack thereof of HFPO-DA nationwide. The partial UCMR5 data is not reflective of all systems for populations over 3,300 or a “representative

sampling” of nationwide systems serving 3,300 or fewer people, as required by the statute. 42 U.S.C. § 300j-4(g)(7)(A)-(B) *as amended by* Pub. L. 115-270, § 2021 (2018), 132 Stat. 3765, 3861. As of the time of the rulemaking, only approximately *one-third* of systems had reported collection of even *one* sample. JA-[FR_32601].

This partial UCMR5 data cannot support a determination that HFPO-DA does *not* occur frequently, particularly in light of the state data. As EPA explained, “[i]t is difficult to determine that a contaminant is *not* occurring or *not* likely to occur based on non-national data because the data are limited in scope and the contaminant could be occurring in other parts of the country that have not been monitored.” JA-[Reg_Det_Protocol_21] (emphasis added). In contrast, “a compilation of non-national data sources *can* support a determination that there *is* a substantial likelihood that the contaminant will occur in [public water systems] with a frequency and at levels of public health concern.” JA-[Reg_Det_Protocol_21] (emphasis added; quotations omitted); *see NRDC v. EPA*, 529 F.3d 1077, 1086 (D.C. Cir. 2008) (affording EPA “wide latitude in determining the extent of data-gathering necessary to solve a problem” and “defer[ring] to an agency’s decision to proceed on the basis of imperfect scientific information” (internal quotations omitted)).

The partial UCMR5 data demonstrates neither the existence nor absence of occurrence of HFPO-DA at frequencies and levels of public health concern because there simply is not a representative enough sample to draw conclusions. In contrast, the state data definitively demonstrates that HFPO-DA is currently present in at least 13 states and is currently present at levels of public health concern in at least 5 states. JA-[Occurrence_Support_205-216]. EPA cannot reasonably ignore valid and complete data demonstrating that HFPO-DA *does* occur in five geographically dispersed states at levels of public health concern.

iv. Similarly, Petitioners incorrectly assert that the Department of Defense and National Drinking Water Information System data in the occurrence database “confirm the UCMR5 data that HFPO-DA does not occur frequently in public water systems.” Industry Br. 49. But this non-state data simply shows that HFPO-DA did not occur at those particular test sites. JA-[Occurrence_Support_216-19]. This data does not negate state data demonstrating other sites where contamination is known to occur.

v. Finally, contrary to Petitioners’ assertion, EPA did not “refus[e] to consider” the UCMR5 data. Industry Br. 47. Although not required to do so, EPA fully considered the available data as well as its limitations. JA-[FR_32557, 32559, 32601-05]; JA-[Occurrence_Support_252-58]; JA-[RTC_6-68_to_6-101]. EPA explained that, although the UCMR5 data was “not available for this rule’s

proposal, [was] not complete, and [was] not a basis for informing the agency’s decisions for the final rule,” the data “generally confirm[ed] the extensive occurrence analyses the agency has conducted: namely, that all six regulated PFAS occur in finished drinking water and that the six regulated PFAS co-occur with one another.” JA-[FR_32601]. For HFPO-DA specifically, although less than one-quarter of UCMR5 data was available, the data showed 17 water systems reporting HFPO-DA detections, with one water system exceeding the level of public health concern, thus confirming its occurrence. JA-[Occurrence_Support_252-53]; JA-[RTC_6-69]. Because this data was insufficiently comprehensive to demonstrate the presence or absence of occurrence *anywhere* in the country and does not represent the “best available public health information,” and because extensive state data demonstrates HFPO-DA occurrence in geographically dispersed areas of the country, EPA reasonably determined there is a substantial likelihood HFPO-DA will occur at frequencies and levels of public health concern.

3. EPA Reasonably Determined There Is a Substantial Likelihood PFNA Will Occur at Frequencies and Levels of Public Health Concern.

EPA considered the “best available” data from UCMR3, state monitoring, Department of Defense monitoring, and National Water Information System data when determining to regulate PFNA.

a. Petitioners argue EPA erred in relying on UCMR3 data because that data was reported at minimum levels *higher* than the health reference levels at issue in this rulemaking. Utility Br. 42-43. But this simply means that the UCMR3 likely *underreported* the frequency of occurrence of the Index PFAS, and PFNA specifically. Public water systems in seven states reported detections of PFNA over 20 ng/L—twice the 10 ng/L health reference level in EPA’s regulatory determination. JA-[FR_32556]. Thus, based solely on the UCMR3 data, PFNA occurs in public drinking water at a minimum of *double* the concentration EPA deems the “level of public health concern” at systems in at least those seven states. JA-[FR_32556].

b. Extensive state monitoring data at reporting thresholds lower than the UCMR3 further demonstrates that PFNA occurs at a frequency and levels of public health concern well beyond a single region of the country; it has been detected in 19 states and detected at levels above the health reference level in 12 states. JA-[Occurrence_Support_174-87]; *contra* Utility Br. 49-50. The 12 states with concentrations above the health reference level are geographically diverse, ranging from Maine to Alabama. JA-[Occurrence_Support_174-187]. Similarly, Department of Defense data identified eleven military bases in which PFNA was detected in water samples, two of which—in South Dakota and in Texas—had detections above the health reference level. JA-[Occurrence_Support_189-90]. In

short, ample evidence demonstrates PFNA currently occurs, and there is a substantial likelihood it will occur, at a frequency and level of public health concern throughout the United States.

c. Finally, although eight PFNA manufacturers committed to cease PFNA production in the United States by 2015, legacy stock may still be used domestically, products manufactured prior to 2015 may still contain PFNA, and products made with PFNA may be manufactured abroad and imported into the United States. JA-[FR_32556]; JA-[Occurrence_Support_160]. Additionally, other chemicals break down into PFNA. JA-[FR_32536]. And PFNA is “very stable chemically” with a “resistance to essentially all forms of degradation other than atmospheric processes.” JA-[Occurrence_Support_162-63]. PFNA thus is very persistent in the environment. Accordingly, “there is a substantial likelihood that environmental contamination of sources of drinking water [with PFNA] will continue.” JA-[FR_32556]. Given these factors, EPA reasonably found there is a substantial likelihood that PFNA will occur at a frequency and levels of public health concern. JA-[FR_32556-57].

4. EPA Reasonably Determined There Is a Substantial Likelihood Mixtures of the Index PFAS Will Occur at Frequencies and Levels of Public Health Concern.

EPA analyzed state monitoring data and determined there is a substantial likelihood that mixtures of the Index PFAS will co-occur at frequencies and levels

of public health concern. JA-[Occurrence_Support_220-46]; JA-[FR_32590-600]. EPA considered the frequency with which two or more PFAS are detected together and detected together above the health reference level in reported data. JA-[Occurrence_Support_220-35]. EPA then also conducted a statistical analysis of the data that further demonstrates the odds of finding one Index PFAS increase substantially when a second Index PFAS is present. JA-[Occurrence_Support_238-46].

a. EPA Properly Considered Reported Co-Occurrences of Index PFAS.

Twenty-one of 27 states reported combinations of two or more Index PFAS occurring above the health reference level. JA-[Occurrence_Support_220-35]; *contra* Utility Br. 51-52 (asserting EPA only considered “mere detections...irrespective of their concentrations”). Petitioners incorrectly argue that co-occurrence should only matter if the individual contaminants co-occur at levels at which *each* contaminant exceeds its individual health reference level. Utility Br. 51-53. But this misunderstands the purpose of regulation of the chemicals as a hazard index as opposed to individually. As explained in Pt.II.B, *infra*, because these chemicals all elicit the same or similar health effects, combinations of even very low doses of these chemicals can result in more harmful effects than if the chemicals occurred alone. JA-[RTC_4-368_to_4-371, 4-418_to_4-419]. Regulation via a hazard index is thus necessary to protect against

the health effects of exposure to combinations of the Index PFAS. JA-[RTC_4-424_to_4-425].

b. EPA Reasonably Statistically Analyzed Index PFAS Co-Occurrence.

EPA conducted extensive statistical analysis of the occurrence of the Index PFAS and found the Index PFAS are likely to co-occur. EPA calculated the odds ratio⁹ for every pair of Index PFAS using the non-targeted state data, which demonstrates the Index PFAS are between 5.2 and 66.0 times more likely to occur in mixtures of two or more Index PFAS than they are to occur alone. JA-[Occurrence_Support_243-44].

Petitioners ignore the entirety of EPA's statistical analysis of state monitoring data and focus exclusively on perceived lack of occurrences in EPA's purely illustrative analysis of the partial UCMR5 data. Industry Br. 40. At the

⁹ Odds ratios “represent the change in the odds of observing a first chemical given that a second chemical is known to be present relative to the odds of observing the first chemical given that the second chemical is not present.” JA-[Occurrence_Support_242]. This is different than calculating the probability of occurrence (or “odds”). *Contra* Industry Br. 40. Odds ratios greater than 1 indicate increasingly higher likelihoods of finding the first chemical if the second chemical is present than if it were not present. An odds ratio of 1 indicates that there is the exact same likelihood of finding the first chemical if the second chemical is present as if it were not present (i.e., there is no relationship between the odds of finding the two chemicals). Odds ratios between 0 and 1 indicate a greater likelihood of *not* finding the first chemical if the second chemical is present. And an odds ratio of 0 indicates missing data in the formula such that there is a null set. JA-[Occurrence_Support_242].

outset, EPA’s regulatory determination is based on its analysis of state data, not UCMR5 data, for the reasons outlined in Pt.II.A.2.b *supra*. JA-[Occurrence_Support_252] (“Since the UCMR5 dataset is currently incomplete, it does not serve as the basis for informing the agency’s decisions for the regulatory determinations and [regulations].”). Nevertheless, because EPA received comments on the preliminary UCMR5 data that had begun to be reported between the preliminary and final regulatory determinations, EPA conducted a purely illustrative analysis of the UCMR5 data. JA-[Occurrence_Support_252-58]. Because this data did not form the basis of EPA’s determination, Petitioners’ arguments are irrelevant. Moreover, Petitioners misstate the data in a number of respects.

First, by focusing on instances where all Index PFAS are present, Petitioners misunderstand the hazard index. Industry Br. 40. As EPA explained, the hazard-index approach addresses the fact that “where drinking water contains any combination of *two or more* of the four PFAS that are the subject of this action—PFHxS, PFNA, HFPO-DA, and PFBS—the hazard associated with each PFAS in the mixture must be added together to determine whether the mixture exceeds a level of public health concern.” JA-[RTC_4-418] (emphasis added).

Second, Petitioners are wrong that “[c]o-occurrence of even three of the Index [PFAS] is extremely rare” and “EPA has not identified a single sample

containing detectable levels of all four Index Substances occurring together.”

Industry Br. 40. The state data identifies 31 samples across 20 systems (1% of systems) in which all four Index PFAS were present, and an additional 1,919 samples across 362 systems (25.9% of systems) in which three Index PFAS were present. JA-[Occurrence_Support_240]. Moreover, given that only approximately one-third of systems had reported *any* UCMR5 data, it is not surprising or relevant that the mere 24 samples containing HFPO-DA in that data did not happen to contain *all* other Index PFAS. JA-[Occurrence_Support_252]; JA-[FR_32601].

Third, Petitioners’ assertion that “EPA admits that odds of co-occurrence of [HFPO-DA and PFNA] are 0.0%,” with a citation to odds *ratios* at JA-[Occurrence_Support_256] both misstates the data and fundamentally misunderstands the difference between “odds” and an “odds ratio.” Industry Br. 40. As explained in n.9 *supra*, these are different concepts, and the odds ratio cannot be expressed as a percentage. An odds ratio of 0 demonstrates a null dataset, not a lack of probability of co-occurrence. *See* n.9. Moreover, EPA’s analysis of the state data demonstrates an odds ratio of 15.9 for these two chemicals, meaning that it is 15.9 times more likely that PFNA will be present if HFPO-DA is present. JA-[Occurrence_Support_243].

Finally, EPA did not dilute the “substantial likelihood” standard by adding in “enough compounds to the hazard index” to “always claim the occurrence

criterion is met.” *Id.* As fully explained in Pt.II.B, *infra*, EPA carefully considered inclusion of these specific Index PFAS to ensure sufficient similarity in the systems and tissues affected by the chemicals, and EPA’s extensive co-occurrence analyses here demonstrate the high likelihood that at least two of these chemicals will co-occur at frequencies and levels of public health concern. EPA thus fully supported its determination to regulate the Index PFAS as mixtures.

B. The Record Supports EPA’s Determination that the Index PFAS May Have an Adverse Effect on the Health of Persons.

The record fully supports EPA’s determination that combinations of two or more Index PFAS “*may* have an adverse effect on the health of persons.” 42 U.S.C. § 300g-1(b)(1)(A)(i) (emphasis added). In keeping with SDWA’s health-protective focus, this threshold is not onerous; it does not require definitive proof, but rather a reasonable *possibility* of adverse health effects. *Fed. Trade Comm’n v. Morton Salt Co.*, 334 U.S. 37, 46 (1948) (interpreting statute’s use of “may” to require “only that there is a reasonable possibility that they ‘may’ have had such an effect”). The record evidence here easily meets this standard by demonstrating that the four Index PFAS have the same or similar health effects.

EPA explained that each of the four Index PFAS “can disrupt signaling of multiple biological pathways, resulting in a shared set of adverse effects....” JA-[FR_34545]. Exposure to each of these chemicals elicit many adverse health effects, including effects on development, the liver and kidney, and endocrine,

respiratory, and reproductive systems. JA-[MCLG_1-8]; JA-[FR_32552]; JA-[RTC_4-373_to_4-375, 4-428]. Although each chemical's individual health reference level is set based on its most sensitive health effect (its "critical effect"), exposure to each of these chemicals causes many of the same adverse health outcomes. JA-[MCLG_1-8_to_1-10, 2-1_to_2-5, 2-8, 2-11]. For example, exposure to each of the four PFAS leads to endocrine, liver, and kidney toxicity. JA-[MCLG_1-8_to_1-10]. EPA thus reasonably determined that these chemicals are dose-additive. JA-[Framework_33-34] ("[I]t is considered a health-protective conclusion that PFAS that can be demonstrated to share one or more...adverse health outcomes will produce dose-additive effects from co-exposure.").

Petitioners assert three challenges to this framework, none of which is availing.

1. Petitioners misstate both the Science Advisory Board's recommendations and the science underlying EPA's dose-additivity analysis. Petitioners incorrectly assert that the Board advised that EPA's "dose[-]additivity assumptions...cannot sanction regulation." Industry Br. 41. In fact, the Board explicitly supported consideration of PFAS dose-additivity. JA-[SAB-Report_90] (The Board PFAS Review Panel "supports dose[-]additivity based on a common outcome, instead of a common mode of action as a health protective default assumption and does not propose another default approach."). The Board *never*

suggested that the Index PFAS dose-additivity “cannot sanction regulation.” *Id.*; *contra* Industry Br. 41.

Petitioners further misstate the science supporting EPA’s dose-additivity analysis by asserting that EPA relied exclusively on studies of PFAS that did not include the Index PFAS and that “none of the relied-upon studies evaluates the specific mixtures regulated by EPA’s hazard index here.” Industry Br. 41. At the outset, the hazard-index approach does not regulate only when all four Index PFAS are present; it regulates mixtures of two or more Index PFAS. JA-[RTC_4-418]. And EPA detailed numerous studies of various mixtures of the Index PFAS. JA-[Framework_33-37]; JA-[RTC_4-368_to_4-371]. Based on both studies of the individual Index PFAS and their various mixtures, EPA determined the Index PFAS likely are dose-additive. JA-[Framework_38] (“PFAS data reported in the literature support an assumption of similarity in toxicity profiles for several health effect domains.”).

2. Petitioners next erroneously assert that dose-additivity pertain *only* when there is “an overlap of critical effects.” Industry Br. 41-42. But the sole document Petitioners cite for this position explicitly endorses use of the hazard index with substances with *different* critical effects, explaining an index in these circumstances is “health-protective” because it “increases the confidence of a minimal hazard...” JA-[Adv_Dose_Add_EPA-HQ-OW-2022-0114-3122_2-26].

Importantly, EPA need only establish the contaminant “*may* have an adverse effect on the health of persons.” 42 U.S.C. § 300g-1(b)(1)(A)(i) (emphasis added).

A “critical effect” in the context of developing a reference dose is the effect “typically observed at the lowest tested dose among the available data.” JA-[FR_32547]; *contra* Industry Br. The critical effect is not the *only* effect of the chemical, or even the only effect at low levels. For example, EPA selected liver effects as the critical effect for HFPO-DA, but exposure to HFPO-DA also elicits many additional adverse health effects, including increased kidney weight. JA-[MCLG_1-8_to_1-10, 2-1_to_2-2]; *see also* Pt.III.E, *infra*. Similarly, EPA selected the thyroid as the most critical effect for PFBS, but PFBS exposure also elicits many other adverse effects, including increased kidney weight. JA-[MCLG_1-8_to_1-10, 2-4_to_2-5]. Because *both* these chemicals affect the kidney, exposure even at levels that individually would not likely result in adverse effects, may result in adverse kidney effects when exposure to both chemicals occurs simultaneously. JA-[RTC_4-368_to_4-378, 4-497_to_4-498]. EPA cites a multitude of studies demonstrating this. JA-[RTC_4-368_to_4-378]; JA-[Framework_33-37]. Notably, Petitioners cite no scientific evidence disproving the dose-additivity of these chemicals.

3. Finally, Petitioners assert that the Index approach is “novel” and overly broad. Industry Br. 43-44. To the extent Petitioners intend these vague

criticisms, combined with a single case citation, to invoke the major questions doctrine, Petitioners have failed to preserve this argument. Industry Br. 44 (citing *UARG v. EPA*, 573 U.S. 302, 324 (2014)); *Consol. Edison Co. of New York, Inc. v. FERC*, 347 F.3d 964, 970 (D.C. Cir. 2003) (argument only “hint[ed] at” in the opening brief deemed waived). Moreover, as fully explained in Pt.I.A, *supra*, far from an “extraordinary case” departing from longstanding practice, EPA’s use of the hazard index here is in line with its longstanding “history” of regulating contaminants in groups and is not a new grant of authority of “economic and political significance.” *West Virginia v. EPA*, 597 U.S. 697, 721 (2022). Moreover, the PFAS combined here are not an “overly broad” assertion of authority. The Index PFAS are chemically and structurally similar compounds that affect the same health endpoints and have been shown to co-occur in drinking water with considerable frequency. JA-[FR_32552, 32592-93]; JA-[NPRM_18642-43]. They thus are amenable to regulation via a hazard index, and their regulation falls within the heartland of EPA’s regulatory authority.

III. The Rule’s Standards Are Lawful, Reasonable, and Supported by the Record.

Each of Petitioners’ myriad challenges to the Rule’s Standards fail. As to PFOS and PFOA, the record demonstrates that these Standards meet the Act’s requirement to be as close to the Goals as “feasible,” and that EPA addressed Petitioners’ comments regarding regulatory alternatives. As to Index PFAS

mixtures, the Act authorizes EPA to promulgate Standards in the form of a hazard index, and EPA supported its selection of this Standard as an appropriate tool to address the dose-additive effects of these four PFAS. As to HFPO-DA, EPA considered and reasonably rejected each of Petitioners' objections, and EPA's conclusions on these scientific issues merit deference. Finally, EPA adequately consulted its Science Advisory Board before proposing the Standards.

A. EPA Set the Standards for PFOS and PFOA at the Level That Is as Close to the Goals as Feasible.

While no Petitioner challenges the Goals EPA set for PFOS and PFOA, Industry Petitioners dispute whether EPA set the final Standards closer to those Goals than "feasible."¹⁰ Industry Br. 23-27. EPA's feasibility determination for the final Standards of 4.0 ng/L was reasonable, and the record demonstrates that EPA considered and addressed the very concerns Industry Petitioners raise here.

EPA must set the Standard for a contaminant "as close to the [Goal] as is feasible." 42 U.S.C. § 300g-1(b)(4)(B). For purposes of this analysis, "feasible" means:

¹⁰ Notably, Utility Petitioners—whose members include the public water systems that actually have to implement the Rule—do not challenge whether the PFOS and PFOA Standards are feasible within the meaning of SDWA. While their brief includes a throwaway reference to feasibility, Utility Br. 53-54, their arguments only concern EPA's finding that the Rule's benefits justify its costs, which is distinct from the feasibility determination under 42 U.S.C. § 300g-1(b)(4)(B). See *infra* Pt.IV.A; *City of Portland v. EPA*, 507 F.3d 706, 712 (D.C. Cir. 2007).

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). In other words, “feasible” means “technically possible and affordable.” *City of Portland*, 507 F.3d at 712 (citing *Am. Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 509-512 (1981)). While this analysis does not entail balancing costs against benefits, pursuant to Congress’s express guidance, EPA considers cost in this analysis by considering whether the costs of compliance are affordable for large public water systems. *Id.*; *see also* H.R. Rep. No. 93-1185, at 18, 1974 U.S.C.C.A.N. 6454, 6470-71 (stating Committee’s intent that feasibility determinations are “to be based on what may reasonably be afforded by large metropolitan or regional public water systems”).

In addition to evaluating the feasibility of *treatment* to the level of the Standard, EPA also considers “the *analytical limits* of [the] best available treatment and testing technology.” JA-[FR_32573] (emphasis added) (quoting S. Rep. No. 104-169, at 3 (1995)); *see Int’l Fabricare*, 972 F.2d at 399 (“Before the EPA can set the enforceable limit...it first must ascertain how low a concentration of that chemical reliably can be measured[.]”). By considering these analytical limitations, EPA “ensure[s] that any public water system nationwide can monitor, determine compliance, and deliver water that does not exceed” the Standard. JA-[FR_32573].

EPA supported its Standards for PFOS and PFOA through a robust feasibility analysis. *See generally* JA-[FR_32573-78]; JA-[RTC_5-44_to_5-50, 5-164_to_5-165, 5-316_to_5-317]. Far from limiting its analysis to the “two sub-issues” Petitioners identify, Industry Br. 24, EPA considered all aspects relevant to determining what level is as close as feasible to each contaminant’s Goal. First, EPA identified the lowest levels at which PFOA and PFOS can be “reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions” using EPA-approved methods, known as the practical-quantitation level. JA-[FR_32573]. For contaminants with a Goal of zero (like PFOS and PFOA), EPA commonly sets the Standard at the contaminant’s practical-quantitation level so long as treatment to that level is otherwise feasible. *Id.*; *see Int’l Fabricare*, 972 F.2d at 398-400 (upholding Standard based on this methodology). Here, EPA considered laboratories’ current technical capabilities and found that they can reliably detect and quantify PFOS and PFOA at a level of 4.0 parts per trillion. JA-[FR_32574-76]; JA-[RTC_5-44_to_5-46]. Petitioners do not challenge EPA’s identification of the practical-quantitation level.

Second, EPA evaluated the best available technologies for removing PFOS and PFOA from drinking water and concluded that several technologies, including granular activated carbon, are available and effective under field conditions for

treating these contaminants to levels below the Standards. JA-[FR_32577, 32622-24]; JA-[RTC_5-316_to_5-317]; JA-[Best_Available_Tech_EPA-HQ-OW-2022-0114-3087]. EPA concluded that the costs of these technologies are reasonable at a system and national level. JA-[FR_32575]; JA-[RTC_5-164_to_5-165]. And in any event, the Act provides that use of granular activated carbon is *per se* “feasible” for the control of synthetic organic chemicals, which include PFAS. 42 U.S.C. § 300g-1(b)(4)(D); JA-[FR_32575]. Petitioners do not challenge EPA’s identification of the best available technologies or its conclusion that these technologies are affordable for public water systems.

Third, EPA evaluated numerous other practical concerns regarding the Standards’ implementation, including available laboratory capacity for sample analysis and disposal costs associated with treatment technologies. *See* JA-[FR_32575-77]. EPA considered each of these issues and explained why they did not alter its conclusion that the Standards are feasible.

Industry Petitioners claim that EPA failed to adequately respond to two of these practical concerns: the supply of materials and personnel to build and operate treatment technologies, and the sufficiency of laboratory capacity to analyze systems’ compliance with the Standards. Industry Br. 25-27. EPA considered and responded to both these concerns. Regarding the supply of treatment materials and personnel, EPA acknowledged the possibility of short-term issues but did not

merely “assume[] without explanation that these problems would simply resolve themselves.”¹¹ Industry Br. 26. Instead, EPA relied on record evidence—including comments from treatment-system suppliers—showing excess capacity and investment in expanded production. JA-[FR_32623]; JA-[RTC_10-201_to_10-202, 10-209]. EPA also noted the availability of federal funding to support operator training and certification programs. JA-[RTC_12-15].

While EPA *also* projected that increased demand for treatment will lead to supply increases and innovation, that was not the only factor supporting its decision, and it was based on EPA’s experience with multiple rulemakings rather than mere speculation. JA-[RTC_10-202]. And in any event, the Act does not preclude EPA from relying on reasonable projections of technology availability. Indeed, Congress in 1986 removed the Act’s previous requirement that Standards reflect “generally available” technology, indicating that EPA may base Standards on technology that is not currently in widespread use. *Id.*

Regarding available lab capacity, EPA reasonably explained its conclusion that adequate capacity exists to support implementation of the Standards. First, EPA noted that 53 labs spread throughout the country are already accredited for use of EPA’s PFAS testing methods as part of the UCMR5 sampling program. JA-

¹¹ EPA extended the Standards’ compliance deadline by two years to mitigate any potential supply chain issues and spread out peak demand for capital improvements. *See* JA-[FR_32632-33].

[RTC_5-47]. Those 53 labs have sufficiently accommodated the testing needs of UCMR5, which requires quarterly or semi-annual sampling by *every* medium and large system in the United States and by 800 smaller systems. *Id.* Second, apart from the labs approved to participate in UCMR5, EPA identified an additional 25 labs accredited for use of the relevant test methods. JA-[RTC_5-48]. Third, EPA noted that unlike the more frequent sampling required in UCMR5, many systems will qualify for reduced monitoring under this Rule and will only need to submit samples for analysis annually or triennially, easing the burden on laboratory capacity. *Id.* Fourth, EPA projected that laboratory capacity will grow in response to the Rule and state monitoring efforts. *Id.* And fifth, the final Rule allows systems to submit previously collected data to meet their initial monitoring requirements, potentially easing the Rule's testing burden by tens of thousands of samples. *See* JA-[FR_32616]. EPA's conclusions were corroborated by the commercial environmental testing community, which represented that laboratory capacity is not expected to be an "ongoing concern." *Id.*

Finally, EPA responded to commenters claiming it had overestimated the number of commercial labs accepting samples for analysis. Industry Br. 26-27. In particular, EPA noted that the database on which commenters relied excludes laboratories in some states and likely underestimates the actual number of accredited or certified commercial labs. JA-[RTC_5-47].

Accordingly, EPA addressed all of Industry Petitioners' concerns and reasonably concluded that the Standards for PFOS and PFOA are feasible.

B. EPA Adequately Considered Alternative Standards.

EPA also addressed Industry Petitioners' comments suggesting that EPA consider specific alternative Standards for PFOS and PFOA. Industry Br. 27-30. At the outset, the Act does not require EPA to consider any particular number or range of alternatives to the Standards it proposes. It simply provides that *if* EPA elects to consider alternatives as part of its rulemaking, it must analyze the incremental costs and benefits of those alternatives in the Economic Analysis required under Section 300g-1(b)(3)(C). 42 U.S.C. § 300g-1(b)(3)(C)(i)(III). Petitioners do not dispute that EPA satisfied that requirement for the alternatives it considered of 5.0 and 10.0 parts per trillion, *see* JA-[FR_32634], and their objections to how EPA selected those alternatives over other potential alternatives are legally irrelevant. *See* Industry Br. 29-30.

At bottom, Industry Petitioners simply complain that EPA did not sufficiently consider their preferred regulatory alternatives of 20 and 40 ng/L for PFOA and PFOS, respectively. Industry Br. 28. But EPA met its burden to respond to these public comments and provided a reasoned explanation for rejecting these alternative Standards. Industry Petitioners suggested these levels because they reflected the minimum reporting levels for PFOS and PFOA adopted

in 2012 for the UCMR3 sampling program.¹² See JA-[ACC_Comments_EPA-HQ-OW-2022-0114-1841_at_53]; 77 Fed. Reg. 26072 (May 2, 2012). EPA explained that in the 12 years that had elapsed since 2012, analytical accuracy and precision had improved such that 20 and 40 ng/L no longer represented the analytical limits of the best available technology. JA-[RTC_5-198]; *see also* JA-[RTC_13-524]; JA-[FR_32574] (noting use of 4.0 ng/L as minimum reporting levels for more recent UCMR5). Given the Act’s command to set the Standards “as close to the [Goals] as is feasible,” EPA reasonably decided not to consider alternative Standards based on outdated analytical limits. 42 U.S.C. § 300g-1(b)(3)(A), (b)(4)(B).

Industry Petitioners suggest that EPA nonetheless should have considered their preferred alternatives because EPA could have selected them as the closest “feasible” levels to the Goals based on their “incremental costs” compared to the final Rule’s Standards. Industry Br. 28-29. But Petitioners appear to be conflating the “feasibility” analysis required by Section 300g-1(b)(4)(B) with EPA’s separate requirement to conduct an Economic Analysis and determine whether a Standard’s benefits justify its costs under Section 300g-1(b)(3)(C) and (b)(4)(C). As

¹² In their brief, Industry Petitioners also argue (apparently for the first time) that an EPA guidance document supports their preferred alternative Standards. Industry Br. 28. Petitioners do not explain how their cited guidance—which addresses how to conduct animal toxicity studies for purposes of a different statute—is relevant to setting Standards under the Act.

discussed in Pt.IV.A, *infra*, these are two distinct requirements, and feasibility under the Act does not depend on the incremental costs or benefits of one alternative Standard compared to another. As this Court recognized in *City of Portland*, “[n]othing in Section 300g-1(b)(4)...allows EPA to choose a [Standard] other than the most stringent feasible.” 507 F.3d at 712 (holding “feasible” simply means “technically possible and affordable”). Accordingly, there is no conflict between EPA’s decision not to consider these alternatives and its obligation to determine what Standard is feasible.

C. EPA Has Authority to Promulgate Standards in the Form of a Hazard Index.

For mixtures containing two or more of the Index PFAS, EPA promulgated a Goal and Standard in the form of a hazard index. JA-[FR_32571, 32580]. No Petitioner challenges whether the Standard selected is “as close to the [Goal] as feasible.” 42 U.S.C. § 300g-1(4)(A), (B). Instead, they simply challenge the *form* of the Standard. Utility Br. 34-36. Contrary to their arguments, the best reading of the statutory term “maximum contaminant level” clearly authorizes EPA’s selection of a hazard index as the Standard, and the hazard index approach is consistent with Standards EPA has promulgated for other contaminants. *Loper*, 144 S. Ct. at 2266.

Nothing in the Act requires a Standard to take any particular form. JA-[RTC_5-386]. Instead, a Standard that sets a “maximum contaminant level”

simply must state “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). To meet this definition, a Standard must specify a “level” for the relevant contaminant. JA-[RTC_5-386]. And for practical purposes, it must be capable of being validated to assess a system’s compliance. *Id.* The hazard index in the final Rule satisfies these requirements. It establishes the level that the relevant contaminant—here, any mixture of two or more Index PFAS—may not exceed in drinking water. And it can be validated because regulated systems use their monitoring results as inputs to determine whether their water contains a mixture of Index PFAS exceeding that level. *Id.*

Petitioners fail to explain how a Standard based on a hazard index does not establish a “level.” They claim that a “level” must be expressed as the “concentration” of an individual substance in water. Utility Br. 34. But their own brief concedes that “level” has a broader meaning that includes any measure of “relative position or rank on a scale” or a “relative degree...[of] intensity.” *Id.*; *accord* RANDOM HOUSE COLLEGE DICTIONARY 770 (Laurence Urdang et al. eds., 1973) (defining “level” as “a position in a graded scale of values; status; rank”). The hazard index is a scale measuring the relative intensity of the hazard presented, with a value above 1 representing amounts of the mixture at which there are known or anticipated adverse health effects and values at or below 1

representing amounts at which no such effects are expected. JA-[RTC_4-418_to_4-419].

Petitioners are wrong that all of EPA's other Standards are "expressed and described as a concentration level"; in fact, the example they cite disproves their argument. Utility Br. 34 (discussing Standards for radionuclides). The Standards for combined radium and for gross alpha particle radioactivity are each expressed in picocuries per liter. 40 C.F.R. § 141.66(b), (c). These units do not represent the *concentration* of any particular radionuclides in water, but rather the *intensity of radioactivity* in the water, measured via the rate of radioactive decay. *City of Waukesha*, 320 F.3d at 232 n.1; *see also* 51 Fed. Reg. 34836, 34850 (Sept. 30, 1986) (providing background on radionuclides and their measurement in advance notice of proposed rulemaking). Likewise, the Standard for beta particle and photon radioactivity is expressed in millirems per year, which measures the dose of radiation received over a set time period and accounts for both the quantity and energy of radiation present. 40 C.F.R. § 141.66(d); *City of Waukesha*, 320 F.3d at 232 n.2.

Like the hazard index, each of these Standards uses a metric other than the concentration of a contaminant in water to set the maximum permissible "level." Notably, EPA's reason for taking this approach with radionuclides is directly analogous to its reason for using a hazard index here: the need to "account for the

different potencies of the mixture components.” JA-[RTC_4-429]; *see* 65 Fed. Reg. 76708, 76720 (Dec. 7, 2000) (explaining factors affecting hazards of various radionuclides). Because the mixture components are not equally hazardous and may occur in different proportions at different times and locations, a Standard set in the form of a total concentration of these components would not adequately protect against adverse health effects and would be over-protective in some cases and under-protective in others. JA-[RTC_4-430]. Petitioners’ narrow reading of “level” would hamstring EPA’s ability to address these kinds of mixtures.

Likewise, there is nothing “fundamentally different” about a Standard that “depends on the relative occurrence of four different contaminants in a sample of drinking water.” Utility Br. 35. The same is true of *any* Standard that limits a contaminant as a group, like EPA’s Standards for disinfection byproducts or radionuclides. 40 C.F.R. §§ 141.64(b), 141.66. For example, a system’s compliance with the Standard for haloacetic acids will depend on “fluctuations in the relative concentrations of” the five acids collectively regulated by that Standard, Utility Br. 36, just as a system’s compliance with the hazard index in this Rule will depend on the measured concentrations of different Index PFAS in its water. The only distinction here is that the concentrations of Index PFAS are given different weights before adding them together to reflect the lower potency of one component (PFBS) compared to the other Index PFAS. *See* JA-[RTC_4-368]

(noting for contaminants with dose-additive effects, overall risk depends on sum of individual contaminant concentrations “scaled for potency”).

Nor is the hazard index made “fundamentally different” by use of a “mathematical equation” to determine compliance with the Standard. Utility Br. 35. Again, the mathematical steps involved in calculating the hazard index (division and addition of individual contaminant concentrations) are no different or more complex than the steps required for the many Standards for which compliance is based on a running annual average of quarterly sampling results. JA-[RTC_5-391]; *see* 40 C.F.R. §§ 141.23, 141.24, 141.26, 141.133. Thus, a Standard expressed as a hazard index is consistent with the Act and with EPA’s past practice.

D. The Index PFAS Standard Appropriately Regulates Mixtures of Index PFAS.

Petitioners largely repackage arguments regarding the regulatory determination of the Index PFAS as arguments that the Standard is arbitrary and capricious. *Compare* Industry Br. 40-44 *with* Utility Br. 36-40; Pt.II.A.3. These arguments are no more availing regarding the Standard.

First, Petitioners assert the Index PFAS have different health effects. Utility Br. 36-38. As explained in Pt.II.A.3, *supra*, this is incorrect. Exposure to different Index PFAS elicit many similar adverse health effects, including effects on development, the liver, and kidney, and endocrine, respiratory, and reproductive

systems. JA-[FR_32552]; JA-[RTC_4-373_to_4-375, 4-424_to_4-429]; JA-[MCLG_1-7_to_1-10].

Second, Petitioners misstate the Board's recommendations regarding use of a hazard index. Contrary to Petitioners' assertion, Utility Br. 38-39, the Board never stated that a hazard index is "most appropriate" as a screening tool. JA-[SAB_Report]. EPA sought the Board's input on its original proposal to use a tiered approach to evaluate noncancer health risks associated with PFAS mixtures in which the hazard index could be used as the first tier before more data-intensive steps were taken. JA-[RTC_4-423_to_4-426]. The Board agreed that the hazard index was "a reasonable approach" for regulating PFAS mixtures because of their dose-additivity, but specifically recommended that EPA remove additional tiers of evaluation and use a simplified structure like the hazard index. JA-[SAB_Report_91, 110]; JA-[RTC_4-424]. Thus, far from criticizing this approach, the Board endorsed it.

Finally, Petitioners misrepresent the EPA guidance document they claim requires consistent proportions. Utility Br. 39-40. Petitioners conflate the concept of a mixture generally with a specific type of mixture *analysis* called the "whole-mixture" approach. JA-[Chem_Mix_Guidance_EPA-HQ-OW-2022-0114-0075_3]. As the guidance document explains, there are different methods of analyzing mixtures that include both "whole-mixture" approaches and component-

based approaches (like a hazard index). JA-[Chem_Mix_Guidance_3]. The references to similarities in proportions and components that Petitioners cite relate to one particular type of analysis under the “whole-mixture” approach, *not* a hazard-index approach. JA-[Chem_Mix_Guidance_10, 37-38]. Indeed, EPA explained that the variability of proportions of individual PFAS within the mixtures of the Index PFAS was the very reason it is using the hazard-index approach. JA-[Chem_Mix_Guidance_79-80]; JA-[RTC_4-420_to_4-421]. And although Petitioners quibble with EPA’s use of the term “mixture” to describe combinations of Index PFAS because they claim the “common sense” definition of “mixture” requires “components and respective portions [that] exist in approximately the same pattern,” Utility Br. 40, the longstanding definition of a mixture in chemistry is “an aggregate of two or more substances that are not chemically united and that exist *in no fixed proportion to each other.*” *Mixture*, DICTIONARY.COM, available at <https://www.dictionary.com/browse/mixture> (emphasis added); *Mixture*, RANDOM HOUSE COLLEGE DICTIONARY 865 (Laurence Urdang et al. eds. 1973) (same).

Accordingly, EPA’s decision to regulate the Index PFAS using a hazard-index methodology is reasonable and supported by record evidence.

E. The HFPO-DA Individual Standard Is Reasonable and Supported by the Record.

EPA thoroughly reviewed the scientific data to develop the HFPO-DA Goal and Standard. Petitioners challenge two inputs into the Goal: EPA's consideration of non-drinking water exposure to HFPO-DA (the "relative source contribution") and various aspects of the Toxicity Assessment. Neither of these arguments is availing.

1. EPA Reasonably Considered Non-Drinking Water Exposure to HFPO-DA.

To set a Goal at the level of HFPO-DA in drinking water at which "no known or adverse effects on the health of persons occur and which allows an adequate margin of safety," EPA must consider not only human exposure to HFPO-DA through drinking water, but also non-drinking water HFPO-DA exposure. JA-[MCLG_2-3, A-8_to_A-15]; JA-[RSC_Guide_EPA-HQ-OW-2022-0114-0882_1-5_to_1-8]. EPA does this through assessment of the "relative source contribution." 42 U.S.C. § 300g-1(b)(4); JA-[MCLG_2-3]; JA-[RSC_Guide_1-7_to_1-8]. EPA takes "a conservative approach to public health" by assuming 20% of exposure is from drinking water and 80% from other exposure sources "when adequate exposure data do not exist...." JA-[RSC_Guide_1-7]. Here, EPA fully evaluated the available peer-reviewed scientific studies and determined that inadequate data existed to calculate the specific amount of exposure to HFPO-DA

an individual would likely receive from each media. JA-[MCLG_2-3, A-8_to_A-15]. Thus, pursuant to EPA’s longstanding methodology, EPA determined that a relative source contribution of 20% was appropriate. The Court affords EPA particular deference for its evaluation of this type of scientific data within its “technical expertise.” *NYC C.L.A.S.H., Inc. v. Fudge*, 47 F.4th 757, 763 (D.C. Cir. 2022).

EPA thoroughly explained its consideration of peer-reviewed scientific studies—including all articles Petitioner Chemours provided—to determine whether HFPO-DA exposure may occur from non-drinking water sources. JA-[MCLG_A-8_to_A-15]; JA-[RTC_4-587_to_4-590]; *contra* Industry Br. 55. At the outset, much of what Petitioner Chemours provided was not valid scientific data or peer reviewed studies (*e.g.*, internal PowerPoint slides and public-service announcements) or failed to even reference HFPO-DA. JA-[RTC_4-587_to_4-590]. Nevertheless, EPA included a table in its response to comments specifically addressing each document submitted, confirming EPA considered the valid scientific studies therein, and explaining why each document that was not considered failed to meet the statutory standard for consideration. JA-[RTC_4-587_to_4-590]. Notably, Petitioners do not disagree with EPA’s assessment of any of these documents. Industry Br. 54.

Contrary to Petitioners assertion, Industry Br. 56, EPA did not disregard data showing a lack of non-drinking water exposure routes. EPA fully discussed both studies that demonstrated HFPO-DA presence and studies that did not. JA-[MCLG_A-11_to_A-15]. Collectively, the studies demonstrated the presence of HFPO-DA in certain foods, but not in others. JA-[MCLG_A-11_to_A-12]. Studies also detected HFPO-DA in soil and sewage sludge, air emissions, rainwater, and indoor dust. JA-[MCLG_A-12_to_A-15]. EPA thus concluded that several studies showed people may be exposed to HFPO-DA through non-drinking water exposure routes. JA-[MCLG_A-11_to_A-15]. Critically, Petitioners identify no error in EPA's reliance on *any* of these studies. Industry Br. 55-56. And although Petitioners cite to an extra-record email regarding preliminary data on PFAS in dust that Petitioners claim EPA failed to consider, Industry Br. 56, the final results of that study merely document that, at the ten specific military bases studied, HFPO-DA overwhelmingly was not present in *any* form. *See* ATSDR Report at 57, <https://www.atsdr.cdc.gov/pfas/docs/PFAS-EA-Final-Report-508.pdf>. EPA thus reasonably concluded exposure may occur through non-drinking water sources.

EPA then explained that, because “the available information [on HFPO-DA exposure] is limited” and “does not allow for the quantitative characterization of the relative levels of exposure among these difference sources,” EPA would follow

its standard methodology of applying a relative source contribution of 20%. JA-[MCLG_2-3, A-15]. EPA's protocol does not "strongly caution[] against" using a 20% value. *Contra* Industry Br. 55. It states that "[w]hen other sources or routes of exposure are anticipated but data are not adequate" to quantify the precise amount of exposure from drinking water versus other media, "there is an even greater need to make sure that public health protection is achieved," and "the 20 percent default will still generally be used." JA-[RSC_Guide_4-6]. Petitioners do not identify a single peer-reviewed scientific study that quantifies HFPO-DA exposure through drinking water as compared to other exposure media, nor do Petitioners offer any evidence to *specifically calculate* a relative source contribution value EPA should have used. *See generally* Industry Br. 54-57.

EPA's extensive discussion of the scientific literature of HFPO-DA exposure surpasses its obligation to consider all relevant factors and demonstrate a reasonable connection between the record facts and policy choice. *Sinclair Wyo.*, 101 F.4th at 882.

2. EPA Reasonably Relied on Rodent Studies Showing HFPO-DA Elicits a Constellation of Adverse Liver Effects Relevant to Humans.

EPA thoroughly analyzed the available scientific literature before relying on rodent studies to determine that a constellation of adverse liver effects is the most critical effect observed after HFPO-DA exposure to derive a Goal at "the level at

which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.” JA-[MCLG_1-1, 2-1]. Although Petitioners disagree with EPA’s reliance on these studies and conclusions, the record—including *multiple* rounds of independent expert peer reviews—overwhelmingly supports EPA’s conclusions. JA-[HFPO-DA_TA_Appx_D]; JA-[HFPO-DA_1st_Peer_Review_13-31]; JA-[HFPO-DA_2nd_Peer_Review_10-15]. These factual findings are entitled to an “extreme degree of deference.” *NYC C.L.A.S.H., Inc.* 47 F.4th at 763.

a. Petitioners incorrectly assert that *no* liver effects in rodents are relevant to humans. Industry Br. 57-60. But EPA’s analysis is supported by peer-reviewed scientific literature and was affirmed by multiple rounds of external peer review by independent human health scientists.

Petitioners incorrectly assert all liver effects observed in rodents result from a toxicity pathway (or “mode of action”) called PPAR-alpha, which they claim is not relevant to humans. Industry Br. 57-58. But there are multiple modes of action for liver effects in rodents other than PPAR-alpha, including the cytotoxic mode of action. JA-[RTC_4-517_to_4-520]. EPA identified scientific literature demonstrating that only a *decrease* in one type of liver cell death (apoptosis) is associated with PPAR-alpha, whereas other modes of action relevant to humans are associated with the specific liver effects at issue here—*increases* in apoptosis,

various types of necrosis, and increased serum liver enzyme concentrations, *i.e.*, a “constellation of liver effects”). JA-[RTC_4-516_to_4-521]; JA-[HFPO-DA_TA_29, 42-45, 51-54, 72-77, 82-90, Appx_D]; JA-[HFPO-DA_1st_Peer_Review_13-21]; JA-[Draft_HFPO-DA_TA_RTC_EPA-HQ-OW-2022-0114-3616_12-15, 34-35]; JA-[Resp_Chem_IQA_EPA-HQ-OW-2022-0114-3629_7-14]. Petitioners ignore EPA’s cited studies, and instead erroneously assert EPA’s analysis was based on “specula[tion].” Industry Br. 57.

Notably, EPA *twice* sought external peer review regarding whether the specific rodent studies relied upon were relevant to humans, and both panels unanimously agreed they were. JA-[HFPO-DA_1st_Peer_Review_17-21, 25-31]; JA-[HFPO-DA_2nd_Peer_Review_10-15]. And, when Petitioner Chemours previously challenged a specific type of liver cell death reported in studies EPA considered when determining HFPO-DA’s toxicity to humans, EPA even convened a *third* group of independent experts, the Pathology Working Group at the National Institutes of Health, to conduct an independent analysis of the pathology slides from the studies. JA-[Draft_HFPO-DA_TA_RTC_11-15]; JA-[HFPO-DA_TA_Appx_D]. The Group generally supported the original study’s findings, concluding that the pathology slide evaluations demonstrated a range of adverse liver effects, including increased single-cell necrosis, cytoplasmic alteration, focal necrosis, and apoptosis—collectively, a “constellation of

lesions”—that it identified as adverse effects observed after exposure to HFPO-DA. JA-[HFPO-DA_TA_D-22].

Although Petitioners now complain that the Group did not make any specific findings regarding the relevance of the constellation of lesions to humans, Industry Br. 59-60, Petitioners misunderstand the Group’s role. The Group was asked to diagnose the liver effects using a particular type of liver diagnostic criteria (the “Elmore” criteria. JA-[HFPO-DA_TA_D-22]. Evaluation of whether a particular rodent effect can be extrapolated to humans follows an analysis of “the Hall criteria,” which is conducted *after* identification of the specific liver effect. JA-[RTC_4-517]; JA-[FR_32548-49]. Two panels of experts also unanimously affirmed EPA’s “Hall criteria” analysis. JA-[HFPO-DA_1st_Peer_Review_17-21, 25-31]; JA-[HFPO-DA_2nd_Peer_Review_10-15].

Thus, although Petitioners may disagree with EPA’s scientific assessment, EPA’s analysis and conclusions are supported by ample evidence in the record and are well-explained.

b. The record demonstrates that EPA appropriately considered the Chappell article Petitioner Chemours identified in its comments. Industry Br. 58; JA-[RTC_4-517_to_4-520].

First, EPA considered the Chappell article in conjunction with the other available scientific studies on this issue. JA-[HFPO-DA_TA_76-77]. EPA

determined, in its technical expertise, that the weight of evidence supported the human relevance of the liver effects resulting from HFPO-DA exposure. JA-[HFPO-DA_TA_76-77]; JA-[RTC_4-517_to_4-520]; JA-[Resp_Chem_IQA_8]. For example, although the Chappell study did not find necrosis in the slides studied, the seven pathologists in the Pathology Working Group analyzed the same slides and found necrosis in addition to apoptosis. JA-[HFPO-DA_TA_D-20_to_D-21_Tbl_1]. Although Petitioners may disagree with EPA's weighing of this evidence, this Court affords EPA's evaluation of within its technical expertise particular deference. *Huntsman Petrochem.*, 114 F.4th at 735.

Second, Petitioners are incorrect that the Chappell study concluded that *no* modes of action other than PPAR-alpha are at issue in *any* liver effects resulting from HFPO-DA exposure. Industry Br. 58. The article did not address all other potential modes of action, including the cytotoxic mode of action, and thus cannot refute the potential applicability of other modes of action. JA-[Chappell_study_EPA-HQ-OW-2022-0114-3431_505-06]; JA-[RTC_4-518_4-519].

Finally, EPA explained that Chappell's finding of apoptosis is consistent with other studies that demonstrate that apoptosis is part of the constellation of liver effects seen in response to HFPO-DA exposure. JA-[RTC_4-519_to_4-520]. EPA thus fully considered the Chappell study.

3. EPA Reasonably Applied Both Subchronic-to-Chronic and Database Uncertainty Factors of 10.

When deriving a Goal and Standard, EPA must first determine the reference dose (an estimate of daily oral exposure that is “likely to be without an appreciable risk of deleterious effects during a lifetime”) by analyzing the scientific literature and applying certain “uncertainty factors.” JA-[Reference_Dose_Protocol_EPA-HQ-OW-2022-0114-0100_G-7, 4-40_to_4-41]. Uncertainty factors are numerical values of 1, 3, or 10 that account for gaps or uncertainties in the available scientific data for the chemical. JA-[Reference_Dose_Protocol_4-40_to_4-41]. Because of gaps in the scientific studies conducted on HFPO-DA at the time of the rulemaking, EPA reasonably set both the subchronic-to-chronic and database uncertainty factors in its derivation of the HFPO-DA chronic reference dose at 10.

First, EPA’s guidance regarding application of uncertainty factors to chronic reference doses explains that a “default value of 10 for [the subchronic-to-chronic uncertainty factor] is applied...on the assumption that effects from a given compound in a subchronic study occur at a 10-fold higher concentration than in a corresponding (but absent) chronic study.” JA-[Reference_Dose_Protocol_4-45_to_4-46]. Although EPA originally set this value at 3 when drafting its initial toxicity assessment in 2018, additional studies became available that indicated studies of longer duration were needed. JA-[HFPO-DA_TA_92-93]. Contrary to

Petitioners' assertion, Industry Br. 53-54,¹³ EPA fully explained the reasons for this increase. JA-[HFPO-DA_TA_41-45, 92-93]; JA-[HFPO-DA_2nd_Peer_Review_10]. Specifically, based on the Pathology Working Group's reanalysis of pathology slides, EPA revised its assessment of the most sensitive population from parental males to lactating females. JA-[HFPO-DA_TA_41-45, 92-93]; JA-[HFPO-DA_2nd_Peer_Review_10]; JA-[HFPO-DA_Draft_TA_EPA-HQ-OW-2022-0114-0521_60]. EPA explained that female test subjects had been exposed to HFPO-DA for a shorter duration than the exposure duration for males, thus requiring an increase in the subchronic-to-chronic uncertainty factor. JA-[HFPO-DA_TA_92-93]; JA-[HFPO-DA_2nd_Peer_Review_20]. Additionally, because the available studies demonstrated female rodents had progressing liver effects over longer durations of exposure to HFPO-DA, EPA explained it was "critical to have a 2-year chronic study in the mouse to understand the progression of these liver effects," but no such studies existed. JA-[HFPO-DA_TA_93].

¹³ EPA had no heightened burden to "supply a reasoned analysis," Industry Br. 54 (quoting *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 57 (1983)), for revising this uncertainty factor between the draft and final toxicity assessment in response to public comment and updated scientific studies. *State Farm* refers to an agency "changing its course" by revising a final regulation, not a draft scientific assessment. *State Farm*, 463 U.S. at 57.

Second, Petitioners question why EPA increased its database uncertainty factor from 3 to 10 in response to additional studies and findings. Industry Br. 52-53. But EPA explained that scientific papers published after the draft assessment identified new health effects needing more study—specifically, reproductive, developmental, and neurotoxic effects. JA-[HFPO-DA_TA_93-96]; JA-[HFPO-DA_2nd_Peer_Review_15]; JA-[Draft_HFPO-DA_TA_RTC_23-24]. For example, one study observed placental lesions in pregnant mice following exposure to higher doses of HFPO-DA, and EPA explained that additional studies were needed both at lower doses and to determine how those lesions “might impact reproductive and developmental outcomes.” JA-[HFPO-DA_TA_94]. Similarly, three studies published after the draft toxicity assessment showed alterations in thyroid hormones in pregnant subjects after gestational exposure to HFPO-DA, but EPA explained the potential neurodevelopmental effects that might result from the thyroid hormone effects required additional investigation at lower doses. JA-[HFPO-DA_TA_96]. Thus, contrary to Petitioners’ assertion, Industry Br. 52-53, EPA specifically identified the critical data gaps it had discovered between the draft and final toxicity assessments. JA-[HFPO-DA_TA_93-96].

Third, EPA’s proposal to increase both the subchronic-to-chronic and database uncertainty factors from 3 to 10 was supported by a panel of independent experts. JA-[HFPO-DA_2nd_Peer_Review_15-24].

Accordingly, EPA considered the “relevant factors” and articulated a “reasonable connection” between the facts found and the choice made. *Sinclair Wyo.*, 101 F.4th at 882.

F. EPA Satisfied Its Procedural Requirements for Consultation with the Science Advisory Board.

EPA sought the Board’s comments on the key scientific issues involved in its regulations for these contaminants and addressed the Board’s recommendations in its proposed and final Rule. JA-[FR_32729-31]. The Act does not require more. And ultimately, any procedural deficiencies in EPA’s consultation with the Board would constitute harmless error that does not warrant any remedy—certainly not “vacating the Rule” in its entirety. Industry Br. 39.

The Act requires EPA to “request comments from the Science Advisory Board...prior to proposal of a [Goal] and [Standard].” 42 U.S.C. § 300g-1(e). Other than specifying when EPA must solicit comment, this broad language leaves EPA significant discretion regarding how and on what issues to seek the Board’s input prior to proposal. Contrary to Petitioners’ suggestion, SDWA does not require EPA to submit the specific Goals and Standards it proposes for the Board’s

review.¹⁴ Industry Br. 39. If Congress had intended to require as much, it would have done so explicitly.

That it did not is unsurprising. The Board exists only to provide “scientific advice” to EPA. 42 U.S.C. § 4365(a). EPA’s selection of a specific Goal and Standard for a contaminant involves policy questions (including what constitutes an “adequate margin of safety” and what level is “feasible”) that the Board is neither authorized nor qualified to address. *See id.* § 300g-1(b)(4). Moreover, requiring EPA to solicit the Board’s comment on the specific Goal and Standard it proposes would be impractical, as it could trap EPA in a feedback loop of continuous consultation. EPA would have to go back to the Board for further comment each time it changes its proposed rules, even if it were changing the proposal in response to the Board’s feedback. JA-[RTC_4-427].

In practice, EPA considers hundreds of scientific issues for any given regulation under the Act, and EPA must focus its consultation with the Board on the most important or novel issues.¹⁵ *Id.* Here, EPA identified the most critical

¹⁴ Petitioners appear to recognize as much: they do not challenge EPA’s consultation with the Board regarding PFOS or PFOA, notwithstanding that EPA also did not solicit the Board’s comments on those specific Goals or Standards. Industry Br. 38.

¹⁵ *See, e.g.*, 86 Fed. Reg. 4198, 4276 (Jan. 15, 2021) (describing issues for which EPA sought Board comment on lead and copper Standards); 78 Fed. Reg. 10270, 10341 (Feb. 13, 2013) (total coliform Standard); 66 Fed. Reg. 45676 (Aug. 29, 2001) (Standards for microbial pathogens, disinfectants, and disinfection byproducts).

scientific issues to its forthcoming proposals that had not yet undergone peer review, where Board commentary would be most valuable. *Id.* EPA submitted questions to the Board on these issues, including dose-additivity and the reasonableness of using a hazard index or other methods for assessing risks of PFAS mixtures. *Id.*; see JA-[Response_to_Final_SAB_Recommendations_EPA-HQ-OW-2022-0114-0043_at_46-71]. The Board met on four occasions to deliberate on these charge questions and others EPA submitted for this rulemaking; published a draft report; considered oral and written public comments; and provided numerous recommendations to EPA. JA-[RTC_4-426]. EPA considered these recommendations and included its responses to the Board in its proposed and final Rule. *Id.* The Act does not require more.

Finally, even if the Court agrees with Petitioners, any procedural violation was harmless error. *See City of Waukesha*, 320 F.3d at 246. Petitioners do not claim to have suffered any prejudice from EPA's alleged failure to consult with the Board and do not show further consultation would have altered or improved anything about the Rule—particularly given that EPA accepted all of the Board's recommendations with respect to PFAS mixtures. JA-[Response_to_Final_SAB_Recommendations_at_12, 46-71]. Moreover, while Congress may have considered Board consultation a worthwhile effort, it clearly did not intend this requirement to be essential. The Act does not even require the

Board to respond to EPA's solicitation, and it prohibits EPA from delaying final promulgation of a Standard to allow for Board consultation. 42 U.S.C. § 300g-1(e).

IV. EPA Appropriately Considered Costs and Benefits in Promulgating the Rule.

Petitioners' challenges to EPA's consideration of costs and benefits in the Rule fail for numerous reasons. First, Petitioners' assertion that what is "feasible" under SDWA depends on a balance of costs and benefits is wrong as a matter of law. Second, the Act does not permit judicial review of EPA's separate determination that the Rule's benefits justify its costs. Third, to the extent it is reviewable here, EPA's determination was reasonable because it properly considered the Rule's substantial nonquantifiable benefits, considered certain Standards' impacts collectively to accurately account for their overlapping costs and benefits, and addressed each of Petitioners' objections on the record. Finally, if the Court agrees with Petitioners on any issue, vacatur of the Rule is inappropriate.

A. EPA's Selection of "Feasible" Standards Does Not Depend on Comparison of Costs and Benefits.

Petitioners' arguments challenging the Standards based on purported deficiencies in the Economic Analysis rely on a fundamentally mistaken proposition: that in order to set a Standard that is as close to the Goal as

“feasible,” EPA must strike some particular balance between the Standard’s benefits and costs. *See* Utility Br. 2, 53-57; Industry Br. 6, 14-23. Petitioners improperly conflate EPA’s analysis of what Standard is “feasible” under subparagraph (b)(4)(B) with its separate determination of whether such a Standard’s benefits justify its costs under subparagraph (b)(4)(C). As this Court already held in *City of Portland*, SDWA’s text, structure, and legislative history confirm that these analyses are distinct and that whether a Standard is “feasible” does not turn on its relative benefits and costs. 507 F.3d at 712.

The text and structure of the Act make clear that subparagraphs (b)(4)(B) and (b)(4)(C) involve different analyses based on different factors. Subparagraph (b)(4)(B) directs EPA to set a contaminant’s Standard as close as “feasible” to its health-protective Goal. 42 U.S.C. § 300g-1(b)(4)(B). This analysis focuses on the availability and performance of the best available technology for treating a contaminant. JA-[FR_32573]. Although EPA’s evaluation of what is “feasible” also involves some “consideration” of cost, *see* 42 U.S.C. § 300g-1(b)(4)(D), that consideration is limited to whether the costs of compliance are *affordable* for large public water systems and does not seek to balance costs against benefits. *City of Portland*, 507 F.3d at 712; JA-[FR_32573].

By contrast, subparagraph (b)(4)(C) explicitly directs EPA to determine whether the benefits of a Standard set pursuant to (b)(4)(B) justify its costs based

on the results of an Economic Analysis conducted specifically for that purpose. 42 U.S.C. § 300g-1(b)(4)(C). EPA's determination under subparagraph (b)(4)(C) does not alter or influence its determination of what Standard is as close to the Goal as feasible under (b)(4)(B). Instead, it is the first step in a separate process through which EPA "may" decide (in its discretion) to promulgate a Standard that is *not* as close to the Goal as feasible. *See* 42 U.S.C. § 300g-1(b)(6).

Specifically, if EPA finds the benefits of a Standard set pursuant to subparagraph (b)(4)(B) justify the costs, then it cannot depart from that process, even if a Standard set at a different level might have greater net benefits. But if EPA determines the benefits do not justify the costs, it "may" promulgate a less stringent Standard at a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits." *Id.* § 300g-1(b)(6)(A). This is the only circumstance in which SDWA authorizes EPA to set a contaminant's Standard based on its evaluation of the relative costs and benefits.

EPA's interpretation that "feasible" does not require comparing costs and benefits is not only the best reading of the Act, it is the *only* reading that is consistent with this statutory framework. Paragraph (b)(6) offers a discretionary release valve allowing EPA to depart from the Act's normal Standard-setting requirements where they result in Standards that are not justified by their benefits. If determining "feasibility" already required balancing costs and benefits, this

release valve would be unnecessary: any Standard for which benefits did not justify costs would by definition be infeasible and would have to be adjusted upward under subparagraph (b)(4)(B) until the benefits justified the costs, without any need to resort to the provisions of paragraph (b)(6). Thus, Petitioners' interpretation would read paragraph (b)(6)—one of the most prominent changes included in Congress's 1996 amendments to SDWA—out of the statute.

This Court has already squarely rejected Petitioners' reading of the feasibility requirement for precisely these reasons. In *City of Portland*, petitioners claimed that alleged errors in EPA's Economic Analysis under subparagraph (b)(3)(C) undermined EPA's determination that the challenged Standard was feasible. 507 F.3d at 712. The petitioners argued that a Standard "is only 'feasible' if its benefits outweigh its costs." *Id.* This Court disagreed, noting that "when Congress wanted EPA to undertake cost-benefit analysis, it said so expressly." *Id.* Likewise, if "feasible meant that the [Standard's] benefits justified its costs," then the release valve offered by paragraph (b)(6) "would be surplusage." *Id.* The Court concluded that feasibility does not require balancing costs against benefits and simply means "technically possible and affordable." *Id.*

Finally, the legislative history confirms this Court's and EPA's reading of the statute. The Senate Committee's report discussed feasibility as a separate concept from comparison of costs and benefits, noting that paragraph (b)(6) would

give EPA “discretionary authority to establish less stringent standards (than *feasible*), when the Administrator determines that the benefits of a [Standard] set at the *feasible level* would not justify the costs” S. Rep. 104-169, at 31 (emphases added). That report also emphasized that EPA could still choose to set the Standard for a contaminant as close to its Goal as feasible, “even if the Administrator determines that the benefits of the [Standard] at this level do not justify the costs”—a choice that would be impossible if determining feasibility itself required a finding that benefits justify costs. *Id.* at 33. And the House Committee’s report noted that the 1996 amendments would “retain[] the basic standard setting process” from earlier iterations of the Act, indicating that neither the cost-justification determination in subparagraph (b)(4)(C) nor the requirement to conduct an Economic Analysis in subparagraph (b)(3)(C) were intended to change how EPA determined feasibility under subparagraph (b)(4)(B). H.R. Rep. No. 104-632, at 27 (1996).

Petitioners’ interpretation of the feasibility requirement is incompatible with the statute and foreclosed by *City of Portland*. Accordingly, the Court should reject their arguments.

B. The Act Precludes Judicial Review of EPA’s Finding That the Rule’s Benefits Justify Its Costs.

Because feasibility under SDWA does not involve comparison of a Standard’s costs and benefits, Petitioners’ challenges to the Economic Analysis can

only be relevant to the merits of EPA's separate determination under Section 300g-1(b)(4)(C). But the Act does not permit judicial review of that determination where, as here, EPA sets the Standard for a contaminant as close to its Goal as feasible. Instead, judicial review is only available where EPA exercises its discretion to adopt an alternative Standard that is less stringent than otherwise required.

SDWA separately addresses judicial review of EPA's cost-justification determinations. It states that EPA's determination as to whether the benefits of a Standard justify its costs "shall be reviewed by the court pursuant to section 300j-7...*only* as part of a review of a final [Standard] that has been promulgated *based on the determination.*" 42 U.S.C. § 300g-1(b)(6)(D) (emphases added). Those circumstances are not presented here.

The only Standards that are "promulgated based on" such a determination are those set under subparagraph (b)(6)(A) at a level less stringent than what is feasible. Standards under subparagraph (b)(6)(A) are "based on" EPA's determination regarding costs and benefits because in order to promulgate such Standards, EPA must first determine that the benefits of a Standard at the feasible level "would not justify" the costs. 42 U.S.C. § 300g-1(b)(6)(A). And in order to select the appropriate alternative Standard under this provision, EPA must also

affirmatively determine whether the benefits of its chosen alternative *do* justify the costs. *Id.*

By contrast, a Standard that is set pursuant to subparagraph (b)(4)(B) (*i.e.*, as close to the Goal as feasible) is not one that has been promulgated “based on the determination” of whether its benefits justify the costs. This is evident from the fact that under SDWA’s plain text, EPA may set the Standard as close to the Goal as feasible *regardless of the outcome* of its assessment of benefits and costs under subparagraph (b)(4)(C). If EPA finds the benefits of a Standard at the feasible level justify the costs, it must proceed to set the Standard as close to the Goal as feasible. But even if it finds the benefits *do not* justify the costs, the statutory text leaves EPA with discretion to set the Standard at the feasible level. 42 U.S.C. § 300g-1(b)(6)(A) (stating EPA “may” promulgate alternative Standard if benefits do not justify costs); *see also* S. Rep. No. 104-169, at 33 (stating EPA “is not precluded from using the authority of section 1412(b)(4)” to set Standard at the feasible level, “even if the Administrator determines that the benefits of the [Standard] at this level do not justify the costs”). Either way, EPA’s choice of the Standard under subparagraph (b)(4)(B) is not and cannot be “based on” its determination whether benefits justify costs.

EPA’s interpretation represents the best reading of the statute. It is supported by the text discussed above and the statutory framework, which notably

situates this provision addressing judicial review of EPA's cost-benefit determination within the provisions granting EPA limited discretionary authority to promulgate alternative Standards based on that determination. In fact, the existence of this provision alone is telling: if Congress had meant to authorize judicial review of *every* cost-benefit determination EPA makes in promulgating a Standard, it would not have needed to insert a special judicial-review provision specifying when such review is available at all.

EPA's interpretation is also consistent with the legislative history of SDWA's 1996 amendments, which demonstrates that Congress intended EPA's choice of whether to exercise its authority under paragraph (b)(6) to be "entirely discretionary." S. Rep. No. 104-169, at 35. The Senate Committee's report emphasized that even where EPA finds the benefits of a Standard at the feasible level do not justify the costs, "[n]o court may compel the Administrator to set a standard using the authority of" paragraph (b)(6). *Id.* Allowing judicial review of EPA's cost-benefit determination for every rulemaking under the Act would undermine Congress's grant of broad discretion to EPA to adopt a Standard that is as close to the corresponding Goal as feasible regardless of whether the benefits justify the costs.

Accordingly, Section 300g-1(b)(6)(D) precludes this Court from reviewing EPA's determination that the benefits of this Rule's Standards justify their costs.

C. EPA Reasonably Determined that the Rule's Benefits Justify Its Costs.

To the extent judicial review is permitted here, EPA's determination that the benefits of the Standards justify their costs is not arbitrary or capricious. As indicated by the term "justify," SDWA grants EPA significant discretion regarding how to make such a determination for a Standard, and this Court's review is limited to examining whether EPA failed to consider a relevant factor. EPA properly considered the quantifiable and nonquantifiable costs and benefits of the Standards, supported its determination in the record with a robust Economic Analysis, and adequately responded to each of the objections Petitioners raise below.

1. To the Extent the Court May Review EPA's Assessment of Costs and Benefits, The Scope Is Limited to Arbitrary-and-Capricious Review.

If the Court concludes it may review EPA's cost-justification determination under subparagraph (b)(4)(C), it may not set aside EPA's determination "unless the court finds that the determination is arbitrary and capricious." 42 U.S.C. § 300g-1(b)(6)(D). This standard of review is highly deferential and focuses on whether EPA "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible

that it could not be ascribed to a difference in view or the product of agency expertise.” *State Farm*, 463 U.S. at 43.

SDWA does not require EPA to use any particular metric for determining whether a Standard’s benefits “justify” its costs, such as evaluating whether the benefits “outweigh” the costs or whether less stringent Standards would yield higher net benefits. *Contra* Industry Br. 6, 17; Utility Br. 56. To the contrary, Congress understood that the term “justify” does not mean “exceed” or “outweigh,” and nothing in the Act requires EPA to “demonstrate that the dollar value of the benefits are greater (or lesser) than the dollar value of the costs.” S. Rep. No. 104-169, at 33. Even where EPA exercises its discretion under paragraph (b)(6) to promulgate less stringent Standards, the Act still does not require EPA to set those Standards at a level that provides greater benefits than costs or otherwise maximizes net benefits. *See* 42 U.S.C. § 300g-1(b)(6)(A) (stating alternative Standard must “maximize[] health risk reduction benefits at a cost that is justified by the benefits”).

In the absence of specific instructions from Congress, EPA has discretion regarding how to determine whether a Standard’s benefits justify its costs. *See Michigan v. EPA*, 576 U.S. 743, 759 (2015) (stating that where statute requires consideration of cost, it is “up to the Agency to decide (as always, within the limits of reasonable interpretation) *how* to account for cost”) (emphasis added). Where

(as here) the Court reviews EPA's cost-benefit determination for arbitrariness, the Court may not "substitute its judgment for that of the agency" and must cabin its review to whether EPA "examined the relevant data and has articulated an adequate explanation for its action." *State Farm*, 463 U.S. at 43; *Int'l Fabricare*, 972 F.2d at 389.

2. EPA Properly Based Its Determination on Both the Quantified and Nonquantifiable Costs and Benefits.

In preparing its Economic Analysis under Section 300g-1(b)(3)(C), EPA must consider all the "quantifiable and nonquantifiable" health risk-reduction benefits and costs of its Standards for which there is a "factual basis in the rulemaking record to conclude that such [benefits and costs] are likely to occur." 42 U.S.C. § 300g-1(b)(3)(C)(i)(I)-(III). Here, EPA developed a robust, well-supported Economic Analysis that assessed these factors, along with all of the other factors required under subparagraph (b)(3)(C), and determined that the benefits of the Rule's Standards justify their costs. *See* JA-[FR_32633-718].

EPA concluded that the Rule's quantified benefits alone not only justified its costs, but slightly *exceeded* them. *See* JA-[FR_32709_Tbl.68] (identifying expected total net benefits of \$760,000 annually). But as the Act requires, EPA proceeded to also consider the Rule's nonquantifiable benefits and costs. *See* JA-[FR_32715_Tbl.73] (summarizing costs and benefits EPA considered and whether each was quantified or nonquantifiable).

EPA described the nonquantifiable health benefits that were expected to result from reductions in PFOS and PFOA exposure and the record evidence supporting EPA's conclusion that they are likely to occur, including benefits associated with reductions in developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects. JA-[FR_32696-700]; *see also* JA-[FR_32543-52] (describing evidence of adverse health effects from regulated PFAS). EPA also described the nonquantifiable health benefits it expected from the Rule's reductions in Index PFAS (as well as other unregulated PFAS that would be captured by treatment technologies through co-removal), including reductions in many of the same health effects. JA-[FR_32700-02]. EPA summarized additional nonquantifiable costs associated with the Rule. JA-[FR_32713]. Finally, EPA explained how each category of nonquantifiable costs or benefits was likely to impact the Rule's overall costs and benefits. JA-[FR_32714_Tbl.72].

Notably, EPA found based on the evidence available that “the nonquantifiable human health benefits associated with reductions in drinking water PFAS exposure are substantial and may reasonably exceed the benefits the agency was able to quantify for this final rule.” JA-[Economic_Analysis_EPA-HQ-OW-2022-0114-3084_1-3]. Based on this analysis, along with EPA's consideration of costs (both quantified and nonquantifiable) and quantified benefits, EPA

reaffirmed its determination from the proposed rule that the benefits of the Rule justify its costs. JA-[FR_32716].

While Petitioners dispute several aspects of EPA's determination, many of their arguments are premised on discounting or completely ignoring the Rule's significant nonquantifiable benefits. *See, e.g.*, Industry Br. 17 (claiming Standards for Index PFAS are "not justified" based solely on net quantified benefits of those Standards). Petitioners do not dispute that EPA must account for nonquantifiable benefits in its Economic Analysis under subparagraph (b)(3)(C). *Id.* at 20. Instead, they argue that EPA was not allowed to consider any of the benefits it relied on because the term "nonquantifiable" does not include benefits that "*can* be measured but as to which the agency lacks sufficient evidence or data to make an adequately supported measurement." *Id.* at 21.

This argument fails for several reasons. As a threshold matter, Petitioners have waived this issue because they did not raise it in their comments on the proposed Rule. "It is black-letter administrative law that absent special circumstances, a party must initially present its comments to the agency during the rulemaking in order for the court to consider the issue." *Appalachian Power Co. v. EPA*, 251 F.3d 1026, 1036 (D.C. Cir. 2001) (cleaned up). By failing to raise this issue during the comment period, Petitioners denied EPA the opportunity to articulate its response in the final Rule, including by explaining in the record how a

finding that these benefits are not truly “nonquantifiable” would impact EPA’s determination of whether the Rule’s benefits justify its costs. Accordingly, Petitioners are precluded from advancing this argument here.

In any event, EPA did not err by treating benefits it was unable to quantify due to data limitations as “nonquantifiable” benefits. Petitioners’ sole support for their cramped statutory interpretation is to point out that the dictionary defines “nonquantifiable” as “not capable of being quantified.” Industry Br. 21. Even taken at face value, this argument gets Petitioners nowhere. Both the cited definition and the Act are agnostic as to the *reasons why* a “nonquantifiable” benefit might not be “capable of being quantified.” Some benefits or costs may be nonquantifiable because they “by their nature cannot be measured,” *id.*; others are not “capable of being quantified” because the information necessary to accurately quantify them simply does not exist, is inaccessible to EPA, or would be impractical to develop.

Petitioners’ definition of “nonquantifiable” costs and benefits is also inconsistent with the rest of the Act. The Economic Analysis provision requires EPA to consider all benefits and costs “for which there is a factual basis in the rulemaking record to conclude that [they] are likely to occur.” 42 U.S.C. § 300g-1(b)(3)(C)(i)(I)-(III). Many rulemakings involve benefits and costs that are expected to occur (or in some cases, are *certain* to occur), and that might

conceivably be measurable, but for which the data necessary to quantify their impacts is unavailable. Petitioners' reading of the Act would place EPA in an impossible position: it would have to either exclude these impacts from its Economic Analysis, violating its duty to consider all costs and benefits "for which there is a factual basis in the rulemaking record," *id.*; or else devote extensive time and resources to developing the information necessary to quantify these impacts, needlessly delaying its efforts to protect public health.

Congress did not require EPA to wait until it has perfect information before acting to address contaminants in drinking water. Indeed, the Act's provisions governing the Economic Analysis explicitly recognize that gaps may exist in EPA's knowledge and direct EPA to account for those gaps by considering "the quality and extent of the information" available and "the uncertainties in the analysis." 42 U.S.C. § 300g-1(b)(3)(C)(i)(VII). Likewise, the Act requires EPA to carry out its Standard-setting functions using "the best *available*, peer-reviewed science and supporting studies," not to affirmatively develop new information that is not already available. *Id.* § 300g-1(b)(3)(A) (emphasis added). This Court has generally recognized that agencies have "wide latitude in determining the extent of data-gathering necessary to solve a problem." *NRDC v. EPA*, 529 F.3d 1077, 1086 (D.C. Cir. 2008); *see Nat'l Ass'n for Surface Finishing v. EPA*, 795 F.3d 1, 12-13 (D.C. Cir. 2015) (finding EPA did not act arbitrarily by proceeding with the best

data available to it). Consistent with that precedent, the Court should not adopt an interpretation of “nonquantifiable” that would effectively freeze EPA by bogging it down in an endless cycle of data-gathering and read the term “nonquantifiable” out of the Act.

Industry Petitioners also question whether the nonquantifiable benefits EPA relied on will materialize, cherry-picking various phrases from the Rule and presenting them out of context to suggest that these benefits reflect “pure guesswork.” Industry Br. 22-23. But Petitioners do not address the extensive supporting evidence EPA gathered in the record substantiating these benefits. EPA conducted a systematic review of the scientific literature regarding the health effects of PFAS, which provided evidence linking exposure to these contaminants with a broad range of adverse health outcomes. *See* JA-[FR_32696-702] (summarizing results of literature review). This effort more than satisfied EPA’s requirement to support any nonquantifiable benefits with “a factual basis in the rulemaking record to conclude that such benefits are likely to occur.” 42 U.S.C. § 300g-1(b)(3)(C)(i)(I).

3. EPA Was Not Required to Conduct a Stand-Alone Economic Analysis for Each Individual Standard in the Rule.

EPA did not err by considering the impacts of some portions of the Rule together with one another. Industry Br. 15-18. The benefits and costs of the

Rule's various Standards are highly interrelated, and the best interpretation of the Act is one that authorizes EPA to meaningfully analyze them.

As an initial matter, EPA did not “lump[] substances together into a single cost-benefit analysis.” Industry Br. 15. EPA used contaminant-specific information to analyze the Rule's costs and benefits, permitting comparison of some Standards' incremental costs and benefits on a more granular level than for the entire Rule. For example, while EPA did not *individually* assess the costs and benefits of the Rule's Standards for PFOS and PFOA, EPA did evaluate the costs and benefits of promulgating those two Standards without the Rule's other Standards, and EPA found that their benefits justify the costs. JA-[RTC_13-513_to_13-514]; *see* JA-[FR_32710_Tbl.69] (summarizing costs and benefits of PFOS/PFOA Standards alone). EPA also evaluated the costs and benefits of adopting the PFHxS Standard on top of the PFOS and PFOA Standards, and determined that the benefits of this grouping justified the costs as well. JA-[RTC_13-514]. Finally, EPA considered the incremental impact on costs and benefits from adopting each of the other Index PFAS Standards (for PFNA, HFPO-DA, and mixtures of Index PFAS) and again found that the benefits justify costs for any grouping of these Standards and the PFOS/PFOA Standards.¹⁶ *Id.*

¹⁶ While Petitioners cite the Index PFAS Standards to illustrate how EPA's approach purportedly “obscur[ed]” some unjustified requirements, it is their own

EPA also explained in the record its reasons for evaluating the costs and benefits of the Rule's various Standards in this manner. Specifically, many characteristics of the regulated PFAS make it difficult to accurately evaluate the costs and benefits of regulating one contaminant in isolation from the others, including their tendency to co-occur, the dose-additivity of the Index PFAS, and the shared health impacts of many of these PFAS. JA-[RTC_13-513]. Notably, Standard-specific analyses would significantly overestimate the treatment costs of each Standard because they would fail to account for the cost efficiencies afforded by co-removal of the other regulated PFAS. *Id.* Finally, EPA explained that because it had already finalized a regulatory determination for PFOS and PFOA prior to this Rule, it was already obligated to promulgate Standards for those contaminants and any regulatory scenario considered in the Economic Analysis would need to account for the existence of Standards for both. *See* JA-[RTC_13-352, 13-513].

EPA's approach to evaluating the costs and benefits of the Standards promulgated in this Rule is permitted under SDWA. Nothing in the statute requires EPA to conduct a separate analysis for each individual Standard. Both subparagraph (b)(3)(C) (regarding the Economic Analysis) and subparagraph

analysis that "obscures" the true benefits of these Standards by failing to account for any nonquantifiable benefits. Industry Br. 17.

(b)(4)(C) (regarding EPA’s determination of whether benefits justify costs) speak in terms of what EPA must do when proposing a “national primary drinking water regulation.” SDWA itself recognizes that a single national primary drinking water regulation may specify Standards for multiple contaminants simultaneously. 42 U.S.C. § 300f(1) (defining term as a regulation that “specifies *contaminants* which” may have adverse health effects and specifies a Standard for “*each* such contaminant”) (emphasis added); *see* JA-[RTC_13-352] (noting PFOS/PFOA Standards are “not two ‘separate regulations’” but “two [Standards] included in one regulation”).

While subparagraphs (b)(3)(C) and (b)(4)(C) spell out the analyses EPA must conduct for “each” Standard that is contained within a national primary drinking water regulation, neither provision requires that EPA conduct those analyses in isolation for each Standard.¹⁷ Instead, EPA may “publish, seek public comment on, and use” a single Economic Analysis so long as it analyzes all seven of the statutory factors for each Standard contained within the rule. 42 U.S.C. § 300g-1(b)(3)(C)(i).

Petitioners’ alternative reading would unnecessarily constrain EPA’s discretion over how to analyze the costs and benefits of its regulations without

¹⁷ This Court has previously declined to read SDWA strictly as requiring EPA to analyze the costs and benefits of “each” Standard included in a rule. *See City of Waukesha*, 320 F.3d at 245.

promoting the Act's overall goals. For regulations like this one, in which the contaminants involved have strong co-occurrence, co-removal, dose-additivity, and shared health effects, disentangling the costs and benefits of one contaminant's Standard from another would be impractical. Moreover, it would likely yield misleading results. For example, analyzing one of the Rule's Standards in isolation would necessarily overestimate its treatment costs because it would fail to account for the sunk costs and economies of scale associated with co-treatment of that contaminant at systems that are already required to install treatment systems to address other PFAS. *See* JA-[RTC_13-513]. And because the regulated PFAS are co-removed by treatment processes, assessing benefits for each Standard separately would likely either overestimate the expected benefits (by double-counting them as attributable to each Standard) or underestimate them (by excluding benefits from co-removal), either of which would be inconsistent with Congress's desire for an accurate accounting of the Standards' benefits. *See* 42 U.S.C. § 300g-1(b)(3)(C)(i)(I)-(II). Considering the Rule's impacts in a holistic manner allows EPA to more accurately evaluate the costs and benefits to make an informed determination on whether they are justified.

4. EPA Addressed Petitioners' Specific Concerns with the Economic Analysis in the Record.

Petitioners claim that EPA failed to respond to various objections that they raised regarding the Rule's Economic Analysis. To the contrary, EPA considered

each of Petitioners' concerns and addressed each of them in the administrative record. Because EPA adequately responded to these comments, its Economic Analysis was not arbitrary or capricious.

First, EPA responded to Petitioners' comments asserting it had underestimated the costs of compliance with the Standards based on a cost modeling report (the "Black & Veatch Study"), case studies, and other information they submitted to EPA. Utility Br. 54. Regarding the use of "older studies that do not account for inflation," Utility Br. 54, EPA responded to Petitioners' comments by adjusting its cost inputs to reflect the most recent data. EPA updated its equipment costs to 2022 dollars, collected new price quotes from vendors for cost driver equipment components, and made other adjustments to its cost model. JA-[FR_32645]; JA-[RTC_13-117, 13-217].

With respect to the Black & Veatch Study, EPA provided a detailed explanation of its areas of disagreement on the methodologies and assumptions used to develop that study's cost model. JA-[FR_32642-47_Tbls._24-26]; JA-[RTC_13-119_to_13-123]. EPA identified numerous assumptions in that report regarding the systems expected to require treatment, the capital costs of treatment technology, and operation and maintenance costs that compounded to significantly overestimate the compliance costs of this Rule's Standards. Notably, when applied to the case studies submitted with Utility Petitioners' comments, the Black &

Veatch Study's model overestimated the costs 88 percent of the time. *See* JA-[FR_32645]. By contrast, when EPA compared its own cost model's results to the costs of treatment technology packages supplied by a vendor of these systems, its results generally fell within 10 percent of the vendor costs. *Id.* Petitioners fail to address any of the responses EPA provided to this study.

With respect to the case studies submitted, EPA explained that commenters did not provide sufficient information to meaningfully compare the costs in these case studies with EPA's peer-reviewed cost models. JA-[RTC_13-217]. For example, the report provided only minimal information about the systems involved and did not state which cost figures were estimates versus as-built costs; whether all of the case study costs were directly associated with PFAS treatment as opposed to other improvements; or whether the design parameters would be similar to the values used in EPA's models. *Id.*

And regarding possible increases in cost related to higher demand, Utility Br. 54, EPA responded that treatment costs are unlikely to significantly increase as a result of compliance with the Rule. JA-[RTC_13-117]. EPA explained that the Rule's two-year compliance extension, together with the availability of multiple available treatment technologies and non-treatment options for compliance, were expected to alleviate price pressure on treatment systems. *Id.*

Second, Petitioners suggest that EPA underestimated the number of systems that would be impacted by the Rule by relying solely on sampling data from the UCMR3 program, in which the reporting thresholds for PFAS were higher than the Rule's Standards. Industry Br. 19-20. But this argument is misplaced because EPA's occurrence estimates did not simply rely on UCMR3 data alone. Rather, EPA used data from UCMR3 to inform a statistically robust, peer-reviewed occurrence model, together with more recently collected data from state datasets using lower reporting thresholds. JA-[FR_32597-98]. EPA's use of this model allowed it to generate reasonable estimates of occurrence for the PFAS contaminants regulated in this Rule, including at levels below the UCMR3 reporting thresholds. *Id.*

Moreover, the preliminary results available from UCMR5 did not undermine EPA's occurrence estimates. EPA was not "obligated to use" its preliminary data gathered pursuant to UCMR5, Industry Br. 20, because that data did not represent the "best *available* public health information," JA-[FR_32601]. Indeed, the UCMR5 data was not actually "available" for use in the rulemaking at all. At the time of the Rule's promulgation, EPA had only received approximately 24 percent of the total data expected to be submitted under UCMR5, with the participating systems having varying degrees of completeness in their sample collection. *Id.*

While this preliminary data did not form the basis of this rulemaking, EPA did consider the results it had received, which confirmed EPA's conclusions based on the extensive UCMR3 and state data utilized in its occurrence modeling analyses. *Id.* The preliminary results did not suggest that EPA underestimated the number of systems that would incur compliance costs. *Contra* Industry Br. 20. While the preliminary results showed that 15.8 percent of systems reported at least one sample above the level of the Standards, these results do not represent *exceedances* of the Standards, since compliance is determined based on a running annual average. JA-[FR_32601]. Although the preliminary UCMR5 data was insufficient to actually calculate such averages, EPA observed that 9.4 percent of systems reported mean concentrations above the level of the Standards, consistent with the 6.2-10.1 percent range predicted by EPA's occurrence model. JA-[FR_32602, 32605]. And even this figure likely overestimates occurrence, since the UCMR5 results overrepresent large systems. *See* JA-[FR_32605] (estimating only 7.8 percent of systems would have mean concentrations exceeding a Standard after weighting for system size).

Third, Petitioners argue that EPA failed to account for the costs of treating HFPO-DA, PFNA, and PFBS to comply with the Standards. Industry Br. 18-19. But far from omitting these costs, EPA went out of its way to account for them in its Economic Analysis. EPA explained that it lacked sufficient nationally

representative data to precisely estimate the occurrence of these three contaminants and, thus, to estimate the number of systems that would incur costs to comply with the Standards applicable to them. *See* JA-[FR_32533]. Nevertheless, EPA accounted for the costs of treating HFPO-DA, PFNA, and PFBS as nonquantifiable costs in its Economic Analysis, as required by Section 300g-1(b)(3)(C)(i)(III). JA-[FR_32671-72]. And to better understand the potential impact of these costs, EPA performed a quantitative sensitivity analysis to estimate the impact that treating these contaminants might have on the Rule's overall costs. JA-[FR_32533]; JA-[Economic_Analysis_App'x_EPA-HQ-OW-2022-0114-3085_N.3-N.4]. This sensitivity analysis indicated that the costs of treating these contaminants would likely increase the national cost impacts by \$82.4 million, or approximately 5 percent of the Rule's overall quantified costs. JA-[FR_32672].

Petitioners appear to believe that EPA cannot possibly have considered these costs because if it had, EPA would have had to reject the Standards applicable to these contaminants as unjustified. But Petitioners yet again fail to consider the significant nonquantifiable benefits associated with reductions in HFPO-DA, PFNA, and PFBS, which SDWA requires EPA to account for in its Economic Analysis. *See* JA-[FR_32700] (summarizing nonquantifiable benefits).

V. None of Petitioners' Arguments Warrant Vacatur of the Entire Rule.

Setting aside the substantive and procedural defects in Petitioners' arguments, the relief they request—vacatur of the Rule in its entirety—far exceeds the scope of any argument they present. Utility Br. 57; Industry Br. 60. In the event that the Court concludes any of Petitioners' arguments have merit, any relief should be limited to the specific provisions of the Rule for which the Court finds error.

EPA finalized several distinct actions in this Rule, including: a regulatory determination for mixtures of Index PFAS; individual regulatory determinations for three of those Index PFAS (PFHxS, PFNA, and HFPO-DA); Goals for PFOS, PFOA, PFHxS, PFNA, HFPO-DA, and mixtures of the Index PFAS; and Standards for those same contaminants. JA-[FR_32532]. EPA's actions for each contaminant are independent of one another and can be implemented on their own. JA-[FR_32731-32]. Accordingly, a finding that EPA erred in addressing one of these contaminants cannot support vacatur of EPA's actions for the other contaminants. Likewise, EPA's actions at the various steps of the regulatory process are severable. For example, a finding that EPA erred in setting the Standard for a contaminant (*e.g.*, by selecting a level that is not feasible) cannot justify vacatur of the Goal or the regulatory determination for that contaminant. JA-[FR_31732].

Each of Petitioners' arguments focuses on individual provisions of the Rule; nowhere in their briefs do Petitioners raise any global issue that might affect the validity of the Rule as a whole. Indeed, no Petitioner has articulated any challenge to EPA's regulatory determinations for PFOS and PFOA or its Goals for those contaminants. Thus, Petitioners cannot justify vacatur of the entire Rule.

Petitioners' arguments regarding the Rule's analysis of costs and benefits are no exception. *See* Industry Br. 15. Even if the Court finds EPA's Economic Analysis was arbitrary and capricious, any error in that analysis cannot possibly justify vacatur of those portions of the Rule that, under the statutory text, are not based on consideration of cost. In particular, because the Economic Analysis under Section 300g-1(b)(3)(C) plays no role in the regulatory determination or the Goal for a contaminant, any defects in that analysis would not provide grounds for the Court to vacate *those* portions of the Rule. *See* 42 U.S.C. § 300g-1(b)(1).

And in any event, even where the benefits of a Standard set at the feasible level do not justify its costs, the Act grants EPA *discretionary* authority either to promulgate a less stringent alternative Standard or proceed with setting a Standard at the feasible level. *Id.* § 300g-1(b)(6). Thus, on remand from a decision of this Court reversing EPA's determination that the Rule's benefits justify its costs, EPA could simply decide in its discretion to retain some or all of the Rule's Standards at their current levels. Given that reasonable possibility, it would be unnecessarily

disruptive to vacate those Standards in the interim. *See Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993).

CONCLUSION

The Court should deny the petitions for review.

Respectfully submitted,

Dated: December 23, 2024

TODD KIM
Assistant Attorney General

Of Counsel:
HEIDI NALVEN
U.S. Environmental Protection
Agency
Office of General Counsel

/s/ Kimere J. Kimball
KIMERE J. KIMBALL
ANDREW D. KNUDSEN
U.S. Department of Justice
Env't & Natural Resources Div.
P.O. Box 7611
Washington, DC 20044
(202) 514-2285 (Kimball)
(202) 353-7466 (Knudsen)
Kimere.Kimball@usdoj.gov
Andrew.Knudsen@usdoj.gov

Counsel for Respondents

CERTIFICATES OF COMPLIANCE AND SERVICE

I certify that this document complies with Fed. R. App. P. 32(a)(5) and (6) because it uses 14-point Times New Roman, a proportionally spaced font, with 1-inch margins.

I also certify that this document complies with Fed. R. App. P. 32(a)(7)(B)(i) and the Court's Briefing Order (ECF No. 2072754) because according to Microsoft Word's count, it has 25,699 words, excluding the parts of exempted under Fed. R. App. P. 32(f) and D.C. Cir. R. 32(e)(1).

Finally, I certify that on December 23, 2024, I electronically filed this document with the Court's CM/ECF system, which will serve each party's counsel of record.

/s/ Kimere J. Kimball
KIMERE J. KIMBALL

EXHIBIT C

ORAL ARGUMENT NOT YET SCHEDULED

Case No. 24-1188 and Consolidated Cases

**IN THE UNITED STATES COURT OF APPEALS
FOR THE D.C. CIRCUIT**

AMERICAN WATER WORKS ASSOCIATION, ET AL.,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, ET AL.,
Respondents.

On Petition for Review of Actions by Environmental Protection Agency

RESPONDENTS' MOTION FOR PARTIAL VACATUR

Dated: September 11, 2025

ADAM R.F. GUSTAFSON
Acting Assistant Attorney General

Of Counsel:

HEIDI NALVEN

U.S. Environmental Protection
Agency
Office of General Counsel

ROBERT STANDER
Deputy Assistant Attorney General

KIMERE J. KIMBALL
Trial Attorney

U.S. Department of Justice
P.O. Box 7611
Washington, DC 20044
(202) 514-2285
Kimere.Kimball@usdoj.gov

Counsel for Respondents

TABLE OF CONTENTS

TABLE OF CONTENTS.....	i
TABLE OF AUTHORITIES	ii
INTRODUCTION	1
BACKGROUND	3
A. Statutory Background.....	3
B. Administrative Procedural Background.....	6
C. Litigation Procedural Background	7
STANDARD OF REVIEW	9
ARGUMENT	10
I. EPA Lacks Statutory Authority to Propose a National Primary Drinking Water Regulation for a Contaminant Simultaneously with a Preliminary Regulatory Determination of that Contaminant.....	10
II. EPA Waives the Harmless Error Defense.....	16
III. In the Alternative, the Error Was Not Harmless as to the Goals and Standards.....	17
IV. Vacatur of the Regulatory Determinations and Regulations for PFNA, PFHxS, HFPO-DA, and the Index PFAS Is Appropriate.	20
CONCLUSION.....	22
CERTIFICATE OF COMPLIANCE.....	23

TABLE OF AUTHORITIES

Cases

Agnew v. Gov’t of Dist. of Columbia,
 920 F.3d 49 (D.C. Cir. 2019)15

Allied–Signal, Inc. v. Nuclear Regulatory Commission,
 988 F.2d 146 (D.C. Cir. 1993) 20, 21

Am. Water Works Ass’n v. EPA,
 40 F.3d 1266 (D.C. Cir. 1994)20

Arej v. Sessions,
 852 F.3d 665 (7th Cir. 2017)16

Chlorine Chemistry Council v. EPA,
 206 F.3d 1286 (D.C. Cir. 2000)9

City of Waukesha v. EPA,
 320 F.3d 228 (D.C. Cir. 2003) 9, 19

Clark v. Martinez,
 543 U.S. 371 (2005)12

Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.,
 603 U.S. 799 (2024)12

Int’l Fabricare Inst. v. EPA,
 972 F.2d 3849

Keck v. O’Malley,
 No. 22-1716, 2024 WL 3935441 (7th Cir. Aug. 26, 2024)17

Keller v. Berryhill,
 754 F. App’x 193 (4th Cir. Nov. 29, 2018)17

Loper Bright Enters. v. Raimondo,
 603 U.S. 369 (2024) 9, 10

McLouth Steel Prods. Corp. v. Thomas,
 838 F.2d 1317 (D.C. Cir. 1988)17

NASDAQ Stock Market LLC v. SEC,
961 F.3d 421 (D.C. Cir. 2020)15

Nat. Res. Def. Council v. EPA,
67 F.4th 397 (D.C. Cir. 2023) 4, 20

Rudisill v. McDonough,
601 U.S. 294 (2024).....14

Sprint Corp. v. FCC,
315 F.3d 369 (D.C. Cir. 2003)17

Standing Rock Sioux Tribe v. U.S. Army Corps of Eng'rs,
985 F.3d 1032 (D.C. Cir. 2021)20

Sugar Cane Growers Co-op. of Fla. v. Veneman,
289 F.3d 89 (D.C. Cir. 2002)19

U.S. Sugar Corp. v. EPA,
113 F.4th 984 (D.C. Cir. 2024).....9

Wash. Post v. Wash.-Balt Newspaper Guild,
787 F.2d 604 (D.C. Cir. 1986)11

Statutes

5 U.S.C. § 706(2)(A).....9

42 U.S.C. § 300g-1(a)(3)5, 6

42 U.S.C. § 300g-1(b)(1)(A).....4, 5

42 U.S.C. § 300g-1(b)(1)(B).....12

42 U.S.C. § 300g-1(b)(1)(B)(i).....4

42 U.S.C. § 300g-1(b)(1)(B)(i)(I)5

42 U.S.C. § 300g-1(b)(1)(B)(ii) 2, 4, 11, 12, 16

42 U.S.C. § 300g-1(b)(1)(B)(ii)(I)..... 4, 11, 13

42 U.S.C. § 300g-1(b)(1)(B)(ii)(II).....13

42 U.S.C. § 300g-1(b)(1)(B)(ii)(III) 4, 13
42 U.S.C. § 300g-1(b)(1)(B)(ii)(IV)13
42 U.S.C. § 300g-1(b)(1)(B)(iii) 2, 13, 14, 16
42 U.S.C. § 300g-1(b)(1)(E) 2, 5, 6, 10, 11, 12, 13, 14, 15, 18
42 U.S.C. § 300g-1(b)(3)(C)16
42 U.S.C. § 300g-1(b)(4)(A)5
42 U.S.C. § 300g-1(b)(4)(B)5
42 U.S.C. § 300g-1(b)(6)(A)16
42 U.S.C. § 300g-1(b)(9)21
42 U.S.C. § 300g-1(d)5
42 U.S.C. § 300g-1(e) 5, 16

Regulations

40 C.F.R. § 141.902(b)(1)(xi)21

Federal Register

74 Fed. Reg. 51850 (Oct. 8, 2009)6
81 Fed. Reg. 81099 (Nov. 17, 2016)6
85 Fed. Reg. 14098 (Mar. 10, 2020)6
86 Fed. Reg. 12272 (Mar. 3, 2021)6
87 Fed. Reg. 68060 (Nov. 14, 2022)6
88 Fed. Reg. 18638 (Mar. 29, 2023)6, 7
89 Fed. Reg. 32532 (Apr. 26, 2024)7

INTRODUCTION

Last year, the U.S. Environmental Protection Agency (EPA) issued a rule under the Safe Drinking Water Act regulating six per- and polyfluoroalkyl substances (PFAS) as drinking water contaminants for the first time. “PFAS National Primary Drinking Water Regulation,” 89 Fed. Reg. 32532 (Apr. 26, 2024). EPA initially attempted to defend the Rule against forceful legal challenges raised in these petitions for review. Now, after further reviewing the statute pursuant to a publicly announced reconsideration process, EPA agrees with petitioners that parts of the rulemaking process were unlawful and parts of the Rule are thus invalid.

Consequently, EPA respectfully moves for partial vacatur of the Rule. First, EPA requests vacatur of its determination to regulate three PFAS individually—perfluorononanoic acid (PFNA), perfluorohexane sulfonic acid (PFHxS), and hexafluoropropylene oxide dimer acid (HFPO-DA)—and to regulate mixtures of those three PFAS and a fourth PFAS, perfluorobutane sulfonic acid (PFBS), through a “hazard index” (collectively, the Index PFAS). Second, EPA requests vacatur of the Maximum Contaminant Level Goals (Goals) and Maximum Contaminant Levels (Standards) EPA set for those PFAS. As explained below, EPA does not seek vacatur of, and intends to defend, the portions of the Rule governing perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid

(PFOS) because the Agency's actions for those contaminants—in contrast to actions related to the Index PFAS—adhered to the statute's requirements.

The Act requires EPA to publish and seek comment on a preliminary regulatory determination for a contaminant *before* it may propose a national primary drinking water regulation that sets Goals and Standards for that contaminant. 42 U.S.C. § 300g-1(b)(1)(B)(ii), (iii). The Act further requires EPA to take final action on the preliminary regulatory determination before or at the same time as proposing the national primary drinking water regulation. *Id.* § 300g-1(b)(1)(E). For PFOA and PFOS, EPA followed the statutorily prescribed sequencing by proposing and finalizing a regulatory determination through notice and comment before proposing and finalizing a regulation through a further round of notice and comment. For the Index PFAS, however, EPA departed from the statutory scheme by proposing and finalizing a regulatory determination and regulation simultaneously and in tandem. Upon review, EPA acknowledges that its prior reading of the Act as authorizing such simultaneous promulgation, and defense of the Rule on this basis before this Court, were in error. EPA further acknowledges that this error denied the public and the regulated community the opportunity to adequately comment on and participate in the rulemaking process for the Index PFAS Goals and Standards with the benefit of the finalized regulatory determinations.

EPA has announced its plan to reconsider the regulatory determinations, Goals, and Standards for PFNA, PFHxS, HFPO-DA, and the Index PFAS, and thus seeks partial vacatur of the Rule to facilitate prompt judicial resolution of an important legal question that will affect its rulemaking. Prompt resolution is preferable to holding the case in abeyance. The key disputed issue is a pure question of law that can be resolved immediately, and finalizing a potential new rule under the cloud of a disputed legal issue would only lead to more litigation, burdening the Agency and this Court with needless additional proceedings.

Counsel for EPA has conferred with Counsel for all Petitioners and Respondent-Intervenors. Petitioners consent to this motion. Respondent-Intervenors oppose the motion and intend to file a response.

BACKGROUND

A. Statutory Background

The Safe Drinking Water Act authorizes EPA to evaluate drinking water contaminants and promulgate national primary drinking water regulations, which specify enforceable standards limiting contaminants in public water systems. As amended in 1996, the statute requires the Agency to take specific actions in a particular sequence meant to identify the universe of possible contaminants, select contaminants for regulation, and determine how to regulate the selected

contaminants. *See Nat. Res. Def. Council v. EPA*, 67 F.4th 397, 399 (D.C. Cir. 2023).

EPA must issue and regularly update a contaminant candidate list naming contaminants that are not yet regulated but occur or are anticipated to occur in public water systems. 42 U.S.C. § 300g-1(b)(1)(B)(i). EPA must determine whether to regulate at least five contaminants on the list every five years, although it may also propose to regulate a contaminant not included on the list when appropriate. *Id.* § 300g-1(b)(1)(B)(ii)(I), (III).

Next, the Act provides a specific process by which EPA can determine to regulate a new contaminant. *Id.* § 300g-1(b)(1)(B)(ii)(III). EPA must publish a preliminary determination and provide an opportunity for public comment before making its determination to regulate the contaminant. *Id.* § 300g-1(b)(1)(B)(ii), (iii). When making its final regulatory determination, EPA must determine that (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).

Finally, for each contaminant EPA decides to regulate, it must propose a Goal and a proposed national primary drinking water regulation that includes an appropriate Standard. *Id.* § 300g-1(a)(3), (b)(1)(A), (d). Goals are non-enforceable public health goals set at the level below which “no known or anticipated adverse effects” occur with an “adequate margin of safety.” *Id.* § 300g-1(b)(4)(A). The Standard generally must be set “as close to the [Goal] as is feasible.” *Id.* § 300g-1(b)(4)(B).¹

The Act imposes express limits on the sequencing of and deadlines for EPA’s regulatory determination and standard-setting processes. It states that EPA: “shall propose the [Goal] and national primary drinking water regulation [setting the Standard] for a contaminant not later than 24 months after the determination to regulate . . . , and may publish such *proposed* regulation concurrent with the determination to regulate.” *Id.* § 300g-1(b)(1)(E) (emphasis added). The Act thus requires, in addition to the iterative listing of candidate contaminants, sequencing: (1) a preliminary regulatory determination, a public comment period, and a final regulatory determination; and (2) a proposed substantive regulation no earlier than the *final* regulatory determination, a second public comment period, and then a final regulation. *Id.*

¹ The Act also requires EPA to consult with various federal entities and the Scientific Advisory Board at specific stages of the regulatory sequence. 42 U.S.C. § 300g-1(b)(1)(B)(i)(I), (d), (e).

B. Administrative Procedural Background

In 2020, EPA published in the Federal Register a preliminary determination to regulate PFOA and PFOS—both of which had previously been included on the contaminant candidate list—and solicited public comment. 85 Fed. Reg. 14098 (Mar. 10, 2020); 74 Fed. Reg. 51850 (Oct. 8, 2009); 81 Fed. Reg. 81099 (Nov. 17, 2016); 87 Fed. Reg. 68060 (Nov. 14, 2022). In March 2021, EPA published its final determination to regulate those chemicals. 86 Fed. Reg. 12272 (Mar. 3, 2021). This triggered the 24-month deadline for EPA to propose Goals and Standards for PFOA and PFOS. 42 U.S.C. § 300g-1(a)(3), (b)(1)(E).

In March 2023, EPA proposed the Rule challenged here. 88 Fed. Reg. 18638 (Mar. 29, 2023). This proposal included proposed Goals and Standards for PFOA and PFOS. *Id.* at 18666-68. At the same time, however, the proposed rule also introduced the Index PFAS into the rulemaking for the first time. In relevant part, the proposed rule included: (1) a preliminary determination to regulate the four Index PFAS both individually and as a mixture and (2) a proposed Goal and Standard applicable to the four Index PFAS as both a mixture and individually, using the hazard index approach. *Id.* at 18645-52, 18668-81, 18729-31. A hazard index is a mathematical formula used to account for the dose-additive effect of mixtures of contaminants with different toxicities where the mixtures may have

differing combinations of the contaminants and at differing concentrations. *Id.* at 18639.

In April 2024, EPA finalized the Rule challenged here. 89 Fed. Reg. 32532 (Apr. 2024). In the final Rule, EPA finalized the Goals and Standards for PFOA and PFOS. *Id.* at 32567, 32577. EPA also finalized individual regulatory determinations for three of the four Index PFAS—PFNA, PFHxS, and HFPO-DA—but not for PFBS. *Id.* at 32563. EPA finalized its regulatory determination for mixtures of all four Index PFAS (including PFBS). *Id.* at 32562-63. EPA also simultaneously finalized Goals and Standards for PFNA, PFHxS, and HFPO-DA individually and (together with PFBS) for the four Index PFAS collectively as mixtures using a hazard index approach. *Id.* at 32571-73.

C. Litigation Procedural Background

In June 2024, Petitioners timely filed petitions for review of the Rule. ECF 2058535; ECF 2058848; ECF 2059361. On October 7, 2024, Petitioners filed their opening merits briefs, challenging EPA's final Goals and Standards for PFOA and PFOS, EPA's final regulatory determinations for PFNA, PFHxS, and HFPO-DA individually and the Index PFAS as a mixture, and EPA's final Goals and Standards for PFNA, PFHxS, and HFPO-DA individually and the Index PFAS as a mixture. ECF 2078734; ECF 2078731. EPA filed its combined response brief on December 23, 2024, defending all challenged portions of the Rule. ECF 2091318.

Respondent-Intervenors filed their brief on January 17, 2025, also defending the challenged portions of the Rule. ECF 2094834.

On January 20, 2025, a new Administration took office. On February 7, 2025, before Petitioners filed their reply briefs, EPA moved to put this matter in abeyance to allow the new Administration to consider the Rule. ECF 2099439. In May 2025, EPA announced that it intended to keep the current standards for PFOA and PFOS in place, adjust certain compliance deadlines, and intended to “reconsider the regulatory determinations for PFHxS, PFNA, HFPO-DA (commonly known as GenX), and the Hazard Index mixture of these three plus PFBS to ensure that the determinations and any resulting drinking water regulation follow the legal process laid out in the Safe Drinking Water Act.” May 14, 2025, EPA Press Release (available at: <https://www.epa.gov/newsreleases/epa-announces-it-will-keep-maximum-contaminant-levels-pfoa-pfos>). EPA has now determined that its decision to publish and seek comment on its proposed Goals and Standards for the Index PFAS (individually and as a mixture) simultaneously with EPA’s *preliminary* regulatory determination for those contaminants was inconsistent with the statute, and EPA no longer seeks to defend the relevant portions of the Rule and associated regulatory determinations on this basis. Ex. 1 (Browne Decl.).

STANDARD OF REVIEW

In reviewing EPA's actions under the Act, this Court follows the Administrative Procedure Act's standard of review. *City of Waukesha v. EPA*, 320 F.3d 228, 247 (D.C. Cir. 2003). Under that standard, the Court evaluates whether EPA's action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992) (quoting 5 U.S.C. § 706(2)(A)). The Court reviews questions of statutory interpretation de novo. *U.S. Sugar Corp. v. EPA*, 113 F.4th 984, 991 (D.C. Cir. 2024). In deciding questions of statutory interpretation, "[c]ourts must exercise their independent judgment" to determine the "single, best meaning" of the statute, but "[c]areful attention to the judgment of the Executive Branch may help inform that inquiry." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412-13 (2024).

Where this Court has found EPA's rules to be unlawful under the Act, it has vacated the relevant portions of the rulemaking. *See, e.g., Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1291 (D.C. Cir. 2000) (vacating EPA's Goal for chloroform because it was "arbitrary and capricious and in excess of statutory authority").

ARGUMENT

I. EPA Lacks Statutory Authority to Propose a National Primary Drinking Water Regulation for a Contaminant Simultaneously with a Preliminary Regulatory Determination of that Contaminant.

The Safe Drinking Water Act specifically requires the Agency to take a seriatim approach to regulation in which the Agency must first propose to regulate a particular drinking water contaminant and seek public comment on whether regulation is appropriate. 42 U.S.C. § 300g-1(b)(1)(E). Only *after* the public has had the opportunity to comment on that proposal and when EPA has finalized a determination to regulate may EPA publish a proposed regulation of that contaminant, either simultaneously with the final regulatory determination or after that final determination. *Id.*

Thus, the Act specifically requires two sequential public comment periods before a national primary drinking water regulation may be finalized. In the challenged actions, EPA interpreted the statute for the first time as authorizing the Agency to simultaneously publish a preliminary regulatory determination and a proposed regulation for public comment, and to simultaneously publish a final regulatory determination with a final regulation. *See* EPA Brief (ECF 2091318) at 29-37. EPA now acknowledges this reading was in error and inconsistent with the “single, best meaning” of the statute as informed by “all relevant interpretive tools.” *Loper Bright*, 603 U.S. at 400.

“The starting point for all questions of statutory interpretation is, of course, the plain language of the provisions at issue.” *Wash. Post v. Wash.-Balt. Newspaper Guild*, 787 F.2d 604, 606 (D.C. Cir. 1986). Here, the statute states that EPA “shall propose the [Goal] and [Standard] for a contaminant not later than 24 months after the determination to regulate under subparagraph (B), and may publish such *proposed* regulation concurrent with the determination to regulate.” 42 U.S.C. § 300g-1(b)(1)(E) (emphasis added). The best reading of this provision is that the soonest EPA may publish a proposed regulation is with the *final* regulatory determination, not with the preliminary regulation.

Significantly, “determination to regulate” appears twice in this statutory provision. The first occurrence explicitly cross-references “the determination to regulate under subparagraph (B)” of section 300g-1. Subparagraph (B) indisputably sets forth the specific steps EPA must take when issuing the *final* “determination to regulate.” *Id.* § 300g-1(b)(1)(B)(ii); *see* EPA Brief (ECF 2091318) at 30. One of the intermediate steps subparagraph (B) identifies in the progression to the “determination to regulate” is providing “notice of the *preliminary* determination and opportunity for public comment” 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I) (emphasis added). Because the reference to the “preliminary determination” is a step necessary to the “determination to regulate,” the only valid

reading of “the determination to regulate under subparagraph (B)” is that it is the final determination.

In its second usage of “determination to regulate” in the Act’s provision sequencing the regulatory determination and the regulation, the statute provides that EPA “may publish [a] proposed regulation concurrent with the determination to regulate.” *Id.* § 300g-1(b)(1)(E). Despite no meaningful distinction in the language between the two clauses, EPA previously argued that this second usage of “determination to regulate” refers to a preliminary regulatory determination rather than a final regulatory determination. EPA Brief (ECF 2091318) at 30. EPA now acknowledges that the best reading of the statute is one in which this same phrase is given the same meaning throughout the statutory provision. *See, e.g., Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 821-22 (2024) (rejecting the argument that “the same words . . . *in a single statute* should mean different things in different contexts” (emphasis in original)); *Clark v. Martinez*, 543 U.S. 371, 378 (2005) (“To give these same words a different meaning for each category would be to invent a statute rather than interpret one.”).

Critically, the statute uses the precise term “determination to regulate” *only* to refer to the final determination. *See, e.g.,* 42 U.S.C. § 300g-1(b)(1)(B)(ii), (b)(1)(E). The statute only refers to “determination to regulate” in subsections 300g-1(b)(1)(B) when outlining the steps necessary for the final regulatory

determination and in subsection 300g-1(b)(1)(E) when setting forth the sequencing of the final regulatory determination and the regulation.

Subsection 300g-1(b)(1)(B)(ii)(I) states that, after receiving public comments, EPA shall make “determinations of whether or not to regulate [particular] contaminants.” Because these determinations are made after notice and comment are completed, it is clear from the context that determinations referred to here are final determinations, though they may be determinations either for or against regulation. Subsection 300g-1(b)(1)(B)(ii)(II) and (III) then use the term “determination to regulate a contaminant” to refer to a final determination—not a preliminary determination—that the statutory criteria are satisfied and that regulation is warranted. Finally, subsection 300g-1(b)(1)(B)(ii)(IV) states that “[a] determination under this clause not to regulate a [particular] contaminant shall be considered final agency action and subject to judicial review.” That provision, too, refers to a final determination, made after the Agency has considered public comments, that a particular contaminant should *not* be regulated.

Although EPA previously argued that the statute’s use of the term “determination” to refer to a preliminary determination elsewhere in the statute demonstrates that second usage of “determination” in subsection 300g-1(b)(1)(E) could refer to a preliminary determination, EPA Brief (ECF 2091318) at 30 (citing 42 U.S.C. § 300g-1(b)(1)(B)(iii)), upon further analysis EPA acknowledges the

context of that provision obviates the need for the word “preliminary.” Because § 300g-1(b)(1)(B)(iii) specifically addresses the requirement for public comment on “the determination,” the context makes clear that it refers to a preliminary determination without requiring the specific term “preliminary.” Moreover, this provision refers to a “determination” put out for public comment; it does not use the specific term “determination to regulate” at issue subsection 300g-1(b)(1)(E).

In short, although section 300g-1 sometimes uses the term “determination” to refer to a preliminary determination, it uses the specific phrase “determination to regulate” (as well as the phrase “determination under this clause not to regulate” and the umbrella phrase “determinations of whether or not to regulate”) only to refer to the final determinations that EPA makes after completing notice and comment on the preliminary determination. Because courts “generally presume differences in language . . . convey differences in meaning,” *Rudisill v. McDonough*, 601 U.S. 294, 308 (2024), Congress’s specific use of “determination to regulate” should be construed to refer to the final determination to regulate here.

Upon further analysis, EPA’s prior argument relying on the term “publish” to interpret the second usage of “determination to regulate” in subsection 300g-1(b)(1)(E) as a preliminary determination was similarly erroneous. *See* EPA Br. (ECF 2091318) at 31. Nothing in the text of the Act suggests that final regulatory

determinations do not need to be “publish[ed],” and thus nothing suggests that this verb may *only* be used in relation to preliminary regulatory determinations.

Additionally, further careful analysis of this subsection demonstrates that reading the second usage of “determination to regulate” as the *final* determination is the only reading that gives independent meaning to this phrase when considered as part of subsection 300g-1(b)(1)(E) as a whole. *Agnew v. Gov’t of Dist. of Columbia*, 920 F.3d 49, 57 (D.C. Cir. 2019) (“a statute [should] not be interpreted in a way that renders any part of it superfluous”); *NASDAQ Stock Market LLC v. SEC*, 961 F.3d 421, 426 (D.C. Cir. 2020) (explaining a “statutory interpretation must account for both the specific context in which the language is used and the broader context of the statute as a whole” (internal quotations omitted)); *contra* EPA Brief (ECF 2091318) at 31-32. The best reading of subsection 300g-1(b)(1)(E) demonstrates that it provides a very specific window in which a regulation may be proposed. The first usage of subsection 300g-1(b)(1)(E) provides that the *latest* EPA can propose a regulation is 24 months after a final regulatory determination. The second usage provides that the *earliest* EPA can propose a regulation is concurrent with a final regulatory determination. Put differently, the statute provides that EPA has exactly 24 months to propose a regulation starting from the date the final regulatory determination is published. EPA’s prior reading failed to give full effect to this statutorily prescribed window.

Finally, reading both the first and second usages of “determination to regulate” as referring to the final regulatory determination effectuates Congress’s goal in the 1996 amendments to the Act. *Contra* EPA Brief (ECF 2091318) at 33. This reading maintains EPA’s deadline to propose a regulation within 24 months of the final regulatory determination, while also maintaining Congress’s commitment to ensuring EPA’s ultimate regulation benefits from substantial and varied external input. *See, e.g.*, 42 U.S.C. § 300g-1(b)(1)(B)(ii), (b)(1)(B)(iii), (b)(3)(C), (b)(6)(A), (e). Thus, the provision accelerates the rulemaking process while ensuring that the resulting regulation affords the public and regulated entities multiple rounds of opportunity to inform its analysis and contents.

Accordingly, EPA acknowledges that it misread the statute when interpreting it as allowing EPA to publish a final regulatory determination concurrently with a final regulation. EPA further acknowledges that it erred when it published the final regulatory determinations concurrently with the final regulation setting the Goals and Standards for PFNA, PFHxS, and HFPO-DA individually, and the four Index PFAS as a mixture.

II. EPA Waives the Harmless Error Defense.

Harmless error is a waivable defense. *See, e.g., Arej v. Sessions*, 852 F.3d 665, 669 (7th Cir. 2017) (Sykes, J. concurring) (noting government waived harmless error defense in petition for review of immigration removal decision);

Keller v. Berryhill, 754 F. App'x 193, 199 (4th Cir. Nov. 29, 2018) (holding Social Security Administration waived harmless-error defense by failing to raise it in appeal); *Keck v. O'Malley*, No. 22-1716, 2024 WL 3935441, at *4 (7th Cir. Aug. 26, 2024) (Kirsch, J. concurring) (same). EPA withdraws the portion of its opening brief in which it asserted the harmless error defense for both the final regulatory determination and the Goals and Standards for PFNA, PFHxS, and HFPO-DA individually and the Index PFAS. *See* EPA Brief (ECF 2091318) at 36-38. Because EPA has waived this defense, the Court should vacate both the regulatory determination and the Goals and Standards for these PFAS.

III. In the Alternative, the Error Was Not Harmless as to the Goals and Standards.

Contrary to its original position, EPA now recognizes that its publication of the final regulation concurrently with the final Goals and Standards for PFNA, PFHxS, and HFPO-DA individually and the Index PFAS as a mixture was not harmless. The burden to demonstrate harm in this context is low. *See Sprint Corp. v. FCC*, 315 F.3d 369, 377 (D.C. Cir. 2003) (holding that “a showing of actual prejudice [was] not required under the prejudicial error rule” when the agency had “failed to issue a new NPRM to afford proper notice and opportunity for comment”); *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1324 (D.C. Cir. 1988) (placing burden to establish prejudice on petitioner is inappropriate

when the agency “completely failed” to comply with relevant procedural requirements).

Here, EPA did solicit public comments on the proposed regulatory determinations, and on the proposed Goals and Standards. But the statute specifically requires EPA to afford the public two *sequential* opportunities to comment: first on whether or not to regulate a contaminant and then, once the public knows the basis and outcome of the final regulatory determination, on the proposed regulation. 42 U.S.C. § 300g-1(b)(1)(E). EPA both entirely failed to provide the public with the separate, sequential public comment period for the Goals and Standards, and failed to allow the public to comment on the proposed Goals and Standards with the benefit of the outcome and basis for the final regulatory determination.

Notably, the preliminary and final regulatory determinations were markedly different. The preliminary determination proposed to regulate all four Index PFAS—PFNA, PFHxS, HFPO-DA, *and* PFBS—as mixtures and, because the mixture in the proposal could contain only one contaminant, also individually. 88 Fed. Reg. at 18638, 18668, 18671. The final regulatory determination, however, only determined to regulate three of the Index PFAS—PFNA, PFHxS, and HFPO-DA—individually, but still determined to regulate mixtures of PFNA, PFHxS, HFPO-DA, *and* PFBS. In so doing, EPA deprived the public of an adequate

opportunity to comment on the Goals and regulations setting the Standards with the statutorily mandated benefit of the final regulatory determination.

There are any number of ways the public could have commented on the proposed regulation had they had full knowledge of the regulatory determination at the appropriate time, and EPA cannot speculate as to the full extent of the harm this error has caused. *See, e.g., City of Waukesha*, 320 F.3d at 246 (petitioners need not always show “what additional comments they would have submitted had notice been adequate” in order to establish prejudice); *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002) (petitioners “need not . . . indicate[] additional considerations they would have raised in a comment procedure”).

Had EPA finalized the regulatory determinations for mixtures of the Index PFAS before or concurrent with issuance of proposed Goals and Standards, then the public’s comments on the proposed rule could have accounted for the Agency’s decision to regulate PFBS as part of mixture but not individually. Because of this error, the public lacked the opportunity to comment on EPA’s proposal with the certainty of the final regulatory determinations. Accordingly, this error fatally infected the Goals and Standards for PFNA, PFHxS, HFPO-DA, and the Index PFAS.

IV. Vacatur of the Regulatory Determinations and Regulations for PFNA, PFHxS, HFPO-DA, and the Index PFAS Is Appropriate.

In reviewing whether to vacate a rule under the Safe Drinking Water Act, this Court applies the two-part test set forth in *Allied-Signal, Inc. v. Nuclear Regulatory Commission*, 988 F.2d 146, 150-51 (D.C. Cir. 1993). *See Am. Water Works Ass'n v. EPA*, 40 F.3d 1266, 1273 (D.C. Cir. 1994). “The decision whether to vacate depends on ‘the seriousness of the order’s deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed.’” *Allied-Signal*, 988 F.2d at 150-51 (internal quotations omitted).

The first *Allied Signal* prong, concerned with the seriousness of the alleged agency error, weighs the extent to which the agency can correct the error on remand. *See Standing Rock Sioux Tribe v. U.S. Army Corps of Eng’rs*, 985 F.3d 1032, 1051 (D.C. Cir. 2021). Here, where the Agency must essentially restart the regulatory process, including taking two new rounds of public comment and considering those comments, the “extent of doubt whether the agency chose correctly” is substantial. *Allied-Signal*, 988 F.2d at 150-51.

Additionally, leaving the Rule in place could actually inhibit EPA from meaningfully considering public comment and addressing that comment in a new rule. Pursuant to this Court’s precedent, EPA cannot rescind a regulatory determination based on additional data or analysis. *Nat. Res. Def. Council*, 67

F.4th at 405. Moreover, it cannot revise a regulation without “maintain[ing], or provid[ing] for greater, protection of the health of persons.” 42 U.S.C. § 300g-1(b)(9). This is particularly problematic where the public lost first the opportunity to focus exclusively on whether or not EPA should regulate the Index PFAS (individually and/or as a mixture), and then a second, subsequent opportunity to separately focus exclusively on the manner in which EPA should regulate the Index PFAS (individually and/or as a mixture). Moreover, the public did not have the opportunity to comment on the Goals and Standards for PFNA, PFHxS, HFPO-DA, or the Index PFAS as a mixture with the certainty of final regulatory determinations. The public should have the benefit of these comment periods and EPA should be able to consider all public comments to assess whether to make a new regulatory determination and, if necessary, set the Goals and Standards appropriately.

The second prong—the potentially disruptive effects of vacatur—similarly weigh in favor of vacatur. Here, vacatur of the regulatory determinations and the Goals and Standards for PFNA, PFHxS, HFPO-DA, and the Index PFAS would not cause “the disruptive consequences of an interim change that may itself be changed.” *Allied-Signal*, 988 F.2d at 150-51. The first deadline (an initial monitoring deadline) for these contaminants is April 26, 2027, so obligated parties are not yet subject to requirements that would change with vacatur of the Rule. 40

C.F.R. § 141.902(b)(1)(xi). Moreover, in the absence of vacatur, obligated parties could eventually be forced to comply with regulations that may ultimately change and are, in EPA’s view, unlawful under the statute.

In sum, the Court should vacate the portion of the Rule finalizing regulatory determinations and regulations for PFNA, PFHxS, and HFPO-DA individually and the Index PFAS as mixtures.

CONCLUSION

For the foregoing reasons, the Court should grant EPA’s motion to partially vacate the Rule. EPA will identify those portions of its previously filed brief it no longer advances at an appropriate time.

September 11, 2025

Respectfully submitted,

ADAM R.F. GUSTAFSON
Acting Assistant Attorney General

ROBERT STANDER
Deputy Assistant Attorney General

/s/ Kimere J. Kimball
KIMERE J. KIMBALL
Trial Attorney

Of Counsel:

HEIDI NALVEN
Attorney
U.S. ENVIRONMENTAL
PROTECTION AGENCY

U.S. Department of Justice
Env’t & Natural Resources Div.
P.O. Box 7611
Washington, DC 20044
(202) 514-2285 (Kimball)
Kimere.Kimball@usdoj.gov

CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) this document contains 4,704 words.

2. This document 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 document has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman font.

/s/ Kimere J. Kimball
KIMERE J. KIMBALL

Counsel for Respondents

EXHIBIT

1

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

AMERICAN WATER WORKS
ASSOCIATION, ET AL.

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION
AGENCY, ET AL.,

Respondents.

Case No. 24-1188 and
consolidated cases

DECLARATION OF PEGGY S. BROWNE

I, Peggy S. Browne, declare that the following statements are true and correct to the best of my knowledge and belief and are based on my personal knowledge, information contained in the records of the United States Environmental Protection Agency (“EPA” or “the Agency”), and information supplied to me by current EPA employees.

1. I am Principal Deputy Assistant Administrator, and I am currently also serving as Acting Assistant Administrator, for the Office of Water in the EPA. I have served in these positions since March 9, 2025.
2. As Acting Assistant Administrator, I am responsible for, and provide counsel to, the Administrator on policy, planning, program development and

implementation, management, and control of the technical and administrative aspects of the Office of Water. I manage the Agency's programs under several statutes, including the Safe Drinking Water Act ("SDWA"). Within EPA's Office of Water, Office of Ground Water and Drinking Water has primary responsibility for developing the decision to regulate a contaminant and the drinking water standards under SDWA.

3. Upon review of the rule and rulemaking process that resulted in the final action entitled "PFAS National Primary Drinking Water Regulation," 89 Fed. Reg. 32532 (Apr. 26, 2024), the EPA no longer seeks to defend the portions of the rule regarding three per- and polyfluoroalkyl substances (PFAS) individually—perfluorononanoic acid (PFNA), perfluorohexane sulfonic acid (PFHxS), and hexafluoropropylene oxide dimer acid (HFPO-DA)—and mixtures of those three PFAS and a fourth PFAS, perfluorobutane sulfonic acid (PFBS) or the associated regulatory determinations for those PFAS, and has asked the Department of Justice to file a motion for vacatur of those portions of the action cited above.

Dated: September 11, 2025

Digitally signed by Browne,
Peggy
Date: 2025.09.11 17:20:17
-04'00'

Browne, Peggy
Peggy S. Browne
Acting Assistant Administrator
Office of Water
U.S. Environmental Protection Agency