ORAL ARGUMENT NOT YET SCHEDULED

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

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

AMERICAN WATER WORKS ASSOCIATION, et al.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,

Respondents,

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

Respondent-Intervenors.

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

FINAL REPLY BRIEF OF PETITIONERS AMERICAN WATER WORKS ASSOCIATION AND ASSOCIATION OF METROPOLITAN WATER AGENCIES

(Names and addresses of counsel appear inside cover.)

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases: **Pages(s)**

Cases—Continued: **Page(s)**

Statutes: **Page(s)**

Regulations:

Administrative Materials:

Administrative Materials—Continued: **Page(s)**

Other Authorities:

GLOSSARY

Act	Safe Drinking Water Act, 42 U.S.C. § 300f *et seq.*
AMWA	Petitioner Association of Metropolitan Water Agencies
AWWA	Petitioner American Water Works Association
Buxmont Br.	Brief of Respondent-Intervenors Buxmont Coalition for Safe Water, Concerned Citizens of WMEL Water Authority Grassroots, Environmental Justice Task Force, Fight for Zero, Merrimack Citizens for Clean Water, Natural Resources Defense Council, Newburgh Clean Water Project, Clean Haw River, Clean Cape Fear
EPA or **Agency**	U.S. Environmental Protection Agency
Goal	Maximum Contaminant Level Goal
HFPO–DA	Hexafluoropropylene oxide dimer acid
Index PFAS	PFHxS, PFNA, PFBS, and HFPO–DA
Industry Br.	Opening Brief of Petitioners National Association of Manufacturers, American Chemistry Council, and The Chemours Company FC, LLC
Level	Maximum Contaminant Level
ng/L	Nanograms per liter
PFAS	Per- and polyfluoroalkyl substances
PFBS	Perfluorobutane sulfonic acid
PFHxS	Perfluorohexane sulfonic acid
PFNA	Perfluorononanoic acid
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctane sulfonic acid

Rule	PFAS National Primary Drinking Water Regulation, 89 Fed. Reg. 32,532 (Apr. 26, 2024)
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 5	Fifth Unregulated Contaminant Monitoring Rule
Utility Br.	Opening Brief of Petitioners AWWA and AMWA
Water Associations	AMWA and AWWA

INTRODUCTION AND SUMMARY OF ARGUMENT

EPA acted with disregard for the science and law when it promulgated the Rule[1]—the latter, EPA has now openly conceded. Just as bad, EPA's cost-benefit analysis oversold the benefits and undersold the true costs of the Rule's regulatory levels. This Court should grant the petitions for review and vacate the Rule.

I. EPA's decision to propose regulations for the Index PFAS—PFHxS, PFNA, PFBS, and HFPO-DA—**before** issuing final determinations to regulate the same is unsupportable under the Safe Drinking Water Act ("Act"). That approach violated the Act's carefully prescribed standard-setting processes. Indeed, EPA has effectively conceded the error in the motion for partial vacatur that the Agency filed after submitting its brief. *See* Resp'ts' Mot. for Partial Vacatur 2-3, 10-16 (Sept. 11, 2025), Doc. 2134523 ("EPA Motion"). EPA's error is fatal, and the Court should vacate the determinations to regulate the Index PFAS and the regulations, i.e., the maximum contaminant level goals ("Goals") and maximum contaminant levels ("Levels"), all of which are affected by the error.

II. EPA's asserted justifications for the determinations to regulate HFPO-DA, PFNA, and the Index PFAS (as mixtures) demonstrate the boundless, and ultimately arbitrary, discretion it contemplates for itself regarding the statutory

[1] 89 Fed. Reg. 32,532 (Apr. 26, 2024), JA1-226.

criterion for a determination to regulate a contaminant nationally based on a "substantial" likelihood of its occurrence in drinking water "with a frequency and at levels of public health concern." 42 U.S.C. § 300g-1(b)(1)(A)(ii). The Agency believes it satisfied that mandate by cobbling together occurrence data from handfuls of states—varying in quality and scope—and stale data from the Third Unregulated Contaminant Monitoring Rule ("UCMR 3"). The Act requires more, and the Court should vacate the determinations to regulate HFPO-DA, PFNA, and mixtures of the Index PFAS.

III. EPA's explanation for why the Hazard Index constitutes a Level under the Act for the Index PFAS is similarly boundless. The Agency apparently believes it can group together disparate contaminants based on the relative intensities of their adverse effects. Laughably, EPA and Intervenors replaced the actual statutory term—Maximum Contaminant ***Level***—in their briefs with the term "Standard" in hopes this Court will ignore the Act's true language. The Agency's reading, though, is divorced from the text of the Act and prior agency practice implementing the same and lacks any meaningful limiting principle. It likewise should be struck down.

IV. EPA's cost-benefit analysis for the Rule was flawed in estimating costs, improperly relied on nonquantifiable benefits lacking support in the record, and (contrary to EPA's assertion) is judicially reviewable.

ARGUMENT

I. EPA's procedural violations warrant vacatur of the Index PFAS provisions of the Rule.

A. EPA violated the Act by issuing proposed regulations before making a final determination to regulate.

1. EPA concedes that it committed error by proposing regulations for the Index PFAS **before** issuing its final determination to regulate the same, in contravention of the Act. *See* EPA Motion 2-3, 10-16. This Court should credit EPA's concession and vacate those portions of the Rule.

2. In any event, the arguments in support of EPA's action lack merit. The chief argument—really, the only argument—relates to the third clause of 42 U.S.C. § 300g-1(b)(1)(E). That clause provides that EPA "may publish [a] proposed regulation concurrent with the determination to regulate." EPA claims that the phrase "determination to regulate" as used in that clause "refers to EPA's *preliminary* determination, such that EPA may concurrently proceed with a preliminary determination and proposed regulation." EPA Br. 29.

This argument fails because—using EPA's own words—that reading results in the phrase "'determination to regulate' taking a different meaning" in the second and third clauses of section 300g-1(b)(1)(E). EPA Br. 30. EPA "admit[s]" that it's asking this Court to hold that the same words mean two different things when used twice *in the same sentence* of the statute—i.e., that its case turned entirely on the

Court's willingness to conclude that the phrase "determination to regulate" means final determination when used in the second clause but means the preliminary determination when used in the third clause. *Id.* EPA's puzzling contention that its reading "best comports with the Act's structure," *id.*, is at odds with a lengthy line of cases confirming that Congress generally intends the same words and phrases to have a uniform meaning throughout a statute. *See* Utility Br. 24 (collecting cases).[2]

Water Associations' reading, by contrast, is both sensible and simple: When Congress meant to refer to the *preliminary* determination, it used the words "preliminary determination," and when Congress meant to refer to the *final* determination, it used the words "determination to regulate." Tellingly, EPA cannot point to any place in the Act where Congress used the words "determination to regulate" to mean anything other than the final determination. Instead, EPA contends that Congress elsewhere used the separate phrase "determination for a contaminant" to mean a preliminary determination to regulate. *See* EPA Br. 29, 33-34; *accord* States' *Amici* Br. 24. That is wrong. Utility Br. 28. But even if EPA were right about the meaning of this phrase, it does the Agency no good. Notwithstanding the States' boggling claim that "determination for a contaminant" and "determination to

[2] EPA has elsewhere agreed that "attribut[ing] different meanings to the same phrase in the same sentence" is "contrary to fundamental principles of grammar and statutory construction." Br. of EPA at 28, *Mingo Logan Coal Co. v. EPA*, 714 F.3d 608 (D.C. Cir. 2013), 2012 WL 4960376 (Oct. 17, 2012) (citation omitted).

regulate" are "the very same phrase," those words are in fact quite different. *Contra* States' *Amici* Br. 24. That Congress may have used the words "determination for a contaminant" to refer to the preliminary determination is no license to interpret the phrase "determination to regulate" to also refer to the preliminary determination, especially given EPA's admission that "determination to regulate" clearly means the final determination when used elsewhere in the Act.

Furthermore, EPA's argument departs markedly from the plain meaning of the text. Dictionary definitions make clear that the word "determination" refers unambiguously to a *final* decision; the phrase "determination to regulate" therefore cannot be a reference to the preliminary determination, which all agree is not final. Utility Br. 22 & n.5. EPA offers no response, and its "strained effort to avoid the available dictionary evidence" is classic arbitrary decision-making. *Noel Canning v. NLRB*, 705 F.3d 490, 509 (D.C. Cir. 2013) (citation omitted), *aff'd*, 573 U.S. 513 (2014).

3. EPA next offers a confusing argument based on the use of the word "publish." *See* EPA Br. 30. The argument, though, appears nowhere in the rulemaking documents, and EPA's action is judged upon "the grounds upon which the agency acted." *See FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 587 (2025) (quoting *SEC v. Chenery Corp.*, 318 U.S. 80, 95 (1943)). And the argument makes little sense. EPA apparently means to argue that (1) section 300g-

1(b)(1)(B)(iii) refers to the "publish[ing]" of a preliminary determination; (2) the third clause of section 300g-1(b)(1)(E) also refers to "publish[ing]" a "proposed regulation"; and thus (3) Congress "must have meant" that the preliminary determination and the proposed regulation could be "publish[ed]" together. *See* EPA Br. 30. But the fact that the Act uses the word "publish" to refer to two documents does not suggest that Congress intended to authorize those documents to be published simultaneously.[3] To see why, the Court only need compare to the Administrative Procedure Act ("APA"), which authorizes agencies to "publish[]" both notices of proposed rulemaking and final rules, while making clear that the former publication will always precede the latter. 5 U.S.C. § 553(b), (d).[4]

EPA's remaining statutory arguments are unpersuasive and were addressed in Water Associations' opening brief. *See* Utility Br. 29 n.6 (addressing superfluity

[3] EPA contends that "[n]o provision of [the Act] refers to publication of a *final* regulatory determination." EPA Br. 30. But if Water Associations are correct that "determination to regulate" in the third clause of section 300g-1(b)(1)(E) means the *final* determination, then that clause itself "refers to publication of a final regulatory determination."

[4] EPA, moreover, glosses over the fact that the fourth clause of section 300g-1(b)(1)(E) also uses the word "publish" when referring to the final regulations. If the Court were to follow EPA's lead, the use of the word "publish" in that fourth clause would apparently amount to permission for EPA to release the final regulations at the same time as proposed regulations—an absurd outcome.

argument raised at EPA Br. 31-32); *id.* at 30-31 (addressing "acceleration" argument raised at EPA Br. 29-30,31, 32 and States' *Amici* Br. 24-25).

4. EPA next conveniently dismisses the fact that its procedural approach in this case departs from past agency practice. *Cf.* EPA Br. 35 (cited documents did not "represent EPA's definitive interpretation"). While EPA is correct that it has never before promulgated regulations for a newly listed contaminant after finalizing a determination to regulate since the 1996 amendments to the Act, *see* EPA Br. 35, it obfuscates the fact it has published more than a dozen preliminary and final regulatory determinations, contaminant lists, preambles, and other like documents in the *Federal Register*. A variety of those documents include statements that plainly contravene EPA's new, for-this-case-only reading of the Act. Utility Br. 26-27. It was arbitrary for EPA to depart from those statements in this proceeding without reasoned explanation, or even an acknowledgment that it was doing so. *See United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1284 (D.C. Cir. 2019) (statement in final rule's preamble arbitrarily departed without explanation from prior statement provided during an earlier rulemaking).[5]

[5] Indeed, after Petitioners filed their opening briefs, EPA published a new series of preliminary determinations to regulate. *See* 90 Fed. Reg. 3,830 (Jan. 15, 2025). The document explained that "*after considering public comment on the preliminary regulatory determination*, … the agency *then* may make a positive final determination that regulation is appropriate *and proceed to develop* an MCLG and NPDWR [i.e., a proposed regulation]." *Id.* at 3,840 (emphases added). In other

B. EPA's error was not harmless.

1. EPA has withdrawn and waived its previously asserted harmless error defense. EPA Mot. 16-17. Harmless error is an affirmative defense that may be waived by an administrative agency, and the Court should give effect to EPA's intentional relinquishment. *See id.*[6]

2. Moreover, EPA's previous harmless error argument misreads this Court's case law. EPA asserted in its brief that Petitioners cannot show prejudice because they have supposedly "fail[ed] to demonstrate that if EPA had proceeded through a bifurcated rulemaking process, they 'would have submitted additional, different comments.'" EPA Br. 36 (quoting *City of Waukesha v. EPA*, 320 F.3d 228, 246 (D.C. Cir. 2003) (per curiam)); *see* Buxmont Br. 11-12. *Waukesha*, though, **rejected** the notion that a petitioner must always show "what additional comments they would have submitted had notice been adequate" in order to establish prejudice; such a requirement would "improperly merge the analysis on the merits" with the

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words, EPA laid out an understanding of the procedures under the Act that the Agency had violated for the Rule.

[6] *Cf. United States v. Pryce*, 938 F.2d 1343, 1348 (D.C. Cir. 1991) (opinion of Williams, J.) ("Where the government does *not* raise the harmless error issue, I would deem errors 'harmless' only where satisfaction of that standard is *beyond serious debate*." (second emphasis added)); *id.* at 1353 (Silberman, J., dissenting in part) ("[R]espect for the adversary process makes it inappropriate to address [harmless error] at all." (citation omitted)).

"prejudice analysis." *Waukesha*, 320 F.3d at 246; *accord 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").

EPA skips past the true teaching of *Waukesha*, which is that "prejudice need *not* be shown" when the agency "entirely failed to comply" with relevant procedural obligations and when the agency "has offered no persuasive evidence that possible objections to its final rules have been given sufficient consideration." *Waukesha*, 320 F.3d at 246 (emphasis added) (quoting *Shell Oil Co. v. EPA*, 950 F.2d 741, 752 (D.C. Cir. 1991) (per curiam)); *see Sprint Corp. v. FCC*, 315 F.3d 369, 377 (D.C. Cir. 2003). Prejudice may be assumed in those cases, given that the Court will not be able to say "with certainty" that petitioners' comments would not "have had some effect if they had been considered." *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1324 (D.C. Cir. 1988); *see id.* (inappropriate to place burden on petitioner where the agency "completely failed" to comply with procedural requirements).

Such is the case here. EPA now concedes it bypassed a required notice-and-comment period. *See* EPA Mot. 2. EPA's "outright dodge" of the Act's procedural requirement is sufficient to establish prejudice. *Chamber of Commerce of U.S. v. SEC*, 443 F.3d 890, 904 (D.C. Cir. 2006). Allowing EPA to "skip" the second comment period and then "protect[itself] from judicial review" by claiming

harmless error would "eviscerate[]" and "virtually repeal" the Act. *Sugar Cane*, 289 F.3d at 96.

3. Even if the Court were to require Water Associations to establish that their comments would have been different had the proper process been followed, they easily discharge that burden. *Accord* EPA Mot. 18-19. Consider the timeline: In March 2023, EPA issued the combined preliminary determination to regulate and proposed regulations supported by occurrence data derived from UCMR 3, supplemented by 23,130 results from state datasets. 88 Fed. Reg. 18,638, 18,678 (Mar. 29, 2023), JA267. Petitioners were permitted to comment on that data, which bore on both the statutory criteria to regulate and the costs of compliance. In April 2024, EPA issued the combined final determination to regulate and final regulations. "Based on public comment," that second document included an updated occurrence analysis that was based on the UCMR 3 dataset plus "65,537 analytical results from 1,156 systems across 28 states," including "data from 9 states that were not available at the time of proposal." JA52, JA67. There was no comment period on that expanded data.

Had the process unfolded as the Act requires, EPA would first have published the preliminary determination, interested parties would have commented and submitted additional data, EPA would have published its final determination and proposed regulation (including the final data on which EPA would rely), and then

Water Associations would have been afforded a second opportunity to comment. That second comment period would have provided an opportunity to provide expert views on the interplay between (1) the vastly expanded occurrence data made available during the first comment period and (2) the cost/benefit analysis, which is relevant to determining the maximum containment level goal, which is in turn relevant to developing the proposed and final regulations. Instead, EPA provided just one comment period, and the final regulations were therefore based on tens of thousands of analytical results on which Petitioners never got to comment. EPA eliminated the statutorily required second comment period for the most costly rule in the Act's history. It cannot establish that all "possible objections" to its regulations were given "sufficient consideration." *Waukesha*, 320 F.3d at 246 (citation omitted).

AWWA recommended that the Agency not move forward "without considering incoming data" that was then being "collect[ed] … under the Fifth [Unregulated Contaminant Monitoring Rule ("UCMR 5")]" and then allowing interested parties to analyze and comment on that data. JA1311, JA1319; *see* JA1309-10, JA1321-26, JA1330-31. AWWA also explained that, with that data in hand, it would be possible to improve EPA's "occurrence" analysis, especially with respect to "occurrence for smaller systems." JA1316-21, JA1352. This bolsters the case for prejudicial error. *See Window Covering Mfrs. Ass'n v. CPSC*, 82 F.4th 1273, 1285 (D.C. Cir. 2023) (prejudice where petitioner "expressed several concerns about

the [agency's] data that might have been further developed or amplified" if petitioner had been given all the data on which the agency ultimately relied); *Waukesha*, 320 F.3d at 246 (similar).

4. EPA ignores all of this and pretends that Water Associations' complaint is that EPA's process gave them an insufficient amount of time to comment. *Cf.* EPA Br. 35-36. True, commenters were deprived the full time typically afforded rulemaking under the Act. But the more significant prejudice is that there was only one comment period and not the required two. EPA itself has repeatedly described those two inquiries as "distinct." Utility Br. 31 & n.8; *see also* 90 Fed. Reg. at 3,840 ("[T]he analyses associated with a regulatory determination process are distinct from the more detailed analyses needed to develop a[] [regulation].").[7] EPA's choice to combine those two distinct steps meant that Petitioners bore an artificially inflated burden to convince EPA to "change [its] course," rather than having a meaningful chance to influence EPA's decision about whether to propose a regulation in the first

[7] The Respondent-Intervenors (but not EPA) claim Water Associations "waived" their opportunity to demonstrate prejudice by failing to address prejudice in their opening brief. Buxmont Br. 10-12. Wrong. The Associations' brief, and their standing declarations, explained the harms attributable to combining the comment periods on whether to regulate and how to shape the regulation, which are "very different" questions. Utility Br. 31 n.8; *id.* at 32; *accord id.* at SA-9 (Mehan Decl. ¶ 23); *see Air Transp. Ass'n of Am. v. FAA*, 169 F.3d 1, 8 (D.C. Cir. 1999) (although petitioner had no "opportunity to provide comments" to agency on relevant documents, this Court found prejudice based on portions of "Petitioner's *reply* brief" that explained "the nature of [petitioner's] objection to the" information in question (emphasis added)).

instance. *Sierra Club v. Marsh*, 872 F.2d 497, 500 (1st Cir. 1989) (Breyer, J.); *see* Michael Sant'Ambrogio & Glen Staszewski, *Democratizing Rule Development*, 98 Wash. U.L. Rev. 793, 798 & nn.15-16 (2021) (noting that "sunk organizational costs" and "path dependence" mean that "agency officials who have already devoted substantial thought and effort to a problem are reluctant to reverse or dramatically change course").

C. EPA's error warrants vacatur of the determinations to regulate and regulations for the Index PFAS.

EPA's error warrants vacatur of both the determinations to regulate and the regulations of the Index PFAS. Utility Br. 32. *Contra* EPA Br. 118. An agency's failure to meet statutorily required procedures normally requires vacatur of the action. *See Am. Pub. Gas Ass'n v. U.S. Dep't of Energy*, 72 F.4th 1324, 1342-43 (D.C. Cir. 2023). Moreover, the fact that EPA moved forward with both actions on the same track, relying and justifying the actions in each case on new information not previously made available for comment, *see supra* Section I.B., means that both actions are affected by the error. *See Am. Pub. Gas*, 72 F.4th at 1342. EPA provides no reason to think that vacatur will be disruptive. *Cf.* EPA Br. 121-22. Nor could it. Although the Index PFAS regulations' compliance dates loom, they have not yet arrived. JA4. This is **not** a situation where the "egg has been scrambled" with "no apparent way to restore the status quo ante." *Am. Pub. Gas*, 72 F.4th at 1342 (quoting *Sugar Cane*, 289 F.3d at 97).

II. EPA's determinations to regulate HFPO-DA, PFNA, and mixtures of two or more of the Index PFAS should be vacated.

1. EPA's determination for these PFAS also flies in the face of Congress's logical decision to impose ***national*** regulations (as opposed to equally permissible state drinking water regulations) only when the problem is national, and not merely localized, in scope. The Act provides that in order for EPA to promulgate a "*national* primary drinking water regulation for a contaminant," the Agency must find that "the contaminant is known to occur or there is a *substantial likelihood* that the contaminant will occur in public water systems with a frequency and at levels of public health concern." 42 U.S.C. § 300g-1(b)(1)(A) (emphases added). This is a statutory criterion that EPA must implement and consider. *See Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004). The language, as best read, means that to support regulation of a contaminant, its occurrence in drinking water must be (1) national in geographic scope and (2) either known to occur or have a "substantial" (e.g., considerable, large) likelihood of occurrence at a frequency and at levels of public health concern. Utility Br. 44-46; *see* S. Rep. No. 104-169, at 12-13 (1995) (cautioning against regulation of contaminants that "occur so infrequently in public water systems that the costs of monitoring … far outweigh any health benefit that could be realized at the few systems that may detect the contaminant").

EPA previously adhered to such an understanding, repeatedly **declining** to regulate contaminants where those contaminants occurred, relative to the contaminants' health reference levels (i.e., the level below which adverse health effects are not expected to occur), in less than 0.1% of water systems nationally, or where EPA lacked a nationally representative dataset of occurrence in public water systems. Utility Br. 42, 45-46 & n.13; *see Lissack v. Comm'r*, 125 F.4th 245, 259 (D.C. Cir. 2025) (considering, among things, the agency's "consistency with earlier and later pronouncements").[8]

But here, EPA rushed forward with determinations to regulate HFPO-DA, PFNA, and mixtures of the Index PFAS without a nationally representative occurrence dataset, which was still being collected at the time the Rule was issued. *See* JA6. EPA's record here instead principally relied on the non-targeted occurrence data from only 19 states, JA22, far from a national cross-section, and occurrence data from UCMR 3, which omitted HFPO-DA and was in no way tailored to monitor the remainder according to the health reference levels EPA identified for the Rule,

[8] Contrary to EPA's telling (at 43-44), the Agency explained in its action on the contaminant *Acanthamoeba* that it "ha[d] no national monitoring data to indicate occurrence of *Acanthamoeba* cysts in drinking water." 68 Fed. Reg. 42,898, 42,903 (July 18, 2003); *see* 67 Fed. Reg. 38,222, 38,231 (June 3, 2002) (same in proposed action). There is no reason to think that the lack of national occurrence data did not inform the Agency's negative determination to regulate, given that occurrence is a statutory criterion. *See* 42 U.S.C. § 300g-1(b)(1)(A)(ii).

JA24-26. That record, even taken as a whole, was inadequate. *See* Utility Br. 40-53. Because EPA failed to satisfy a statutory criterion to regulate HFPO-DA, PFNA, and mixtures of the Index PFAS, the determinations to regulate should be vacated.[9]

2. EPA claims that the Act's regulatory determination criteria have "no geographic mandate" and that the Agency "has discretion to regulate a contaminant anywhere in the United States if the contaminant either does or likely will occur"—curiously omitting the substantiality requirement—"at both frequencies and levels of public health concern." EPA Br. 38-40; *see also* Buxmont Br. 13. This position is plainly atextual as it gives no effect to—indeed, intentionally ignores—two key terms in the Act: "national" regulation and "substantial" likelihood. 42 U.S.C. § 300g-1(b)(1)(A); *see Doherty v. Turner Broad. Sys., Inc.*, 72 F.4th 324, 329 (D.C. Cir. 2023) (courts "must give effect, if possible, to every word of a statute" and faulting litigant for "read[ing]" a term "out of the statute" (cleaned up)).[10] EPA's

[9] Because a determination to regulate a contaminant is a predicate for a regulation of the same contaminant, *see* 42 U.S.C. § 300g-1(b)(1)(A), the regulations for HFPO-DA, PFNA, and mixtures of the Index PFAS should likewise be vacated. Leaving the regulations in place without the associated determinations to regulate would run counter to the Act's carefully crafted standard-setting process.

[10] Contrary to EPA's assertion (at 39-40), the titles of statutory sections, which are passed by Congress, can be indicative of legislative intent. *See Fla. Dep't of Revenue v. Piccadilly Cafeterias, Inc.*, 554 U.S. 33, 47 (2008); *accord Children's Hosp. Ass'n of Tex. v. Azar*, 933 F.3d 764, 772 n.2 (D.C. Cir. 2019). Moreover, the term "*national* primary drinking water regulation" is also present in the relevant operative statutory text. 42 U.S.C. § 300g-1(b)(1)(A) (emphasis added).

reading is clearly **not** the best reading of the statute. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024).

Worse, by ignoring statutory terms, EPA appears to think that so long as it cobbles together **some** available occurrence data for a contaminant (or mixture thereof)—no matter its limited geographic scope, poor and/or varying quality, disconnect with the relevant health reference levels, or detachment from any reasonably explained numerical threshold (e.g., 0.1% of water systems nationally)—it can reach an affirmative determination to regulate. The low bar that EPA envisions for itself is evident from the record:

HFPO-DA. Only **five** states reported HFPO-DA at levels above the health reference level used for the Rule (i.e., the level below which adverse health effects are not expected). EPA Br. 46.[11] Moreover, because HFPO-DA was not included in

[11] Although EPA includes Virginia, Virginia provided the Agency, in part, with "targeted" data, meaning data selectively drawn from areas of known or potential contamination. JA2392 (designating data as "Targeted / Non-Targeted" and drawn from a study that "prioritize[d] sites"); *see* JA2307 (defining "targeted data"). Contrary to EPA's position now, *cf.* EPA Br. 41 (characterizing targeted data as "highly relevant"), targeted data is far less useful in establishing the occurrence criterion. *See* JA22 ("EPA focused the evaluation of the state data on the non-targeted or non-site specific … monitoring efforts from 19 states. Non-targeted or non-site-specific monitoring is likely to be more representative of general occurrence . . . ."); *id.* (targeted monitoring data more likely to "over-represent concentrations at locations of known or suspected contamination").

UCMR 3, EPA had not gathered **any** nationally representative data pursuant to the Act. JA26.

PFNA. EPA asserts that twelve states reported PFNA at levels above the health reference level, *see* EPA Br. 54, but two states (Michigan and Ohio) did so in less than 0.1% of systems, *see* JA2370, and one state (Alabama) submitted data with "no information on the total number of samples collected to determine percent detection," i.e., no denominator for its sample, JA2. *See* Utility Br. 49-51. PFNA was included in UCMR 3, yet the measuring threshold (20 ng/L) was materially different from the health reference level used in the Rule and to analyze the state-level data (10 ng/L). JA25. EPA was therefore left to speculate without relevant data ("EPA expects") whether the UCMR 3 data would support regulation. *Id.*

Mixtures of two or more of the Index PFAS. EPA asserts that 21 of 27 states "reported combinations of two or more Index PFAS occurring above the health reference level." EPA Br. 56. That assertion is misleading because datasets from 9 of those states relied, at least in part, on targeted monitoring data,[12] which is less "representative of general occurrence" than non-targeted occurrence data. JA22; *see supra* n.11. And again, UCMR 3 did not include one of the Index PFAS (HFPO-

[12] Arizona, California, Colorado (2013-2017), Iowa, Maine (2013-2020), Maryland (Phases 1 and 2), Oregon, Pennsylvania, and Virginia. *Compare* JA2408-13, *with* JA2307-13.

DA) and used measuring thresholds disconnected from the health references used in the Rule and to analyze the state-level data. JA24-26.

Preliminary UCMR 5 occurrence data. EPA disclaimed reliance on the preliminary UCMR 5 data available to it at the time of rulemaking—the data was "not a basis for informing the agency's decisions for the final rule." JA6; *see* EPA Br. 57-58 (preliminary UCMR 5 data was "purely illustrative").

* * *

If the above-described dataset—an assemblage of disparate state occurrence data coupled with stale UCMR 3 data—can satisfy the statutory occurrence criterion for **national** regulation, *cf.* EPA Br. 38-40, then the requirement will be defanged. The onus was on EPA to demonstrate that the best available occurrence data was sufficient to satisfy the occurrence criterion for each contaminant. Although Water Associations understand that there is unlikely to be "a simple threshold" for the occurrence criterion, JA21, EPA's reading must provide **some** meaningful constraint, namely that the occurrence is "national" and indicates, at least, a "substantial" likelihood of occurrence at a frequency and at levels of public health concern. *See* 42 U.S.C. § 300g-1(b)(1)(A)(ii); *cf. Loper Bright Enters.*, 603 U.S. at 395 (agencies "regulate subject to the limits" of the terms or phrases in a statute). What EPA assembled did not do so.

Because EPA failed to do so, its determinations to regulate HFPO-DA, PFNA, and mixtures of the Index PFAS violate the Act and should be vacated. *See ACA Int'l v. FCC*, 885 F.3d 687, 697, 699 (D.C. Cir. 2018) (agency's interpretation and implementation of statutory term took on "an eye-popping sweep" and was "unreasonable in [its] breadth"); *Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 643 (D.C. Cir. 2021) (similar).

III. The Hazard Index is not a Level.

EPA's principal defense of the Hazard Index as a permissible Level for mixtures of the Index PFAS is that the Act permits a Level "to take any particular form," including a unitless hazard index of multiple contaminants like the one used in the Rule. EPA Br. 73-74. EPA's reframing of the term in its brief is telling: EPA redefines the statutory term Maximum Contaminant *Level* as "Standard" in hopes that the Court might ignore the *actual* statutory term in favor of EPA's preferred reinterpretation. But a Level is not a Standard. As above, EPA's resort to a novel interpretation with seemingly no fixed boundaries is misplaced and should be struck down. *See ACA Int'l*, 885 F.3d at 697, 699; *Genus Med.*, 994 F.3d at 643.

1. EPA's reading is incorrect, let alone the best. Utility Br. 34-36. The Act defines a Level to mean "the maximum permissible level of a contaminant in water." 42 U.S.C. § 300f(3). In context, the definition connotes the degree of physical presence of a contaminant detected in drinking water, relative to what is maximally

permissible under the regulation based on its adverse health effects. *See* Utility Br. 34. As Congress understood it, Levels were to be "[g]enerally … stated as concentrations … (in parts per million or parts per billion)." S. Rep. No. 104-169, at 3. Indeed, EPA has traditionally regulated organic contaminants other than PFAS according to their physical concentration in drinking water. 40 C.F.R. § 141.61(a), (c) (milligrams per liter). The Hazard Index is a sharp departure from this longstanding understanding.

EPA nevertheless contends that the Hazard Index conforms with the Act because it is a unitless "scale measuring the relative intensity of the hazard presented" by the mixtures of contaminants captured by the Hazard Index. EPA Br. 74. EPA's argument shows how untethered its interpretation is from statutory text. The consideration "intensity of the hazard" is nowhere to be found in the Act's definition of a Level, and it is conceptually distinct from the measurement of the physical degree of a contaminant in drinking water, i.e., what the Act does say.

EPA's formulation lacks any meaningful limiting principle to guide its implementation. *See ACA Int'l*, 885 F.3d at 697, 699; *Genus Med.*, 994 F.3d at 643. By focusing on the intensity of adverse health effects that may arise from combinations of distinct contaminants, EPA implicitly assumes that a **single** Level may be used to capture **any number** of contaminants (PFAS or not)—so long as some indeterminate degree of "co-occurrence" and "dose-additive" health effects are

purportedly present. JA4. No matter that the Agency relies upon disparate health effects and health endpoints for the constituents. *See* JA19-22; Utility Br. 37-39; Industry Br. 42-46. To EPA, those numerous contaminants then may be combined to derive a single ratio that governs the regulation of water systems—along with the attendant liabilities and reputational consequences for violations that may follow. And from there, violations may ebb and flow depending upon fluctuations of only a handful of the many included constituents. That is a far cry from what Congress could have reasonably contemplated by the language "level of a contaminant in water," 42 U.S.C. § 300f(3), which were intended to be easily measurable and verifiable concentrations, *see* S. Rep. No. 104-169, at 3. Thus, even if the Court assumes EPA's proffered interpretation is not literally foreclosed by the Act, it nevertheless "falls outside the bounds of reasonableness." *Goldstein v. SEC*, 451 F.3d 873, 880-81 (D.C. Cir. 2006).[13]

2. EPA points to the Agency's regulation of radionuclides and disinfection byproducts as supporting the Hazard Index. EPA Br. 74-75; *accord*

[13] Respondent-Intervenors suggest (p. 42) that the Court should apply *Skidmore* deference. EPA, however, has **not** done so, instead arguing that it puts forth "the best reading of the statutory term 'maximum contaminant level,'" with no invocation of interpretive deference. EPA Br. 73. The Court should refrain from "plac[ing] an uninvited thumb on the scale in favor of the government." *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 140 S. Ct. 789, 790 (2020) (statement of Gorsuch, J.).

Buxmont Br. 24-25. Neither lends support to EPA's newfound interpretation of what constitutes an enforceable "Level" under the Act. Regarding radionuclides, the Levels for combined radium (radium-226 and -228) and for gross alpha particle radioactivity are measured in picocuries per liter ("pCi/L"), a measure of radioactive decay. 40 C.F.R. § 141.66(b), (c); *Waukesha*, 320 F.3d at 232 n.1. That unit of measure serves as a proxy for mass concentration. *See* 65 Fed. Reg. 76,708, 76,712-13 & nn.2-3 (Dec. 7, 2000) (relationship between "mass concentration (µg/L) and activity (pCi/L)" in drinking water). And in contrast with the Hazard Index here, the Level for the radionuclides captured by the regulation is tied to the same common adverse health effect of cancer risk. *Compare* 65 Fed. Reg. at 76,720; 65 Fed. Reg. 21,576, 21,603-04 (Apr. 21, 2000).

Regarding disinfection byproducts, EPA's action addressed situations where disinfectants (used by water systems to destroy pathogens like *Cryptosporidium*) react with naturally occurring materials in water to produce harmful byproducts. *See* 63 Fed. Reg. 69,390, 69,394 (Dec. 16, 1998). Yet, unlike with the Hazard Index, EPA regulated those disinfection byproducts as groups of contaminants simply according to the sum of their mass concentrations (measured in milligrams per liter), *see id.* at 69,408; 40 C.F.R. §§ 141.2, 141.64(b), rather than based on a ratio derived from weighted averages of the contaminants' particular health effects.

In sum, neither example lends support to EPA's newfound interpretation of what constitutes an enforceable "Level" under the Act. Indeed, they instead highlight the Agency's departure from what it has previously done.

IV. EPA's evaluation of costs and benefits was fatally flawed.

EPA's required cost-benefit analysis for the Rule suffered from fatal flaws that undermined its accuracy and reliability. *See* Utility Br. 53-57; Industry Br. 15-25; *cf.* Chamber *Amicus* Br. 7-16.

1. Responding to arguments that the Agency improperly relied on nonquantifiable benefits as part of its cost-benefit analysis and to justify the Rule, *see* Industry Br. 22-25; Utility Br. 56,[14] EPA argues there was sufficient basis for the asserted nonquantifiable benefits. EPA Br. 107 (citing "the extensive supporting evidence EPA gathered in the record substantiating these benefits"). That assertion is belied by the record. As examples, EPA asserted that evidence on the carcinogenic effect of PFOS in human is "mixed but plausible"; that evidence on the relationship between PFAS exposure and high cholesterol is "not conclusive"; and that "there is

[14] Contrary to EPA's assertion (pp. 104-06), this line of argument was raised before the Agency. *See* JA1343-44 (critiquing asserted association between PFOA and PFOS and cholesterol and birthweight, as used in benefits calculation); JA1605-06, JA1607-08, JA1610-11 (similar); JA1204-08 (observing that EPA relied on "possible" or "potential," rather than "likely," nonquantifiable benefits); *see also Ohio v. EPA*, 603 U.S. 279, 296 (2024) (agency need only "notice of the challenge during the public comment period" and observing that comments by non-petitioner commenters alerted the agency of the challenge at issue (cleaned up)).

moderate evidence" between PFOA and PFOS and birth weights. JA35, JA105, JA106. The Act requires EPA to identify quantifiable and nonquantifiable health risk reductions "for which there is a *factual basis in the rulemaking record*" and that are "*likely* to occur as the result of treatment to comply with each level." 42 U.S.C. § 300g-1(b)(3)(C)(i)(I), (II) (emphases added); *see Maine Lobstermen's Ass'n v. Nat'l Marine Fisheries Serv.*, 70 F.4th 582, 585 (D.C. Cir. 2023) (the term "likely" ordinarily means "probable" or "[i]n all probability" (citation omitted)). Yet, the Agency relied on nonquantifiable benefits that the record calls merely "mixed but plausible," "moderate," or "not conclusive."

2. EPA claims its cost-benefit analysis is unreviewable. EPA Br. 96-99. That is flatly incorrect. The Act requires EPA to publish, seek public comment on, **and use** a "[h]ealth risk reduction and cost analysis," when promulgating Levels pursuant to paragraph (b)(4). *See* 42 U.S.C. § 300g-1(b)(3)(C)(i). Here, EPA issued an Economic Analysis alongside the Rule and set forth the explicit finding that the Rule's benefits "justify" its costs. *See* JA3, JA102-03. This Court has previously reviewed the adequacy of a cost-benefit analysis that EPA issued alongside a paragraph (b)(4) Level. *See Waukesha*, 320 F.3d at 242-43. That is precisely what Petitioners ask the Court to do here. *See* Utility Br. 53-57; *accord* Industry Br. 15-25. Administrative agencies, moreover, must adequately consider a "statutorily

mandated factor"—here, the subparagraph (b)(3)(C) cost-benefit analysis. *See Pub. Citizen*, 374 F.3d at 1216.[15]

EPA attempts to confuse matters by pointing to paragraph (b)(6). That paragraph, though, pertains to the situation where the Agency makes the distinct determination that the cost-benefit analysis, which it is already obligated to undertake, justifies a Level higher than one as close as feasible to the Goal. *See* 42 U.S.C. § 300g-1(b)(6)(A). The fact that discrete determination is subject to judicial review, *see id.* § 300g-1(b)(6)(D), does not mean that the Act precludes judicial review of the adequacy of a cost-benefit analysis used for a Level under paragraph (b)(4). Indeed, the fact that the Agency may make the determination to regulate a contaminant at a Level higher than one as close as feasible to the Goal bolsters the importance of the cost-benefit analysis to the standard-setting process—its accuracy influences the selection of the particular Level.[16]

[15] Respondent-Intervenors incorrectly suggest that even if the Court finds EPA's cost-benefit analysis flawed, it could not then set aside the Levels. *See* Buxmont Br. 35-36. The cost-benefit analysis is a statutorily required consideration for the establishment of a Level under the Act. *Contra* Buxmont Br. 35. An error in fulfilling that mandate—e.g., issuing an arbitrary-and-capricious cost-benefit analysis—is grounds for setting aside the action. *See* 5 U.S.C. § 706(2).

[16] Accordingly, EPA's error was not harmless. *Contra* EPA Br. 89-92. That EPA determined its cost-benefit analysis did not justify a higher-than-feasible Level is the prejudice.

CONCLUSION

The Court should grant the petition for review, vacate the Rule, and remand to EPA.

Date: March 6, 2026

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation provided in this Court's order of September 3, 2024 (Doc. 2072754) because it contains 6,434 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1).

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

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CERTIFICATE OF SERVICE

I hereby certify that, on March 6, 2026, I electronically filed the foregoing brief with the Clerk of the Court for the U.S. Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system, and served copies of the foregoing via the Court's CM/ECF system on all ECF-registered counsel.

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