

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' COMBINED REPLY IN SUPPORT OF THEIR MOTION
FOR PARTIAL VACATUR AND OPPOSITION TO INTERVENORS'
MOTION TO FILE REVISED AND EXPANDED BRIEF**

Dated: December 3, 2025

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TABLE OF CONTENTS

TABLE OF CONTENTS.....	i
TABLE OF AUTHORITIES	ii
INTRODUCTION	1
ARGUMENT	2
I. The Motions Panel Should Decide This Motion.	2
II. EPA Lacks Authority to Propose a National Primary Drinking Water Regulation for a Contaminant Simultaneously with a Preliminary Regulatory Determination of that Contaminant.	4
A. EPA Has Not Reversed Any Longstanding Interpretation Entitled to Special Weight under <i>Loper Bright</i>	4
B. Section 300g-1(b)(1)(E) Requires Separate and Consecutive Regulatory Determinations and Regulations.....	6
III. EPA Waives Any Harmless Error Defense.	17
IV. The Error Was Not Harmless.	18
V. Vacatur of the Regulatory Determinations and Regulations for the Index PFAS Is Appropriate.	19
A. Vacatur Is Warranted Because the Error Is Serious.....	19
B. Vacatur Would Not Be Disruptive.....	21
VI. The Court Should Deny Intervenors’ Motion to File a Revised and Enlarged Brief.....	23
CONCLUSION.....	24
CERTIFICATE OF COMPLIANCE.....	25

TABLE OF AUTHORITIES

CASES

<i>Agnew v. Gov’t of Dist. of Columbia</i> , 920 F.3d 49 (D.C. Cir. 2019).....	15
<i>Allied–Signal, Inc. v. Nuclear Regul. Comm’n</i> , 988 F.2d 146 (D.C. Cir. 1993).....	19, 20, 21
<i>Arej v. Sessions</i> , 852 F.3d 665 (7th Cir. 2017)	17
<i>Clark v. Martinez</i> , 543 U.S. 371 (2005).....	13
<i>Clean Air Council v. Pruitt</i> , 862 F.3d 1 (D.C. Cir. 2017).....	2
<i>Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.</i> , 603 U.S. 799 (2024).....	13
<i>Env’tl Integrity Project v. EPA</i> , 425 F.3d 992 (D.C. Cir. 2005).....	10
<i>First Am. Discount Corp. v. CFTC</i> , 222 F.3d 1008 (D.C. Cir. 2000).....	17
<i>Loper Bright Enters. v. Raimondo</i> , 603 U.S. 369 (2024).....	3, 4, 5, 6, 17
<i>McLouth Steel Prods. Corp. v. Thomas</i> , 838 F.2d 1317 (D.C. Cir. 1988).....	18
<i>NASDAQ Stock Market, LLC v. SEC</i> , 961 F.3d 421 (D.C. Cir. 2020).....	15
<i>Sosa v. Alvarez-Machain</i> , 542 U.S. 692 (2004).....	7

<i>Sprint Corp. v. FCC</i> , 315 F.3d 369 (D.C. Cir. 2003)	18
<i>W. Va. v. EPA</i> , 597 U.S. 697 (2022)	5
<i>Wash. Post v. Wash.-Balt. Newspaper Guild</i> , 787 F.2d 604 (D.C. Cir. 1986)	6

STATUTES

42 U.S.C. § 300f	8
42 U.S.C. § 300g-1(a)(3)	15
42 U.S.C. § 300g-1(b)(1)(B)	13, 14
42 U.S.C. § 300g-1(b)(1)(B)(ii)	7, 8, 16
42 U.S.C. § 300g-1(b)(1)(B)(ii)(I)	8, 9
42 U.S.C. § 300g-1(b)(1)(B)(ii)(II)	9, 11
42 U.S.C. § 300g-1(b)(1)(B)(ii)(III)	10, 11, 12
42 U.S.C. § 300g-1(b)(1)(B)(ii)(IV)	12
42 U.S.C. § 300g-1(b)(1)(B)(iii)	12, 16
42 U.S.C. § 300g-1(b)(1)(E)	6, 7, 13, 14, 15, 16
42 U.S.C. § 300g-1(b)(3)(C)	16
42 U.S.C. § 300g-1(b)(4)(A)	10
42 U.S.C. § 300g-1(b)(4)(B)	10
42 U.S.C. § 300g-1(b)(6)(A)	16
42 U.S.C. § 300g-1(b)(8)	15

42 U.S.C. § 300g-1(b)(13)(F)	15
42 U.S.C. § 300g-3(e)	22
42 U.S.C. § 7545(o)(2).....	10
42 U.S.C. § 7675(e)	10
Pub. L. No. 104-182, 110 Stat. 1619	6

CODE OF FEDERAL REGULATIONS

40 C.F.R. § 141.902(b)(1)(xi).....	21
------------------------------------	----

FEDERAL REGISTER

73 Fed. Reg. 60262 (Oct. 10, 2008).....	14
76 Fed. Reg. 7762 (Feb. 11, 2011)	5, 14
86 Fed. Reg. 12272 (Mar. 3, 2021).....	5
89 Fed. Reg. 32532 (Apr. 26, 2024)	22, 23

INTRODUCTION

The Safe Drinking Water Act requires EPA to address drinking water contaminants through a stepwise regulatory process. First, EPA determines whether to regulate a contaminant after considering statutory factors. Second, if EPA issues a determination to regulate, EPA must issue a regulation for the contaminant that includes all statutorily required elements. The statute requires the Agency to engage the public at each stage through separate and sequential comment periods. EPA now concedes it violated the Act when it collapsed this mandatory stepwise process into a single proposal and single comment period for both the determinations to regulate and regulations for the Index PFAS.¹ This error renders both the regulatory determinations and the regulations invalid because neither was promulgated with the statutorily mandated, standalone notice-and-comment period. Because resolution of this threshold question would obviate the need for the Court to consider highly technical record-based challenges to the appropriateness of EPA's decisions, EPA respectfully requests the motions panel vacate the portion of the challenged Rule regarding EPA's regulatory determinations and the regulations of the Index PFAS.

¹ Index PFAS refers to perfluorononanoic acid (PFNA), perfluorohexane sulfonic acid (PFHxS), and hexafluoropropylene oxide dimer acid (HFPO-DA) individually, as well as mixtures of those contaminants together and with perfluorobutane sulfonic acid (PFBS).

ARGUMENT

I. The Motions Panel Should Decide This Motion.

The sole issue presented in this motion is a discrete, threshold question concerning EPA's notice-and-comment obligations when issuing National Primary Drinking Water Regulations under the Safe Drinking Water Act. This Court may resolve this type of threshold, statutory interpretation question through motions panels. *See, e.g., Clean Air Council v. Pruitt*, 862 F.3d 1 (D.C. Cir. 2017) (granting motion to vacate agency action because EPA action did not comport with proper statutory interpretation of Clean Air Act). And decision of this issue by a motions panel in this instance would best preserve both judicial economy and the parties' resources.

Because this motion presents the threshold question of whether EPA violated the statute when simultaneously issuing (1) a preliminary determination to regulate the Index PFAS and (2) proposed regulations of the Index PFAS, deciding this issue by motions panel would obviate the need for the Court to dig into thorny, record-based challenges to each of the four separate regulatory determinations and four separate regulations for the Index PFAS. *See* Utility Br. (ECF 2078734) at 33-53; Industry Br. (ECF 2078731) at 39-60. Moreover, a motion panel's resolution of this issue would avoid unnecessary additional briefing on these issues. Petitioners' reply would not need to address *any* regulatory determinations

or the ultimate regulations for the Index PFAS. And such a decision would moot Intervenor's extraordinary request to *double* the word count of their brief.

Intervenor's Opp'n (ECF 2137412) at 30-35; *see also* Pt.VI *infra*.

Intervenor's incorrectly assert that this question concerning EPA's interpretation of its notice-and-comment obligations is inextricably intertwined with challenges to the merits of EPA's final regulation. Intervenor's Opp'n at 5-8. But the Court must make an initial determination whether EPA properly promulgated the regulation before addressing whether the regulation is reasonable. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412 (2024) ("Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires."). Because that threshold question could obviate the need for further briefing on these issues entirely, and because that question involves *no* consideration of the technical record, this issue can and should be decided now.

Petitioners support EPA's motion for vacatur while, at the same time, asserting various arguments regarding the appropriateness of the Index PFAS regulatory determinations and regulations (including challenges to EPA's authority to regulate mixtures using a hazard index and challenges to the data on which EPA based its regulatory determinations and regulations). *See* Utility Resp. (ECF 2137385) at 16-19; Industry Resp. (ECF 2137406) at 6-13. But those additional

challenges are not relevant to the question presented to the Court because EPA has not moved—and Petitioners did not cross-move—for vacatur of the regulatory determinations or regulations on those bases. Accordingly, Petitioners’ merits arguments are not before the Court in this motion and should not be considered now.

The motions panel can and should decide only the threshold question of statutory interpretation presented in EPA’s motion: Whether EPA has authority to propose a national regulation for a contaminant before finalizing a determination to regulate the contaminant. And, if not, whether the determination to regulate and the regulatory standards for the Index PFAS must be vacated because EPA exceeded its statutory authority.

II. EPA Lacks Authority to Propose a National Primary Drinking Water Regulation for a Contaminant Simultaneously with a Preliminary Regulatory Determination of that Contaminant.

A. EPA Has Not Reversed Any Longstanding Interpretation Entitled to Special Weight under *Loper Bright*.

EPA, through this motion, is correcting its erroneous 2023 interpretation of the Safe Drinking Water Act. Under *Loper Bright*, this Court ascertains the best reading of the statute itself using all the traditional tools of statutory interpretation. 603 U.S. at 400-01. Intervenors assert that EPA’s current position constitutes a reversal of the 2023 interpretation. *See* Intervenors’ Opp’n at 18. But EPA’s erroneous 2023 interpretation was not an “interpretation...issued roughly

contemporaneously with enactment of the statute” that “remained consistent over time” or a “longstanding practice of the government” that “like any other interpretive aid[,] can inform the court’s determination of what the law is.” *Loper Bright*, 603 U.S. at 386 (internal quotations omitted).

Prior to the rulemaking at issue in this litigation, EPA had never taken a position on the relevant provision of the Act. *Accord* EPA Br. (ECF 2091318) at 35. Indeed, the procedure EPA followed for regulatory determinations and regulations prior to this rulemaking is consistent with the procedure EPA advances here. *Cf. W. Va. v. EPA*, 597 U.S. 697, 725 (2022) (“[J]ust as established practice may shed light on the extent of power conveyed by general statutory language, so the want of assertion of power by those who presumably would be alert to exercise it, is equally significant in determining whether such power was actually conferred.”). In the only three determinations to regulate EPA issued in the 27 years preceding the challenged Rule, EPA proposed, sought comment on, and finalized the regulatory determinations *before* proposing a regulation. *See* 76 Fed. Reg. 7762 (Feb. 11, 2011) (perchlorate); 86 Fed. Reg. 12272 (Mar. 3, 2021) (PFOA & PFOS).

And EPA’s 2023 interpretation—unveiled for the first time 27 years after the 1996 enactment of the statutory provision at issue here—is not entitled to any special “respect” from this Court because the interpretation was neither

promulgated contemporaneously with passage of the Act nor longstanding. *See Loper Bright*, 603 U.S. at 386; Safe Drinking Water Act Amendments of 1996, Pub. L. No. 104-182, 110 Stat. 1619. Instead, EPA advanced the 2023 interpretation to explain its choice to proceed for the first time with a single, simultaneous rulemaking—a choice the Agency now concedes is unlawful. EPA now simply seeks to advance the best and most natural reading of the statute, which requires two separate and consecutive regulatory actions informed by distinct notice-and-comment processes. 42 U.S.C. § 300g-1(b)(1)(E).

B. Section 300g-1(b)(1)(E) Requires Separate and Consecutive Regulatory Determinations and Regulations.

The “single, best meaning” of 42 U.S.C. § 300g-1(b)(1)(E), *Loper Bright*, 603 U.S. at 400, requires a two-step process for regulating a drinking water contaminant under that provision. EPA must first propose and seek comment on a preliminary determination to regulate the contaminant. Only *after* fully considering those comments and finalizing a regulatory determination may EPA propose a regulatory limit for the contaminant, which may occur no *earlier* than simultaneous with the final regulatory determination.

“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 maximum contaminant level goal [Goal] and national

primary drinking water regulation 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 EPA may publish a proposed regulation, at the earliest, when it issues the *final* regulatory determination. It may not, as Intervenor’s argue, issue the proposed regulation contemporaneous with the regulatory determination process. *Contra* Intervenor’s Opp’n at 10-18. Indeed, *every* reference to a “determination to regulate” in the statute makes clear that this phrase refers exclusively to the final determination to regulate.

1. Subsection 300g-1(b)(1)(B)(ii)

The title of Subsection 300g-1(b)(1)(B)(ii) provides the first use of the term “determination to regulate.” Interpreting this term as only the final determination gives effect to differences in the language of different provisions of that subsection. *Sosa v. Alvarez-Machain*, 542 U.S. 692, 711 n.9 (2004) (“[W]hen the legislature uses certain language in one part of the statute and different language in another, the court assumes different meanings were intended.”). The subsection refers to “criteria” when referring to the process of making a determination. *See, e.g.*, 42 U.S.C. § 300g-1(b)(1)(B)(ii). And it uses different and explicitly preliminary language when referring to the intermediate steps necessary to reach

the final “determination to regulate,” including referring to a “*preliminary* determination....” 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I) (emphasis added). The best and plainest reading of the term “determination to regulate” in the title and throughout this section thus is as the final determination to regulate.

Indeed, if “determination to regulate” does not refer to the final determination, Intervenor’s point to no language in the statute that *does* refer to a final determination. *See* Intervenor’s Opp’n at 10-17. And taking Intervenor’s arguments in turn demonstrates the fallacy of their interpretation.

Intervenor’s first assert that the title, “Determination to regulate,” must refer to the entire process simply because it lists the intermediate steps necessary for the final determination. Intervenor’s Opp’n at 11. But this interpretation belies how headings and titles are routinely used. A recipe entitled “Chocolate Cake” will include a list of preliminary steps, but the term “chocolate cake” still exclusively refers to the final product – not the ingredients, not the batter, not the act of baking, but only the resultant “cake.” Here, too, the title is best and most plainly understood to refer to the final determination.

Moreover, Intervenor’s assertion that the entirety of subsection 300g-1(b)(1)(B)(ii) is a “definition” of “determination to regulate” belies the structure of the statute. *See* Intervenor’s Opp’n at 11. The statute has an explicit definitions section at 42 U.S.C. § 300f. Nothing in the statute’s use of “Determination to

regulate” as a title suggests it refers to a process rather than the final outcome.

And every usage of “determination to regulate” referenced in the intermediate steps simply reaffirms this interpretation.

Subclause I, which Intervenor conveniently ignore, refers to “determinations of whether or not to regulate” that are made “*after* notice of the preliminary determination and opportunity for public comment....” 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I) (emphasis added). This reference to either possible final decision, and to it occurring only *after* the other intermediate steps, demonstrates that a “determination to regulate” can only be the final determination and not the process. Indeed, interpreting the provision as the “process of determining whether to regulate” would make no sense given the statute’s mandate that it only come “after notice of the preliminary determination and opportunity for public comment.” *Id.*

Subclause II mandates that “[a] determination to regulate a contaminant *shall be based*” on a series of findings. *Id.* § 300g-1(b)(1)(B)(ii)(II). The use of the past participle “based” demonstrates that “determination to regulate” in this provision refers to a future *completed* act, *i.e.*, a final determination, not the process of completing the determination.

Intervenors erroneously argue that “determination to regulate” must refer to the entire regulatory determination process because the criteria identified also must

be considered in a preliminary regulatory determination. Intervenor's Opp'n at 12. But when setting forth the requirements of the National Primary Drinking Water Regulations, the statute does not separately identify the criteria for the proposed and final maximum contaminant level goals ("Goals") and final Goals, or for the proposed maximum contaminant levels ("Standards") and the final Standards. *See, e.g.*, 42 U.S.C. § 300g-1(b)(4)(A)-(B). Indeed, statutes directing agency rulemaking routinely set forth the criteria for the rulemaking without explicitly stating that that same criteria must also be considered in the proposed rule. *See, e.g., id.* § 7545(o)(2) (Clean Air Act Renewable Fuel Standard rulemaking specifications); *id.* § 7675(e) (American Innovation and Manufacturing Act rulemaking specifications). Basic administrative law dictates that requirements of a proposal are simply those necessary to afford sufficient opportunity to comment on the agency's ultimate action. *See, e.g., Env't Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) ("Given the strictures of notice-and-comment rulemaking, an agency's proposed rule and its final rule may differ only insofar as the latter is a 'logical outgrowth' of the former." (internal citations omitted)).

Subclause III states EPA "may make a determination to regulate a contaminant...if the determination to regulate is made pursuant to subclause (II)." 42 U.S.C. § 300g-1(b)(1)(B)(ii)(III) (emphasis added). Replacing "determination to regulate" with "process to determine to regulate" demonstrates the fallacy of

Intervenors' interpretation. *Contra* Intervenors' Opp'n at 12-13. Intervenors' reading would create an entirely circular interpretation whereby EPA could only "make a [process to determine to regulate]...if the [process to determine to regulate] is made pursuant to subclause (II)," but subclause II *also* would then only set forth the requirements of the findings on which the "[process to determine to regulate]" rather than the final determination must be based. *See id.*; 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II)-(III). The far plainer interpretation of this statutory language is that the reference to "determination to regulate" means a final determination to regulate. With this interpretation, the statutory provision provides clear authority: EPA "may make a [final] determination to regulate a contaminant...if the [final] determination is made pursuant to subclause (II)," and subclause II provides that a "[final] determination to regulate a contaminant shall be based on findings that the [identified] criteria...are satisfied." 42 U.S.C. at § 300g-1(b)(1)(B)(ii)(II)-(III).

Moreover, as in subclause II, the use of the past participle in subclause III – "the determination to regulate *is made* pursuant to subclause (II)," – demonstrates that the determination to regulate refers to a future *completed* act, not an ongoing process. *Id.* at § 300g-1(b)(1)(B)(ii)(III); *contra* Intervenors' Opp'n at 12-13.

Subclause IV further demonstrates that the "determination to regulate" is the final determination by noting that its converse—a "determination...not to

regulate” is a “final agency action subject to judicial review.” *Id.* at § 300g-1(b)(1)(B)(ii)(IV). It would make no logical sense for the *only* final determination referenced in the subsection to be a negative final determination, with no reference whatsoever to an affirmative final determination.

2. Subsection 300g-1(b)(1)(B)(iii)

As EPA explained in its opening motion, the reference to a “determination” *instead of* a “determination to regulate” in subsection 300g-1(b)(1)(B)(iii), combined with its reference to publication for public comment, demonstrates that this provision refers to the preliminary action. Mot. (ECF 2134523) at 13-14. When referring to the final determination, the statute uses the specific phrase “determination to regulate” or “determination not to regulate” and continues to use that exact phrase even when using it twice in the same sentence. *See, e.g.*, 42 U.S.C. § 300g-1(b)(1)(B)(ii)(III) (EPA “may make a *determination to regulate* a contaminant that does not appear on a list under clause (i) if the *determination to regulate* is made pursuant to subclause (II).” (emphasis added)). Thus, as EPA explained, and contrary to Intervenor’s assertion, subsection 300g-1(b)(1)(B)(iii)’s reference to public comment for a mere “determination” rather than a “determination to regulate” demonstrates that Congress knew how to differentiate this language, and did so when necessary. *See* Mot. at 13-14; Intervenor’s Opp’n at 12-13.

3. Subsection 300g-1(b)(1)(E)

With the statute's usage of "determination to regulate" referring to only the final determination to regulate firmly established in subsection 300g-1(b)(1)(B), the statute then provides that, "for each contaminant that [EPA] determines to regulate..." EPA "shall propose the [regulation] 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*." *Id.* § 300g-1(b)(1)(E) (emphasis added). The best reading of this provision interprets both references to mean the final determination to regulate. *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.").

Intervenors offer a tortured reading of subsection 300g-1(b)(1)(E) that ignores the consistent usage of "determination to regulate" both throughout the statute and in the subsection itself. *See* Intervenors' Opp'n at 13-14. At the outset, Intervenors interpret the first reference to the "determination to regulate," which starts EPA's "enforceable 24-month deadline" to issue a proposed regulation, as a reference to the *entire* "determination to regulate process." *Id.* at 14-15. But this

is an infeasible interpretation because it provides no clear deadline whatsoever. The time between a proposed and final regulatory determination can span *years*. *Id.*; *see e.g.*, 73 Fed. Reg. 60262 (Oct. 10, 2008) (preliminary determination to regulate perchlorate); 76 Fed. Reg. 7762 (Feb. 11, 2011) (final determination). Congress could not possibly have intended the starting point of a very specific 24-month clock to be so amorphous and open-ended. Instead, both the first and second usages of “determination to regulate” in subsection 300g-1(b)(1)(E), like every usage of “determination to regulate” in subsection 300g-1(b)(1)(B), should be interpreted as the final determination to regulate.

Intervenors next argue that, because the Act allows EPA to “publish [a] proposed regulation *concurrent with* the determination to regulate” in subsection 300g-1(b)(1)(E)’s second usage of “determination to regulate”, it must refer to the entire process. Intervenors’ Opp’n at 15-17. Intervenors distinguish the Act’s use of “concurrent with” from other usages of “simultaneous” to argue that the Act must have intended that the determination to regulate *process* could run contemporaneously with the notice-and-comment period for the regulation. *Id.* But this argument fares no better.

The Act’s use of “concurrent with” in subsection 300g-1(b)(1)(E) more reasonably indicates the permissive nature of the provision, which merely *allows* EPA to propose a regulation as early as the date the final determination to regulate

publishes but does not *require* publication on that very date. *See* 42 U.S.C.

§ 300g-1(b)(1)(E). Notably, every use of “simultaneous” in section 300g-1 refers to the specific date of a mandatory deadline. *See* 42 U.S.C. § 300g-1(a)(3) (requiring that Goals and Standards “*shall* be proposed simultaneously,”); (b)(8) (requiring EPA “*shall* simultaneously promulgate a rule” setting forth criteria to seek variances from disinfectant rulemakings with the disinfectant rulemakings); (b)(13)(F) (requiring EPA “*shall*, simultaneously with the promulgation of [a Standard for radon], promulgate an alternative [Standard]” that meets other criteria)). Far from suggesting that EPA could propose a regulation at any point in the potentially multi-year process of determining whether to even regulate the contaminant in the first place, the Act’s use of “concurrent with” simply indicates the more permissive nature of that starting point.

Moreover, careful analysis of this subsection demonstrates that reading the second usage of “determination to regulate” as the final determination is the only reading that avoids surplusage. *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 that a “statutory interpretation must account for both the specific context in which language is used and the broader context of the statute as a whole”) (internal quotations omitted).

As EPA explained in its opening motion, its 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. Intervenor's reading fails to give full effect to this statutorily prescribed window.

Finally, Intervenor's do not dispute that 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 Br. 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.

Thus, in summary, EPA’s interpretation of “determination to regulate” as denoting the final determination to regulate is the “single, best meaning” of the provision. *Loper Bright*, 603 U.S. at 400. EPA’s interpretation is the only interpretation that makes grammatical and logical sense in each and every usage of “determination to regulate” in section 300g-1.

III. EPA Waives Any Harmless Error Defense.

EPA can and has waived harmless error as a defense to the lawfulness of the deficient regulatory determinations and regulations of the Index PFAS. As EPA noted in its opening brief, 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). Although Intervenor’s argue that an agency cannot waive a harmless error defense, the cited case does not even discuss waiver of the defense, much less hold the defense unwaivable. Intervenor’s Opp’n at 19; *First Am. Discount Corp. v. CFTC*, 222 F.3d 1008, 1014-16 (D.C. Cir. 2000).

Accordingly, EPA withdraws the portion of its opening brief in which it asserted the harmless error defense for both the final regulatory determinations and the regulations for the Index PFAS. *See* EPA Br. at 36-38. Because EPA has waived this defense, the Court should vacate both the regulatory determination and the regulations for the Index PFAS.

IV. The Error Was Not Harmless.

Additionally, as explained in EPA’s opening motion, publication of the final regulatory determination concurrently with regulations for the Index PFAS as a mixture was not harmless as to the regulations, especially because 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).

Intervenors argue that reliance on cases in which notice-and-comment requirements were entirely foregone is misplaced. Intervenors’ Opp’n at 21. But EPA *did* entirely forego the second, sequential notice-and-comment period required by the Act. This is akin to *Sprint Corp.*, in which the agency “failed to issue a new NPRM....” 315 F.3d at 377. The fact that EPA solicited public input at earlier stages of the regulatory process does not excuse its failure to complete the very specific seriatim process set forth in the statute.

V. Vacatur of the Regulatory Determinations and Regulations for the Index PFAS Is Appropriate.

As fully explained in EPA’s opening motion, EPA’s failure to follow the statutorily-mandated sequence for regulating a drinking water contaminant requires vacatur under this Court’s precedents. *Allied-Signal, Inc. v. Nuclear Regul. Comm’n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993) (“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.’” (internal quotations omitted)).

A. Vacatur Is Warranted Because the Error Is Serious.

EPA’s error here was serious and is not correctible on remand. Because 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 these portions of the Rule in place 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 regulations for the Index PFAS 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 regulations appropriately.

Intervenors' assertion that "unless it gets the vacatur order it seeks, there is more than a 'significant possibility' that EPA may reach the same substantive result" is circular and meritless. Intervenors' Opp'n at 27 (internal citations omitted). The Court considers how much a rule is likely to change for the purpose of assessing the "extent of doubt whether the agency chose correctly," a question that drives whether vacatur is appropriate. *Allied-Signal*, 988 F.2d at 150-51. Asking the inverse question – how *little* might a rule change if the Court does *not* vacate the rule – tells the Court nothing about the seriousness of the error or "whether the agency chose correctly." *Id.*

Intervenors also try to downplay the error here by arguing that EPA allowed at least some comment period. Intervenors' Opp'n at 24-25. But EPA's misinterpretation of the statute deprived the public of a full *half* of the statutorily mandated comment period and the benefit of the certainty of EPA's final determinations, including the full scope of contaminants EPA is regulating. Moreover, by denying the public the opportunity of a second comment period, EPA deprived the public of the opportunity to understand the scope of the final

regulatory determinations before commenting on the resulting regulations. This is not a “defect of relative insignificance.” *Contra* Intervenor’s Opp’n at 25 (internal quotations omitted). This is a complete failure to provide a mandatory opportunity for informed public engagement.

Finally, Intervenor’s incorrectly contend that EPA has identified no “error in the Index PFAS Determinations.” Intervenor’s Opp’n at 9. The statutory error at issue applies not only to the regulations, but also to the determinations. As explained above, the statute requires one notice-and-comment period for the regulatory determination and a separate, sequential notice-and-comment period for a regulatory standard. Collapsing those two periods renders both the regulatory determinations and the regulations invalid because neither is promulgated with its statutorily mandated, standalone notice-and-comment period. The error infects both simultaneously, and both should be vacated.

B. Vacatur Would Not Be Disruptive.

Additionally, vacatur of the regulatory determinations and the regulations for 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 still over a year away (April 26, 2027). 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.

Intervenors do not—and cannot—contest that all deadlines flowing from the Rule are still nearly a year and a half away. Intervenors' Opp'n at 27-29. As such, their assertion that vacatur would result in "an interim change that itself would be changed," *id.* at 27, is simply incorrect.

And although Intervenors note that some states have already voluntarily conformed to the new standards, Intervenors' Opp'n at 28-29, this is not relevant. Because the Act explicitly allows state drinking water standards to be more stringent than the national Standards, *see* 42 U.S.C. § 300g-3(e), these states would not need to do anything additional to meet their obligations under the Act if the Court vacated the regulatory determinations and regulations for the Index PFAS.

Intervenors' assertion that vacating the regulatory determinations and regulations for the Index PFAS, both individually and as mixtures, would threaten public health is overstated. Intervenors' Opp'n at 22-23. As EPA explained in the rulemaking, the vast majority of quantifiable health benefits achievable from the Rule are achieved via regulation of PFOA and PFOS, which EPA continues to defend. 89 Fed. Reg. 32532, 32600 (Apr. 26, 2024). Although Intervenors note that 300-700 water systems likely exceed the Standards for the Index PFAS, Intervenors' Opp'n at 22, only 100-300 of those water systems—less than 0.5

percent of the approximately 66,000 water systems in the U.S. regulated by these Standards—were estimated to exceed Standards for the Index PFAS without *also* exceeding the Standards for PFOA or PFOS. 89 Fed. Reg. 32600, 32653. And again, none of these drinking water protections are currently in place, leaving EPA ample time to consider the issues and extend protections as necessary and appropriate.

In sum, the Court should vacate the portion of the Rule finalizing regulatory determinations and regulations for the Index PFAS.

VI. The Court Should Deny Intervenor’s Motion to File a Revised and Enlarged Brief.

Finally, the Court should deny Intervenor’s request to file a revised brief that is *double* the number of words the Court afforded them in this litigation.

Intervenor’s Opp’n at 30-35. At the outset of this litigation, the Court afforded each Petitioner 13,000 words for their opening briefs, EPA 26,000 words for its combined response, and Intervenor 9,100 words, without regard to what arguments any party may or may not make in their briefs. EPA’s changed position thus should have no bearing on Intervenor’s total word count.

Moreover, if the Court grants this motion, Intervenor need no additional words. If the Court defers consideration to the merits panel, EPA would not oppose Intervenor filing a revised brief of 9,100 words, given that their original brief may refer to portions of EPA’s initial brief that the Agency may withdraw.

Allowing Intervenor to file a revised brief of the *same* number of words they originally had would ensure Intervenor are not harmed by EPA's change in position. But Intervenor have no entitlement to an agency taking or maintaining any particular litigating position and thus cannot demonstrate any basis to double their word count.

CONCLUSION

The Court should grant EPA's motion to partially vacate the Rule. Additionally, the Court should deny Intervenor's motion to file a revised and enlarged brief.

December 3, 2025

Respectfully submitted,

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