Appointment

From: Donahue, Sean [donahue.sean@epa.gov]
Sent: 4/8/2025 4:30:00 PM
To: Donahue, Sean [donahue.sean@epa.gov]; Bradner, Kai <Kai_Bradner@afandpa.org> [Kai_Bradner@afandpa.org]; Payne, James (Jim) [payne.james@epa.gov]; Paul_Noe@afandpa.org; Browne, Peggy [Browne.Peggy@epa.gov]; Szabo, Aaron [Szabo.Aaron@epa.gov]; Tardif, Abigale (Abbie) [Tardif.Abigale@epa.gov]; Dominguez, Alexander [dominguez.alexander@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Breen, Barry [Breen.Barry@epa.gov]; Cook, Steven [cook.steven@epa.gov]; Irizarry, Gilberto [Irizarry.Gilberto@epa.gov]; Atagi, Tracy [Atagi.Tracy@epa.gov]; Strauss, Linda [Strauss.Linda@epa.gov]
CC: Lewis, Jen [Lewis.Jen@epa.gov]; Youngblood, Charlotte [Youngblood.Charlotte@epa.gov]
BCC: DCRoomWJCN4045-OGC [DCRoomWJCN4045-OGC@epa.gov]

Subject: OGC/ American Forest & Paper Association Meeting
Attachments: AFPA Trump Letter and Attachment.pdf; Noe-TRRID-v14i1-2025.pdf
Location: Microsoft Teams Meeting; DCRoomWJCN4045-OGC

Start: 4/9/2025 3:00:00 PM
End: 4/9/2025 4:15:00 PM
Show Time As: Busy

Recurrence: (none)

Required Attendees: Bradner, Kai <Kai_Bradner@afandpa.org>; Payne, James (Jim); Paul_Noe@afandpa.org; Browne, Peggy; Szabo, Aaron; Tardif, Abigale (Abbie); Dominguez, Alexander; Kramer, Jessica L.; Breen, Barry; Cook, Steven; Irizarry, Gilberto; Atagi, Tracy; Strauss, Linda
Optional Attendees: Lewis, Jen; Youngblood, Charlotte

Consolidating into one meeting from 11:00-12:00

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Tenant key: Ex. 6 - Personal Privacy (PP)

Video ID: Ex. 6 - Personal Privacy (PP)

More info

For organizers: Meeting options | Reset dial-in PIN

This meeting may be recorded. If the meeting is recorded, it will be announced via a banner showing "this meeting is being recorded." Participation in a recorded meeting will be deemed as consent to be recorded. Meeting recordings may be official agency records subject to appropriate policy, rules and regulations.

American Forest & Paper Association

Office of the President

December 5, 2024

Dear President-elect Trump,

On behalf of the American Forest & Paper Association (AF&PA) and our member companies, we congratulate you on your election to the Presidency. We look forward to working with you and your Administration to accomplish your agenda of growing the American manufacturing economy, creating new, high-paying jobs throughout our country, particularly in rural America, and ensuring that regulations are sustainable and do more good than harm. The forest products industry accounts for approximately 5% of the total U.S. manufacturing GDP, manufactures about $350 billion in essential products annually and employs about 925,000 people. The industry meets a payroll of about $65 billion annually. We are U.S. Manufacturing!

AF&PA serves to advance U.S. paper and wood products manufacturers through fact-based public policy and marketplace advocacy. The forest products industry is circular by nature. AF&PA member companies make essential products from renewable and recyclable resources, generate renewable bioenergy and are committed to continuous improvement through the industry's sustainability initiative — Better Practices, Better Planet 2030: Sustainable Products for a Sustainable Future.

Manufacturing Excellence and Value to Rural Communities

The forest products industry is a top ten manufacturing employer in 43 states – such as Wisconsin, Georgia, Pennsylvania, North Carolina, Michigan, Virginia, South Carolina and Ohio. Over 75 percent of our member company facilities are in counties that are overwhelmingly rural. Our facilities and our member companies provide good, high-paying, family-wage jobs, and our employees are the backbone of these communities.

We are proud of the hard-working men and women in our industry who work every day to bring essential products to all Americans, and we maintain strong relationships with our labor partners. The facilities and workers generate a strong tax base for these communities and support multiple small businesses, landowners, and others throughout the forest products industry supply chain. We estimate that each forest products industry job supports 3.25 additional jobs in supplier industries and in local communities across rural America.

Cumulative Burden of Regulations Undermine U.S. Innovation and Job Growth

We believe the American free enterprise system has been a significant engine for prosperity and can deliver a promising future for the United States and the world. The U.S. manufacturing sector has been a fundamental driver of this success, but our nation faces growing challenges in a highly competitive global economy. The cost, complexity and volume of regulations is greater than ever. As a result of our cumbersome air and water permitting processes, manufacturers that want to expand and create jobs with cleaner, more efficient technology are often stymied.

At the same time, we recognize that reasonable, evidence-based regulations can provide important benefits, such as the protection of the environment, health, and safety for our country, communities and employees. Unfortunately, poorly designed regulations that fail to balance costs and benefits and disregard the best available science unintentionally can cause more harm than good, waste limited resources, undermine sustainable development, and erode public confidence in government.

The U.S. Supreme Court recently made clear that regulators must follow the best reading of statutes; they must only act within the boundaries of their statutory authority, and consider all relevant factors, including balancing costs and benefits. Accordingly, it is essential that regulations be designed to provide net benefits to the public based on best available scientific and technical information through a transparent and accountable rulemaking process, with due consideration of the cumulative regulatory burden.

Your administration and Congress have an historic opportunity to dramatically improve the regulatory process to better serve the public interest, create jobs, and strengthen the competitiveness of American manufacturing. We welcome the opportunity to talk with your team about systemic reforms to our regulatory process. In addition, while not exhaustive, we have attached a list of over a dozen of our top priority regulations we request be considered for immediate attention. In addition, priority issue areas for our members include:

Carbon Neutrality of Biomass

One of the primary policy challenges for our industry is ensuring the federal government recognizes the carbon neutrality of our biomass energy. The pulp and paper industry is a leading producer of carbon-neutral bioenergy, and our efficient use of forest products manufacturing residuals provides two-thirds of the energy used at our pulp and paper mills and also provides bioelectricity for the grid. For many years, the Environmental Protection Agency (EPA) had treated biomass as carbon neutral, in line with the rest of the world, but in 2010, EPA issued its Tailoring Rule which for the first time failed to recognize the carbon benefits of our bioenergy and created regulatory uncertainty that impedes investment planning and growth. Since then, the EPA has done extensive work on bioenergy, and in 2017, came very close to formally recognizing the carbon neutrality of biomass. Unfortunately, the rule was never made final, and we have continued to work extensively with federal agencies and Congress to resolve this lingering regulatory uncertainty.

Tax Reform

Our industry is made up of both C-corporations and pass-through entities, which invest heavily in equipment and improvements, making our industry one of the most capital-intensive among all US manufacturing. The paper and wood products industry invests roughly $16 billion per year in plant and equipment items such as recovery boilers, turbine generators, paper machines, and environmental controls that are critical to maintaining technologically advanced manufacturing facilities that compete in an extremely competitive global marketplace.

As an industry that is a key economic driver, especially in rural communities, we support several key elements of the US tax code including the 21 percent corporate rate enacted as part of the 2017 Tax Cuts and Jobs Act (TCJA), restoring 100 percent full expensing for investments in new and used property, maintaining the TCJA's original interest deduction limitation provision, and restoring the full research and development tax credit as enacted. Finally, as a globally competitive industry, it is crucial that we ensure the United States is on a level playing field with other countries – TCJA had a number of provisions designed to encourage businesses back to the United States and make them competitive with other countries. We need to ensure those provisions are preserved.

Trade

U.S. forest products exports account for a significant piece of the industry's total sales and in 2023, the industry's global exports totaled over $9 billion. AF&PA strongly supports free but fair trade and in today's globalized market, it is critical for the U.S. forest products manufacturing sector to achieve unrestricted access to international markets and level the playing field among international competitors by eliminating both tariff and non-tariff barriers such as restrictive import regulations.

AF&PA member companies procure the vast majority of their fiber from healthy, American forests but our companies also procure some fiber from key trading partners and additional tariffs would negatively impact the U.S. forest products industry's ability to compete with other international forest products producers. Additionally, some paper manufacturing machinery and equipment that is used by our member companies to produce our essential products comes from other countries and cannot currently be made in the United States. While we support domestic manufacturing policies that will ultimately make that possible, we oppose tariffs on machinery and pieces of equipment our companies use that objectively cannot be made in the U.S.

In 2023, the European Union (EU) enacted the EU Deforestation-free Regulation (EUDR), a regulation that aims at eliminating products sold in the EU that are linked to deforestation, is unworkable and disadvantages the U.S. forest products industry, small U.S. family forest owners, and threatens to disrupt trade with the EU valued at more than $3.5 billion. The U.S. forest products industry is among the most responsible suppliers of forest fiber in the world, and a strong proponent of international efforts to suppress deforestation and forest degradation. The prescriptive requirements of the regulation, however, will unjustifiably increase compliance costs and weaken U.S. producers' market access to established EU trading partners.

The U.S. forest products industry does not contribute to global deforestation or forest degradation, and we will need your direct engagement with EU government authorities to ensure U.S. wood, pulp and paper producers and our supply chain, which includes nearly 11 million small, private landowners, can remain competitive and continue to ship our essential products into the EU without disruption.

Recycling Policy
Paper recycling is a success story, no matter how you measure it. Paper is one of the most widely recycled materials in America, and paper recycling rates in the U.S. have consistently increased in recent decades. In fact, the paper industry recycles nearly 60% more paper today than it did in 1990, when the industry set its first recycling rate goal. In 2023, the paper recycling rate was 65-69% and the rate for cardboard recycling was 71-76%. In the United States, paper is recycled into new products every day.

The success of paper recycling has been accomplished through our industry's voluntary leadership and investment in market-based solutions. The use of recycled paper in manufacturing is driven by availability, performance, and cost, allowing recovered paper to be directed toward its highest-value end use. While nearly half of our industry's fiber needs are satisfied from recycled fiber, fresh fiber from sustainably managed forests is also a crucial source of material to sustain the fiber supply. We do not support government mandates for postconsumer recycled content in specific products. We support the U.S. EPA waste hierarchy, which recognizes a clear distinction between recycling and energy recovery and prioritizes recycling.

Conclusion
Again, we want to congratulate you on your election victory. We look forward to working with you over the next four years to enact policies that will allow pulp, paper, packaging and wood products manufacturers to continue as an American success story. Please let us know how we can assist your team in this endeavor.

Sincerely,

Heidi Brock

Heidi Brock
President and CEO
American Forest & Paper Association

Cc: Vice-President elect J.D. Vance

Attachment

American Forest & Paper Association

Summary of Key Regulatory Concerns of AF&PA and Recommended Reforms (Dec. 2024)

The regulations and recommended reforms summarized below cut across many regulatory areas, such as the environment, energy and product-specific issues. While each regulation has its own technical aspects, a common thread across them all is the adverse impacts they have on the competitiveness of U.S. pulp, paper and wood products manufacturers, which must operate efficiently to successfully compete in our global marketplace. The U.S. forest products industry provides family wage jobs that support rural communities across America. Our industry employs 925,000 hard-working people who make essential paper and wood products that over 330 million Americans, as well as billions more around the world, depend on in their daily lives.

Environmental Protection Agency:

- **Carbon Neutrality of Biomass:**

Paper and wood products mills are the largest producers and users of carbon-neutral bioenergy of any other industrial sector. Unfortunately, EPA's policy shift in 2010 on biogenic CO_2 emissions has created counterproductive regulatory uncertainty for the industry that has lingered for almost 15 years.

  - **We recommend that bioenergy produced by pulp, paper and wood products mills be considered carbon neutral in rules and policies by EPA, as well as in the clean electricity tax credit rules and policies by the Department of Treasury, and by other relevant agencies.**

- **Air Permit Gridlock and PM NAAQS:**

Every five years, EPA must decide whether its National Ambient Air Quality Standards (NAAQS) are sufficiently protective of public health. Over time, as NAAQS (for particulate matter (PM), ozone, sulfur dioxide and nitrogen oxides) have been lowered close to background levels, it has become increasingly difficult to get permits approved for projects to modernize, expand, or build state-of-the-art American manufacturing plants. Given extremely stringent NAAQS recently issued by EPA, especially the PM NAAQS, a broad array of American industries, in addition to ours, across our country now face permitting gridlock. EPA should modernize its air permitting process based on credible approaches and adjust its modeling criteria to reflect actual impacts. The challenges with the ever-lower NAAQS are exacerbated by a lack of a credible

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implementation plan, including inappropriate emission measurement methods, poor estimates of emissions, use of unrealistic air dispersion models, and several unduly rigid permitting policies.

- **We recommend that EPA withdraw and reconsider the recent PM NAAQS due to its flawed and legally questionable rushed review, the failure to provide a workable implementation plan, and the scientific uncertainties. (RIN 2060-AV52)**
- **We recommend that EPA address the air permitting gridlock given the lack of "headroom" by committing sufficient resources to develop a credible NAAQS implementation program based on the best technical practices, including using more realistic receptor locations and emissions, exposures, and modeling data within the next year.**

- **PFAS Regulations (CERCLA Listing of PFOA/PFOS as Hazardous Substances; SDWA Maximum Contaminant Level (MCL)):**

In paper products manufacturing, sustainable materials management includes the beneficial use of paper mill residuals, largely composed of tree fiber, as a fertilizer. These mill residuals can be beneficially used for agricultural or forest lands, providing reduced soil erosion, less need for irrigation, increased soil nutrient-holding capacity, and reduced soil compaction, all of which significantly improves plant growth. It is important to ensure that the listing of PFOA and PFOS as hazardous substances under CERCLA does not lead to unintended outcomes, including impeding or preventing the safe and beneficial use of paper mill residuals as fertilizer.

Paper mills also sometimes serve as small drinking water systems for workers and local communities, and any drinking water MCLs under the Safe Drinking Water Act (SDWA) should be consistent with the law's requirements, including requirements for quality of science and data, as well as consideration of cost to all categories of public water systems.

- **We recommend that EPA reconsider the CERCLA Rule, which is legally flawed and could produce a host of unintended outcomes (RIN: 2050-AH09).**
- **We recommend that EPA reconsider the PFAS MCL Rule, to ensure it is consistent with the law's requirements for quality of science and data and the consideration of cost (RIN: 2040-AG18).**

- **Water Permit Gridlock and Human Health Water Quality Criteria (HHWQC):**

Under the Clean Water Act, states have the primary responsibility for issuing water quality standards and establishing acceptable risk levels in those standards. Based on a novel and far-reaching legal theory, EPA has established extraordinarily stringent water policy in two rules, the HHWQC Rule for Washington State and the Tribal Reserved Rights Rule. Both rules will lead to unattainable water quality standards and unattainable

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limits in Clean Water Act NPDES permits needed to operate U.S. manufacturing facilities.

- **We recommend that EPA reconsider the HHWQC Rule for Washington State (RIN: 2040-AG21) and the Tribal Reserved Rights Rule (RIN: 2040-AG17).**

- **Pulp and Paper MACT Risk and Technology Reviews:**

The pulp and paper industry has invested billions of dollars to significantly reduce hazardous air pollutants (HAPs) from its operations due to stringent Maximum Achievable Control Technology (MACT) requirements set under section 112 of the Clean Air Act. EPA determined that the remaining public health risk at both pulp and paper mills is acceptable based on a thorough analysis of post-MACT emissions. In 2020, a federal circuit court remanded back to EPA the "Pulp MACT" (Subpart MM National Emissions Standard for Hazardous Air Pollutants (NESHAP)), ruling EPA failed to revise the MACT as required under section 112(d)(6). *See Louisiana Environmental Action Network v EPA*, 955 F.3d 1088 (2020) ("*LEAN*").

EPA recently has misinterpreted their obligation under *LEAN* (and section 112(d)(6)) to set standards for more HAPs and more equipment at facilities. Section 112(d)(6) obligates EPA to "review and revise as ***necessary***," which is broad language that courts have interpreted in similar situations as requiring the consideration of all relevant factors, including costs, and balancing costs and benefits before imposing any new obligations. The recent Supreme Court *Loper Bright Enterprises* decision provides further support that EPA should change its approach to reviewing NESHAPs such as the Pulp and Paper MACTs.

In November 2024, EPA initiated its review of the Pulp MACT by sending a comprehensive survey of pulp mill operations and equipment to seven major companies. Once responses are evaluated, EPA plans to require about 200 HAP tests at 45 mills costing several million dollars. (EPA is simultaneously reviewing the "Paper MACT," so called the Subpart S NESHAP, and plans to send out a similar survey in 2025 and mandate additional HAP testing in 2026.) Unfortunately, much of the HAP testing data will be hard to assess due to poor quality and variability.

- **We recommend that EPA reconsider its plans to require pulp mills to undertake extensive HAP testing next spring by first determining whether new standards are "necessary" for each HAP-equipment combination -- considering all relevant factors, including public health risks, likely control costs, technical feasibility to accomplish testing, adequacy of current requirements, value of additional data and other relevant factors.**
- **Based on an assessment of public health benefits and costs (including any new test data) under section 112(d)(6), we recommend that EPA promptly complete its review of the pulp and paper MACT and only set new standards**

(either work practices or limits) that are "necessary" and reasonable and achievable.

- **Formaldehyde Risk Evaluation**

Under TSCA as amended, EPA's evaluation of priority chemicals has focused mainly on hazards and making unduly conservative assumptions about exposures, which leads to unnecessarily stringent and unworkable regulation. EPA routinely relies on conservative hazard determinations rather than the weight of the scientific evidence, as TSCA requires. EPA also is creating occupational exposure levels for existing chemicals in commerce even if the chemical has been adequately regulated by OSHA, which has led to confusing regulatory duplication.

An example of the problems in the chemical risk evaluation process under TSCA is its current draft Risk Evaluation for Formaldehyde. EPA calculated an extremely stringent occupational exposure level that is below background concentrations of formaldehyde in the air. Even facilities that do not use formaldehyde directly in manufacturing will have difficulty meeting the EPA level, which is far lower than the existing and protective OSHA permissible exposure level and much lower than occupational levels developed in Europe and other countries. EPA must incorporate the best available science in rulemaking to comply with TSCA and to ensure the U.S. is on a level playing field with its competitors around the world.

- **We recommend that EPA revise its formaldehyde risk evaluation under TSCA.**
- **We recommend that EPA use the best available science when evaluating chemicals such as formaldehyde and rely on the work of authoritative scientific bodies instead of operating independently and ignoring the weight of the scientific evidence.**

- **Good Neighbor Plan:**

In 2023, EPA promulgated the so-called Good Neighbor Plan regulation under the Clean Air Act to impose control requirements for nitrogen oxide (NO_x) emissions in 23 states from fossil fuel boilers in power plants -- and for the first time -- seven manufacturing industries, including paper mills. EPA ignored AF&PA's comments showing that the paper industry should have been excluded from the rule, both because the paper industry's emissions were below EPA's emissions threshold and because its very high control costs exceeded EPA's cost threshold.

States, AF&PA, and other industries challenged the rule. In June 2024, the U.S. Supreme Court issued a rare stay of the rule pending review on the merits by the D.C. Circuit Court of Appeals. *See Ohio v EPA*, 144 S. Ct. 2040 (2024), which found that industry petitioners likely would succeed on the merits.

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- **We recommend that EPA withdraw and reconsider the Good Neighbor Plan (RIN: 2060-AV51)**

Department of Labor, Occupational Safety and Health Administration (OSHA):

- **OSHA Heat Injury and Illness Prevention Proposed Rule:**

AF&PA recognizes the importance of protecting workers from heat-related injury and illness and wants to accomplish this objective in a practical, reliable, and scientifically sound manner. We understand OSHA's desire to establish a baseline for workplaces to address this hazard, but the scope of the rulemaking covers a very broad range of industries (including both outdoor and indoor work), regional climates, and worker populations. The rule needs to provide significant flexibility across workplaces to effectively manage the hazard of heat. AF&PA members already employ many controls outlined in the proposed rule and effectively protect workers from heat on a site-specific basis. Like other industries, we are concerned that certain aspects of the proposed rule are unreasonably prescriptive, burdensome, and unnecessary – and could be counterproductive.

- **We recommend that OSHA carefully review the proposed heat rule (RIN:1218-AD39) to add flexibility and recognize the effective efforts currently underway.**

Securities and Exchange Commission (SEC) and Federal Acquisition Regulatory (FAR) Council

- **Greenhouse Gas Reporting and Goals Rules (SEC Climate Disclosure Rule; FAR Council Proposed Rule on Greenhouse Gas (GHG) Emissions Reporting and Goals for Federal Contractors):**

As part of the Biden Administration's "whole of government" approach to climate regulation, the SEC finalized a rule requiring publicly listed companies to extensively report on their GHG emissions. In addition, the FAR Council (the General Service Administration, the Department of Defense, NASA, and OMB's Office of Federal Procurement Policy) proposed an extraordinarily far-reaching rule to require both GHG emissions reporting as well as GHG reduction goals by major federal contractors. Both rules raised a host of legal and practical concerns, and the SEC final rule currently is under legal challenge.

- **We recommend that the SEC reconsider and revise its climate disclosure rule (RIN: 3235-AM87) to ensure it is within the bounds of its statutory authority and is not arbitrary and capricious or counterproductive.**

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- **We recommend that the FAR Council withdraw its GHG emissions reporting and goals proposed rule (RIN: 9000-AO32) given its host of legal flaws and potential unintended outcomes.**

Department of Treasury

- **Clean Electricity Tax Credits:**

Under the Inflation Reduction Act, the Department of Treasury was required to issue regulations to implement the production tax credit and investment tax credit under sections 45Y and 48E of the Internal Revenue Code. Under the IRA, qualified facilities have a greenhouse gas emissions rate of not greater than zero. AF&PA filed with Treasury extensive comments and many scientific studies showing that the energy systems at pulp and paper mills should be included as qualified facilities in Treasury's final rule and annual table.

- **If pulp and paper mills' energy systems are not included as qualified facilities in the final rule (RIN: 1545-BR17) and annual table, we recommend that the final rule and annual table be withdrawn and reconsidered.**

Federal Trade Commission (FTC)

- **Green Guides Update:**

The Green Guides provide guidance to help marketers avoid making environmental claims that mislead consumers. The FTC is in the process of finalizing an update to the Green Guides. AF&PA supports the update of the Green Guides and looks forward to the opportunity to comment on the proposed updates.

- **Updating the Green Guides to reflect current trends and concerns in the marketplace is important to ensure consistency across states and avoiding a potential patchwork of state regulation of marketing claims.**

Message

From: McLain, Jennifer L. [McLain.Jennifer@epa.gov]
Sent: 5/22/2025 12:54:23 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]
CC: Burneson, Eric [Burneson.Eric@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Brooks, Wes [Brooks.Wes@epa.gov]
Subject: RE: UCMR5 PFAS data
Attachments: UCMR5_DataSummary_Apr2025_250520c_draft.docx

Attached is our proposal for modifying the UCMR5 Data Summary for the current and future quarterly reports to include an explanation of EPA's planned actions related to PFAS NPDWR. Please let us know if you agree with this approach or want to discuss further.

Thank you,
Jennifer

From: McLain, Jennifer L.
Sent: Tuesday, May 6, 2025 4:53 PM
To: Kramer, Jessica L. kramer.jessical@epa.gov; Browne, Peggy Browne.Peggy@epa.gov
Cc: Burneson, Eric Burneson.Eric@epa.gov; Tiago, Joseph Tiago.Joseph@epa.gov; Risley, David <Risley.David@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Brooks, Wes <Brooks.Wes@epa.gov>
Subject: UCMR5 PFAS data

In response to your question about the preliminary UCMR occurrence estimates, Eric's team prepared the attached cost/bene analysis. Please let us know if you have any questions or need additional information.

Jennifer

Message

From: Risley, David [Risley.David@epa.gov]
Sent: 6/2/2025 6:21:34 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]; Brooks, Wes [Brooks.Wes@epa.gov]; McHale, Caitlin [McHale.Caitlin@epa.gov]
CC: Haga, Ellie [Haga.Ellie@epa.gov]; Lanier, Lynsey [Lanier.Lynsey@epa.gov]; Guzda-Struck, Kathleen [GuzdaStruck.Mary@epa.gov]; Bender, Emily [Bender.Emily@epa.gov]; Minton, Gabrielle [minton.gabrielle@epa.gov]
Subject: TPs for WH Meeting with Georgia County Commissioners
Attachments: WH Georgia County Commissioners Speech.docx

Jess –
Here are your draft talking points for tomorrow's meeting with Georgia County Commissioners. This was a recent addition to your schedule. Thanks to the comms team for quickly pulling together talking points.

I've included Wes and Caitlin primarily for situational awareness.

Best,
David

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

WHITE HOUSE STATE LEADERSHIP CONFERENCE
JUNE 3, 2025, TIME
Jess Kramer's Remarks

Who: The Georgia County Commissioners

What: Speak in place of the Administrator for 15 minutes including Q/A.

Location: EEOB Room 474

Open press:

Other EPA Speakers: No

Format: Keynote and Q/A

Key Topic Requested: "PFAS Regulations"

Run of Show

Time	Speaker	Notes
9:00 AM	Alex Meyer	Welcome Speech and overview of IGA
9:05 AM	Secretary Turner – HUD	Overview, updates on department and Q&A
9:20 AM	Secretary Collins – VA	Overview, updates on department and Q&A
9:45 AM	Scott Centorino – Domestic Policy Council	5-minute break for transition
10:00 AM	Break	
10:10 AM	Bryan Kellogg – DOE	Overview, updates on department and Q&A
10:30 AM	Greg Wischer – DOI	5-minute break for transition
10:45 AM	Open	Overview, updates on department and Q&A
11:00 AM	Bethany Hudson – DOD	Overview, updates on department and Q&A
11:30 AM	John Eunice – EPA, OCIR Jess Kramer – EPA, AO	Overview, updates on department and Q&A
11:35 AM	Open	5-minute break for transition
11:50 AM	Open	Overview, updates on department and Q&A
12:15 PM	Break	5-minute break for transition
12:20 PM	Administrator Loeffler – SBA	Overview, updates on the Small Business Association and Q&A
12:30 PM	Secretary Kennedy – HHS	Overview, updates on HHS and Q&A
12:45 PM	Closing	Closing (leaving room for discussion running over)

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Note: John Eunice will introduce you (and cover Okefenokee).

Introduction

- Thank you for the introduction John.
- Jess' list of caveats (Senior Advisor until confirmed…)
- **Powering the Great American Comeback** – not just a talking point. We are ensuring that everything the Office of Water does aligns with this goal.
    - Pillar 1: Clean Air, Land, and Water for Every American
    - Pillar 2: Restore American Energy Dominance
    - Pillar 3: Permitting Reform, Cooperative Federalism, and Cross-Agency Partnership
    - Pillar 4: Make the United States the Artificial Intelligence Capital of the World
    - Pillar 5: Protecting and Bringing Back American Auto Jobs

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PFAS, Generally

- **Addressing PFAS** is a priority for EPA.
  - Administrator Zeldin outlined an overarching plan in April.
  - The Office of Water will be central to advancing progress.
- Recognize that one of the best ways to **address PFAS is at the source**.
- A few weeks ago (on April 28), **Administrator Zeldin outlined a suite of EPA actions to address PFAS**.
- It included the **development of ELGs for certain PFAS and certain industries** – namely PFAS manufacturers and metal finishers.
- We're currently discussing internally and look forward to announcing next steps soon.

PFAS National Primary Drinking Water Regulation

- The Trump Administration **reviewed the 2024 National Primary Drinking Water Regulation that established standards for six PFAS**.
- This has been a **holistic review—including the science**, the monitoring data, statutory authority, Safe Drinking Water Act process, implementation flexibilities, etc.
- **When it comes to the science, especially when it comes to PFOA and PFOS, the agency's underpinning of the rule is robust and interconnected.**
- We have found that it's **not based on one study or one factor** that if changed, would change the outcome.

- Rather, if you **pull one string, the web of scientific underpinning remains substantial and compelling**.
- With that said, the Administrator gave direction that will **provide significant relief to drinking water systems, ensure that water systems can stay in business and protect American families from water rate hikes while reducing exposure to these substances in drinking water.**
- I will talk about the Administrator's intent to:
    - **Keep the current regulations for PFOA and PFOS and un-pause litigation** while
    - **Extend compliance deadlines**
    - Establish a **federal exemption framework**
    - Pursue **proactive technical assistance to water systems**—especially in rural and small communities
    - Use tools available to **hold polluters accountable**
- **At the same time, we intend to rescind the regulations with respect to four additional PFAS.**
    - Specifically, the agency intends to **rescind the regulations and reconsider the regulatory determinations** for PFHxS, PFNA, HFPO-DA (commonly known as GenX), and the Hazard Index mixture of these three PFAS plus PFBS.
    - This action will ensure that the determinations and any resulting drinking water regulation **follow the legal process laid out in the Safe Drinking Water Act**.
- In terms of the **compliance deadlines for PFOA and PFOS**, the 2024 regulation **gave public water systems until 2029** to comply with the maximum contaminant levels, or MCLs.

- Water systems, associations, elected officials, and others have shared with us that **the compliance schedule is one of the biggest challenges for implementation**.
- The Administrator agrees with this, **especially in light of stacking requirements** on PFOA and PFOS and the Lead and Copper Rule.
- To that end, EPA plans to **develop a rulemaking** to provide additional time for compliance, including proposing an **extension of the compliance date to 2031**.
- EPA plans to issue a **proposed rule this fall** and finalize this rule in the Spring of 2026.
- In addition, in light of this extra time, **EPA encourages states seeking primacy for implementing the PFAS drinking water regulation to request additional time** for developing their applications.
- We also announced our **intent to establish a federal exemption framework for PFOA and PFOS**.
- And we are committed to working with communities to meet their needs through our **new PFAS OUT initiative**.
    - PFAS OUT will enhance engagement on addressing PFAS by **proactively connecting with every public water utility** known to need capital improvements to address PFAS in their systems.
    - `EPA will **share resources, tools, funding and technical assistance** opportunities to help utilities meet the federal drinking water standards.
    - PFAS OUT will ensure that **no community is left behind** as we work to protect public health and bring utilities into compliance with federal drinking water standards.

- It is critical to underscore that drinking water systems are **passive receivers of PFAS into their source waters, including PFOA and PFOS**.

Policy Meets Practicality

- The Office of Water intends to align policy with practicality. We want to make sure our policies:
  - Follow the law (SDWA, CWA, SCOTUS)
  - Consider the state of the science

  Informed by practical, on the ground implementation

401

- On May 22, we rolled out a **memo reinforcing the alignment between Clean Water Act Section 401 and the "Powering the Great American Comeback" Initiative**
- This memo emphasizes the agency's position that states and Tribes must **utilize section 401 only for its statutory purpose – to protect water quality** – and not for policy or political goals unattached to real and direct water quality concerns.
- We also announced our **intent to seek input on implementation challenges** by issuing a Federal Register Notice and opening a docket for public comment. I **look forward to your input** through this process.

WOTUS

- We fully recognize that **communities have been particularly affected by WOTUS ping pong** – meaning the back and forth of

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different Administrations changing definitions. This has been going on for a decade or longer.

- We know that **your constituents need certainty**.
- The **Sackett decision added much-needed clarity**.
- We intend to provide **clear rules of the road that fully implement SCOTUS' direction** in Sackett v. EPA.
- The agencies have already taken action, by issuing a **memo to the field** addressing a confusing and expansive view of which wetlands are waters of the US.
- The memo clarifies that **wetlands are only considered jurisdictional if they directly abut a WOTUS and have a continuous surface connection**.
- Additionally, we **will undertake a rulemaking process to revise the 2023 definition of WOTUS** to ensure that it fully implements direction from the Supreme Court.
- We just wrapped up **listening sessions** to gather real-world perspectives and experiences with WOTUS implementation.

Steam Electric ELGs

- We have announced our **intent to revise costly wastewater regulations for coal burning power plants** issued in 2024.
- Our goal is ensuring that **all Americans can rely on low-cost electricity while also protecting our nation's water resources**.
- EPA will **reconsider the 2024 standards and consider how to provide immediate relief and flexibility in terms of compliance planning** (e.g., retirement decisions) **and existing requirements**.

- We've heard from a lot of power utilities that the electricity landscape is changing, with AI coming in, and they need more time to plan. We intend to accommodate that.

Oil and Gas ELGs

- We have announced our **intent to modernize outdated regulations on wastewater discharges for oil and gas extraction facilities to lower energy costs while supporting environmentally sustainable water reuse**.
- The agency's review will evaluate modern technologies and management strategies to provide regulatory flexibility for oil and gas wastewater – also known as produced water – to be **treated for beneficial reuse, including for Artificial Intelligence and data center cooling, rangeland irrigation, fire control, power generation, and ecological needs**.

Technical Assistance

- I want to close by talking about **Technical Assistance**.
- EPA stands ready to partner with your communities to **address their most-pressing water needs**.
- Through our Technical Assistance programs, which you can request by emailing [HYPERLINK "mailto:WaterTA@epa.gov"], we can engage directly with communities to understand their needs and help identify right-sized solutions.
- Additionally, EPA recently announced **$30 million** for technical assistance available through **NRWA, RCAP, and the**

Environmental Finance Center at the University of New Mexico.

Close

- Thank you and I look forward to our discussion today and over the coming years.

Message

From: Underwood, Patricia ST OSD OUSD A-S (USA) [patricia.underwood6.civ@mail.mil]
Sent: 6/3/2025 6:19:54 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]
CC: Risley, David [Risley.David@epa.gov]; Lanier, Lynsey [Lanier.Lynsey@epa.gov]
Subject: Re: Huawei - New Chip Chemical Firm
Attachments: Re: Huawei - New Chip Chemical Firm

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Message

From: Haga, Ellie [Haga.Ellie@epa.gov]
Sent: 6/3/2025 10:21:20 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Risley, David [Risley.David@epa.gov]; Lanier, Lynsey [Lanier.Lynsey@epa.gov]
Subject: Meeting materials for Wednesday, June 4, 2025
Attachments: MATERIALS: EPA Office of Water meeting with Fairfax Water; Imperial County Ltr to EPA Admin Zeldin - New River Border Pollution.pdf; OW-OWOW Bi-Weekly 06-04-25.docx; OW-OWM Biweekly Agenda 06.04.2025.docx

Hi Jess,
Here are the materials for your meetings tomorrow, **Wednesday, June 4, 2025**, including:

- Office of Water Meeting with Fairfax Water
- Meeting with Imperial County, CA Local Leaders-Board of Supervisors; Re: New River Cross-Border Water Pollution
    - Imperial County letter to EPA Administrator Zeldin

Also attaching for your awareness the biweekly updates from OWOW and OWM.

Let us know if you need anything else.

Best,
Ellie

Ellie Haga
Special Assistant
Office of Water
U.S. Environmental Protection Agency
WJC East 3219-D
Desk Phone: 202-564-3854
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Haga.ellie@epa.gov

Message

From: Jessica Love [jlove@fairfaxwater.org]
Sent: 6/2/2025 2:34:17 PM
To: Lanier, Lynsey [Lanier.Lynsey@epa.gov]; Risley, David [Risley.David@epa.gov]; Eng, Connie [Eng.Connie@epa.gov]
CC: Jamie Bain Hedges [jhedges@fairfaxwater.org]; Erica Brown [ebrown@fairfaxwater.org]; Brian Redder [bredder@fairfaxwater.org]
Subject: Discussion Topics for June 4th EPA/Fairfax Water Meeting

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Good morning,

On behalf of Fairfax Water General Manager/CEO Jamie Bain Hedges, please see the below email regarding discussion topics for the upcoming EPA/Fairfax Water meeting:

Fairfax Water is looking forward to meeting with you this week to discuss several important issues of mutual interest.

In advance of our conversation, we would like to share a list of questions we hope to explore during the limited time we have together. We understand that EPA may not yet have answers to all of these items and recognize that time constraints may prevent us from covering each one in full. Nonetheless, we would greatly appreciate any insights, updates, or guidance you're able to provide.

Please do not hesitate to reach out if there are any questions ahead of Wednesday's meeting. We appreciate your time and look forward to our discussion.

1. EPA indicated in its May 14, 2025, press release that it would issue a rulemaking to extend the compliance date for the PFOA and PFOS MCLS by two years. Some questions on this rulemaking include:
    a. Will it apply to all water systems universally, including large systems, or are there any eligibility criteria based on system size or capacity?
    b. Will it address only the compliance date extension and will the rescission of the Hazard Index PFAS be addressed by Executive Order 14219, the *Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative.*
    c. What is the anticipated timeline for the entirety of actions EPA plans to administer related to revising the PFAS NPDWR?

2. Will there be elements included in the federal exemption framework that would apply to Fairfax Water's situation?

3. EPA mentioned in its press release that it would be encouraging states to request additional time for primacy applications. Will EPA be encouraging primacy applications to carry out the federal exemption framework, or does the Agency intend to retain that authority? If a state such as VA applies for primacy anyway and it is granted, how would you recommend Fairfax Water proceed?

4. Also in the May 14 release, EPA states that the actions to rescind a portion of the rule and extend the compliance deadline will be paired with effluent limitations guidelines (ELGs) - Is the intent to follow a similar timeline for all of these? What other source water protection initiatives are expected from EPA and is there a timeline for these actions?

5. What does EPA have planned in terms of POTW biosolids regulation with respect to PFAS?

6. Does the Agency have a plan to address the possible scenario in which the LCRI is removed and the LCRR is reactivated – immediately requiring water systems to comply with requirements that were postponed to 2027?

7. While we are aware EPA is still evaluating its next steps with the Lead and Copper Rule, are there any topics or implementation challenges the Agency would like more information or details on?

Thank you,
Jessica

Jessica Love
Executive Office Administrative Specialist
Fairfax Water
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Cell: 571-595-8178

Message

From: Risley, David [Risley.David@epa.gov]
Sent: 6/4/2025 8:44:14 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]; Brooks, Wes [Brooks.Wes@epa.gov]; McHale, Caitlin [McHale.Caitlin@epa.gov]
CC: Guzda-Struck, Kathleen [GuzdaStruck.Mary@epa.gov]; Bender, Emily [Bender.Emily@epa.gov]
Subject: Desk Statement on PFAS Litigation Abeyance

Jess and Wes –
OGWDW developed the following desk statement on our request to continue holding litigation on the PFAS drinking water rule in abeyance. It looks good to me, and we already have a press inquiry where we plan to use this. Sharing mostly as an FYI, but please let me know if you have questions/comments/concerns!

Desk Statement

Ex. 5 Deliberative Process (DP)

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

Message

From: Dan Hartnett [hartnett@amwa.net]
Sent: 1/24/2025 2:02:39 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
Subject: Welcome and congratulations!
Attachments: AMWA-Trump_transition_letter11-14-24.pdf; Water Priorities Transition letter 12-13-24.pdf

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Hi Jess,

I'm not sure if this email account is active yet, but I heard that you will be starting at EPA in a couple of weeks so I wanted to reach out to say hello and congratulations on your new role. I am confident that the president could not have made a better choice to lead the Water office, so I am thrilled to have the chance to work with you again!

I'm sure you are going to be extremely busy as you get settled in, but whenever you have a moment I would love to set up a time to come by and say hello. I'm sure my boss would be happy to join us as well and talk about how AMWA can be most helpful to you in the coming weeks and months.

In the meantime, for your information I'm attaching copies of two letters AMWA sent to the incoming administration late last year — one that we sent ourselves outlining some topline water policy issues, and another that was sent in collaboration with others in the sector, which gets into a bit more detail. I know these are all issues that you are extremely well versed in, but since the letters were shared with Zeldin's team I wanted to make sure you had them directly as well.

Again, congratulations on your new position, and let's try to meet up once you are officially onboard!

Dan Hartnett
Chief Policy Officer
Association of Metropolitan Water Agencies
hartnett@amwa.net
202-331-2040

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LEADERS IN WATER

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P 202.505.1565
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November 14, 2024

The Honorable Donald J. Trump
President-Elect of the United States
Washington, DC

Dear President-Elect Trump:

On behalf of the Association of Metropolitan Water Agencies (AMWA), congratulations on your election as the next President of the United States. AMWA is an organization of the nation's largest publicly owned drinking water systems, and each day our members collectively serve clean and safe drinking water to more than 160 million Americans from coast to coast. We are eager to work with you and your administration in the coming weeks and months to develop and implement policies that ensure Americans continue to have access to the best drinking water in the world.

Your administration is uniquely positioned to help the nation's public water systems prepare for and respond to the range of challenges facing our communities. We therefore urge you to adopt a water policy agenda focused on three key pillars: development of sound regulations, robust investment in water infrastructure, and collaboration with water sector entities to address physical, cyber, and natural risks.

Pillar One: Develop sound drinking water regulations

Americans are fortunate to have access to some of the best drinking water in the world. EPA has set federal standards for more than 90 different drinking water contaminants and through cooperative federalism, individual states are empowered to set their own standards for contaminants that might present local or regional concerns.

Today, drinking water utilities know more about potential contaminants than in previous decades, thanks to advanced detection capabilities that can identify contaminants at concentrations of as little as a single drop in several Olympic-sized swimming pools. But the Safe Drinking Water Act, or SDWA, wisely recognizes that the mere presence of a miniscule amount of a substance in drinking

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Pittsburgh Water

Shaun Pietig
WaterOne

Holly Rosenthal
Phoenix Water Services Department

Todd Swingle
Toho Water

Kenneth Waldroup
Cape Fear Public Utility Authority

water does not necessarily equate to a public health risk. Instead, binding drinking water regulations are to be developed through a transparent process that is based in peer-reviewed science and which appropriately considers both potential public health benefits and compliance costs.

Unfortunately, in recent years EPA has pursued expansive new regulations based on questionable science with seemingly little regard for their costly effects on water systems and their ratepayers. For example, earlier this year EPA finalized new drinking water standards for several per- and polyfluoroalkyl substances (PFAS). While AMWA agreed with EPA's initial decision to regulate several of these PFAS, the final regulation sets the standards well below what is feasible and cost-effective for many communities. As a result, the regulation will be tremendously costly for water systems and their ratepayers. A study completed last year by the Policy Navigation Group on behalf of AMWA estimated that the PFAS regulations will cost community water systems across the country as much as $6.4 billion each year – a sum that translates to additional annual per-household costs of $1,700 for community water systems serving between 501 and 1,000 people.[1]

This year, EPA also finalized a rule to designate certain PFAS as hazardous substances under federal law. While intended to hold polluters accountable, in practice this new regulation will put thousands of drinking water systems across the country at risk of being sued to cover the cost of cleaning up the disposal site of water treatment residuals containing PFAS – substances that water systems only possessed because they had to comply with EPA's drinking water standards for PFAS. The cost of this liability for communities nationwide will be immense.

Finally, this year EPA also finalized a suite of revisions to the federal Lead and Copper Rule, which had just been strengthened and updated during your first administration. The revised rule includes a mandate for drinking water systems nationwide to remove and replace all lead service lines over ten years – even service lines that are the private property of individual homeowners. While AMWA strongly agrees with the aspiration of eliminating lead service lines nationwide, a requirement for all communities to finish the task within ten years represents a massive unfunded mandate. The cost of replacing lead service lines alone could cost water systems as much as $12.6 billion annually over ten years.[2] And of course, these costs will ultimately be paid by ratepayers.

During the first year of your administration, EPA is expected to propose several new drinking water regulations, including standards to limit perchlorate and to update microbial disinfectant byproduct rules. As these tasks are carried out, AMWA urges your administration to base its decisions on sound science and achievable public health benefits – while being conscious of technical feasibility, cost, and the effects on local ratepayer affordability.

---

[1] https://www.amwa.net/testimonycomments/amwa-comments-proposed-pfas-national-primary-drinking-water-regulation

[2] https://www.amwa.net/system/files/linked-files/AMWA_EPA_%202024%20comments%20on%20LCRI.pdf

Pillar Two: Make robust investments in water infrastructure

These regulatory compliance costs will be layered on water systems across the country that are already struggling to maintain and upgrade their infrastructure without placing excessive burdens on their ratepayers. The needs are well documented: EPA estimates that the nation's drinking water systems require $625 billion in additional investment over the next two decades just to maintain current levels of service.[3] For wastewater systems, the sum is $630 billion,[4] equating to a total water and wastewater infrastructure need of more than $1.2 trillion over the next twenty years.

Helping local water systems address these costs is one area where investments in EPA's budget can pay dividends in communities across the nation. Even the Heritage Foundation has identified EPA's water infrastructure assistance programs as "one very targeted area where increased spending would be in the nation's interest."[5] AMWA therefore urges you to make strong investments in water infrastructure a hallmark of your administration.

Specifically, we request that your administration pursue full funding for several core drinking water and wastewater infrastructure programs administered by EPA. While these funds flow through EPA, and in some cases states, they are ultimately received by local communities to plan and carry out projects to build and renew the critical infrastructure necessary to promote public health and facilitate economic growth:

- **$3.25 billion for the Drinking Water State Revolving Fund.** The DWSRF supports capitalization grants to states that in turn offer low-interest loans to communities carrying out water infrastructure projects that benefit public health or achieve compliance with the Safe Drinking Water Act. Fully funding the DWSRF will help states maintain adequate resources to fund these projects.

- **$3.25 billion for the Clean Water State Revolving Fund.** The CWSRF is the primary federal clean water financing tool that communities and public clean water utilities utilize to help meet their Clean Water Act obligations and infrastructure needs. The CWSRF has been instrumental to communities' successes in advancing water quality and public health protection.

- **$80 million for the Water Infrastructure Finance and Innovation Act (WIFIA) program.** WIFIA offers competitive, low-cost financing to help communities pay for large-scale drinking water and wastewater projects that are generally expected to cost at least $20 million. Because WIFIA funds are leveraged, this investment would support several billion dollars in direct credit assistance for water projects nationwide.

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[3] EPA 7th Drinking Water Infrastructure Needs Survey. https://www.epa.gov/system/files/documents/2023-09/Seventh%20DWINSA_September2023_Final.pdf

[4] EPA 2022 EPA Clean Watershed Needs Survey Report. https://www.epa.gov/system/files/documents/2024-05/2022-cwns-report-to-congress.pdf

[5] https://static.project2025.org/2025_MandateForLeadership_CHAPTER-13.pdf

- **$100 million for Reducing Lead in Drinking Water grants.** This program offers direct funding to help communities reduce risks associated with lead in drinking water by fully replacing lead service lines or conducting inventory inspections to determine where lead pipes are located.

- **$50 million for the Midsize and Large Drinking Water System Infrastructure Resilience and Sustainability Program.** This program is designed to help drinking water systems take steps to prepare to withstand the effects of natural disasters and cyber threats. Eligible projects include those that help communities efficiently utilize water supplies, modify or relocate infrastructure threatened by natural hazards or extreme weather, or deploy measures to reduce a water system's cyber vulnerabilities.

Again, by supporting these critical programs within EPA's budget, your administration will help communities in every state in the nation construct essential water infrastructure while protecting individual ratepayers from excessive and unaffordable water bills.

Pillar Three: Collaborate to address physical, cyber, and natural risks

America's critical infrastructure is vulnerable. Not only to natural disasters and terrorist organizations, but also to cyber criminals who are attacking water utilities on a monthly basis. The water sector recognizes this and has proactively taken steps to help drinking water and wastewater systems increase their preparedness to these risks. However, the sector needs your administration's help to expand access to these resources.

One underutilized resource available to communities is the Water Information Sharing and Analysis Center, or WaterISAC. Established in 2002, today WaterISAC is one of more than two-dozen sector-specific ISACs in operation. It collects, analyzes, and disseminates actionable threat information to member drinking water and wastewater systems, while also offering guidance on risk mitigation tools, best practices, and response actions that contribute to an all-hazards resiliency posture.

However, as an independent non-profit organization, WaterISAC receives no state or federal grant funding and therefore operates as a dues-based subscription service. Currently utility staff from roughly 600 water and wastewater systems nationwide are members of WaterISAC. But a federal investment of just $1 million per year would enable WaterISAC to service all 50,000 community water systems across the country.

Your administration has an excellent opportunity to recognize the value of WaterISAC and take steps to help the service reach more communities. With more entities participating in WaterISAC, more communities will be able to take advantage of its threat analysis and response services, and therefore be prepared to repel incidents that do occur. WaterISAC also facilitates information sharing among participating utilities, so expanding the reach of the service will also help the sector develop more and better intelligence about emerging threats to water systems.

AMWA also encourages the preservation of exiting federal efforts to help communities maintain resilience to a range of threats. For example, EPA's Creating Resilient Water Utilities (CRWU) initiative provides drinking water, wastewater, and stormwater utilities with practical tools, training, and technical assistance to increase system resilience to extreme weather events and other natural hazards. CRWU helps promote a clear understanding of weather data and helps water systems identify potential resilience strategies, implementation options, and infrastructure financing opportunities. In your administration this initiative should continue to play a valuable role in helping water systems maintain critical operations.

Finally, AMWA urges your administration to avoid ill-advised regulatory mandates that purport to increase security, but instead only impose new regulatory burdens on water systems. Once such example was a 2023 plan by EPA to require states to conduct reviews of utilities' cyber-preparedness while carrying out unrelated inspections of water facility operations. AMWA and other water sector stakeholders warned that such a plan would not increase cybersecurity, and could actually lessen it by making information about individual systems' vulnerabilities public. The plan was only halted when a federal court blocked it from moving forward. AMWA looks forward to your administration taking a collaborative approach to addressing physical and cyber risks in cooperation with the water sector.

Conclusion

Again, AMWA congratulates you on your election as President of the United States, and the association looks forward to working with your administration to advance policies that advance the promise of clean drinking water to promote public health and economic development. We are eager to collaborate on the development of sound regulation, smart investments in drinking water infrastructure, and cooperative efforts to promote water system security.

AMWA would also be honored to meet with members of your transition team to discuss these topics in more detail and explore additional ways that we can work together over the next four years. The association stands ready to assist you in the weeks, months, and years ahead.

Sincerely,

Tom Dobbins
Chief Executive Officer

American Water Works Association
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ASSOCIATION OF METROPOLITAN WATER AGENCIES

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WATEREUSE

December 13, 2024

The Honorable Donald J. Trump
President-Elect of the United States
Washington, DC

Dear President-Elect Trump,

Congratulations on your election as the next President of the United States of America. The undersigned organizations stand ready to work with you to advance policies that strengthen the nation by recognizing water as a national priority.

Our organizations represent utilities, communities, the front-line water workforce, and advocates across the drinking water, wastewater, water recycling, and stormwater communities. America's network of drinking water, wastewater, water recycling and stormwater infrastructure plays a central, critical role in supporting public health and economic development, and therefore we urge your administration to prioritize policies that promote affordable, reliable and well-functioning water systems.

The opportunities to strengthen our water systems are clear. A 2024 report by the Value of Water Campaign identified a $91 billion gap between the nation's water infrastructure needs and spending. If left unaddressed, this gap will grow to more than $2 trillion by 2043.[1] While the investment needs are daunting, they also present a profound opportunity. Robust investment in water will grow our economy, create jobs, address water quantity and quality challenges, and help protect communities from natural disasters. Our organizations are eager to help your administration develop a comprehensive strategy to address pressing topics like water affordability, infrastructure funding, and informed regulations to position the nation's water systems for success.

Outlined below are select consensus policy recommendations that we encourage you to adopt as the core of your water policy agenda in 2025 and beyond. Our organizations would welcome the opportunity to meet with members of your transition team at their earliest convenience to discuss these priorities and other common areas of interest.

Support Robust Investment in the Nation's Water Infrastructure

The need for long-term investment in water systems is urgent, with local utilities facing unprecedented challenges that threaten public health, environmental quality, and economic growth. While the federal government took steps to address this challenge by providing a one-time infusion of nearly $50 billion in additional drinking water, wastewater, and water recycling funding, those extra funds will expire during your term. Support for water infrastructure investments creates economic opportunity for all Americans through jobs and local economic

[1] The Value of Water Campaign, "Bridging the Gap: The Power of Investment in Water." 2024, https://uswateralliance.org/wp-content/uploads/2024/05/Bridging-the-Gap_-The-Power-of-Investment-in-Water-Fact-Sheet.pdf.

development that is stable, domestic, well-paying, and community-based. We therefore urge your administration to prioritize increased funding for critical drinking water, wastewater, and water recycling projects that will renew our critical infrastructure from coast to coast.

EPA's most recent investment needs surveys, the 7th Drinking Water Infrastructure Needs Survey and Assessment[2] and the 2022 Clean Watersheds Needs Survey,[3] underscore the need for additional water infrastructure investment.

The 7th Drinking Water Infrastructure Needs Survey, which was collected by EPA, states, and water systems in 2021, includes infrastructure projects that are necessary over the next 20 years for water systems to continue to provide safe drinking water. These projects include infrastructure needs that are eligible for, but not necessarily financed by, the Drinking Water State Revolving Fund (DWSRF). The survey identified a total need of $625 billion over the next 20 years.

Similarly, the 2022 Clean Watersheds Needs Survey identified an estimated $630 billion in unfunded clean water needs over the next 20 years to maintain existing levels of service. The largest share, 55%, is required for centralized wastewater treatment and collection systems, and 18% of the total need is for municipal stormwater systems. The survey also identified nearly $8 billion in needed investment in recycled water conveyance, above and beyond the investment needed in water recycling systems themselves.

Infrastructure needs for drinking water, clean water, and water recycling systems play a vital role in safeguarding public health and ensuring that all communities have access to safe, clean water. Many water systems are aging, with pipes and treatment facilities that are well beyond their intended lifespan. Meanwhile, utilities are working to address new, emerging challenges and regulatory mandates related to PFAS, lead service line replacement, and compliance with evolving water quality standards. Critically, EPA's estimates only include the costs of maintaining current levels of service and do not incorporate looming new regulatory expenses. These emerging obligations underscore how evolving challenges require significant, sustained investment beyond current levels of federal support.

Water utilities rely first and foremost on ratepayer revenue to cover the majority of infrastructure costs, but federal investment programs play a critical role in helping communities upgrade their infrastructure more affordably. Both the DWSRF and Clean Water State Revolving Fund (CWSRF) are critical lifelines for local utilities, helping to finance essential infrastructure projects in communities across the country. However, outside of the recent additional funding provided by Congress, both programs have received stagnant federal funding for many years. Without reliable federal funding, households will be increasingly burdened by rising water costs which may also hinder progress on essential improvements.

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[2] 7th EPA Drinking Water Infrastructure Needs Survey. Source: https://www.epa.gov/system/files/documents/2023-09/Seventh%20DWINSA_September2023_Final.pdf

[3] EPA 2022 EPA Clean Watershed Needs Survey Report, released May 2024. Source: https://www.epa.gov/system/files/documents/2024-05/2022-cwns-report-to-congress.pdf

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Several additional federal programs provide critical support for water infrastructure across the country. The Title XVI Water Reclamation and Reuse Grants Program and Pilot Program for Alternative Water Source Grants provide federal cost share for water recycling projects across the country. These programs help communities build drought resilience, keep nutrients and other pollutants out of sensitive waterways, save billions of dollars relative to importing water, and grow local economies. They are key economic development and water resource management tools. Despite recent investments, the need for capital for water recycling projects far outstrips available funding, and this demand will only grow as recurring drought and other pressures continue to threaten local and regional water resources.

These investments will not only protect public health but also enhance environmental outcomes, support job creation, and encourage economic development throughout the country. A strong federal commitment to water infrastructure is essential to ensuring every community, regardless of size or location, has access to safe and reliable water services.

Support the 'Polluter Pays' Principle for PFAS Cleanup

Earlier this year, the EPA finalized a hazardous substance designation for two per- and polyfluoroalkyl substances (PFAS) - perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) - under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). While intended to hold polluters accountable, the CERCLA designation for these two PFAS will have far-reaching implications for water systems that are on the front lines of water quality protection.

CERCLA was built on a "polluter pays" goal, intended to hold the companies that produced and profited from hazardous substances responsible for their cleanup from the environment. However, without explicit liability protections, water systems that passively receive PFAS substances into their systems could face retroactive, strict, joint and several liability under CERCLA simply because an upstream polluter released the chemicals into the wastewater stream or the environment.

This threat of liability creates an unjust burden for water systems and their customers, who could be forced to foot the bill for PFAS twice—once to pay for the treatment technology to address PFAS in their water supplies and again for potentially massive legal and cleanup costs at a Superfund site. Without liability protection for water systems, private parties who directly manufactured, profited from, and then released PFAS into the environment are able to sue local utilities to share their cleanup burden, potentially inflicting massive costs to water customers. While EPA may not intend for water systems to share this undue burden, without an explicit statutory exemption from liability, other potentially responsible parties including chemical companies may seek to shift their legal cost burden to water systems.

We urge your administration to uphold the original "polluter pays" intent of CERCLA by ensuring that chemical companies and other polluters cannot shift the cost of their contamination

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onto local communities. To protect water system ratepayers, we ask you to call on Congress to provide narrow and targeted statutory CERCLA liability protections for water systems for PFAS.

Promote Regulations Based on Sound Science and Fair Policies; Increase Interagency Coordination

For 50 years, the drinking water, wastewater, and stormwater sector has protected public health and environmental quality based upon regulations developed through a systematic and science-based process. The Safe Drinking Water Act and the Clean Water Act are the sector's primary regulatory mechanisms, but the clarity these statutes once provided has become blurred. Due in part to other federal regulatory mechanisms such as CERCLA and the Clean Air Act, and a patchwork of state regulations, utilities are often forced to allocate limited ratepayer funds toward projects or compliance standards that may have limited overall public health or environmental benefit.

In recent years, our organizations' members have struggled to navigate a shifting landscape of regulatory obligations. Water systems rely on the certainty provided by a regulatory development process that follows a thorough scientific and public feedback process.

As your administration begins to establish its policy priorities, we call upon you to direct federal agencies to base the development of future regulations with these principles in mind:

- Use sound science and technical merit to advance regulations and policies.
- Ensure that regulations accurately and fairly consider the costs and economic impacts to the affected entities and their constituencies.
- Support policies that advance the modernization and affordability of critically needed water infrastructure investments.
- Bolster research and development to find innovative solutions to pressing challenges in water.
- Ensure a thorough and robust public review process and ensure final regulations reflect public input.

Additionally, as your administration looks to take action on regulations impacting the water sector, we urge you to increase interagency coordination by reestablishing the Water Subcabinet. During your first term, the establishment of a Water Subcabinet by Executive Order 13954 was strongly supported by the signers of this letter. The Subcabinet helped to align missions and eliminate duplication through formal coordination among all stakeholders, including federal and state regulators, local communities, and all segments of industry. Improving interagency coordination is critical to efficiently and effectively manage and modernize the nation's water supplies and systems while also eliminating duplication between agencies.

Take Action to Promote Water Reuse and Recycling Efforts

During the first term of the Trump Administration, you championed water recycling as a multi-benefit tool to support communities, build the economy, and protect public health. We appreciate

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your leadership on water recycling and stand ready to help you continue this work over the next four years.

Water reuse, also known as water recycling, is the process of intentionally capturing wastewater, stormwater, or graywater and cleaning it as needed for a designated beneficial freshwater purpose, such as drinking, industrial processes, and watershed restoration. Communities across the country are incorporating water reuse into their water management strategies as a proven method for protecting water quality, building reliable and resilient water supplies, and supporting local economic growth.

In 2020, your administration launched the National Water Reuse Action Plan (WRAP), a first-of-its-kind effort to scale up water recycling around the country. Since then, the WRAP has grown to include 157 unique partners collaborating across 69 actions. It is a critical convening tool that continues to advance the practice of water reuse across the country. We urge you to continue to implement and strengthen the WRAP.

Your administration should also maintain the Federal Interagency Working Group on Water Reuse. Congress directed EPA to establish the Working Group to break down silos and align and leverage programs and resources across the federal family. The Interagency Working Group is chaired by EPA and is composed of officials from 15 federal agencies who convene regularly to support and coordinate federal engagement on water reuse. Federal law establishes a sunset date of November 15, 2027 for the Working Group but gives the EPA Administrator the authority to extend the date. Through the Interagency Work Group, your administration should work to integrate water recycling into the programs and policies of departments and agencies across the federal government.

Reauthorize and Fund the Low Income Household Water Assistance Program (LIHWAP)

Access to basic drinking water and sanitation services is essential for public health and economic vitality. That's why in 2020 Congress created the Low Income Household Water Assistance Program (LIHWAP) through legislation that you signed into law. Administered by the Department of Health and Human Services (HHS), LIHWAP has helped 1.7 million low-income households nationwide maintain or restore their drinking water and wastewater service. Impacted households were served by more than 13,000 different water utilities in nearly every state, demonstrating the broad reach of the program.

The benefits of LIHWAP are twofold. Not only does the program promote public health, but it also enables the nation's public water and wastewater systems to invest in critical infrastructure that will allow them to continue serving their communities for decades to come. The vast majority of local water infrastructure investment is supported directly by rate-paying customers at the local level. If some of those customers are unable to afford rising water rates – and therefore leave their bills unpaid – they risk losing their water service while their utility loses revenue needed to sustain the system.

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The need for low-income water affordability assistance is acute and documented. According to HHS, 20% of households nationwide are in debt to their water utility.[4] Meanwhile, the cost of drinking water service has risen 43% over the last decade,[5] and the need to address aging water infrastructure and comply with expanded regulatory mandates is expected to put additional upward pressure on local water rates in the coming years.

Unfortunately, LIHWAP has been unfunded after its initial two tranches of appropriations totaling $1.14 billion expired at the end of the 2023 fiscal year. As a result, water assistance is once again absent from the federal safety net, putting hundreds of thousands of households at risk of losing their water service and leaving tens of thousands of water and wastewater systems without needed operational revenues. Presidential leadership is key to advancing LIHWAP reauthorization as a national priority, so we urge you to make this a key aspect of your public health agenda for the coming year.

Conclusion

Again, on behalf of our organizations representing the nation's drinking water, wastewater, water recycling, and stormwater communities, we congratulate you on your election as President of the United States. Over the next four years we look forward to working with you and your administration to develop and implement a policy agenda that leverages our recommendations to give America the best water and wastewater infrastructure in the world.

We are eager to meet with members of your transition team to discuss these topics and how we may be of assistance as your administration takes shape over the coming weeks and months.

Sincerely,

David LaFrance
CEO
American Water Works Association

Tom Dobbins
CEO
Association of Metropolitan Water Agencies

Adam Krantz
CEO
National Association of Clean Water Agencies

Ralph Erik Exton
Executive Director
Water Environment Federation

Patricia Sinicropi
Executive Director
WateReuse Association

[4] https://www.acf.hhs.gov/sites/default/files/documents/ocs/lihwap-survey-report-03-14-24.pdf

[5] https://www.waterworld.com/water-utility-management/press-release/14209257/water-rates-up-43-over-last-decade

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Message

From: Best-Wong, Benita [Best-Wong.Benita@epa.gov]
Sent: 2/14/2025 7:09:36 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: McLain, Jennifer L. [McLain.Jennifer@epa.gov]; Risley, David [Risley.David@epa.gov]
Subject: RE: FOR REVIEW: PFAS Agency Team Review
Attachments: OW PFAS Potential Actions_2-2025 (002).pptx

Hi Jess – Here are the two slides we propose adding to the slide deck. We kept the second slide intentionally brief to allow leadership the opportunity to more fully define and articulate future actions. A big thank you to Jennifer and David for pulling this together for us.

Thank you,
Benita

Benita Best-Wong
Deputy Assistant Administrator for Management
Office of Water
US EPA
Washington, DC 20460
202-566-1159

From: Kramer, Jessica L. <kramer.jessical@epa.gov>
Sent: Friday, February 14, 2025 1:09 PM
To: Best-Wong, Benita <Best-Wong.Benita@epa.gov>
Cc: McLain, Jennifer L. <McLain.Jennifer@epa.gov>
Subject: RE: FOR REVIEW: PFAS Agency Team Review

You bet – available for the next 45 minutes if that would work? Full disclosure, I'm eating lunch so maybe we could do a Teams?

Otherwise you can just kick it my way for awareness when you're done. Either way is fine with me!

From: Best-Wong, Benita <Best-Wong.Benita@epa.gov>
Sent: Friday, February 14, 2025 12:58 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: McLain, Jennifer L. <McLain.Jennifer@epa.gov>
Subject: FW: FOR REVIEW: PFAS Agency Team Review

Hi, Jess,

Jennifer and I are working to pull together the OW slides for this briefing. We're happy to share with you what we're planning to submit before we include anything. Are you available this afternoon to discuss?

Thank you,
Benita

Benita Best-Wong
Deputy Assistant Administrator for Management
Office of Water
US EPA

Washington, DC 20460
202-566-1159

From: Drinkard, Andrea <Drinkard.Andrea@epa.gov>
Sent: Thursday, February 13, 2025 5:09 PM
To: Beck, Nancy <beck.nancy@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Welch-White, Venus <WelchWhite.Venus@epa.gov>; Shoaff, John <Shoaff.John@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Gwinn, Maureen <gwinn.maureen@epa.gov>; Best-Wong, Benita <Best-Wong.Benita@epa.gov>; McGuire, Karen <Mcguire.Karen@epa.gov>; Hoskinson, Carolyn <Hoskinson.Carolyn@epa.gov>; Gervais, Gregory <Gervais.Gregory@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Rodrigues, Cecil <rodrigues.cecil@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>; Payne, James (Jim) <payne.james@epa.gov>; Youngblood, Charlotte <Youngblood.Charlotte@epa.gov>; Messier, Dawn <Messier.Dawn@epa.gov>; Lewis, Jen <Lewis.Jen@epa.gov>; Klasen, Matthew <Klasen.Matthew@epa.gov>; Burden, Susan <Burden.Susan@epa.gov>
Cc: Atkinson, Emily <Atkinson.Emily@epa.gov>; Vaseliou, Molly <Vaseliou.Molly@epa.gov>
Subject: FOR REVIEW: PFAS Agency Team Review

Hi all—

In preparation for the Administrator's briefing next Tuesday, please see a draft Power Point presentation that your staff helped put together. In the interest of time, I am sending this around to the full leadership team so we can edit it simultaneously. Please make any edits you have in the below referenced document by **1:00pm tomorrow.** We have a COB tomorrow deadline to get this into the Administrator's book.

PFAS Framework for February 20 2025_v2.pptx

Thanks so much!

-Andrea-

Andrea Drinkard
Deputy Associate Administrator for Management
EPA Office of Public Affairs
202.236.7765

Office of Water

- OW is building on accomplishments and commitments from the PFAS Action Plan through Safe Drinking Water Act and Clean Water Act authorities and water infrastructure investments.
- OW is working to:
  - Understand PFAS in water through monitoring programs and by developing analytical methods.
  - Identify sources of PFAS leading to water contamination to get upstream of the problem before it becomes a costly, local government problem.
  - Distribute funding to address PFAS in water through WIFIA, SRF programs, and IIJA grants
  - Provide technical assistance to states and local utilities to help them identify water infrastructure solutions and access funding.
  - Provide information on treatment technologies and treatment waste disposal methods to support water and wastewater systems.

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Office of Water

- Potential EPA CWA and SDWA Actions in 2025 and Beyond
  - Support state primacy for the PFAS drinking water rule and help water systems prepare to comply.
  - Distribute funding appropriated by Congress to states and provide technical assistance to drinking water and wastewater systems dealing with PFAS to help them develop infrastructure plans and access dollars.
  - Provide technical assistance and training to states and local utilities to help them identify and address sources of PFAS from industrial facilities that discharge to Publically Owned Treatment Works (POTWs).
  - Review the best available information and consider opportunities to cost-effectively reduce PFAS discharges from industrial point sources (i.e., PFAS manufacturers, metal finishers/chrome platers, and landfills).
  - Review data and information on PFAS usage and discharges from additional industrial categories, and consider opportunities to address discharges under the Clean Water Act.
  - Review the science and EPA's authorities to reduce exposure to PFOA and PFOS through biosolids.
  - Review the science related to water quality criteria and human

Message

From: Drinkard, Andrea [Drinkard.Andrea@epa.gov]
Sent: 2/15/2025 2:11:24 AM
To: Voyles, Travis [voyles.travis@epa.gov]; Beck, Nancy [beck.nancy@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Vaseliou, Molly [Vaseliou.Molly@epa.gov]; Tardif, Abigale (Abbie) [Tardif.Abigale@epa.gov]; Cook, Steven [cook.steven@epa.gov]; Szabo, Aaron [Szabo.Aaron@epa.gov]; Welch-White, Venus [WelchWhite.Venus@epa.gov]; Shoaff, John [Shoaff.John@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Gwinn, Maureen [gwinn.maureen@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; McGuire, Karen [Mcguire.Karen@epa.gov]; Hoskinson, Carolyn [Hoskinson.Carolyn@epa.gov]; Gervais, Gregory [Gervais.Gregory@epa.gov]; Hall, Jeffrey [Hall.Jeffrey.A@epa.gov]; Rodrigues, Cecil [rodrigues.cecil@epa.gov]; Schmit, Ryan [schmit.ryan@epa.gov]; Donahue, Sean [donahue.sean@epa.gov]; Payne, James (Jim) [payne.james@epa.gov]; Youngblood, Charlotte [Youngblood.Charlotte@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Lewis, Jen [Lewis.Jen@epa.gov]; Klasen, Matthew [Klasen.Matthew@epa.gov]; Burden, Susan [Burden.Susan@epa.gov]; Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]; Dominguez, Alexander [dominguez.alexander@epa.gov]; Brown, Ashley [Brown.Ashley@epa.gov]
CC: McIntosh, Chad [mcintosh.chad@epa.gov]; Corlett, Thomas [Corlett.Thomas@epa.gov]; Amidon, Eric [Amidon.Eric@epa.gov]
Subject: BRIEFING MATERIALS: PFAS Agency Team Review
Attachments: PFAS Framework Administrator Briefing_021825.pptx; OLEM PFAS Final Briefing Paper for Administrator Zeldin.docx

Hi Ashley,

I apologize for the late Friday night email, but attached is a power point presentation for the PFAS briefing on Tuesday afternoon. I am also sharing a background document that OLEM shared on their actions. Please let me know if you need additional information or have questions.

Happy Valentine's Day!!

-----Original Appointment-----
From: ZeldinScheduling <ZeldinScheduling@epa.gov>
Sent: Friday, February 7, 2025 11:48 AM
To: ZeldinScheduling; ZeldinScheduling; Voyles, Travis; Beck, Nancy; Kramer, Jessica L.; Vaseliou, Molly; Tardif, Abigale (Abbie); Cook, Steven; Szabo, Aaron; Drinkard, Andrea; Welch-White, Venus; Shoaff, John; Keigwin, Richard; Gwinn, Maureen; Best-Wong, Benita; McGuire, Karen; Hoskinson, Carolyn; Gervais, Gregory; Hall, Jeffrey; Rodrigues, Cecil; Schmit, Ryan; Donahue, Sean; Payne, James (Jim); Youngblood, Charlotte; Messier, Dawn; Lewis, Jen; Klasen, Matthew; Burden, Susan; Tsirigotis, Peter; Dominguez, Alexander
Cc: McIntosh, Chad; Corlett, Thomas; Amidon, Eric
Subject: PFAS Agency Team Review
When: Tuesday, February 18, 2025 4:30 PM-6:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Alm Room; AlmConfRoom-OA

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Message

From: Drinkard, Andrea [Drinkard.Andrea@epa.gov]
Sent: 2/15/2025 2:28:15 AM
To: Voyles, Travis [voyles.travis@epa.gov]; Beck, Nancy [beck.nancy@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Vaseliou, Molly [Vaseliou.Molly@epa.gov]; Tardif, Abigale (Abbie) [Tardif.Abigale@epa.gov]; Cook, Steven [cook.steven@epa.gov]; Szabo, Aaron [Szabo.Aaron@epa.gov]; Welch-White, Venus [WelchWhite.Venus@epa.gov]; Shoaff, John [Shoaff.John@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Gwinn, Maureen [gwinn.maureen@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; McGuire, Karen [Mcguire.Karen@epa.gov]; Hoskinson, Carolyn [Hoskinson.Carolyn@epa.gov]; Gervais, Gregory [Gervais.Gregory@epa.gov]; Hall, Jeffrey [Hall.Jeffrey.A@epa.gov]; Rodrigues, Cecil [rodrigues.cecil@epa.gov]; Schmit, Ryan [schmit.ryan@epa.gov]; Donahue, Sean [donahue.sean@epa.gov]; Payne, James (Jim) [payne.james@epa.gov]; Youngblood, Charlotte [Youngblood.Charlotte@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Lewis, Jen [Lewis.Jen@epa.gov]; Klasen, Matthew [Klasen.Matthew@epa.gov]; Burden, Susan [Burden.Susan@epa.gov]; Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]; Dominguez, Alexander [dominguez.alexander@epa.gov]
Subject: RE: BRIEFING MATERIALS: PFAS Agency Team Review
Attachments: PFAS Framework Administrator Briefing_021825.pptx

Hi all –

Thank you so much for your help pulling the slide deck together. Since we don't have a chance to do a prep meeting, I thought I'd send this email to divvy up the slides among us. Please let me know if you'd like to make any changes. As far as transitions, you can pass it off to the next speaker.

Travis, please let us know if you have any thoughts.

Slides 2-5: Jennifer McLain (OW)
Slides 6-9: Andrea Drinkard (OPA)
Slides 11-14: Benita Best-Wong (OW) (note that I turned your two slides, turned into three slides)
Slides 15-17: Greg Gervais (OLEM)
Slides 18-20: Rick Keigwin (OCSPP)
Slides 21-23: John Shoaff (OAR)
Slides 24-26: Cecil Rodrigues (OECA)
Slides 27-29: Maureen Gwinn (ORD)
Slide 30: Jennifer McLain (OW)

From: Drinkard, Andrea
Sent: Friday, February 14, 2025 9:11 PM
To: Voyles, Travis <voyles.travis@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Welch-White, Venus <WelchWhite.Venus@epa.gov>; Shoaff, John <Shoaff.John@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Gwinn, Maureen <gwinn.maureen@epa.gov>; Best-Wong, Benita <Best-Wong.Benita@epa.gov>; McGuire, Karen <Mcguire.Karen@epa.gov>; Hoskinson, Carolyn <Hoskinson.Carolyn@epa.gov>; Gervais, Gregory <Gervais.Gregory@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Rodrigues, Cecil <rodrigues.cecil@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>; Payne, James (Jim) <payne.james@epa.gov>; Youngblood, Charlotte <Youngblood.Charlotte@epa.gov>; Messier, Dawn <Messier.Dawn@epa.gov>; Lewis, Jen <Lewis.Jen@epa.gov>; Klasen, Matthew <Klasen.Matthew@epa.gov>; Burden, Susan <Burden.Susan@epa.gov>; Tsirigotis, Peter <Tsirigotis.Peter@epa.gov>; Dominguez, Alexander <dominguez.alexander@epa.gov>; Brown, Ashley <Brown.Ashley@epa.gov>
Cc: McIntosh, Chad <McIntosh.Chad@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Amidon, Eric

<Amidon.Eric@epa.gov>
Subject: BRIEFING MATERIALS: PFAS Agency Team Review

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Cc: McIntosh, Chad; Corlett, Thomas; Amidon, Eric
Subject: PFAS Agency Team Review
When: Tuesday, February 18, 2025 4:30 PM-6:00 PM (UTC-05:00) Eastern Time (US & Canada).
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Message

From: Haga, Ellie [Haga.Ellie@epa.gov]
Sent: 2/20/2025 8:53:18 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Risley, David [Risley.David@epa.gov]; Lanier, Lynsey [Lanier.Lynsey@epa.gov]
Subject: Materials for Friday, February 21, 2025 OW Meetings
Attachments: PFAS NPDWR February 21 2025.pptx

Hi Jess!
Attached are the materials for your one OW briefing tomorrow - Final PFAS National Primary Drinking Water Regulation.

Let us know if you have any questions or need anything else.

Best,
Ellie

Ellie Haga
Special Assistant
Office of Water
U.S. Environmental Protection Agency

Final PFAS National Primary Drinking Water Regulation

February 2025

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Regulatory Determinations for PFAS

- EPA's 2019 PFAS Action Plan committed the Agency to make regulatory determinations for PFOA and PFOS in drinking water.
  - A regulatory determination is a formal decision on whether EPA should develop a national primary drinking water regulation for a specific contaminant or group of contaminants. SDWA specifies that EPA consider health effects, occurrence, and meaningful opportunity.
  - EPA also stated it would consider other information to "inform the development of a national drinking water regulation for a broader class of PFAS in the future."
- EPA proposed regulatory determinations for PFOA and PFOS in 2020, finalizing them in early 2021. Concurrently, the EPA also committed to "making regulatory determinations in advance of the next SDWA deadline for additional PFAS" where the Agency had information meeting the SDWA regulatory criteria.
- EPA made regulatory determinations for four additional PFAS concurrently with the proposed (2023) and final (2024) PFAS drinking water regulation.

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SDWA Regulation Development

- SDWA requires that EPA establish non-enforceable health based Maximum Contaminant Level Goals (MCLGs) and enforceable Maximum Contaminant Levels (MCLs).
- SDWA defines the MCLG as the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety.
- The MCL is the maximum level of a contaminant allowed in drinking water. SDWA requires that MCLs be set as close to MCLGs as feasible.
  - SDWA defines "feasible" as using the best available technology demonstrated in field conditions and taking cost into consideration.
- SDWA requires EPA consider the health risk reduction costs and benefits and determine if the benefits of the rule justify the costs.

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PFAS Standards: Individual Contaminants

- For PFOA and PFOS, EPA set MCLGs at zero.
  - Consistent with science showing that these two contaminants are each likely carcinogens and there is no level of exposure without health risk.
- EPA set PFOA and PFOS MCLs at **4.0 parts per trillion (ppt)**.
  - Based upon the lowest levels that can be measured reliably and consistently by laboratories across the nation.
- For PFNA, PFHxS, and HFPO-DA, EPA set MCLGs of 10 ppt.
- EPA set the MCLs for PFNA, PFHxS, and HFPO-DA at **10 ppt.**
  - EPA determined it was feasible to treat to the level of the MCLG.

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PFAS Standards: PFAS Mixtures

- EPA also set a standard for mixtures of **PFHxS, PFNA, HFPO-DA,** and **PFBS**.
- Research shows some chemicals, including PFAS, can combine in mixtures and have additive health effects, even if the individual chemicals are each present at low levels.
- PFAS are often found together and in varying combinations as mixtures in drinking water.
- The Hazard Index standard applies when 2 or more of these PFAS are present in drinking water together.

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PFAS Standards: Hazard Index

- The Hazard Index is an approach that the EPA has used in the Superfund program to determine the health risks associated with exposure to chemical mixtures.
- The Hazard Index is calculated by summing the ratios of the "water sample concentration to a Health-Based Water Concentration" for each mixture component.

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

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PFAS Standards: Summary

Chemical	Maximum Contaminant Level Goal (MCLG)	Maximum Contaminant Level (MCL)
PFOA	0	4.0 ppt
PFOS	0	4.0 ppt
PFHxS	10 ppt	10 ppt
HFPO-DA (GenX chemicals)	10 ppt	10 ppt
PFNA	10 ppt	10 ppt
Mixture of two or more: PFHxS, PFNA, HFPO-DA, and PFBS	Hazard Index of 1	Hazard Index of 1

*Compliance is determined by running annual averages at the sampling point

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Communication with Public

- PWSs are required to issue public notification to customers if PFAS levels in drinking water violate an MCL.
  - For all PFAS MCL violations, the final rule requires public notification to be provided within 30 days of the violation (Tier 2).
  - For all violations of monitoring, reporting, and testing procedures, annual public notification is required (Tier 3).
- Community water systems are also required to include PFAS information in the Consumer Confidence Reports distributed to their customers.

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Costs and Benefits

	How Much?	What From?	The Potential Impact
Costs	$1.5 Billion per year	Monitoring, communicating with customers, and if necessary, obtaining new or additional sources of water or installing and maintaining treatment technologies.	States, Tribes, and territories with primacy will have increased oversight and administrative costs. **66,000 regulated water systems** will have to conduct monitoring and notifications. **4,100 – 6,700 water systems** may have to take action to reduce levels of PFAS.
	Non-quantified*	Costs for some systems to comply with the Hazard Index, HFPO-DA, and PFNA MCLs.	
Benefits	$1.5 Billion per year	The rule results in fewer cancers, lower incidence of heart attacks and strokes, and fewer birth weight-related deaths. Benefits will prevent over **9,600 deaths and reduce approximately 30,000 serious illnesses.**	**83 – 105 million people** will have improved drinking water as a result of lower levels of PFAS
	Non-quantified*	Increased ability to fight disease, reductions in thyroid disease and impacts to human hormone systems, reductions in liver disease, and reductions in negative reproductive effects such as decreased fertility. Actions taken to implement the rule may also lead to associated health benefits from reductions in other PFAS and unregulated disinfection byproducts	

***Non-quantified benefits and costs are those that EPA could not assign a specific number to as part of its national level quantified analysis. EPA determined that the benefits of the rule justified the costs.**

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Burden Reduction / Flexibilities

- The PFAS rule includes provisions for systems to monitoring less frequently than once per quarter.
  - Systems may use previously collected drinking water data (e.g., UCMR5 or state monitoring) to satisfy the initial monitoring requirements.
  - Small groundwater systems are only required to collect two samples per year.
  - Systems may reduce the monitoring frequency based on initial sampling results.
    - Systems with initial sampling results below the trigger may only be required to collect one sample required every year or even one sample every three years.
- The PFAS rule provides a 2-year capital improvement extension to the typical 3-year deadline to comply with the PFAS MCLs.
  - Provides time for systems until 2029 to plan, design, and fund capital improvements.
- The PFAS rule does not dictate how water systems must reduce PFAS levels the to meet MCLs.

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Consolidated Litigation in D.C. Circuit

- Petitioners
  - American Water Works Association, Association of Metropolitan Water Agencies, American Chemistry Council, National Association of Manufacturers, The Chemours Company
- Intervenors on behalf of EPA
  - Concerned Citizens of WMEL Water Authority Grassroots, Environmental Justice Task Force, Fight for Zero, Merrimack Citizens for Clean Water, Natural Resources Defense Council, Buxmont Coalition for Safe Water, Newburgh Clean Water Project, Clean Haw River, Clean Cape Fear
- Key Issues raised
  - EPA's use of concurrent process to issue NPDWR and regulatory determinations.
  - EPA's regulation of PFAS mixtures and use of the hazard index for MCL.
  - EPA's record to support its regulation of HFPO-DA and basis for MCLG and MCL.
  - EPA's assessment of the costs and benefits of the rule.
- Status: EPA filed a response brief. Case held in abeyance until April 8, 2025.

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Ex. 5 Deliberative Process (DP)

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Water Associations' Concerns and EPA's Response

- *EPA does not have authority to make a preliminary regulatory determination concurrent with a proposed NPDWR.*
  - In litigation EPA argued that its interpretation authorizing concurrent actions is the best reading of the statute because it gives effect to all portions of the statutory text and consistent with Congressional intent. In making the preliminary determinations, EPA provided significantly more information for public comment than is required for a regulatory determination; therefore, commenters were able to fully evaluate EPA's proposed action.
- *EPA does not have authority to regulate contaminant mixtures and cannot use a Hazard Index because it does not meet the SDWA definition of an MCL.*
  - In litigation, EPA argued that its interpretation of the definition of "contaminant" to include mixtures is the best reading of the statute applying all relevant interpretive tools. EPA has similarly regulated groups of contaminants (disinfection byproducts, radionuclides, PCBs). In litigation, EPA argued that the MCL of 1 for the Hazard Index meets the definition of MCL because it established a "level" and can be measured to determine compliance.
- *EPA did not demonstrate the regulatory determination statutory criteria (specifically occurrence) to regulate HPFO-DA and PFNA individually or to regulate Hazard Index mixtures.*
  - For the final rule, EPA presented an updated occurrence analysis including a robust amount of data from UCMR 3 and tens of thousands of sample results from state monitoring to demonstrate there is substantial likelihood these PFAS occur at a frequency and level of public health concern.

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Water Associations' Concerns and EPA's Response

- *EPA's MCLs for PFOA and PFOS are not feasible and should be higher.*
  - The final MCLs are as close as feasible to the MCLGs. EPA determined that the 4 ppt is the lowest level that can be quantified by available laboratory methods and there are multiple treatment technologies capable of removing PFOA and PFOS to this level that are reasonably affordable for large and metropolitan systems.
- *EPA underestimated the rule costs, including underestimating the number of systems expected to exceed one or more MCLs.*
  - EPA conducted an evaluation of the cost data provided by water associations. EPA disagreed with many of the assumptions and conclusions of their study which demonstrated their costs to be significantly overestimated.
  - Using peer-reviewed treatment models, EPA revised its treatment cost estimates for the final rule considering the most recent unit costs.
  - EPA's final rule estimated 6 to 10% of public water systems would exceed one or more PFAS MCLs which is consistent with a weighted evaluation of the more recent UCMR 5 PFAS monitoring results.
- *Disposal of PFAS treatment residuals and possible requirement in future as hazardous waste.*
  - Under federal law, PFAS are not required to be disposed of as hazardous waste. To provide information on the potential costs related to hazardous waste disposal, EPA conducted a sensitivity analysis and presented these costs which were found to result in marginal cost increases.

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Ex. 5 Deliberative Process (DP)

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State Association Concerns and EPA's Response

- *Laboratory capacity to support rule monitoring is uncertain.*
  - EPA determined that there will be adequate laboratory capacity based upon the current number of laboratories providing this analysis and a prediction of the new laboratories that will offer this analysis based upon the increased demand. This conclusion was supported by comments from associations representing independent laboratories. To facilitate the increase in capacity EPA has trained state officials to provide them with the information needed to certify additional laboratories in these PFAS methods.
- *Costs to primacy agencies are incorrectly represented.*
  - In the final rule, EPA adjusted primacy agency costs to reflect information provided by state officials related to certain activities.
- *Funding availability to address NPDWR compliance, particularly for small systems.*
  - Significant federal funding is available to support addressing emerging contaminants, including specific funds available for small systems.

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PFAS Implementation Approach

- EPA has a three-pronged strategy to support implementation: implementation resources, PFAS funding, and direct technical assistance
- EPA has partnered with States in an EPA-State PFAS Implementation Workgroup
- Implementation resources are posted on the PFAS Implementation Webpage
  - Guidance and training for states to obtain primacy
  - Several quick reference guides supporting state and utility implementation
  - Memos clarifying monitoring and reporting requirements under the PFAS Rule
- Additional resources in development
  - PFAS Rule Training
  - PFAS Notification Templates
  - PFAS Small Entity Compliance Guidance
  - Comprehensive PFAS State Implementation Guidance Manual
  - PFAS Treatment Options, Selection, and Waste Disposal

PFAS Funding

- The Infrastructure Investment and Jobs Act (IIJA) dedicates $9 billion specifically to invest in communities with drinking water impacted by PFAS and other emerging contaminants.
  - $4B is in emerging contaminants funding to Drinking Water State Revolving Fund
  - $5B funds the Emerging Contaminants in Small or Disadvantaged Communities (EC-SDC) grant program
- An additional $12 billion in IIJA funding is available for general drinking water improvements.

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EPA Water Technical Assistance (WaterTA) Supports Communities to:

- Identify water challenges
- Plan for solutions
- Increase community engagement
- Improve compliance and access to safe and clean water services
- Build technical, financial, managerial capacity
- Develop application materials to access water infrastructure funding

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Water Technical Assistance (WaterTA)

Tackling Emerging Contaminants (TEC)

- TEC supports communities with addressing ECs and PFAS in drinking water, helps administer the EC-SDC grant, and helps communities comply with the PFAS NPDWR
- TEC will deliver WaterTA to address EC through sampling and analysis, technical plans, implementation support and funding deliverables, operational and training support, and community engagement plans
- TEC aims to assist 200 communities and is preparing to launch in the first 10 communities in R4 & R5
- Share best practices and lessons learned nationally through case studies, factsheets, and webinars

Engineering Support

- WaterTA initiative requested by states to overcome a frequent funding barrier for communities
- Helps communities by identifying needs, conducting preliminary project planning, and producing the engineering documents needed for communities to apply for federal water infrastructure funding
- Bolsters local economies by helping communities get access to funding so they can hire local engineering and construction firms
- Project highlight: Engineering evaluation of alternatives for PFAS MCL compliance for Saipan, CNMI

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Implementation Flexibility - Exemptions

- States (with primacy authority) can grant exemptions for systems meeting specific criteria in accordance with SDWA section 1416(a).
- Exemptions allow eligible systems additional time to achieve and maintain regulatory compliance with new NPDWRs, while continuing to provide acceptable levels of public health protection.
- Exemptions do not allow a water system to violate NPDWRs. Rather, they allow additional time to find a compliance solution (i.e., treatment or a new source).
- All systems that meet the minimum criteria are eligible for an exemption of up to three years (until 2032).
- Further, for small systems serving populations of 3,300 or fewer, exemptions can provide up to six additional years (until 2038) to achieve MCL compliance.
- EPA could consult with states to identify tools and information that EPA could provide to assist them in considering/issuing exemptions.

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Next Steps

Ex. 5 Deliberative Process (DP)

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Appendices

- Map of the fraction of systems by State that exceed one or more of the PFAS MCLs in UCMR 5 monitoring to date (current as of January 2025).
- Additional EPA PFAS Resources

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Ex. 5 Deliberative Process (DP)

More information about the PFAS Rule

- PFAS Rule Frequently Asked Technical Questions
- Monitoring Fact Sheet
- Significant Figures and Rounding Quick Reference Guide
- Hazard Index Fact Sheet
- Small and Rural System Fact Sheet
- Treatment Options Fact Sheet
- Variances and Exemptions Quick Reference Guide

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Message

From: Noe, Paul [Paul_Noe@afandpa.org]
Sent: 3/3/2025 9:54:41 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Bradner, Kai [Kai_Bradner@afandpa.org]; Risley, David [Risley.David@epa.gov]
Subject: RE: Meeting Request with OW Wed, April 9
Attachments: EPA Meeting Request Water AF&PA030325.pdf; AFPA Trump Letter and Attachment.pdf

Flag: Follow up

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Dear Jess: Sorry about the typo; I got bounce-back from you so am resending so this meeting request goes through to you.

Thank you for your consideration.

Best regards,

Paul

Paul Noe
Vice President, Public Policy
Paul_Noe@afandpa.org
Office: (202) 463 - 2777
Cell: (703) 909 - 2895

AMERICAN FOREST & PAPER ASSOCIATION
601 Thirteenth Street NW, Suite 1000 N
Washington, D.C. 20005

From: Noe, Paul <Paul_Noe@afandpa.org>
Sent: Monday, March 3, 2025 4:52 PM
To: Kramer.Jessica@epa.gov
Cc: Bradner, Kai <Kai_Bradner@afandpa.org>; Risley.David@epa.gov
Subject: Meeting Request with OW Wed, April 9

Dear Jess: On behalf of the American Forest & Paper Association, I would like to request a meeting with you and others on EPA's Office of Water team for **Wednesday, April 9**, when members of our Environment Policy Committee will be in Washington DC to meet with your team in person.

I am copying my colleague Kai who can help find a time convenient for you and your team.

Thank you,

Paul

Paul Noe
Vice President, Public Policy
Paul_Noe@afandpa.org
Office: (202) 463 - 2777
Cell: (703) 909 - 2895

AMERICAN FOREST & PAPER ASSOCIATION
601 Thirteenth Street NW, Suite 1000 N
Washington, D.C. 20005

American Forest & Paper Association

Office of the President

December 5, 2024

Dear President-elect Trump,

On behalf of the American Forest & Paper Association (AF&PA) and our member companies, we congratulate you on your election to the Presidency. We look forward to working with you and your Administration to accomplish your agenda of growing the American manufacturing economy, creating new, high-paying jobs throughout our country, particularly in rural America, and ensuring that regulations are sustainable and do more good than harm. The forest products industry accounts for approximately 5% of the total U.S. manufacturing GDP, manufactures about $350 billion in essential products annually and employs about 925,000 people. The industry meets a payroll of about $65 billion annually. We are U.S. Manufacturing!

AF&PA serves to advance U.S. paper and wood products manufacturers through fact-based public policy and marketplace advocacy. The forest products industry is circular by nature. AF&PA member companies make essential products from renewable and recyclable resources, generate renewable bioenergy and are committed to continuous improvement through the industry's sustainability initiative — Better Practices, Better Planet 2030: Sustainable Products for a Sustainable Future.

Manufacturing Excellence and Value to Rural Communities

The forest products industry is a top ten manufacturing employer in 43 states – such as Wisconsin, Georgia, Pennsylvania, North Carolina, Michigan, Virginia, South Carolina and Ohio. Over 75 percent of our member company facilities are in counties that are overwhelmingly rural. Our facilities and our member companies provide good, high-paying, family-wage jobs, and our employees are the backbone of these communities.

We are proud of the hard-working men and women in our industry who work every day to bring essential products to all Americans, and we maintain strong relationships with our labor partners. The facilities and workers generate a strong tax base for these communities and support multiple small businesses, landowners, and others throughout the forest products industry supply chain. We estimate that each forest products industry job supports 3.25 additional jobs in supplier industries and in local communities across rural America.

Cumulative Burden of Regulations Undermine U.S. Innovation and Job Growth

We believe the American free enterprise system has been a significant engine for prosperity and can deliver a promising future for the United States and the world. The U.S. manufacturing sector has been a fundamental driver of this success, but our nation faces growing challenges in a highly competitive global economy. The cost, complexity and volume of regulations is greater than ever. As a result of our cumbersome air and water permitting processes, manufacturers that want to expand and create jobs with cleaner, more efficient technology are often stymied.

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At the same time, we recognize that reasonable, evidence-based regulations can provide important benefits, such as the protection of the environment, health, and safety for our country, communities and employees. Unfortunately, poorly designed regulations that fail to balance costs and benefits and disregard the best available science unintentionally can cause more harm than good, waste limited resources, undermine sustainable development, and erode public confidence in government.

The U.S. Supreme Court recently made clear that regulators must follow the best reading of statutes; they must only act within the boundaries of their statutory authority, and consider all relevant factors, including balancing costs and benefits. Accordingly, it is essential that regulations be designed to provide net benefits to the public based on best available scientific and technical information through a transparent and accountable rulemaking process, with due consideration of the cumulative regulatory burden.

Your administration and Congress have an historic opportunity to dramatically improve the regulatory process to better serve the public interest, create jobs, and strengthen the competitiveness of American manufacturing. We welcome the opportunity to talk with your team about systemic reforms to our regulatory process. In addition, while not exhaustive, we have attached a list of over a dozen of our top priority regulations we request be considered for immediate attention. In addition, priority issue areas for our members include:

Carbon Neutrality of Biomass

One of the primary policy challenges for our industry is ensuring the federal government recognizes the carbon neutrality of our biomass energy. The pulp and paper industry is a leading producer of carbon-neutral bioenergy, and our efficient use of forest products manufacturing residuals provides two-thirds of the energy used at our pulp and paper mills and also provides bioelectricity for the grid. For many years, the Environmental Protection Agency (EPA) had treated biomass as carbon neutral, in line with the rest of the world, but in 2010, EPA issued its Tailoring Rule which for the first time failed to recognize the carbon benefits of our bioenergy and created regulatory uncertainty that impedes investment planning and growth. Since then, the EPA has done extensive work on bioenergy, and in 2017, came very close to formally recognizing the carbon neutrality of biomass. Unfortunately, the rule was never made final, and we have continued to work extensively with federal agencies and Congress to resolve this lingering regulatory uncertainty.

Tax Reform

Our industry is made up of both C-corporations and pass-through entities, which invest heavily in equipment and improvements, making our industry one of the most capital-intensive among all US manufacturing. The paper and wood products industry invests roughly $16 billion per year in plant and equipment items such as recovery boilers, turbine generators, paper machines, and environmental controls that are critical to maintaining technologically advanced manufacturing facilities that compete in an extremely competitive global marketplace.

As an industry that is a key economic driver, especially in rural communities, we support several key elements of the US tax code including the 21 percent corporate rate enacted as part of the 2017 Tax Cuts and Jobs Act (TCJA), restoring 100 percent full expensing for investments in new and used property, maintaining the TCJA's original interest deduction limitation provision, and restoring the full research and development tax credit as enacted. Finally, as a globally competitive industry, it is crucial that we ensure the United States is on a level playing field with other countries – TCJA had a number of provisions designed to encourage businesses back to the United States and make them competitive with other countries. We need to ensure those provisions are preserved.

Trade

U.S. forest products exports account for a significant piece of the industry's total sales and in 2023, the industry's global exports totaled over $9 billion. AF&PA strongly supports free but fair trade and in today's globalized market, it is critical for the U.S. forest products manufacturing sector to achieve unrestricted access to international markets and level the playing field among international competitors by eliminating both tariff and non-tariff barriers such as restrictive import regulations.

AF&PA member companies procure the vast majority of their fiber from healthy, American forests but our companies also procure some fiber from key trading partners and additional tariffs would negatively impact the U.S. forest products industry's ability to compete with other international forest products producers. Additionally, some paper manufacturing machinery and equipment that is used by our member companies to produce our essential products comes from other countries and cannot currently be made in the United States. While we support domestic manufacturing policies that will ultimately make that possible, we oppose tariffs on machinery and pieces of equipment our companies use that objectively cannot be made in the U.S.

In 2023, the European Union (EU) enacted the EU Deforestation-free Regulation (EUDR), a regulation that aims at eliminating products sold in the EU that are linked to deforestation, is unworkable and disadvantages the U.S. forest products industry, small U.S. family forest owners, and threatens to disrupt trade with the EU valued at more than $3.5 billion. The U.S. forest products industry is among the most responsible suppliers of forest fiber in the world, and a strong proponent of international efforts to suppress deforestation and forest degradation. The prescriptive requirements of the regulation, however, will unjustifiably increase compliance costs and weaken U.S. producers' market access to established EU trading partners.

The U.S. forest products industry does not contribute to global deforestation or forest degradation, and we will need your direct engagement with EU government authorities to ensure U.S. wood, pulp and paper producers and our supply chain, which includes nearly 11 million small, private landowners, can remain competitive and continue to ship our essential products into the EU without disruption.

Recycling Policy
Paper recycling is a success story, no matter how you measure it. Paper is one of the most widely recycled materials in America, and paper recycling rates in the U.S. have consistently increased in recent decades. In fact, the paper industry recycles nearly 60% more paper today than it did in 1990, when the industry set its first recycling rate goal. In 2023, the paper recycling rate was 65-69% and the rate for cardboard recycling was 71-76%. In the United States, paper is recycled into new products every day.

The success of paper recycling has been accomplished through our industry's voluntary leadership and investment in market-based solutions. The use of recycled paper in manufacturing is driven by availability, performance, and cost, allowing recovered paper to be directed toward its highest-value end use. While nearly half of our industry's fiber needs are satisfied from recycled fiber, fresh fiber from sustainably managed forests is also a crucial source of material to sustain the fiber supply. We do not support government mandates for postconsumer recycled content in specific products. We support the U.S. EPA waste hierarchy, which recognizes a clear distinction between recycling and energy recovery and prioritizes recycling.

Conclusion
Again, we want to congratulate you on your election victory. We look forward to working with you over the next four years to enact policies that will allow pulp, paper, packaging and wood products manufacturers to continue as an American success story. Please let us know how we can assist your team in this endeavor.

Sincerely,

Heidi Brock

Heidi Brock
President and CEO
American Forest & Paper Association

Cc: Vice-President elect J.D. Vance

Attachment

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American Forest & Paper Association

Summary of Key Regulatory Concerns of AF&PA and Recommended Reforms (Dec. 2024)

The regulations and recommended reforms summarized below cut across many regulatory areas, such as the environment, energy and product-specific issues. While each regulation has its own technical aspects, a common thread across them all is the adverse impacts they have on the competitiveness of U.S. pulp, paper and wood products manufacturers, which must operate efficiently to successfully compete in our global marketplace. The U.S. forest products industry provides family wage jobs that support rural communities across America. Our industry employs 925,000 hard-working people who make essential paper and wood products that over 330 million Americans, as well as billions more around the world, depend on in their daily lives.

Environmental Protection Agency:

- **Carbon Neutrality of Biomass:**

Paper and wood products mills are the largest producers and users of carbon-neutral bioenergy of any other industrial sector. Unfortunately, EPA's policy shift in 2010 on biogenic CO_2 emissions has created counterproductive regulatory uncertainty for the industry that has lingered for almost 15 years.

  - **We recommend that bioenergy produced by pulp, paper and wood products mills be considered carbon neutral in rules and policies by EPA, as well as in the clean electricity tax credit rules and policies by the Department of Treasury, and by other relevant agencies.**

- **Air Permit Gridlock and PM NAAQS:**

Every five years, EPA must decide whether its National Ambient Air Quality Standards (NAAQS) are sufficiently protective of public health. Over time, as NAAQS (for particulate matter (PM), ozone, sulfur dioxide and nitrogen oxides) have been lowered close to background levels, it has become increasingly difficult to get permits approved for projects to modernize, expand, or build state-of-the-art American manufacturing plants. Given extremely stringent NAAQS recently issued by EPA, especially the PM NAAQS, a broad array of American industries, in addition to ours, across our country now face permitting gridlock. EPA should modernize its air permitting process based on credible approaches and adjust its modeling criteria to reflect actual impacts. The challenges with the ever-lower NAAQS are exacerbated by a lack of a credible

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implementation plan, including inappropriate emission measurement methods, poor estimates of emissions, use of unrealistic air dispersion models, and several unduly rigid permitting policies.

- **We recommend that EPA withdraw and reconsider the recent PM NAAQS due to its flawed and legally questionable rushed review, the failure to provide a workable implementation plan, and the scientific uncertainties. (RIN 2060-AV52)**
- **We recommend that EPA address the air permitting gridlock given the lack of "headroom" by committing sufficient resources to develop a credible NAAQS implementation program based on the best technical practices, including using more realistic receptor locations and emissions, exposures, and modeling data within the next year.**

- **PFAS Regulations (CERCLA Listing of PFOA/PFOS as Hazardous Substances; SDWA Maximum Contaminant Level (MCL)):**

In paper products manufacturing, sustainable materials management includes the beneficial use of paper mill residuals, largely composed of tree fiber, as a fertilizer. These mill residuals can be beneficially used for agricultural or forest lands, providing reduced soil erosion, less need for irrigation, increased soil nutrient-holding capacity, and reduced soil compaction, all of which significantly improves plant growth. It is important to ensure that the listing of PFOA and PFOS as hazardous substances under CERCLA does not lead to unintended outcomes, including impeding or preventing the safe and beneficial use of paper mill residuals as fertilizer.

Paper mills also sometimes serve as small drinking water systems for workers and local communities, and any drinking water MCLs under the Safe Drinking Water Act (SDWA) should be consistent with the law's requirements, including requirements for quality of science and data, as well as consideration of cost to all categories of public water systems.

- **We recommend that EPA reconsider the CERCLA Rule, which is legally flawed and could produce a host of unintended outcomes (RIN: 2050-AH09).**
- **We recommend that EPA reconsider the PFAS MCL Rule, to ensure it is consistent with the law's requirements for quality of science and data and the consideration of cost (RIN: 2040-AG18).**

- **Water Permit Gridlock and Human Health Water Quality Criteria (HHWQC):**

Under the Clean Water Act, states have the primary responsibility for issuing water quality standards and establishing acceptable risk levels in those standards. Based on a novel and far-reaching legal theory, EPA has established extraordinarily stringent water policy in two rules, the HHWQC Rule for Washington State and the Tribal Reserved Rights Rule. Both rules will lead to unattainable water quality standards and unattainable

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limits in Clean Water Act NPDES permits needed to operate U.S. manufacturing facilities.

- **We recommend that EPA reconsider the HHWQC Rule for Washington State (RIN: 2040-AG21) and the Tribal Reserved Rights Rule (RIN: 2040-AG17).**

- **Pulp and Paper MACT Risk and Technology Reviews:**

The pulp and paper industry has invested billions of dollars to significantly reduce hazardous air pollutants (HAPs) from its operations due to stringent Maximum Achievable Control Technology (MACT) requirements set under section 112 of the Clean Air Act. EPA determined that the remaining public health risk at both pulp and paper mills is acceptable based on a thorough analysis of post-MACT emissions. In 2020, a federal circuit court remanded back to EPA the "Pulp MACT" (Subpart MM National Emissions Standard for Hazardous Air Pollutants (NESHAP)), ruling EPA failed to revise the MACT as required under section 112(d)(6). *See Louisiana Environmental Action Network v EPA*, 955 F.3d 1088 (2020) ("*LEAN*").

EPA recently has misinterpreted their obligation under *LEAN* (and section 112(d)(6)) to set standards for more HAPs and more equipment at facilities. Section 112(d)(6) obligates EPA to "review and revise as ***necessary***," which is broad language that courts have interpreted in similar situations as requiring the consideration of all relevant factors, including costs, and balancing costs and benefits before imposing any new obligations. The recent Supreme Court *Loper Bright Enterprises* decision provides further support that EPA should change its approach to reviewing NESHAPs such as the Pulp and Paper MACTs.

In November 2024, EPA initiated its review of the Pulp MACT by sending a comprehensive survey of pulp mill operations and equipment to seven major companies. Once responses are evaluated, EPA plans to require about 200 HAP tests at 45 mills costing several million dollars. (EPA is simultaneously reviewing the "Paper MACT," so called the Subpart S NESHAP, and plans to send out a similar survey in 2025 and mandate additional HAP testing in 2026.) Unfortunately, much of the HAP testing data will be hard to assess due to poor quality and variability.

- **We recommend that EPA reconsider its plans to require pulp mills to undertake extensive HAP testing next spring by first determining whether new standards are "necessary" for each HAP-equipment combination -- considering all relevant factors, including public health risks, likely control costs, technical feasibility to accomplish testing, adequacy of current requirements, value of additional data and other relevant factors.**
- **Based on an assessment of public health benefits and costs (including any new test data) under section 112(d)(6), we recommend that EPA promptly complete its review of the pulp and paper MACT and only set new standards**

(either work practices or limits) that are "necessary" and reasonable and achievable.

- **Formaldehyde Risk Evaluation**

Under TSCA as amended, EPA's evaluation of priority chemicals has focused mainly on hazards and making unduly conservative assumptions about exposures, which leads to unnecessarily stringent and unworkable regulation. EPA routinely relies on conservative hazard determinations rather than the weight of the scientific evidence, as TSCA requires. EPA also is creating occupational exposure levels for existing chemicals in commerce even if the chemical has been adequately regulated by OSHA, which has led to confusing regulatory duplication.

An example of the problems in the chemical risk evaluation process under TSCA is its current draft Risk Evaluation for Formaldehyde. EPA calculated an extremely stringent occupational exposure level that is below background concentrations of formaldehyde in the air. Even facilities that do not use formaldehyde directly in manufacturing will have difficulty meeting the EPA level, which is far lower than the existing and protective OSHA permissible exposure level and much lower than occupational levels developed in Europe and other countries. EPA must incorporate the best available science in rulemaking to comply with TSCA and to ensure the U.S. is on a level playing field with its competitors around the world.

- **We recommend that EPA revise its formaldehyde risk evaluation under TSCA.**
- **We recommend that EPA use the best available science when evaluating chemicals such as formaldehyde and rely on the work of authoritative scientific bodies instead of operating independently and ignoring the weight of the scientific evidence.**

- **Good Neighbor Plan:**

In 2023, EPA promulgated the so-called Good Neighbor Plan regulation under the Clean Air Act to impose control requirements for nitrogen oxide (NO_x) emissions in 23 states from fossil fuel boilers in power plants -- and for the first time -- seven manufacturing industries, including paper mills. EPA ignored AF&PA's comments showing that the paper industry should have been excluded from the rule, both because the paper industry's emissions were below EPA's emissions threshold and because its very high control costs exceeded EPA's cost threshold.

States, AF&PA, and other industries challenged the rule. In June 2024, the U.S. Supreme Court issued a rare stay of the rule pending review on the merits by the D.C. Circuit Court of Appeals. *See Ohio v EPA*, 144 S. Ct. 2040 (2024), which found that industry petitioners likely would succeed on the merits.

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- **We recommend that EPA withdraw and reconsider the Good Neighbor Plan (RIN: 2060-AV51)**

Department of Labor, Occupational Safety and Health Administration (OSHA):

- **OSHA Heat Injury and Illness Prevention Proposed Rule:**

AF&PA recognizes the importance of protecting workers from heat-related injury and illness and wants to accomplish this objective in a practical, reliable, and scientifically sound manner. We understand OSHA's desire to establish a baseline for workplaces to address this hazard, but the scope of the rulemaking covers a very broad range of industries (including both outdoor and indoor work), regional climates, and worker populations. The rule needs to provide significant flexibility across workplaces to effectively manage the hazard of heat. AF&PA members already employ many controls outlined in the proposed rule and effectively protect workers from heat on a site-specific basis. Like other industries, we are concerned that certain aspects of the proposed rule are unreasonably prescriptive, burdensome, and unnecessary – and could be counterproductive.

- **We recommend that OSHA carefully review the proposed heat rule (RIN:1218-AD39) to add flexibility and recognize the effective efforts currently underway.**

Securities and Exchange Commission (SEC) and Federal Acquisition Regulatory (FAR) Council

- **Greenhouse Gas Reporting and Goals Rules (SEC Climate Disclosure Rule; FAR Council Proposed Rule on Greenhouse Gas (GHG) Emissions Reporting and Goals for Federal Contractors):**

As part of the Biden Administration's "whole of government" approach to climate regulation, the SEC finalized a rule requiring publicly listed companies to extensively report on their GHG emissions. In addition, the FAR Council (the General Service Administration, the Department of Defense, NASA, and OMB's Office of Federal Procurement Policy) proposed an extraordinarily far-reaching rule to require both GHG emissions reporting as well as GHG reduction goals by major federal contractors. Both rules raised a host of legal and practical concerns, and the SEC final rule currently is under legal challenge.

- **We recommend that the SEC reconsider and revise its climate disclosure rule (RIN: 3235-AM87) to ensure it is within the bounds of its statutory authority and is not arbitrary and capricious or counterproductive.**

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- **We recommend that the FAR Council withdraw its GHG emissions reporting and goals proposed rule (RIN: 9000-AO32) given its host of legal flaws and potential unintended outcomes.**

Department of Treasury

- **Clean Electricity Tax Credits:**

Under the Inflation Reduction Act, the Department of Treasury was required to issue regulations to implement the production tax credit and investment tax credit under sections 45Y and 48E of the Internal Revenue Code. Under the IRA, qualified facilities have a greenhouse gas emissions rate of not greater than zero. AF&PA filed with Treasury extensive comments and many scientific studies showing that the energy systems at pulp and paper mills should be included as qualified facilities in Treasury's final rule and annual table.

- **If pulp and paper mills' energy systems are not included as qualified facilities in the final rule (RIN: 1545-BR17) and annual table, we recommend that the final rule and annual table be withdrawn and reconsidered.**

Federal Trade Commission (FTC)

- **Green Guides Update:**

The Green Guides provide guidance to help marketers avoid making environmental claims that mislead consumers. The FTC is in the process of finalizing an update to the Green Guides. AF&PA supports the update of the Green Guides and looks forward to the opportunity to comment on the proposed updates.

- **Updating the Green Guides to reflect current trends and concerns in the marketplace is important to ensure consistency across states and avoiding a potential patchwork of state regulation of marketing claims.**

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Message

From: Risley, David [Risley.David@epa.gov]
Sent: 3/11/2025 8:49:27 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; McLain, Jennifer L. [McLain.Jennifer@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Albert, Ryan [Albert.Ryan@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Mottley, Tanya [Mottley.Tanya@epa.gov]; Damico, Brian [Damico.Brian@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Nalven, Heidi [Nalven.Heidi@epa.gov]
Subject: MATERIALS: Meeting on Final PFAS Drinking Water Regulations
Attachments: AO Briefing PFAS NPDWR March 12 2025.pdf; AO PFAS Briefing - One Page Summary_03122025.docx

Hi all,
Here are the materials for tomorrow's briefing. We'll use the slides to facilitate the conversation. We also provided a 1 pager for the Administrator's advanced reading to the extent he is available.

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

-----Original Appointment-----
From: ZeldinScheduling <ZeldinScheduling@epa.gov>
Sent: Thursday, March 6, 2025 10:06 AM
To: ZeldinScheduling; McIntosh, Chad; Voyles, Travis; Kramer, Jessica L.; Best-Wong, Benita; Risley, David; McLain, Jennifer L.; Burneson, Eric; Albert, Ryan; Donahue, Sean; Payne, James (Jim); Messier, Dawn
Cc: Wehling, Carrie; Nalven, Heidi; Flaherty, Colleen; Mottley, Tanya
Subject: Meeting on Final PFAS Drinking Water Regulations
When: Wednesday, March 12, 2025 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Alm Room

- Administrator Zeldin
- Chad McIntosh, AO
- Travis Voyles, AO
- Jessica Kramer, AO
- Benita Best-Wong, OW
- David Risley, OW
- Jennifer McLain, OW
- Eric Burneson, OW
- Ryan Albert, OW
- Sean Donahue, OGC
- Jim Payne, OGC
- Dawn Messier, OGC

Final PFAS National Primary Drinking Water Regulation

March 12, 2025

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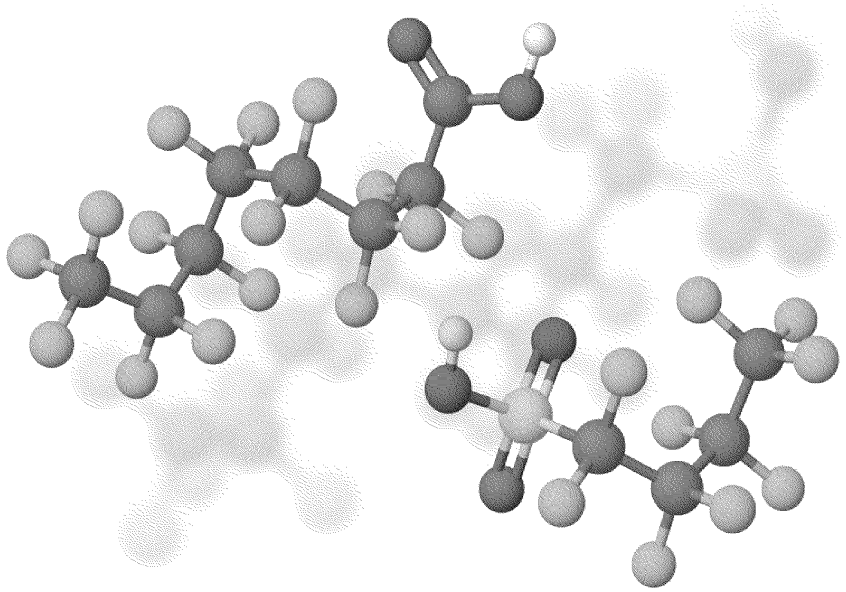
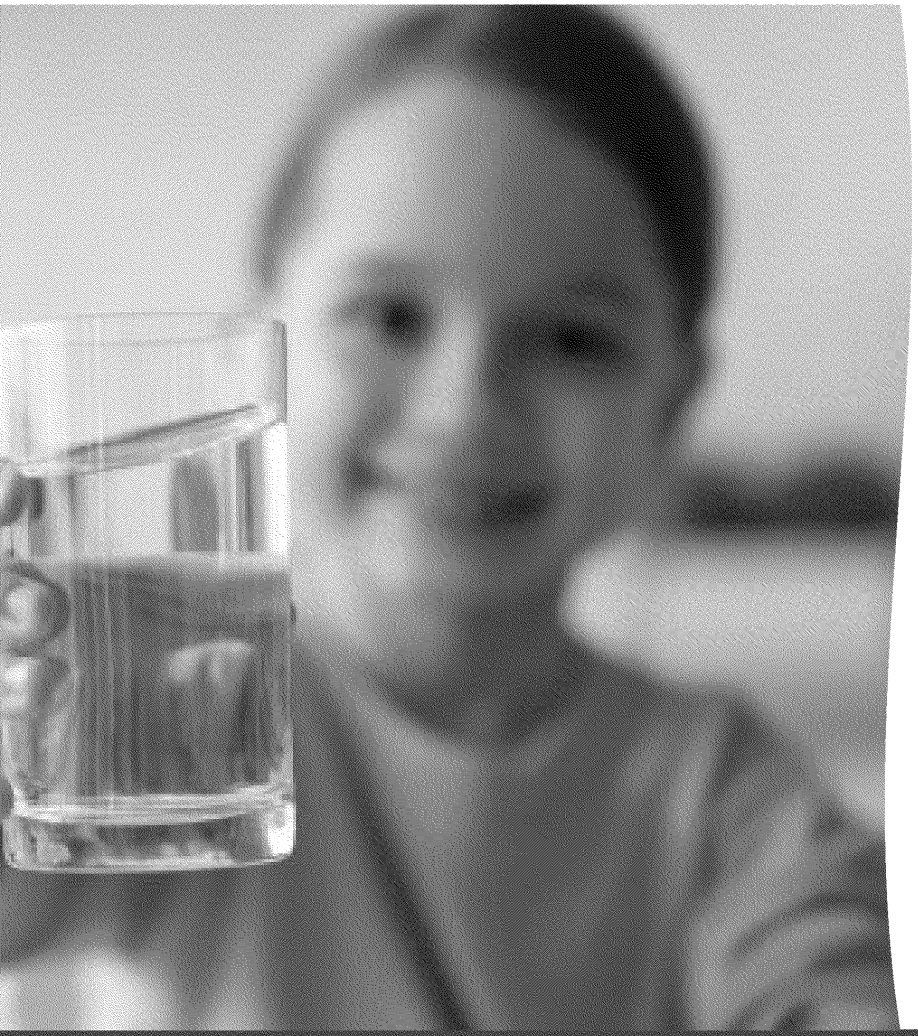
PFAS in Drinking Water

- Certain PFAS cause a variety of health effects, including multiple cancers, heart disease and strokes, and developmental effects, in addition to effects on most other systems in the human body
- Technologies are available that remove PFAS from water
- The PFAS drinking water rule sets feasible limits that consider costs and benefits



ED_018877_00000081-00002



Regulatory Determinations for PFAS

- EPA's 2019 PFAS Action Plan committed the Agency to make regulatory determinations for PFOA and PFOS in drinking water.
- EPA proposed regulatory determinations for PFOA and PFOS in 2020, finalizing them in early 2021.
  - EPA proposed and then committed to "making regulatory determinations in advance of the next SDWA deadline for additional PFAS" when health, occurrence, and other information were available.
- EPA made regulatory determinations for four additional PFAS concurrently with the proposed (2023) and final (2024) PFAS drinking water regulation.

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PFAS Standards: Summary

Chemical	Maximum Contaminant Level Goal (MCLG)	Maximum Contaminant Level (MCL)
PFOA	0	4.0 ppt
PFOS	0	4.0 ppt
PFHxS	10 ppt	10 ppt
HFPO-DA (GenX chemicals)	10 ppt	10 ppt
PFNA	10 ppt	10 ppt
Mixture of two or more: PFHxS, PFNA, HFPO-DA, and PFBS	Hazard Index of 1	Hazard Index of 1

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Costs and Benefits

	How Much?	What From?	The Potential Impact
Costs	$1.5 Billion per year	Monitoring, communicating with customers, and if necessary, obtaining new or additional sources of water or installing and maintaining treatment technologies.	States, Tribes, and territories with primacy will have increased oversight and administrative costs. **66,000 regulated water systems** will have to conduct monitoring and notifications. **4,100 – 6,700 water systems** may have to take action to reduce levels of PFAS.
	Non-quantified*	Costs for some systems to comply with the Hazard Index, HFPO-DA, and PFNA MCLs.	
Benefits	$1.5 Billion per year	The rule results in fewer cancers, lower incidence of heart attacks and strokes, and fewer birth weight-related deaths. Benefits will prevent over **9,600 deaths and reduce approximately 30,000 serious illnesses.**	**83 – 105 million people** will have improved drinking water as a result of lower levels of PFAS
	Non-quantified*	Increased ability to fight disease, reductions in thyroid disease and impacts to human hormone systems, reductions in liver disease, and reductions in negative reproductive effects such as decreased fertility. Actions taken to implement the rule may also lead to associated health benefits from reductions in other PFAS and unregulated disinfection byproducts	

***Non-quantified benefits and costs are those that EPA could not assign a specific number to as part of its national level quantified analysis. EPA determined that the benefits of the rule justified the costs.**

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PFAS Rule – Built-in Burden Reduction / Flexibilities

- Compliance is based on a running annual average
  - Single result above MCL is not an automatic violation
  - Results below the quantitation limit are considered to be zero
  - Annual average is rounded to determine compliance
- Provisions to reduce the monitoring burden
  - Systems may use previously collected drinking water data for initial monitoring
  - Small groundwater systems are only required to collect two samples for initial monitoring
  - Systems may reduce the monitoring frequency based on sampling results
- 2-year extension to the typical 3-year deadline to comply with the PFAS MCLs
  - Provides time for systems until 2029 to plan, design, and fund capital improvements
- Does not dictate how water systems must reduce PFAS levels the to meet MCLs

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NGOs Perspectives on the PFAS Rule

- Support
  - PFOA and PFOS MCLs are readily achievable
  - Serious health risks from mixtures of PFAS
- Concerns
  - Consider all monitoring results with detectable levels of PFAS (rather than considering levels below quantitation limits as zero)
  - No reduced monitoring frequency
  - Require 24-hour public notification instead of 30 days for MCL violations
  - Lower MCLGs to address children's risks
  - Use the authority of other statutes to control PFAS chemicals and other drinking water contaminants at the source

Water Associations' Perspective on the PFAS Rule

- Supported
  - Two-year capital improvements extension for MCL compliance
  - Reduced monitoring frequencies and use of previously collected monitoring data
  - 30 day public notification for MCL violations
- Concerns
  - Water systems are "passive receivers" and should not be responsible for the cost to remove PFAS
  - EPA should not issue concurrent regulatory determinations and proposed rule
  - MCLs for PFOA and PFOS are infeasible and should be higher
  - EPA should not issue a MCL to address a mixture of contaminants (hazard index)
  - EPA should not regulate HFPO-DA or PFNA
  - EPA underestimated number of systems impacted and the costs of rule

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State Associations' Perspective on the PFAS Rule

- Supported
  - Two-year capital improvements extension for MCL compliance
  - Addressing PFAS in groups
  - Ability to use previously acquired data
  - Ability to reduce monitoring frequency
- Concerns
  - Funding insufficient to address needs (particularly for states and small systems)
  - Laboratory capacity to support rule monitoring is uncertain

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Ex. 5 Deliberative Process (DP)

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Consolidated Litigation in D.C. Circuit

- Petitioners
  - American Water Works Association, Association of Metropolitan Water Agencies, American Chemistry Council, National Association of Manufacturers, The Chemours Company
- Intervenors on behalf of EPA
  - Concerned Citizens of WMEL Water Authority Grassroots, Environmental Justice Task Force, Fight for Zero, Merrimack Citizens for Clean Water, Natural Resources Defense Council, Buxmont Coalition for Safe Water, Newburgh Clean Water Project, Clean Haw River, Clean Cape Fear
- Key Issues raised
  - EPA's use of concurrent process to issue NPDWR and regulatory determinations.
  - EPA's regulation of PFAS mixtures and use of the hazard index for MCL.
  - EPA's record to support its regulation of HFPO-DA and basis for MCLG and MCL.
  - EPA's assessment of the costs and benefits of the rule.
- Status: EPA filed a response brief. Case held in abeyance until April 8, 2025.

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PFAS Success Strategy for Reducing Household Costs for Ratepayers

- Goal to ensure all water systems, especially small water systems, have affordable fit-for-purpose solutions that enable sustained operations and maintenance for the delivery of safe drinking water.
- Five prongs that together will support providing clean water to all Americans through innovation, cooperative federalism, and partnerships.

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Prong One: Direct support through funding and technical assistance

- Direct technical assistance rooted in SDWA and the principles of cooperative federalism, such as that provided through the Water Technical Assistance (WaterTA) initiatives, strengthens states and utilities' ability to address PFAS contamination and protect public health.
- Deploy funding resources, like DWSRF and most notably, the Emerging Contaminants in Small or Disadvantaged Communities (EC-SDC) grant, to reduce the financial burdens on small systems in the most cost-effective manner feasible.

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Prong Two: Evaluate innovative technologies and develop data-driven tools to support cost-effective decision making

- Evaluating, demonstrating, and advancing alternative technologies allows systems to choose smarter, more cost-effective solutions to reduce PFAS in drinking water, ensuring safer, cleaner water for all.
- With the right tools and information, decision-makers can make informed, cost-effective choices that streamline technology adoption and future operations & maintenance costs while reducing financial burdens.

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Prong Three: Share PFAS tools and understanding nationally

- Host a national convening through a cross-sector partnership between EPA, states, utilities, and technology industries that will enable the agency to refine its implementation tools and deliver information on the latest technological innovations based on real-world insights to support sound operational decision-making.
- Following the national convening, EPA can host regional technology workshops, in partnership with states and technical assistance providers such as the National Rural Water Association (NRWA) and Rural Community Assistance Partnership (RCAP), to pave the way for scalable, cost-effective PFAS removal strategies that ensure cleaner, safer drinking water for all.

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Prong Four: Highlight SDWA Compliance Flexibilities

- SDWA section 1416(a) provides for exemptions that allow eligible systems additional time to achieve compliance
  - All systems that meet the minimum criteria are eligible for an exemption of up to three years (until 2032).
  - Further, for small systems serving populations of 3,300 or fewer, exemptions can provide up to six additional years (until 2038) to achieve MCL compliance.
- EPA can provide guidance and share best practices for states to:
  - Assess compelling factors that make a system unable to comply or develop an alternative source of water supply by 2029
  - Determine if an exemption poses an "unreasonable risk to health"

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Prong Five: Prevent PFAS Pollution at the Source

- Industrial discharges are one of the primary sources of PFAS in surface water.
- Regulating industrial sources of PFAS puts the financial responsibility on the polluter and not municipalities.
- In January 2021, the EPA announced its intent to regulate facilities engaged in PFAS manufacturing to limit PFAS discharges to surface waters.

Ex. 5 Deliberative Process (DP)

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Next Steps

Ex. 5 Deliberative Process (DP)

Reducing Ratepayer Costs to Address PFAS in Drinking Water

Issue

- EPA estimates the PFAS Drinking Water Rule will result in annualized costs of $1.5 billion per year (including approx. $355 million incurred by systems serving 10,000 or fewer persons per year). EPA estimates $1.5 billion per year in benefits from cleaner drinking water for over 100 million people.
- EPA estimates operating costs will be approximately $1 billion per year (undiscounted) starting in 2029, and between $16-$66 million (undiscounted) spent by PWS on monitoring per year.

Background

- Certain PFAS cause a variety of health effects, including multiple cancers, heart disease and strokes, and developmental effects, in addition to effects on most other systems in the human body.
- Technologies are available that remove PFAS from drinking water to less than the MCL.
- The PFAS Rule does not dictate how water systems will reduce PFAS Levels to meet the MCLs.
- EPA followed the Safe Drinking Water Act's requirements under Section 1412 to set standards as close as feasible to the health-based goals and consider costs and benefits.
- The rule is being challenged in the D.C. Circuit. Case held in abeyance until April 8, 2025.

Key Points

- SDWA and the PFAS rule provide significant flexibilities to reduce implementation burden and support states and utilities.
- Ex. 5 Deliberative Process (DP)

PFAS Success Strategy

-
- Ex. 5 Deliberative Process (DP)

Upcoming Milestones

Ex. 5 Deliberative Process (DP)

Message

From: McLain, Jennifer L. [McLain.Jennifer@epa.gov]
Sent: 3/20/2025 6:34:48 PM
To: Browne, Peggy [Browne.Peggy@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Risley, David [Risley.David@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]
CC: Wehling, Carrie [Wehling.Carrie@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]
Subject: AWWA statement on litigation
Attachments: PFAS Rule AWWA Statement of Litigation Issues 7-15-2024.pdf

ORAL ARGUMENT NOT YET SCHEDULED

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

AMERICAN WATER WORKS ASSOCIATION and ASSOCIATION OF METROPOLITAN WATER AGENCIES, *Petitioners*, *v.* UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and MICHAEL S. REGAN, in his official capacity as Administrator, United States Environmental Protection Agency, *Respondents*.	No. 24-1188 (consolidated with Nos. 24-1191, 24-1192)

NONBINDING STATEMENT OF ISSUES

Pursuant to this Court's June 7, 2024 order, Petitioners American Water Works Association and Association of Metropolitan Water Agencies ("Associations") hereby submit this Nonbinding Statement of Issues with respect to their Petition for Review of the U.S. Environmental Protection Agency's ("EPA") final rule entitled "PFAS National Primary Drinking Water Regulation," 89 Fed. Reg. 32,532 (April 26, 2024) ("Final Rule"). The Final Rule finalizes national

primary drinking water regulations for six per- and polyfluoroalkyl substances ("PFAS"): perfluorooctanoic acid ("PFOA"), perfluorooctane sulfonic acid ("PFOS"), perfluorohexane sulfonic acid ("PFHxS"), perfluorononanoic acid ("PFNA"), hexafluoropropylene oxide dimer acid ("HFPO-DA"), and perfluorobutane sulfonic acid ("PFBS").

The following issues are stated without prejudice to the Associations' right to raise additional issues to explain how EPA acted arbitrarily and capriciously, not in accordance with law, or in excess of its statutory jurisdiction, authority, or limitations in promulgating the Final Rule:

1. Whether EPA violated the Safe Drinking Water Act, *see* 42 U.S.C. § 300g-1, or acted arbitrarily and capriciously or in a manner otherwise not in accordance with law, by proposing preliminary determinations to regulate PFHxS, PFNA, HFPO-DA, and PFBS concurrently with proposed maximum contaminant level goals and national primary drinking water regulations for such contaminants, and issuing final determinations to regulate PFHxS, PFNA, HFPO-DA, and PFBS concurrently with final maximum contaminant level goals and national primary drinking water regulations for such contaminants—individually and/or as part of a novel and unitless "hazard index."

2. Whether EPA violated the Safe Drinking Water Act, or acted arbitrarily and capriciously or in a manner otherwise not in accordance with law, by issuing a

maximum contaminant level goal and national primary drinking water regulation for mixtures containing two or more of PFHxS, PFNA, HFPO-DA, and PFBS in the form of a novel and unitless "hazard index" when:

a. The hazard index is neither a maximum contaminant level nor a treatment technique, the two forms of national primary drinking water regulation authorized by the Safe Drinking Water Act;

b. The Safe Drinking Water Act does not permit the establishment of maximum contaminant level goals and national primary drinking water regulations for mixtures of individual contaminants, particularly based on the data available for these substances; and

c. EPA failed to consider the best available science, *see* 42 U.S.C. § 300g-1(b)(3)(A), and otherwise failed to provide a rational connection between the facts found and the choices made, by deciding to use the hazard index, a health screening tool, as a form of national primary drinking water standard.

3. Whether EPA violated the Safe Drinking Water Act, or acted arbitrarily and capriciously or in a manner otherwise not in accordance with law, by issuing determinations to regulate PFNA, HFPO-DA, and PFBS as individual contaminants and as a mixture of PFHxS, PFNA, HFPO-DA, and PFBS when these substances are

neither known to occur nor have a substantial likelihood that they will occur in public water systems with a frequency and at levels of public health concern. *See* 42 U.S.C. § 300g-1(b)(1)(A)(ii).

4. Whether EPA violated the Safe Drinking Water Act, or acted arbitrarily and capriciously or in a manner otherwise not in accordance with law, by promulgating individual maximum contaminant levels of 10 parts per trillion for PFHxS, PFNA, and HFPO–DA without providing adequate public notice and when those levels are neither "feasible," especially when taking public water systems' costs of compliance into consideration, *see* 42 U.S.C. § 300g-1(b)(4), (b)(3)(C)(i)(III), nor reflective of the best available science or nationally representative occurrence data.

5. Whether EPA violated the Safe Drinking Water Act, or acted arbitrarily and capriciously or in a manner otherwise not in accordance with law, by issuing maximum contaminant levels of 4 parts per trillion for PFOA and PFOS when those levels are neither "feasible," especially when taking public water systems' costs of compliance into consideration, *see* 42 U.S.C. § 300g-1(b)(4), (b)(3)(C)(i)(III), nor reflective of the best available science or nationally representative occurrence data.

6. Whether EPA violated the Safe Drinking Water Act, or acted arbitrarily and capriciously or in a manner otherwise not in accordance with law, by failing to adequately analyze public water systems' costs of compliance with the Final Rule,

or properly assess the benefits as required by the Safe Drinking Water Act. *See* 42 U.S.C. § 300g-1(b)(3)(C).

7. Whether EPA violated the Safe Drinking Water Act, or acted arbitrarily and capriciously or in a manner otherwise not in accordance with law, by failing to take due account of nationally representative occurrence and co-occurrence data of the six PFAS substances in drinking water that were available to EPA prior to its promulgation of the Final Rule and issuance of the underlying economic analysis, such as national data that had already been gathered from EPA's ongoing Fifth Unregulated Contaminant Monitoring Rule.

Dated: July 8, 2024

Respectfully submitted,

/s/ Corinne V. Snow

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Corinne V. Snow
Nathan Campbell
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Phone: (202) 639-6622
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Email: ncampbell@velaw.com

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

CERTIFICATE OF SERVICE

Pursuant to Rule 25 of the Federal Rules of Appellate Procedure, I hereby certify that on July 8, 2024, I electronically filed the foregoing Nonbinding Statement of Issues 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.

Dated: July 8, 2024

Respectfully submitted,

/s/ Corinne V. Snow
Corinne V. Snow

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

Message

From: Wehling, Carrie [Wehling.Carrie@epa.gov]
Sent: 3/20/2025 8:28:57 PM
To: McLain, Jennifer L. [McLain.Jennifer@epa.gov]; Risley, David [Risley.David@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]
CC: Burneson, Eric [Burneson.Eric@epa.gov]; Nalven, Heidi [Nalven.Heidi@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]

Ex. 5 Attorney Work Product (AWP)

Ex. 5 Attorney Work Product (AWP)

Caroline (Carrie) Wehling
Assistant General Counsel
Water Law Office
U.S. Environmental Protection Agency
Washington DC 20004
202-564-5492
wehling.carrie@epa.gov

From: McLain, Jennifer L. <McLain.Jennifer@epa.gov>
Sent: Thursday, March 20, 2025 3:33 PM
To: Risley, David <Risley.David@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Best-Wong, Benita <Best-Wong.Benita@epa.gov>
Cc: Wehling, Carrie <Wehling.Carrie@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>

Ex. 5 Attorney Work Product (AWP)

Ex. 5 Attorney Work Product (AWP)

From: Risley, David <Risley.David@epa.gov>
Sent: Thursday, March 20, 2025 3:30 PM
To: McLain, Jennifer L. <McLain.Jennifer@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Best-Wong, Benita <Best-Wong.Benita@epa.gov>
Cc: Wehling, Carrie <Wehling.Carrie@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: AWWA statement on litigation

Thank you for sharing.

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177

Cell: 202-731-3068

From: McLain, Jennifer L. <McLain.Jennifer@epa.gov>
Sent: Thursday, March 20, 2025 2:35 PM
To: Browne, Peggy <Browne.Peggy@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Risley, David <Risley.David@epa.gov>; Best-Wong, Benita <Best-Wong.Benita@epa.gov>
Cc: Wehling, Carrie <Wehling.Carrie@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Ex. 5 Attorney Work Product (AWP)

Message

From: Haga, Ellie [Haga.Ellie@epa.gov]
Sent: 3/21/2025 8:56:05 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Risley, David [Risley.David@epa.gov]; Lanier, Lynsey [Lanier.Lynsey@epa.gov]
Subject: Review Item and Materials for OW Meetings: Monday, March 24, 2025
Attachments: Ex. 5 Deliberative Process (DP)

Hi Jess,
Attaching a one pager for your review.

Additionally, materials for Monday's meeting are attached, including:

- **PFAS MCL Science Briefing**
  - OWAA Briefing

Ex. 5 Deliberative Process (DP)

Have a great weekend!

Best,
Ellie

Ellie Haga
Special Assistant
Office of Water
U.S. Environmental Protection Agency
WJC East 3219-D
Desk Phone: 202-564-3854
Mobile Phone: 771-242-0793
Haga.ellie@epa.gov

Message

From: Hagerman, Carla [Hagerman.Carla@epa.gov]
Sent: 3/21/2025 6:45:46 PM
To: Haga, Ellie [Haga.Ellie@epa.gov]
CC: Aguirre, Janita [Aguirre.Janita@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Jones, Colin [Jones.Colin@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; OW-IO Audit Team [OW-IO_Audit_Team@epa.gov]
Subject: One-Pager on GAO-24-106523 (PFAS Storage and Disposal Report) for Jess' and Peggy's Binders
Attachments: Summary Document for GAO report GAO-24-106523.docx; Response for Final Report - GAO's PFAS Disposal Destruction and Storage (106523)_January 2025.pdf

Good afternoon, Ellie.

Please find attached for Jess' and Peggy's binders, a one-pager on GAO PFAS engagement report GAO-24-106523 *(Persistent Chemicals: Additional EPA Actions Could Help Public Water Systems Address PFAS in Drinking Water)*, as well as OW's 1/22/2025 response memo to OCFO for reference.

Ex. 5 Deliberative Process (DP)

Please reach out with any questions. Best, Carla

Carla Hagerman
AFC, OW-OPARMS
U.S. Environmental Protection Agency
Office: (202) 564-9499
Email: hagerman.carla@epa.gov

Message

From: Haga, Ellie [Haga.Ellie@epa.gov]
Sent: 3/24/2025 8:09:04 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Risley, David [Risley.David@epa.gov]; Lanier, Lynsey [Lanier.Lynsey@epa.gov]
Subject: OW Meeting Materials: Tuesday, March 25, 2025
Attachments: Ex. 5 Deliberative Process (DP)

Hi Jess,
I've attached one review item for you from Friday if you haven't had time to review yet:

Ex. 5 Deliberative Process (DP)

Also attached are the materials for meetings tomorrow, including:

Ex. 5 Deliberative Process (DP)

Let us know if you need anything else!

Best,
Ellie

Ellie Haga
Special Assistant
Office of Water
U.S. Environmental Protection Agency
WJC East 3219-D
Desk Phone: 202-564-3854
Mobile Phone: 771-242-0793
Haga.ellie@epa.gov

Message

From: Haga, Ellie [Haga.Ellie@epa.gov]
Sent: 3/26/2025 9:04:07 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Risley, David [Risley.David@epa.gov]; Lanier, Lynsey [Lanier.Lynsey@epa.gov]
Subject: OW Materials for Thursday, March 27, 2025
Attachments: Ex. 5 Deliberative Process (DP) 2025.docx; Agenda - Tiger Team with Regions - 3-31-25.docx; DIC Statute and Regs.docx; DIC Inventory Maps.pdf; OWAA Briefing_3.27.25 final.pptx

Hi Jess,
Great job today!

Attached are materials for OW meetings tomorrow, including:

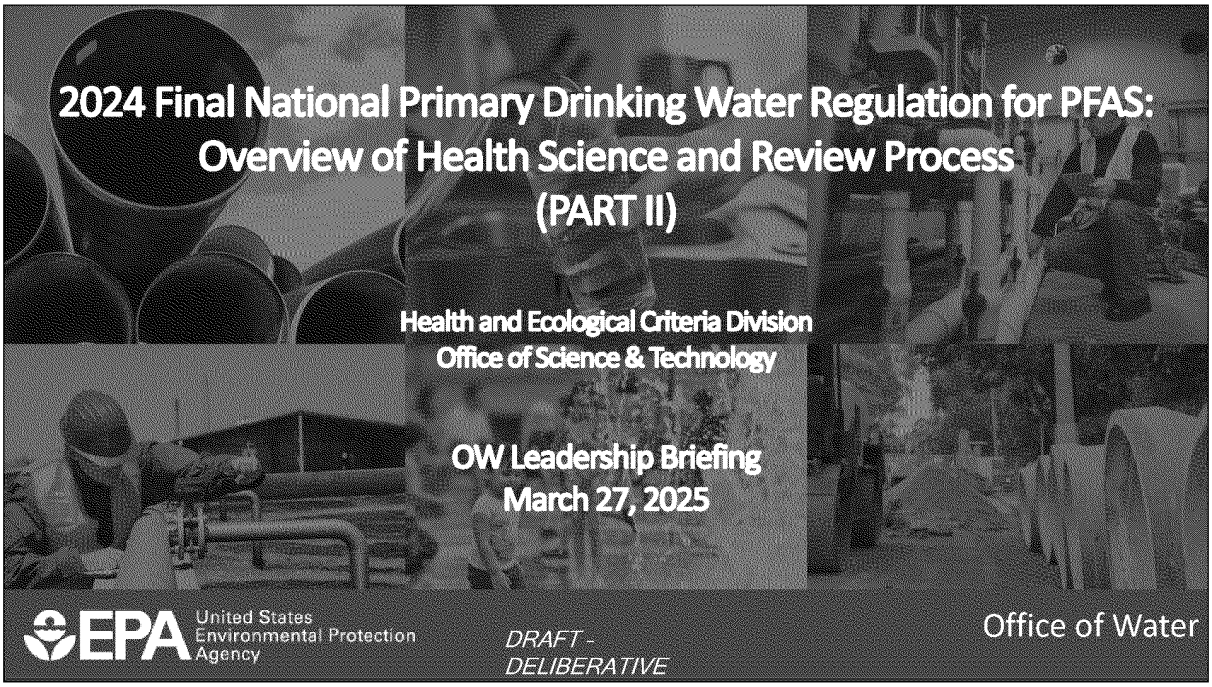
Ex. 5 Deliberative Process (DP)

- PFAS MCL Science Briefing Part 2

Let us know if you need anything else!

Best,
Ellie

Ellie Haga
Special Assistant
Office of Water
U.S. Environmental Protection Agency
WJC East 3219-D
Desk Phone: 202-564-3854
Mobile Phone: 771-242-0793
Haga.ellie@epa.gov


2024 Final National Primary Drinking Water Regulation for PFAS: Overview of Health Science and Review Process (PART II)
Health and Ecological Criteria Division
Office of Science & Technology
OW Leadership Briefing
March 27, 2025
EPA United States Environmental Protection Agency
DRAFT - DELIBERATIVE
Office of Water

Presentation Overview

- Quick recap
- Follow up on questions
- 2021 GenX (HFPO-DA) toxicity assessment
- PFAS Mixtures Hazard Index (HI) MCLG

ED_018877_00000156-00002

Quick Recap

- The Maximum Contaminant Level Goal (MCLG) 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."
  - **Since PFOA and PFOS were each classified as *Likely to be Carcinogenic to Humans*, their MCLGs were set to zero, consistent with SDWA definition of an MCLG and with past precedent.**
    - MCL set "as close to the maximum contaminant level goal as is feasible."
  - **Therefore, the cancer data (human epidemiological and animal toxicological studies) were the driver for PFOA and PFOS drinking water standards.**
- The SAB supported EPA's draft decisions regarding PFOA and PFOS health effects, including:
  - Quantitative use of human epidemiological data to support hazard determinations and derive toxicity values
  - PFOA's cancer classification of *Likely to be carcinogenic to humans*
    - For PFOS, the SAB asked EPA to re-evaluate cancer studies and consider upgrading PFOS to *Likely to be carcinogenic to humans*
  - Decreased antibody production as an adverse health effect resulting from PFOA or PFOS exposure and for use in RfD derivation
  - Uncertainty factor selection for PFOA and PFOS RfD derivation
- No challenges to the toxicity assessment conclusions or MCLGs in the ongoing litigation.

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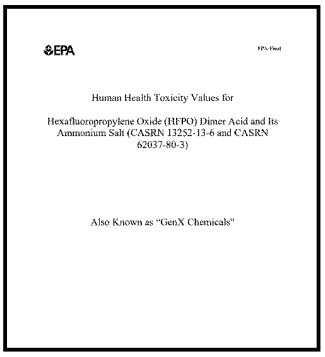
Follow Up on Questions

Ex. 5 Deliberative Process (DP)

ED_018877_00000156-00004

Final Toxicity Assessment for HFPO-DA (GenX Chemicals)



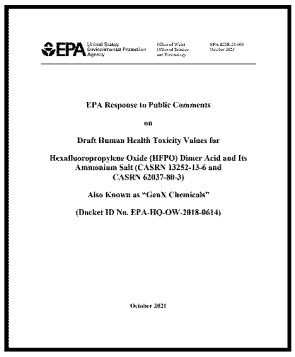
EPA

EPA Final

Human Health Toxicity Values for

Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3)

Also Known as "GenX Chemicals"



EPA United States Environmental Protection Agency

Office of Water
Office of Science and Technology

EPA 822-R-21-001
October 2021

EPA Response to Public Comments

on

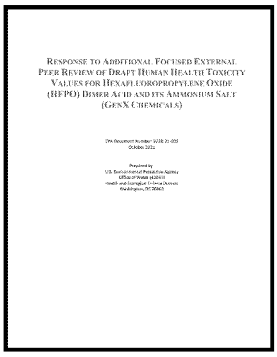
Draft Human Health Toxicity Values for

Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3)

Also Known as "GenX Chemicals"

(Docket ID No. EPA-HQ-OW-2018-0614)

October 2021



RESPONSE TO ADDITIONAL FOCUSED EXTERNAL PEER REVIEW OF DRAFT HUMAN HEALTH TOXICITY VALUES FOR HEXAFLUOROPROPYLENE OXIDE (HFPO) DIMER ACID AND ITS AMMONIUM SALT (GENX CHEMICALS)

EPA Document Number 822R-21-003
October 2021

Prepared by
U.S. Environmental Protection Agency
Office of Water
Health and Ecological Criteria Division
Washington, DC 20460

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HFPO-DA Toxicity Assessment: Assessment Development Process

- **February 2018 – June 2018:** OPPT's prior draft assessment was used as starting point for the 2018 draft assessment; OW collaborated with OPPT and ORD.
- **June - July 2018:** First external peer review of draft assessment
  - Peer reviewers unanimously agreed with:
    - Selected critical study and effect (liver cell death)
    - Selection of uncertainty factors
    - Adversity of the liver cell death
    - Human relevance of the liver cell death in rodent

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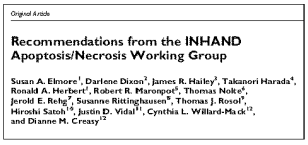
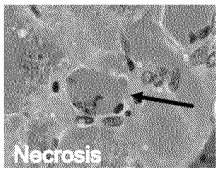
HFPO-DA Toxicity Assessment: Assessment Development Process

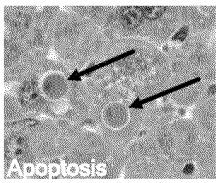
- **November 2018:** Draft assessment released for public comment
- **January 2019:** Public comments raised a concern about the classification and human relevance of the critical liver effect in rodents.
  - Commenters assert that updated liver pathology criteria (Elmore et al. (2016)) changed the effects observed in the liver studies and questioned human relevancy.
  - To resolve this issue, EPA requested that NIEHS-NTP convene a Pathology Working Group to conduct an independent review of liver effects in key studies.
- **October 2019**: Dr. Elmore (lead author of the Elmore criteria cited by the commenters) and six other pathologists on the Pathology Working Group reassessed the liver slides and classified the liver lesions according to the Elmore criteria.
  - The Pathology Working Group reported a constellation of liver effects which together are considered adverse.
  - The Pathology Working Group findings generally supported EPA's selection of the critical effect in the liver but refined the specific adverse endpoints.


Original Article

Recommendations from the INHAND Apoptosis/Necrosis Working Group

Susan A. Elmore[1], Darlene Dixon[2], James R. Hailey[3], Takanori Harada[4], Ronald A. Herbert[2], Robert R. Maronpot[5], Thomas Nolte[6], Jerold E. Rehg[7], Susanne Rittinghausen[8], Thomas J. Rosol[9], Hiroshi Satoh[10], Justin D. Vidal[11], Cynthia L. Willard-Mack[12], and Dianne M. Creasy[13]





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HFPO-DA Toxicity Assessment: Assessment Development Process

- **March 2020 – December 2020**: EPA conducted the final literature search which identified new reproductive, developmental, and neurotoxic effects. This new information impacted the database UF. EPA revised the draft assessment based on new information from the final literature search and the Pathology Working Group's report.
- **April – July 2021:** 2nd external peer review of revised draft assessment
  - All 7 peer reviewers supported the use of liver endpoint and the PWG analysis
  - All 7 peer reviewers agreed liver endpoint was adverse and relevant to humans
  - Majority (5) supported 10X subchronic to chronic duration uncertainty factor (UF_S)
  - All 7 reviewers supported 10X database uncertainty factor (UF_D)

	2018 Public Comment Draft	2021 Final
Critical Study	Oral reproductive and developmental toxicity study (Dupont 18405-1037, 2010)	Oral reproductive and developmental toxicity study (Dupont 18405-1037, 2010)
Critical Effect	Single cell necrosis in parental males	Constellation of liver lesions (defined by the NTP PWG to include cytoplasmic alteration, hepatocellular single cell and focal necrosis, and hepatocellular apoptosis) in parental females
Dosing Duration	84 - 85 days	53 – 64 days (depending on timing of conception)
POD_{HED}	0.023 mg/kg/day	0.01 mg/kg/day
UF_L	1	1
UF_S	3	10
UF_A	3	3
UF_H	10	10
UF_D	3	10
UF_{TOTAL}	300	3000
Chronic RfD	8×10^{-5} mg/kg/day	**3×10^{-6} mg/kg/day**

HFPO-DA Toxicity Assessment: Events After Finalization

- **October 2021:** EPA toxicity assessment finalized; responses to public comments and second peer review published.
- **March 2022**: Chemours files a Request for Correction of the toxicity assessment claiming scientific errors (discussed later as part of the litigation).
- **June 2022**: EPA rejects Chemours Request for Correction and provides detailed rebuttals of the claims made in the Request for Correction. EPA notes that the toxicity assessment was subject to two external peer reviews and those peer reviews supported the conclusions of the assessment.
- **June 2022**: EPA publishes health advisory for HFPO-DA based on 2021 toxicity value.
- **July 2022**: Chemours files petition for review to the 3rd Circuit Court of Appeals regarding the HFPO-DA Health Advisory and the toxicity assessment.
- **July 2024**: Third Circuit dismisses the HA litigation for lack of jurisdiction. The scientific merits of the HA and toxicity assessment are not discussed.

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HFPO-DA Toxicity Assessment: Events After Finalization

- **March 2023**: EPA publication of preliminary Regulatory Determination for HFPO-DA and Proposed PFAS NPDWR for public comment. HFPO-DA is included in the PFAS NDWR.
- **May 2023**: Close of the public comment period for the PFAS NPDWR. Chemours submits similar comments as it did in the Request for Correction and in the HA litigation brief.
- **April 2024:** EPA finalization of the Regulatory Determination for HPFO-DA and the PFAS NPDWR; publication of response to comments document where EPA provides a scientific rebuttal of all of Chemours' claims.
- **June 2024:** Chemours and others file petition for review of the PFAS NPDWR. Chemours provides challenges to the merits of the HFPO-DA toxicity assessment. These challenges are similar to those EPA responded to in the request for correction, the HA litigation, and the response to public comment for the PFAS NPDWR (i.e., critical effect, uncertainty factors).

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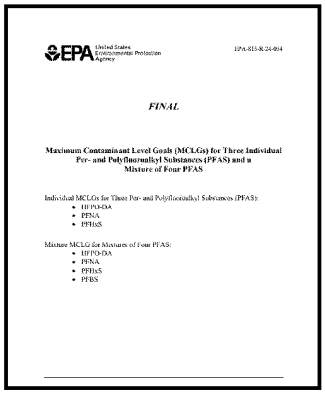
PFAS Dose Additivity: Basis for Hazard Index MCLG



EPA United States Environmental Protection Agency

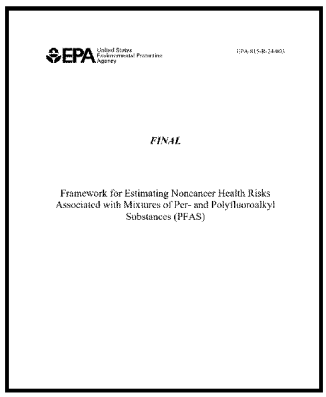
EPA-815-R-24-004

FINAL

Maximum Contaminant Level Goals (MCLGs) for Three Individual Per- and Polyfluoroalkyl Substances (PFAS) and a Mixture of Four PFAS

Individual MCLGs for Three Per- and Polyfluoroalkyl Substances (PFAS):
- HFPO-DA
- PFNA
- PFHxS

Mixture MCLG for Mixtures of Four PFAS:
- HFPO-DA
- PFNA
- PFHxS
- PFBS

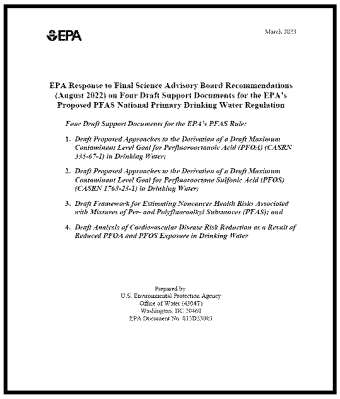


EPA United States Environmental Protection Agency

EPA-815-R-24-003

FINAL

Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)



EPA

March 2023

EPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation

Four Draft Support Documents for the EPA's PFAS Rule:

1. *Draft Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water;*
2. *Draft Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water;*
3. *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS); and*
4. *Draft Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water*

Prepared by:
U.S. Environmental Protection Agency
Office of Water (4304T)
Washington, DC 20460
EPA Document No. 822D23001

ED_018877_00000156-00011

Regulatory Levels: Summary

Chemical	Maximum Contaminant Level Goal (MCLG)	Maximum Contaminant Level (MCL)
PFOA	0	4.0 ppt
PFOS	0	4.0 ppt
PFHxS	10 ppt	10 ppt
HFPO-DA (GenX chemicals)	10 ppt	10 ppt
PFNA	10 ppt	10 ppt
Mixture of two or more: PFHxS, PFNA, HFPO-DA, and PFBS	Hazard Index of 1	Hazard Index of 1

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Hazard Index MCLG

- These 4 PFAS are toxicologically similar, impacting similar health effects (USEPA, 2024a; OSTP, 2023).
- These 4 PFAS often co-occur in drinking water (USEPA, 2024b).
- Recent mixtures studies in animals support dose additivity for PFAS (outlined in USEPA, 2024c).
  - When PFAS are found in a mixture, the effect of the mixture is greater than the effect of any individual PFAS alone.

Endpoint	HFPO-DA	PFNA	PFHxS	PFBS
Molecular/Cellular Perturbations				
PPAR alpha binding/activation	X[1, 2]	X[1-4]	X[1-4]	X[1, 3, 4]
PPAR gamma binding/activation	X[1, 5]	X[1, 5]	X[1, 5]	X[1]
Liver gene induction (PPAR signaling)	X[6, 7]	X[8-10]	X[9-12]	X[10, 11]
Liver gene induction (CAR signaling)	-	X[8]	X[11]	X[11]
Serum bile salts/acids (increased)	X[13]	X[8]	-	X[11]
Serum globulin (reduced)	X[14-16]	X[8]	X[11]	X[11]
Serum albumin:globulin (increased)	X[14-16]	X[8]	X[11, 17]	X[11]
Health Effects				
Serum lipids (reduced cholesterol and/or triglycerides)	X[14-16]	X[8]	X[11, 12, 17]	X[11]
Serum liver enzymes (increased ALT, AST, and/or ALKP)	X[13, 15]	X[8]	-	X[11]
Serum thyroid hormones (reduced T4, T3)	X[6]	X[8]	X[11, 18]	X[11]
Liver weight (increased)	X[6, 14-16, 19-21]	X[8, 22]	X[11, 12]	X[11, 23]
Liver histopathology (nonneoplastic)	X[13, 15, 16, 24]	X[8]	X[11, 12]	X[11]
Thymus weight (reduced)	X[14]	X[8]	-	X[11]
Spleen weight (reduced)	-	X[8]	-	X[11, 25]
Kidney weight (increased)	X[14, 15]	X[8]	X[11]	X[11]
Reduced fetal/pup bodyweight	X[20, 26, 27]	X[22]	-	X[28]
Reduced fetal/pup survival	X[20]	X[22]	X[12]	-
Reduced adult bodyweight	X[29]	X[8]	-	X[11, 25]
Overt toxicity (lethality)	X[14]	X[8]	-	X[11]

Sources: USEPA. 2024a. Maximum Contaminant Level Goals (MCLGs) for Three Individual Per-and Polyfluoroalkyl Substances (PFAS) and a Mixture of Four PFAS. 815–R–24– 004. https://www.epa.gov/system/files/documents/2024-04/pfas-ht-mclg_final508.pdf
USEPA. 2024b. PFAS Occurrence and Contaminant Background Support Document for the Final PFAS NPDWR. 815–R–24–013. https://www.epa.gov/system/files/documents/2024-04/updated-technical-support-document-on-pfas-occurrence_final508.pdf
OSTP (United States Office of Science and Technology Policy). 2023. Per- and Polyfluoroalkyl Substances (PFAS) Report, A Report by the Joint Subcommittee on Environment, Innovation, and Public Health.
https://www.whitehouse.gov/wpcontent/uploads/2023/03/OSTP-March-2023-PFAS-Report.pdf.
USEPA. 2024c. Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS): 815–R–24–003.

Hazard Index MCLG: Health-based water concentrations

$$\boldsymbol{HBWC} = \left(\frac{Oral\ RfV}{DWI\text{-}BW}\right) * RSC$$

Where:

HBWC* = Health-based water concentration (ng/L)

RfV = Chronic toxicity reference value

DWI-BW = Body weight-adjusted drinking water intake – an exposure factor for the 90th percentile body weight-adjusted drinking water intake for the identified population or life stage, in units of liters of water consumed per kilogram body weight per day (L/kg/day)

RSC = Relative source contribution – the percentage of the total exposure attributed to drinking water sources, with the remainder of the exposure allocated to all other routes or sources

**Note: Individual MCLGs for HPFO-DA, PFNA, and PFHxS calculated using same equation and inputs*

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HBWCs for HFPO-DA, PFNA, and PFHxS

Chemical	RfV (mg/kg/d)	DWI-BW (L/kg/d)	RSC	HBWC (ng/L)
HFPO-DA	3×10^{-6} [Based on liver effects (constellation of liver lesions as defined by the NTP Pathology Working Group) in parental female mice exposed from pre-mating through lactation; EPA 2021]	0.0469; 90th percentile for lactating women (age 13 to <50 years)	0.2	**10**
PFNA	3×10^{-6} [Based on decreased body weight gain and delayed eye opening, preputial separation, and vaginal opening in mouse offspring after gestational and presumed lactational exposure; ATSDR 2021]	0.0469; 90th percentile for lactating women (age 13 to <50 years)	0.2	**10**
PFHxS	2×10^{-6} [Based on thyroid follicular epithelial hypertrophy/hyperplasia in parental male rats (exposed 42–44 days); ATSDR 2021]	0.034; 90th percentile for adults 21 years and older	0.2	**10**
PFBS	3×10^{-4} [Based on critical effect of decreased serum total thyroxine in newborn mice after gestational exposure; EPA 2021]	0.354; 90th percentile for women of childbearing age (13 to <50 years)	0.2	**2000**

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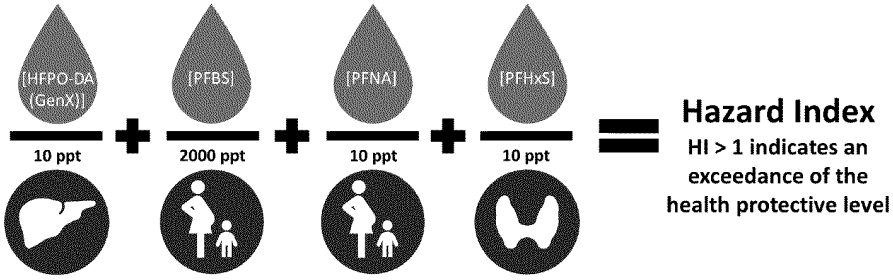
Hazard Index MCLG

- Using dose additivity for noncancer effects, the general Hazard Index approach was selected as the basis of the PFAS mixture MCLG (USEPA, 2024a).
- The HI is a sum of fractions, and each fraction compares the level of each PFAS measured in the water to the health-based water concentration. This is the level that at or below which exposure is unlikely to lead to adverse health effects in humans. It is calculated based on the most sensitive health effect (USEPA, 2024a,b).
- Each of these four PFAS has a health-based water concentration (HBWC), which is set at the level below which adverse effects are not anticipated to occur and allows for an adequate margin of safety.



EPA Response to Science Advisory Board Recommendations for Hazard Index Approach

Recommendation	Action Taken
SAB supported dose additivity as a health protective default assumption to assess potential health risks associated with PFAS mixtures but recommended that EPA more thoroughly and clearly present associated uncertainties.	EPA added information describing uncertainties associated with dose additivity, and deviations such as synergy or antagonism. Available evidence suggests that dose addition should be considered as the default model.
SAB supported the Hazard Index approach, but recommended EPA consider using a menu-based framework to support selection of fit-for-purpose approaches, rather than a tiered approach.	EPA eliminated the tiered approach and restructured the framework as a data-driven, flexible approach.
SAB asked EPA to provide additional clarity and guidance for implementing the Hazard Index to mitigate any inadvertent uncertainties, such as use different ingestion rates when basing mixtures assessments on health-based water concentrations (HBWCs).	EPA added a lengthy discussion about the selection of exposure factors for HBWC development.

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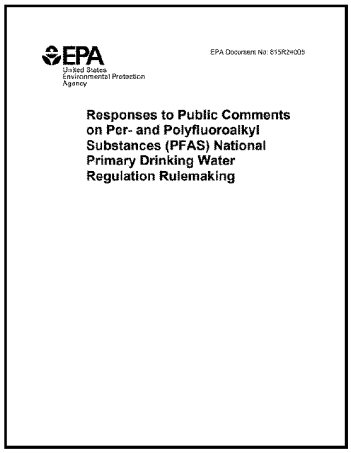
Public Comments on Hazard Index Approach

- Public comments were mixed. Environmental groups and some states were supportive, but industry, utilities, and other states were critical. Commenters challenged:
  1) Scientific support for PFAS dose additivity,
  2) EPA's proposed Hazard Index as an enforceable MCL;
  3) Whether these four PFAS have similar health effects, and
  4) EPA's use of ATSDR assessments for PFHxS and PFNA
- EPA developed detailed responses to each comment.
  - There are over 400 pages of public comments and EPA responses on dose additivity and the Hazard Index approach in the published Response to Comments document.


EPA United States Environmental Protection Agency

EPA Document No: 815R24009

Responses to Public Comments on Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation Rulemaking

ED_018877_00000156-00018

Discussion

ED_018877_00000156-00019

Message

From: Miranda Willson [mwillson@eenews.net]
Sent: 3/26/2025 7:30:14 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
Subject: E&E News follow-up from EPW hearing

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Hi Jessica,

It was nice to meet you today. Thank you for offering to answer a question over email!

I was wondering if you could share more about how you will approach PFAS issues. Would you support EPA taking a look at strategies to reduce PFAS discharges, such as through effluent limitation guidelines?

Similarly, Administrator Zeldin said yesterday that he thinks EPA's new maximum contaminant level for PFAS in drinking water might be set too low. Do you think the MCLs that are in place should remain, or should they be changed?

I'm finishing up an article on the nominations hearing for tomorrow, so my deadline is around 5:30 today. But I would also welcome a response at any time for future reporting, even if you can't get back to me today/tonight in time for my deadline.

Best,
--
Miranda Willson

Reporter, E&E News | POLITICO

mwillson@eenews.net

914-815-3648

May 28th,9:00 – 12:30
Workshop A: Environmental Law Fundamentals 101: A Comprehensive Guide to the EPA Laws Impacting the Regulation of PFAS in the United States

Kickstart your PFAS journey with this essential primer!

Join us for an engaging session designed to equip you with a clear understanding of the core environmental laws shaping the rapidly evolving landscape of PFAS regulation in the U.S: **CERCLA, TSCA, EPCRA, RCRA and Beyond.** This master class sets the tone for the main conference by demystifying the foundational policies driving the future governance of PFAS chemicals.

Topics to be covered will include:

- An overview of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
  - Assessing significant legal, legislative and regulatory developments since the Act's inception
  - Comparing Biden-Harris PFAS Roadmap priorities to Trump administration policies
  - Understanding the recent designation of PFOS and PFOA under CERCLA, classes as hazardous substances
  - What authority does CERCLA provide to the EPA in terms of holding Potentially Responsible Parties (PRPs) liable for environmental contamination?
- A comprehensive analysis of the Emergency Planning and Community Right-to-Know Act (EPCRA)
  - Understanding PFAS reporting under the Emergency Planning and Community Right-to-Know Act, including changes to TRI (Toxic Release Inventory) reporting thresholds and the addition of new PFAS listings
  - Assessing the challenges and implications for facilities now subject to reporting
- A comprehensive analysis of the Toxic Substances Control Act (TSCA)
  - Understanding the full scope of authorities that the TSCA provides to the EPA with regard to the governing of chemical substances in the U.S.
  - Examining significant compliance and enforcement developments under the Act
  - Understanding the recent developments under TSCA, with respect to reporting and removal of several exemptions' thresholds
- Understanding the fundamentals of the Resource Conservation and Recovery Act (RCRA)
  - Analyzing the implications of including a substance on the RCRA list of hazardous constituents
  - Under RCRA, PFAS-containing waste could potentially be classified as hazardous, which would subject it to stringent handling, storage, and disposal requirements

Speakers:

- Timothy J., Bergère, Partner, **Armstrong Teasdale**
- John Gilmour, Partner, **Kelley Drye & Warren LLP**

May 28th, 1:30 – 5:00
Workshop B: The Science Behind PFAS: A Deep Dive into Testing Methodologies, Remediation, and Regulatory Impacts

Join us for an in-depth exploration of the science behind Per- and Polyfluoroalkyl Substances (PFAS). This workshop delves into the latest advancements in understanding PFAS lifecycles, toxicity, and testing methods. Our workshop leaders will look at the real impact of these chemicals, the most reliable testing practices for your products, and the broader implications for your organization.

Topics of discussion will include:

- Understanding PFAS: What are they, and do they truly last "forever"?
- Analyzing different PFAS exposure pathways and exposure levels by life stage
- Exposure pathways and toxicology:
  - Examining exposure levels across life stages and different pathways
  - Assessing health effects studies on PFOA, PFOS, and other PFAS in animals and humans
- Navigating the challenges of PFAS testing—what methods are required by current regulations, and how do they differ across jurisdictions?
  - Reviewing validation technologies available
  - Discerning environmental release levels, product contamination, and choosing the right testing strategies
  - Managing test results—what to do when PFAS are detected and how to integrate findings into your litigation or regulatory response strategy
  - Managing third parties doing the testing
  - Guidance on selecting contract labs and ensuring alignment on testing methodologies and sensitivity thresholds
- Advances in Remediation:
  - Examining the latest PFAS treatment and destruction technologies, and how to translate research into actionable remediation plans
- Understanding how technical and scientific data influence agency rulemaking and enforcement
- Managing results and crafting responses that align with regulatory, litigation, and public relations strategies
- Navigating the challenge of proving causation in PFAS cases
  - Assessing the role of scientific evidence, testing for fluorine levels, and how these findings impact litigation strategies

Speakers:

- Owen P. Jappen, Director, Chemical Products and Technology, **American Chemistry Council**
- Tarek Saba, Ph. D. | Principal Scientist & Office Director, **Exponent**

MAIN DAY ONE: Thursday, May 29th, 2025

7:45

Continental Networking Breakfast and Registration

9:00

Co-Chairs' Welcome Remarks

Matthew Leopold
Partner
Hunton Andrews Kurth LLP

Gwendolyn R. Keyes
Partner
DLA Piper LLP (US)

PFAS in the Era of Trump 2.0

9:15

The Future of PFAS Policy Under a New Administration: Shifting Agendas and Emerging Challenges

With the shift to a new administration, the regulatory landscape surrounding PFAS is poised for significant change. From the expansive PFAS Roadmap built under the Biden administration, to the conservative recommendations outlined in Project 2025, the future of PFAS policy will have far-reaching implications for environmental regulation, corporate compliance, and litigation.

This panel will explore the trajectory of PFAS regulation and enforcement, the potential rollback or intensification of key policies, and the consequences for stakeholders navigating these uncertainties.

- Analyzing the Biden administration's PFAS agenda legacy
  - Understanding the impact of the PFAS Roadmap on regulations under major environmental laws like CERCLA, TSCA, and the Safe Drinking Water Act
  - Evaluating enforcement priorities under the Biden EPA and their influence on PFAS compliance
- Anticipating the Trump Administration's key environmental priorities and how they will impact PFAS
  - Assessing the possibility of reversing CERCLA PFAS designations and federal rollbacks on other PFAS rules, as per Project 2025 recommendations
  - Anticipating potential changes under a new EPA leadership and their impact on TSCA reporting deadlines and requirements

Speakers:

- Adam G. Sowatzka, Partner, **McGuireWoods LLP**
- Gwendolyn R. Keyes, Partner, **DLA Piper LLP (US)**

9:45

Understanding the Role of Administrative Law in the PFAS Landscape: Predictions for *Loper Bright*

The Administrative Procedure Act (APA) is foundational in shaping how federal agencies regulate and enforce PFAS policies. This panel will explore the APA's critical role in driving PFAS regulatory frameworks and how a rollback of *Chevron* deference could open the door to challenges to perceived overly broad or ambiguous EPA regulations.

- Evaluating the potential consequences of *Loper Bright v. Raimondo* on EPA rulemaking and regulatory oversight involving PFAS
- Understanding how the *Loper Bright* fallout may impact federal APA cases, including those in Michigan and the D.C. Circuit
- Examining the administrative landscape under a new administration:
  - Assessing how the new administration's first five months may reshape PFAS regulatory approaches
  - Comparing strategies of Trump 2.0 to those of prior administrations and the implications for industry and enforcement

Speakers:

- Stacey L. VanBelleghem, Partner, **Latham & Watkins LLP**
- Michael K. Murphy, Partner, **Gibson Dunn & Crutcher LLP**

10:15

Morning Networking Coffee Break

Breaking Down EPA's PFAS Roadmap: What It Means for You

These sessions reflect policies during the transition from the Biden-Harris administration to the Trump-Vance Administration. They will be updated over the next several months once more information on the New Administration's plans becomes available.

10:45

A Guide to the Anticipated Federal Reporting Requirements under TSCA (Toxic Substances Control Act) and more EPA Oversight: EPCRA, SDWA

To allow manufacturers and affected entities more time to comply with the final reporting requirements, EPA moved the reporting deadline from May 2025 to July 2026 with an effective date of January 2026.

- Understanding EPA's use of TSCA authority for PFAS testing and enforcement

- Assessing the implications for manufacturers
- Addressing PFAS reporting under the Emergency Planning and Community Right-to-Know Act, including the evolving TRI (Toxic Release Inventory) reporting thresholds and additional PFAS listings
  - What strategies can facilities employ to ensure compliance with these evolving regulations?
  - How are industries adapting to the expanded TRI reporting requirements for PFAS?
- Reviewing EPA's newly imposed MCLs (Maximum Contaminant Levels) under the Safe Drinking Water Act (SDWA)
  - Exploration of the implications for water utilities and public health protection
- Highlighting 'New Use Rule' developments that target future uses of PFAS

Speakers:

- Martha E., Marrapese, Partner, **Wiley Rein**
- Anna Willett, PE, Senior Project Manager, **LANGAN**

11:30

Where Are We Now? EPA's Final CERCLA (Superfund) Hazardous Substances Designations for PFOA and PFOS

EPA's recent developments in CERCLA designations, federal-state dynamics, and strategies for managing contamination and liability risks all set the stage for the overall PFAS Roadmap. Join our panelists as they look at potential changes under the current administration, and the challenges you could face in complying with these new designations.

- How does CERCLA liability impact industries, property owners, and municipalities?
- Analyzing the potential for litigation as parties navigate liability for remediation and natural resource damages
  - Understanding how CERCLA listings enable EPA to mandate cleanup and cost recovery
  - What do CERCLA designations mean for ongoing and future remediation efforts?
  - Reviewing potential liabilities for manufacturers with detectable PFAS discharges during product use or production
- What are the implications of federal CERCLA designations or other PFAS rules being rolled back under a new administration?
- Reviewing how expanding PFAS definitions and lists influence site investigations and remediation strategies

Speakers:

- Lindsay Ann Brown, Partner, **Duane Morris LLP**
- Meaghan G. Boyd, Partner, **Alston & Bird LLP**

- Greg Wall, Partner, **Hunton Andrews Kurth LLP**

12:45
Networking Luncheon

2:00
States Regulators Roundtable: Inside Scoop on PFAS Initiatives from Key State Environmental Agencies

Confirmed:

- Shawn M. LaTourette, Commissioner, **New Jersey Department of Environmental Protection**
- Susanne Miller, Bureau Director, **Maine Department of Environmental Protection**
- Katrina Kessler, Commissioner, **Minnesota Pollution Control Agency**
- Joaquin Esquivel, Board Chair, **California State Water Resources Control Board**
- Amy Rousseau, PFAS Response Coordinator, MtBE Remediation Bureau, **New Hampshire Department of Environmental Services**

3:15
Afternoon Break

3:30
State-Level PFAS Bans Unveiled: Your Essential Guide to Navigating the Patchwork of PFAS Laws Across the Country

Imagine this: you're manufacturing, distributing, or selling products today, but tomorrow, you're in violation of a state's PFAS law you didn't see coming.

State-by-state bans and restrictions are no longer just proposals; they're becoming law. Each state has its own rules, its own deadlines, and its own economic implications. If you operate in multiple jurisdictions or rely on products sold across state lines, your compliance plan must be airtight—or your bottom line will pay the price.

- **California's (AB 1817)**
  - Prohibiting the manufacture, distribution, or sale of textiles with intentionally added PFAS starting January 1, 2025
- **Washington's (Safer Products for Washington Act)**
  - Restricting PFAS in consumer products, particularly textiles, to be implemented by 2025
- **Maine's (LD 1503)**
  - Requiring reporting of PFAS in products and phases out intentionally added PFAS in all products by January 1, 2030, unless deemed unavoidable
- **Colorado's (HB 22-1345)**

- Ban on PFAS in consumer products such as carpets, furniture, and cosmetics starting January 1, 2025

- **Oregon (Toxics-Free Kids Act)**
  - Anticipating PFAS restrictions aligned with Washington and California, emphasizing children's products and environmental safety measures
- **New York's (S 8817A/A 4739C)**
  - Ban on PFAS in apparel and textiles effective January 1, 2025
- **New Jersey's** expanding stringent PFAS monitoring and adopting of drinking water standards under existing legislation

Speakers:

- Marchello Gray, Partner, **Hollingsworth LLP**
- Chris W., Rich, Partner, **Perkins Coie**
- Joo Cha Webb, Partner, **Venable LLP**
- Libby Stennes, Shareholder, **Greenberg Traurig LLP**

4:15

Developing an Environmental Due Diligence Check List for PFAS-Related Transactions: Strategies for Managing Risks, Liability, and Coverage in High-Stakes Deals

Gain practical insights into navigating PFAS challenges in complex transactions, including deal structuring and liability transfer. This panel will explore the latest trends in environmental due diligence, the impact of evolving PFAS regulations on the transactional process, and effective strategies for securing PFAS insurance coverage or mitigating risks when insurance isn't an option.

- Explore how PFAS concerns are impacting mergers, acquisitions, and financing, particularly for cross-border and large-scale transactions
- The importance of environmental due diligence and assessing compliance liabilities, contaminated properties, and the potential costs of cleanup
- The emergence of PFAS-specific insurance policies: What's available, and what steps companies must take to secure coverage
  - Managing liability when insurance options are limited or unavailable
  - Exploring alternative strategies to mitigate PFAS risks in the absence of adequate insurance coverage
- Taking the right steps to enhance insurability and reduce exposure to PFAS-related liabilities before closing a deal
- Understanding the critical role of ASTM (American Society for Testing and Materials) standards in guiding industries through regulatory compliance in environmental assessments

Speakers:

- ~~Scott Carr, PhD, Senior Managing Director, **Ankura Consulting**~~

5:15

Closing Remarks – Conference Adjourns
Cocktail Reception

MAIN DAY TWO: Friday, May 30th , 2025

7:45
Continental Networking Breakfast and Registration

9:00
Co-Chairs' Opening Remarks and Recap of Day One

Matthew Leopold
Partner
Hunton Andrews Kurth LLP

Gwendolyn R. Keyes
Partner
DLA Piper LLP (US)

9:15
Navigating The Ongoing Battle with PFAS in Consumer Products and Highlighting Compliance Challenges and Emerging Trends

PFAS use in consumer products—such as food packaging, textiles, cosmetics, and children's goods—continues to present significant compliance and litigation challenges for companies. This session will explore its wide-ranging implications, focusing on evolving regulations, enforcement actions, and emerging trends.

- Addressing PFAS contamination in food packaging- a sector under scrutiny
  - Reviewing FDA efforts to restrict its use in food contact materials
- Navigating stricter state-level restrictions on PFAS in consumer products and the impact on compliance strategies
- How does PFAS complicates compliance with EPR (Extended Producer Responsibility) frameworks?
  - Particularly for products like food packaging and textiles that may unintentionally contain PFAS
- Considering global supply chain considerations and the challenges of managing PFAS in products manufactured abroad
  - How can companies address gaps in their knowledge about PFAS presence in packaging or textiles?
- Managing variations in state PFAS testing standards, compliance deadlines, and enforcement penalties

Speakers:

- James Pollack, Partner, **Marten Law**
- Guy Temple, Shareholder, **Reinhart Boerner Van Deuren s.c**
- Steven Siros, Partner, **Jenner & Block LLP**
- Bob DeMott, Principal Toxicologist, **Ramboll**

10:15
Morning Networking Break

10:45
The Evolving PFAS Litigation Scene: Trends, Targets, and Emerging Challenges

This session will provide a comprehensive update on key trends in PFAS-related litigation, including groundbreaking cases, the expanding scope of liability, and new legal challenges tied to regulatory developments. Join our panelists, as they review this high-stakes environment and explain the broader implications for risk management and compliance.

- Overview of ongoing class actions and product liability cases (non- AFFF)
    - Identifying key outcomes from landmark PFAS cases and their implications for downstream users of PFAS
- What's coming down the pike in PFAS litigation and how are these cases reshaping industry obligations?
    - Biosolids and air emissions
    - Medical monitoring claims
    - Lawsuits targeting non-users for environmental contamination
- Reviewing third-party testing from a litigation perspective
- Examining successful defenses and whether preemption played a role

Speakers:

- John E. Galvin, Partner, **Thomson Coburn LLP**
- Kegan A. Brown, Partner, **Lowenstein Sandler LLP**
- Benedict Lenhart, Partner, **Covington & Burling LLP**
- Mary Rose-Alexander, **Latham & Watkins LLP**

11:45
PFAS MDL Uncovered: Breaking News, Strategic Insights, and Industry Impacts

Join us for a case study on the evolving multidistrict litigation (MDL) landscape surrounding PFAS contamination and firefighting foam (AFFF). This session will explore settlement trends and the far-reaching impacts on industries, from economic damage suits to complex personal injury claims.

- Updates on the AFFF MDL, including recent settlements and pending claims
    - ➢ The progression from water utility cases to personal injury claims and the complexities of proving personal injury related to PFAS exposure
    - ➢ Litigation in local jurisdictions and efforts to move cases into MDL

- Analyzing the strategic use of MDL by defense lawyers and its impact on the timeline and outcomes of litigation
- Reviewing the growing trend of economic damage cases as a precursor to more complex personal injury claims

Speakers:

- Jacqueline Harrington, **Dechert LLP**

12:45
Networking Lunch

1:45
Industry Roundtable on PFAS Compliance-How are Companies Responding to Evolving PFAS Legal and Regulatory Landscape While Safeguarding Business Interests

In the ever-evolving regulatory landscape surrounding PFAS, companies are grappling with the complexities of managing a patchwork of state reporting requirements, prohibitions, and enforcement actions—often in the absence of cohesive federal guidelines. This panel brings together industry representatives to share practical insights, pain points, and strategies for navigating these competing regulatory demands.

- Federal vs. state dichotomy
  - How are companies balancing state-specific mandates with federal regulatory frameworks?
- Highlighting strategies for managing reporting requirements, prohibitions, and water-related concerns while maintaining operational efficiency
- How do you weigh all competing interests, as a company and strive to make good business decisions?

Speakers:

- Sozi Pedro Tulante, **Dechert LLP**

2:30
International Outlook on PFAS: Contrasting Developments in Canada, the EU, and Beyond

With PFAS regulations advancing across the globe, understanding the latest developments in key jurisdictions is essential. This panel will provide an in-depth look at how Canada and the EU are shaping their approaches to reporting, restrictions, and enforcement. We'll also explore emerging trends in Australia and New Zealand, shedding light on their initiatives and the potential implications for global compliance.

- A review of Canada's approach to reporting requirements for PFAS substances

- Exploring the unique features of Canada's regulatory framework, including its focus on 2023 data, finite substance lists, and obligations covering manufacturing, import, and use
- Is compliance more straightforward than in other regions?
- How are Canadian authorities handling exemption requests or extension requests, and how do the penalties compare to U.S?

- Updates on the EU's progress toward banning PFAS substances as per ECHA (European Chemicals Agency)'s proposal, regulatory timelines, and how these efforts align with global initiatives
- Insights into emerging PFAS regulations in the Asia-Pacific (particularly Australia and New Zealand) region and their implications for international supply chains
- Highlighting the challenges and opportunities in aligning regulatory frameworks and industry compliance efforts across jurisdictions

Speakers:

- Grant Worden, Partner, **Torys LLP**

3:30
Co-Chairs Closing Remarks and Recap of Day Two
Conference Adjourns

Message

From: Risley, David [Risley.David@epa.gov]
Sent: 4/3/2025 8:37:43 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]
Subject: FW: Follow up to Jess's questions on PFAS health effects
Attachments: 040225 human health epi bullets plus WOE.docx; 032625 TK bullets.docx; 0402025 PFOA PFOS RfDs vs ATSDR MRLs.docx; 040325 Use of tox values under CERCLA.docx; Chemours Litigation Summary_3.18.25 for OW IOrev.docx

Jess – Here is some additional information from OST on PFAS health effect. In addition to Colleen's note below, I'm also re-attaching some talking points they provided on Gen-X.

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

From: Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Sent: Thursday, April 3, 2025 4:24 PM
To: Risley, David <Risley.David@epa.gov>
Cc: Mottley, Tanya <Mottley.Tanya@epa.gov>
Subject: Follow up to Jess's questions on PFAS health effects

David,

Attached are revised/new backgrounders to address Jess's most recent questions related to PFAS health science:

Ex. 5 Deliberative Process (DP)

Please let us know if you want me to bring copies of these to tomorrow's 9am briefing or if she has any additional questions.

Thanks,
Colleen

Colleen Flaherty
Director, Health and Ecological Criteria Division
Office of Water, U.S. EPA
1200 Pennsylvania Ave., NW
WJC Connecting Wing, Mail Code 4304T
Washington, DC 20460
Phone: (202) 564-5939| flaherty.colleen@epa.gov

Message

From: Haga, Ellie [Haga.Ellie@epa.gov]
Sent: 4/3/2025 8:49:55 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Risley, David [Risley.David@epa.gov]; Lanier, Lynsey [Lanier.Lynsey@epa.gov]
Subject: OW Meeting Materials: Friday, April 4, 2025
Attachments: Ex. 5 Deliberative Process (DP); Ex. 5 Deliberative Process (DP); Briefing on PFAS in Drinking Water Toolkit_Administrator_4.4.25.pptx; Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Hi Jess,
Here are your materials for tomorrow, **Friday, April 4, 2025**.

For review/awareness:

Ex. 5 Deliberative Process (DP)

Meeting Materials:

Ex. 5 Deliberative Process (DP)

- **Speech Prep**
  - Agenda
- **Meeting on Final PFAS Drinking Water Regulations (Part 2)**
  - Briefing on PFAS in Drinking Water Toolkit

Ex. 5 Deliberative Process (DP)

Best,
Ellie

Ellie Haga
Special Assistant
Office of Water
U.S. Environmental Protection Agency
WJC East 3219-D
Desk Phone: 202-564-3854
Mobile Phone: 771-242-0793
Haga.ellie@epa.gov

Message

From: Hagerman, Carla [Hagerman.Carla@epa.gov]
Sent: 4/1/2025 7:35:26 PM
To: Haga, Ellie [Haga.Ellie@epa.gov]
CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Jones, Colin [Jones.Colin@epa.gov]; OW-IO Audit Team [OW-IO_Audit_Team@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]
Subject: GAO-24-106251 (CWSRF Allotment Formula) - Summary document for OW leadership awareness
Attachments: gao-24-106251.pdf; OW Response to GAO Final Report 24-106251_CWSRF Alottment Formula_December 2024.pdf; Summary Document for GAO-106251 (CWSRF Allotment Formula)-final.docx

Good afternoon, Ellie.

Please find attached for Jess' and Peggy's binders, a summary document on GAO's CWSRF Allotment Formula engagement, report GAO-24-106251 *(Clean Water: Revolving Fund Grant Formula Could Better Reflect Infrastructure Needs, and EPA Could Improve Needs Estimate)*. All parties continue to support the responses outlined in the 12/17/2024 signed memo from Benita to OCFO.

This information is being provided for awareness and for confirmation that new political leadership is comfortable with commitments made to GAO in OW's December 17, 2025 memorandum.

Also attached for reference is OW's 12/17/2024 response memo to OCFO and OIG's final report.

Please reach out with any questions. Best, Carla

Carla Hagerman
AFC, OW-OPARMS
U.S. Environmental Protection Agency
Office: (202) 564-9499
Email: hagerman.carla@epa.gov

Message

From: Haga, Ellie [Haga.Ellie@epa.gov]
Sent: 4/7/2025 7:26:38 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Risley, David [Risley.David@epa.gov]; Lanier, Lynsey [Lanier.Lynsey@epa.gov]
Subject: OW Meeting Materials: Tuesday, April 8, 2025
Attachments: PFAS Questions from NACOLG_for OW review-gs.docx; Jess_Water Week Keynote(1).docx; Ex. 5 Deliberative Process (DP)
Ex. 5 Deliberative Process (DP)

Hi Jess,
I hope you're feeling better! Here are your materials for tomorrow's OW meetings. As always, I'll have printed copies of everything for you.

Flagging that you have your **PIV card pickup** (please bring two forms of ID and your laptop).

- **Pre-Brief for meeting with Aderholt staff**
  - PFAS questions and draft responses
- **NACWA**
  - Water Week Keynote

Ex. 5 Deliberative Process (DP)

Let me know if you need anything else.

Best,
Ellie

Ellie Haga
Special Assistant
Office of Water
U.S. Environmental Protection Agency
WJC East 3219-D
Desk Phone: 202-564-3854
Mobile Phone: 771-242-0793
Haga.ellie@epa.gov

WATER WEEK KEYNOTE
April 8, 2025
3 PM
Jess Kramer Remarks

Who: Water Week Fly-In is hosted by NACWA, WEF, AWWA, AMWA, the WateReuse Association and the Water Research Foundation.

What: This annual Fly-In April 8-9 will be attended by over 600 registrants from across the water sector – primarily public drinking water and wastewater utility leadership and water industry business/engineering/technology leaders. Registrants attend to hear updates on federal water policy initiatives from U.S. EPA, USDA, and Congress and to network. The following day, attendees are encouraged to meet with their delegations on Capitol Hill.

Where: Hilton Washington DC National Mall at the Wharf, [HYPERLINK "https://maps.app.goo.gl/omVHohfH94txqZw47" \h] DC 20024

Funding: Several of the hosting organizations receive EPA funds for water sector research and technical assistance. Other organizations do not receive any federal funds.

Other EPA Speakers: Yes, see agenda attached.

Open press: Yes.

Format:

- Ballroom with a stage that has a fixed podium with microphone. Attendees will be seated with standing room along the perimeter.

Run of Show:

- Mickey Conway, CEO, Metro Water Recovery, Denver CO will introduce YOU
- YOU will provide keynote remarks (20-30 mins)
    - Key areas of interest include infrastructure investment, WOTUS, PFAS, MCLs and Lead and Copper, water affordability and more.

Note for Jess: Provided below are high-level talking points on several topics that are of interest to the audience. These are optional and you have liberty to add other topics that are a priority for you.

Introduction

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Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

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ED_018877_00000204-00011

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Ex. 5 Deliberative Process (DP)

Close

- Before I close, I want to express my gratitude for your partnership and dedication to the sector.

- Thank you for your time!

ED_018877_00000204-00013

Appointment

From: Conrad, Daniel [conrad.daniel@epa.gov]
on behalf of Donahue, Sean [donahue.sean@epa.gov]
Sent: 4/9/2025 2:14:14 PM
To: Bradner, Kai <Kai_Bradner@afandpa.org> [Kai_Bradner@afandpa.org]; Payne, James (Jim) [payne.james@epa.gov]; Paul_Noe@afandpa.org; Browne, Peggy [Browne.Peggy@epa.gov]; Szabo, Aaron [Szabo.Aaron@epa.gov]; Tardif, Abigale (Abbie) [Tardif.Abigale@epa.gov]; Dominguez, Alexander [dominguez.alexander@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Breen, Barry [Breen.Barry@epa.gov]; Cook, Steven [cook.steven@epa.gov]; Irizarry, Gilberto [Irizarry.Gilberto@epa.gov]; Atagi, Tracy [Atagi.Tracy@epa.gov]; Strauss, Linda [Strauss.Linda@epa.gov]
CC: Lewis, Jen [Lewis.Jen@epa.gov]; Youngblood, Charlotte [Youngblood.Charlotte@epa.gov]

Subject: OGC/ American Forest & Paper Association Meeting
Attachments: AFPA Trump Letter and Attachment.pdf; Noe-TRRID-v14i1-2025.pdf
Location: Microsoft Teams Meeting; DCRoomWJCN4045-OGC

Start: 4/9/2025 3:00:00 PM
End: 4/9/2025 4:15:00 PM
Show Time As: Tentative

Recurrence: (none)

Required Attendees: Bradner, Kai <Kai_Bradner@afandpa.org>; Payne, James (Jim); Paul_Noe@afandpa.org; Browne, Peggy; Szabo, Aaron; Tardif, Abigale (Abbie); Dominguez, Alexander; Kramer, Jessica L.; Breen, Barry; Cook, Steven; Irizarry, Gilberto; Atagi, Tracy; Strauss, Linda
Optional Attendees: Lewis, Jen; Youngblood, Charlotte

Consolidating into one meeting from 11:00-12:00

Microsoft Teams Need help?

Join the meeting now

Meeting ID: Ex. 6 - Personal Privacy (PP)

Passcode: Ex. 6 - Personal Privacy (PP)

Dial in by phone

Ex. 6 - Personal Privacy (PP) United States, Richmond Beach

Find a local number

Phone conference ID: Ex. 6 - Personal Privacy (PP)

Join on a video conferencing device

Tenant key: Ex. 6 - Personal Privacy (PP)

Video ID: Ex. 6 - Personal Privacy (PP)

More info

For organizers: Meeting options | Reset dial-in PIN

This meeting may be recorded. If the meeting is recorded, it will be announced via a banner showing "this meeting is being recorded." Participation in a recorded meeting will be deemed as consent to be recorded. Meeting recordings may be official agency records subject to appropriate policy, rules and regulations.

Message

From: Risley, David [Risley.David@epa.gov]
Sent: 4/9/2025 3:16:09 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]; Lanier, Lynsey [Lanier.Lynsey@epa.gov]
CC: Browne, Peggy [Browne.Peggy@epa.gov]
Subject: RE: Invitation to Speak: 2nd Annual Summit on PFAS Regulation, Compliance and Litigation (May 29-30 2025, NYC)
Attachments: PFAS NYC Draft Agenda External 2025.docx

Jess, circling back on this one. We would recommend Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Best,
David

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

From: Kramer, Jessica L. <kramer.jessical@epa.gov>
Sent: Thursday, April 3, 2025 2:55 PM
To: Risley, David <Risley.David@epa.gov>; Lanier, Lynsey <Lanier.Lynsey@epa.gov>
Subject: FW: Invitation to Speak: 2nd Annual Summit on PFAS Regulation, Compliance and Litigation (May 29-30 2025, NYC)

Also flagging this. Thank you!!

From: Ana Condulet <A.Condulet@americanconference.com>
Sent: Thursday, April 3, 2025 11:06 AM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Subject: FW: Invitation to Speak: 2nd Annual Summit on PFAS Regulation, Compliance and Litigation (May 29-30 2025, NYC)

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Hi Jessica,

I wanted to send a quick follow up note and see if you had a chance to consider the invitation below. We'd be honored to have you join our speaker faculty!

Kind regards,
Ana Condulet

Conference Producer
American Conference Institute
A C5 Group Company

T: (+1) 347-964-4941
E: a.condulet@americanconference.com
W: www.americanconference.com

From: Ana Condulet
Sent: Tuesday, April 1, 2025 10:27 AM
To: kramer.jessical@epa.gov
Subject: Invitation to Speak: 2nd Annual Summit on PFAS Regulation, Compliance and Litigation (May 29-30 2025, NYC)

Hi Jessica,

I hope things are going well! I'm reaching out as we are getting ready for the 2nd Annual Summit on PFAS Regulation, Compliance and Litigation **(May 29-30, 2025, NYC)** and it is my pleasure to formally invite you to speak at the upcoming May conference.

I'm reaching out at the recommendation of our co-chair- **Matt Leopold with Hunton Andrews Kurth.**

This is an annual conference that provides a comprehensive overview of the latest developments in PFAS-related legislation, regulatory compliance, and legal challenges. The event features insights from government officials, industry experts, and legal professionals.

We'd be honored to have you join our speaker faculty! I have attached the current draft agenda for your consideration and would like to propose the following panel session but please let me know if something else is of interest:

May 29th, 10:45
A Guide to the Anticipated Federal Reporting Requirements under TSCA (Toxic Substances Control Act) and more EPA Oversight: EPCRA, SDWA

To allow manufacturers and affected entities more time to comply with the final reporting requirements, EPA moved the reporting deadline from May 2025 to July 2026 with an effective date of January 2026.

- Understanding EPA's use of TSCA authority for PFAS testing and enforcement
- Assessing the implications for manufacturers
- Addressing PFAS reporting under the Emergency Planning and Community Right-to-Know Act, including the evolving TRI (Toxic Release Inventory) reporting thresholds and additional PFAS listings
- What strategies can facilities employ to ensure compliance with these evolving regulations?
- How are industries adapting to the expanded TRI reporting requirements for PFAS?
- Reviewing EPA's newly imposed MCLs (Maximum Contaminant Levels) under the Safe Drinking Water Act (SDWA)
- Exploration of the implications for water utilities and public health protection
- Highlighting 'New Use Rule' developments that target future uses of PFAS

Speakers:

- Martha E., Marrapese, Partner, **Wiley Rein**
- Anna Willett, PE, Senior Project Manager, **LANGAN**

Thank you very much for considering this and look forward to hearing from you,

Kind regards,
Ana Condulet
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Message

From: Giffe Johnson [gjohnson@ncasi.org]
Sent: 4/10/2025 5:51:22 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
Subject: PFAS MCL comments
Attachments: NCASI Comments EPA PFOS PFOA MCL_Final.pdf; EPA PFAS MCL NCASI Comments.pdf

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Hi Jessica,

I really appreciated the time you spent at the paper industry meeting yesterday. I wanted to follow up on our discussion on critiquing the science behind the PFAS MCLs. I've attached technical comments we submitted during the rulemaking process. Hopefully, this can be the beginning of continued dialogue about the use of science for policy decision making. Stewart and I are working on gathering some additional subject matter experts to provide you input on these issues. Unfortunately, it looks like Stewart will be out next week and I'll be booked up Tuesday through Thursday; but if you'd like to touch base on a few issues Monday or Friday I'd be happy to. Otherwise, we should definitely set up meeting(s) the week of April 21st to bring in some additional scientists and their perspective.

Let me know if there's any information I can provide to you in the interim.

Thanks!

Giffe

Giffe Johnson, PhD
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Attn: Environmental Protection Agency Science Advisory Board
Dr. Sue Shallal, DFO
via email: shallal.suhair@epa.gov

December 22, 2021

Re: Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water; Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanesulfonic Acid (PFOS) in Drinking Water; Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water; and Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS

NCASI conducts research and technical studies on behalf of forest products companies across the US, and its members represent more than 80% of pulp and paper and two-thirds of wood panels produced nationwide. NCASI has been an active participant at the state and federal levels in technical and scientific aspects of water quality criteria development for many years and, more recently, has collaborated with other researchers to consider approaches to the systematic review of toxicological and epidemiological information when estimating toxicity factors for environmental contaminants.

NCASI appreciates the opportunity to provide technical comments regarding the development of federal drinking water criteria for PFAS. These comments relate specifically to the documents drafted by EPA staff to be considered by the Scientific Advisory Board (SAB) including: *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water*; *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanesulfonic Acid (PFOS) in Drinking Water*; and *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS.*

In our comments, we will highlight scientific issues regarding the development of the toxicity values proposed for PFOA and PFOS, the approach for addressing mixtures of PFAS, and issues related to the systematic review approach taken in the development of these documents.

1.0 MCLG Development for PFOS and PFOA

NCASI agrees with the use of systematic review approaches to evaluate causal relationships and dose-response between chemical exposures and potential health outcomes. However, several elements in the systematic review approach relied on in the MCLG development documents for PFOS and PFOA could be improved to ensure

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that the literature used to develop causal conclusions and points of departure for toxicity values are specifically relevant to the needs of these two assessments and that the body of literature selected represents a robust collection of data that can be relied on with high confidence. For instance, the inclusion criteria in the Population, Exposure, Comparator, Outcome (PECO) statement for exposure is the same for both the assessment of general causation as it is for the selection of points of departure (POD). Literature that may be informative for one of these evaluations may not be relevant for the other; in particular, the inclusion criteria allows for 'Any oral exposure to PFOA or PFOS via oral routes'. This broad PECO component will allow many studies to be considered for the selection of a POD that may lack critical data elements for this evaluation, such as an appropriate resolution of measurement of exposure concentrations, appropriate measurements of intake rates, corroborating serum concentrations, and documented temporal/spatial relationships of measured exposures to health outcomes of interest. Observational epidemiology studies are wide ranging in terms of quality and the collection of critical data elements. Without more specific inclusion criteria, there is the potential to consider studies that lack critical data elements for POD selection within a systematic review of this type.

As well, risk of bias criteria could be improved by more prescriptive treatment of studies with specific types of risk of bias elements that could substantially limit the confidence of these studies. For instance, the studies relied upon for selection of a POD include Grandjean et al. (2012, 2017a, 2017b)[1,2,3], which evaluated antibody response to vaccination in the presence of various PFAS exposure concentrations. However, the outcome of antibody response is highly variable at the inter-individual level due to well characterized genetic factors.[4,5] Zimmerman and Curtis, 2019 note a host of factors that potentially impact antibody response from vaccination, "*These include intrinsic host factors (such as age, sex, genetics, and comorbidities), perinatal factors (such as gestational age, birth weight, feeding method, and maternal factors), and extrinsic factors (such as preexisting immunity, microbiota, infections, and antibiotics)*."[6] The studies relied upon in the MCLG documents fail to measure, control, or adjust for most, if not all of these factors that produce variability in the primary endpoint of these studies. Subtle, non-random distribution of these confounding or effect modifying factors could substantially alter the outcomes of these studies and pose a substantial risk of bias. The current risk of bias approach fails to capture this significant threat to study confidence and could be improved to further qualify these studies appropriately.

---

[1] Grandjean, P; Andersen, EW; Budtz-Jørgensen, E; Nielsen, F; Mølbak, K; Weihe, P; Heilmann, C. (2012). Serum vaccine antibody concentrations in children exposed to perfluorinated compounds. JAMA 307: 391-397.

[2] Grandjean, P; Heilmann, C; Weihe, P; Nielsen, F; Mogensen, UB; Budtz-Jørgensen, E. (2017). Serum Vaccine Antibody Concentrations in Adolescents Exposed to Perfluorinated Compounds. Environ Health Perspect 125: 077018.

[3] Grandjean, P; Heilmann, C; Weihe, P; Nielsen, F; Mogensen, UB; Timmermann, A; Budtz-Jørgensen, E. (2017). Estimated exposures to perfluorinated compounds in infancy predict attenuated vaccine antibody concentrations at age 5-years. J Immunotoxicol 14: 188-195.

[4] Ovsyannikova IG, Dhiman N, Jacobson RM, Poland GA. Human leukocyte antigen polymorphisms: variable humoral immune responses to viral vaccines. Expert Rev Vaccines. 2006 Feb;5(1):33-43. doi: 10.1586/14760584.5.1.33. PMID: 16451106.

[5] Kimman TG, Vandebriel RJ, Hoebee B. Genetic variation in the response to vaccination. Community Genet. 2007;10(4):201-17. doi: 10.1159/000106559. PMID: 17895626.

[6] Zimmermann P, Curtis N. Factors That Influence the Immune Response to Vaccination. Clin Microbiol Rev. 2019 Mar 13;32(2):e00084-18. doi: 10.1128/CMR.00084-18. PMID: 30867162; PMCID: PMC6431125.

It is also important to note, that from a PECO (e.g., defining the outcome) perspective, reduced antibody response from vaccination is not a diagnosable disease outcome. There is no specific criterion for antibody response that can be classified a 'disease or illness' nor is there a threshold where it is understood that an increase in health risk may occur from differential antibody response. The studies considered for a POD selection did not actually identify an increase of the diseases that vaccinations were administered for in any exposure group in the study. Outcomes in systematic reviews for adverse health endpoints should be clearly defined so as to clearly link an exposure response between a specific range of exposures to a specific disease outcome.

The search approach in the review failed to identify an important study that informs the human equivalent dose (HED). When deriving a (HED), it should be understood what the impact of dose is on elimination rate in order to achieve a scientifically defensible value. The kinetics data relied upon by EPA does not capture all the best science available for estimating the half-life of PFAS in humans. Some PFAS are retained in the bloodstream by the kidney, which treats these molecules like fatty acids and uses a similar receptor-based mechanism to prevent their loss from the blood. However, when the concentration of PFAS becomes high enough, this retention system becomes saturated, and the elimination rate of PFAS becomes much higher, shortening the half-life. In animal studies, our observations occur at relatively 'high' concentrations of PFAS compared to observations in humans that are typically much lower. Therefore, the elimination rate we observe in animal studies is faster (because the retention mechanism is saturated) than what occurs in human studies where doses are much lower. However, Elcombe et al. 2013 studied PFAS as a component of a chemotherapeutic regimen for cancer patients and determined that higher doses (more likely to be relevant to human toxicity) of PFAS in humans resulted in faster elimination rates. This study should be captured by the literature search and is important for consideration when developing an HED value.[7]

Potential improvements also exist in the approach to integrate evidence for drawing causal inference and this is particularly notable in the evaluation of PFOA as a carcinogen. The review identifies 8 epidemiological studies that were classified as having 'medium' confidence and one animal model that provided evidence for renal cancer in male rats. However, there is no specified criteria for the integration of these findings, weighted by the risk of bias analysis, to draw a conclusion regarding carcinogenicity. In the absence of a 'high' confidence epidemiological study, an evidence base in the animal toxicology literature should be required to be integrated into the epidemiology evidence base, where the animal toxicology would serve as the primary evidence base and the epidemiology would serve as supporting evidence given the insufficient confidence in that literature. However, only one animal model was identified to support a conclusion of carcinogenicity (among several studies that did not find sufficient evidence of carcinogenicity). Likewise, there is no corroboration of dose-response or specific cancer cell type/site among animal and toxicology studies. A specific evidence integration component in the systematic review protocol would assist in applying these features of the evidence base for drawing conclusions and would perhaps lead to a different conclusion regarding carcinogenicity than is reported in the draft MCLG document for PFOA. NCASI staff have recently coauthored a publication on evidence integration in systematic review that would inform this

[7] Elcombe, C.R., Wolf, C.R., Westwood, A.L., 2013. US Patent Application Publication. Pub. No.: US 2013/0029928. Available at: https://patentimages.storage.googleapis.com/24/ee/73/f58267c7d70dde/WO2011101643A1.pdf

aspect of the systematic review protocol.[8]

Many of these issues could have been addressed by peer review/public comment on the systematic review protocol used in the MCLG development. It is common practice among regulatory agencies to either publish or distribute for comment a proposed protocol that can be revised based on technical feedback as seen in other EPA program areas such as the Integrated Risk Information System (IRIS). Not only does this serve to enhance the transparency of the review process, but also provides additional perspectives on many of the criteria for risk of bias and evidence integration that must be detailed a priori to the actual review. NCASI supports the opportunity to provide technical comments on proposed systematic review protocols.

PFAS Mixtures

NCASI agrees with the general principle that chemicals found to impact the same organ system with the same mechanism of action may be assumed to be additive, proportionate to individual chemical dose response, for the purpose of health protective risk assessment practices. In the tiered approach proposed in the '*EXTERNAL PEER REVIEW DRAFT Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)*', the target organ specific hazard index (TOSHI) relies on this approach. This approach relies on PFAS to have a toxicity value developed (e.g., RfD) for each substance, compared to extant exposure to calculate a hazard quotient, and then the hazard quotients are summed to calculate the hazard index, which is interpreted to be protective of public health when equal to or less than 1.0. However, the draft document would be improved by more clearly defining the data requirements for this approach and the recognition that the class of substances referred to as PFAS are likely to contain unique substances that should not be treated as additive unless organ specificity and mechanism of action specificity criteria are met.

PFAS, as a group, includes thousands of substances with unique physio-chemical properties, unique fate and transport properties, and unique toxicological profiles. Broadly inclusive criteria are unlikely to produce standards or risk assessment approaches with a well characterized margin of safety or that accurately reflects the hazard posed by individual substances within the group. This has been evidenced in the scientific literature, even in studies that have evaluated PFAS of relatively similar chemical structure. As an example, Pizzurro et al. 2019 examined the toxicokinetics of several PFAS compounds and came to the following conclusions:

> *"Overall, our analysis provides one of the first syntheses of available empirical PFAS toxicokinetic data to facilitate interpreting human relevance of findings observed in animal studies and developing health-based criteria for PFAS from such studies. Our analysis highlighted several notable differences among the different PFAS regarding species and substance-specific tissue partitioning, half-life, and transfer to developing offspring via the placenta or lactation, as well as highlighted data gaps for certain substances."*
>
> *"Lastly, the results of this analysis indicate that there are toxicokinetic differences among the different PFAS based on chain length, and these substances should not be regulated as a group*

[8] Julie E. Goodman, Robyn L. Prueitt, Raymond D. Harbison, Giffe T. Johnson. 2020. Systematically evaluating and integrating evidence in National Ambient Air Quality Standards reviews. Global Epidemiology, Volume 2, 2590-1133, https://doi.org/10.1016/j.gloepi.2020.100019.

> *without careful consideration of how the substance-specific toxicokinetics may impact potential toxicity, including differing specific target organ toxicity and overall body burden."*[9]

Also, the draft document refers to several toxicity values derived from the Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Level (MRL). The ATSDR is explicit in its guidance on the use of the MRL and clearly indicates the intended use of this value is not to define clean up levels, such as water quality criteria. As noted in the ATSDR Toxicological Profile for Perfluoroalkyls regarding MRLs (underline added):

> *"These substance-specific estimates, which are intended to serve as screening levels, are used by ATSDR health assessors to identify contaminants and potential health effects that may be of concern at hazardous waste sites. It is important to note that MRLs are not intended to define clean-up or action levels."*
>
> *"Exposure to a level above the MRL does not mean that adverse health effects will occur."*
>
> *"MRLs are intended only to serve as a screening tool to help public health professionals decide where to look more closely."*[10]

Use of the MRL to derive water quality criteria results in criteria that are more conservative than needed to protect public health and will not provide additional public health benefit over an approach more consistent with that used by EPA to develop toxicity values. The draft document should specify that toxicity values such as the RfD, which are intended to inform public health policy should be relied on in a mixtures assessment and not screening level toxicity values such as the MRL, which are not designed for this purpose.

Please feel free to contact me regarding any questions associated with these technical comments.

Respectfully,

Giffe Johnson, PhD
Program Manager and Principal Scientist

[9] Pizzurro, Daniella M.; Seeley, Mara; Kerper, Laura E.; Beck, Barbara D. 2019. Interspecies differences in perfluoroalkyl substances (PFAS) toxicokinetics and application to health-based criteria. Regulatory Toxicology and Pharmacology 106 239–250.

[10] Agency for Toxic Substances and Disease Registry (ATSDR). 2018. Toxicological profile for Perfluoroalkyls. (Draft for Public Comment). Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

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TO: Ms. Alexis Lan
Office of Ground Water and Drinking Water
Standards and Risk Management Division
U.S. Environmental Protection Agency
1200 N. Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Docket: EPA-HQ-OW-2022-0114
Submitted through the Federal eRulemaking Portal

May 30, 2023

RE: "Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Rulemaking"

NCASI conducts research and technical studies on behalf of forest products companies across the US, and its members represent more than 80% of pulp and paper and two-thirds of wood panels produced nationwide. NCASI has been an active participant at the state and federal levels in technical and scientific aspects of risk assessment, water quality criteria development for many years and, more recently, has collaborated with other researchers to consider approaches to the systematic review of toxicological and epidemiological information when estimating toxicity factors for environmental contaminants.

NCASI appreciates the opportunity to provide technical comments regarding the "Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation". Our technical analysis of the proposed rulemaking has identified a number of scientific issues, including:

- A classification of PFOS as a likely carcinogen without a scientifically defensible evidence base.
- Potential implementation challenges due to laboratory limitations for an MCL of 4 ppt and an action level of 1.3 ppt for PFOA and PFOS.
- The inappropriate application of the Hazard Index approach for additionally listed PFAS under the MCL framework.

1.0 PFOS Carcinogen Classification

In the proposed rulemaking, EPA has determined that PFOS is a likely carcinogen. EPA states "the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor Carcinogenic to Humans." (pg. 18663). As recently as in 2021, as noted in the "*Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water; Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanesulfonic Acid (PFOS) in Drinking Water*", EPA had determined that the PFOS MCLG should be based on a non-carcinogenic endpoint , and it is not clear what new information EPA is considering in order to make this new conclusion. EPA relies on "one high confidence" study before concluding that "available study findings support a plausible correlation between PFOS exposure and carcinogenicity in humans." (pg. 18660).

EPA's determination is put in the context of the scientific uncertainties that exist when evaluating the potential carcinogenicity of PFOS: "The available epidemiology studies reported elevated risk of bladder, prostate, kidney, and breast cancers after chronic PFOS exposure. While there are reports of cancer incidence from epidemiological studies, the study designs, analyses, and mixed results preclude a definitive conclusion about the relationship between PFOS exposure and cancer outcomes in humans."

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National Council for Air and Stream Improvement, Inc.

There are additional sources of substantive uncertainty cited in EPA's Health Effects Support Document for Perfluorooctane Sulfonate (PFOS) EPA 822-R-16-002 that indicates: "Several human epidemiology studies evaluated the association between PFOS and cancers including bladder, colon, and prostate, but these data present a small number or cases and some are confounded by failure to adjust for smoking. The associations for most epidemiology endpoints are mixed,"; "The genotoxicity data are uniformly negative,"; and "Human epidemiology studies did not find a direct correlation between PFOS exposure and the incidence of carcinogenicity in worker-based populations."

The single animal study relied upon by EPA for the carcinogenicity of PFOS is described as: "The one high confidence animal chronic cancer bioassay study provides evidence of multi-site tumorigenesis in both male and female rats" and "The single chronic cancer bioassay performed in rats is positive for multi-site and -sex tumorigenesis" (pg. 18638)[12] This limited evidence is not sufficient to support the conclusion that "evidence is adequate" as to human carcinogenicity, particularly when considering that these observations of tumorigenesis are in excess of environmentally relevant concentrations of PFOS.

While EPA indicates that that these conclusions were arrived at with a systematic review, it is not clear whether the systematic review protocol was adequately developed to appropriately apply the noted sources of uncertainty into the conclusion of carcinogenic classification. Many of these issues could have been addressed by peer review/public comment on the systematic review protocol used in the MCL development. It is common practice among regulatory agencies to either publish or distribute for comment a proposed protocol that can be revised based on technical feedback as seen in other EPA program areas such as the Integrated Risk Information System (IRIS). Not only does this serve to enhance the transparency of the review process, but also provides additional perspectives on many of the criteria for risk of bias and evidence integration that must be detailed a priori to the actual review. NCASI supports the opportunity to provide technical comments on proposed systematic review protocols.

2.0 Laboratory limitations for Proposed Regulatory Limits and Action Levels

It is not clear that drinking water providers are able to manage a process to the levels of a Practical Quantitation Level (PQL), as EPA has assumed in their evaluation. Due to variability in samples, sampling technique, laboratories, etc., managing a drinking water treatment process for a variety of water treatment facilities (e.g., ranging from small private to large municipal) to the quantification level may be operationally infeasible. Drinking water providers manage risk by not only restricting concentrations to that of the MCLs, but also rely on action levels well below the MCLs, to provide some level of additional operational certainty. Setting MCLs at the PQL does not allow operators to do this.

The proposed rulemaking indicates trigger levels at 1/3 the MCLs, which equates to 1.3 ppt for PFOA/PFOS and a 0.3 HI for other listed PFAS. This means that action levels are not able to be reliably quantified. EPA recognizes the challenges of finding laboratories that can provide accurate quantitation below 4 ppt: "EPA anticipates there would not be sufficient laboratory capacity if the quantitation level were set at a level below 4.0 ppt. The rigorous laboratory certification and quality assurance/quality

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[1] Thomford, P. 2002. 104-Week Dietary Chronic Toxicity and Carcinogenicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T–6295) in Rats (pp. 1–216). 3M. Available on the internet at: *https://www.ag.state.mn.us/ Office/Cases/3M/docs/PTX/PTX2805. pdf*

[2] Butenhoff, J.L., Chang, S.C., Olsen, G.W., and Thomford, P.J. 2012. Chronic Dietary Toxicity and Carcinogenicity Study with Potassium Perfluorooctane Sulfonate in Sprague Dawley Rats. *Toxicology,* 293:1– 15. *https://doi.org/10.1016/j.tox.2012. 01.003*

control (QA/QC) procedures could limit the number of laboratories that can achieve lower quantitation levels and many water systems would not be able to secure the services of laboratories that are capable of consistently providing precise and accurate quantitation of concentrations of PFOA and PFOS at levels lower than 4.0 ppt." (pg. 18667).

In addition to the inability to operationalize a risk management plan when action levels exist below the PQL, there may not be adequate laboratory capacity to accommodate the enormous amount of testing across the country that would be required under this proposed rulemaking. The PQLs described by EPA are achieved by cutting edge technology and may not be considered standard instrumentation across commercial laboratories. Additionally, laboratories with PFAS analytical capabilities are already receiving increased demand for NPDES permit compliance testing, as well as for testing for remediation projects. If MCL concentrations are promulgated that are reasonably above the PQL, it will broaden the accessibility of robust analytical evaluation for risk management, which would increase the feasibility of operationalizing risk management of drinking water under PFAS MCLs.

3.0 The Inappropriate Application of the Hazard Index Approach for Listed PFAS

In this rulemaking, EPA proposes a Hazard Index (HI) approach that substantially diverges from the intended justification and implementation of HI in standard human health risk assessment applications:

"An important aspect of the proposed 'general HI' approach is that it is based on the availability of a reference value regardless of the critical effect for each mixture component. Unlike a target organ specific Hazard Index which is typically based on either shared mode-of-action or shared health outcome of mixture components, the general HI is based on a non-cancer reference value (RfD or Minimal Risk Level) for the critical (usually the most sensitive) effect of each component."[3][4](pg. 18656)

An HI approach is only justified, in a toxicological sense, when two or more compounds elicit the same endpoint or act on the same biological mode of action in producing an adverse health effect that forms the basis of the health hazard for those substances. PFAS, as a group, includes thousands of substances with unique physio-chemical properties, unique fate and transport properties, and unique toxicological profiles. Broadly inclusive criteria are unlikely to produce standards or risk assessment approaches with a well characterized margin of safety or that accurately reflects the hazard posed by individual substances within the group. This has been evidenced in the scientific literature, even in studies that have evaluated PFAS of relatively similar chemical structure. As an example, Pizzurro et al. 2019 examined the toxicokinetics of several PFAS compounds and came to the following conclusions:

"Overall, our analysis provides one of the first syntheses of available empirical PFAS toxicokinetic data to facilitate interpreting human relevance of findings observed in animal studies and developing health-based criteria for PFAS from such studies. Our analysis highlighted several notable differences among the different PFAS regarding species and substance-specific tissue partitioning, half-life, and transfer to developing offspring via the placenta or lactation, as well as highlighted data gaps for certain substances....Lastly, the results of this analysis indicate that there are toxicokinetic differences among the different PFAS based on chain length, and these substances should not be regulated as a group

[3] USEPA. 2000a. *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures.* EPA 630-R-00-002. Available on the internet at: *https:// cfpub.epa.gov/ncea/risk/recordisplay. cfm?deid=20533.*

[4] USEPA. 1989. Risk assessment guidance for Superfund. Vol. 1. Human Health Evaluation Manual (Part A). EPA/540/1- 89/002.

without careful consideration of how the substance-specific toxicokinetics may impact potential toxicity, including differing specific target organ toxicity and overall body burden." [5]

None of the listed substances under the HI approach in the proposed rulemaking are have RfDs based on the same critical effect, nor is there a link between a mode of action each substance elicits that is related to all of the critical effects that form the basis of the individual RfDs. The EPA acknowledges the diversity of health outcomes exhibited from exposure to these listed PFAS:

"The adverse health effects observed following oral exposure to such PFAS are significant and diverse..."(pg. 18643)

A HI approach is not appropriate for compounds with different toxic modes of action and it's use in the proposed rulemaking is inconsistent with other EPA programs. EPA states that "the application of the HI approach under a regulatory purview is not novel," and EPA uses CERCLA as an example (pg. 18669). While the HI is not novel, in EPA's 2000 "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," EPA lays out three approaches to conducing risk assessments for mixtures, recognizing how the state of the science influences which approaches is appropriate. In the "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," an EPA Risk Assessment Forum Technical Panel, August 2000, further states that the "major concerns for the user are whether the available data are on components or whole mixtures, whether the data are composed of either similar components or similar mixtures that can be thought of as acting by similar toxicologic processes, and whether the data may be grouped by emissions source, chemical structure, or biologic activity." EPA, in the proposed rulemaking does not support that these four additional PFAS compounds act by similar toxicologic processes.

The Hazard Index (HI) approach requires confirmation of the fundamental assumption of dose additivity. Systemic toxicants should be confirmed as having the same mode of action prior to dose summation[6]. The four PFAS species included in the proposed HI summation, PFNA, HFPO-DA, PFHxS, and PFBS, are dissimilar and do not seem to have confirmatory data that they adhere to the dose additivity model as they do not share critical effects as the basis for their individual RfDs. The Supplementary Guidance also explains that the "term additivity is used when the effect of the combination of chemicals can be estimated directly from the sum of the scaled exposure levels (dose addition) or of the responses (response addition) of the individual components." EPA's attempt to use additivity is not based on either of the approaches in the 2000 Guidance.

Further, EPA's additivity approach in the proposed rulemaking appears to assume conclusion on issues that EPA is still considering as to PFAS compounds in other programs. In the CERCLA ANPRM issued in April 2023, EPA is specifically soliciting feedback on whether future CERCLA action could group PFAS compounds, including on the basis of modes of toxicological action:

> EPA is considering whether to initiate a future action that would potentially designate groups or categories of PFAS as hazardous substances. A group or category refers to a set

[5] Pizzurro, Daniella M.; Seeley, Mara; Kerper, Laura E.; Beck, Barbara D. 2019. Interspecies differences in perfluoroalkyl substances (PFAS) toxicokinetics and application to health-based criteria. Regulatory Toxicology and Pharmacology 106 239–250.

[6] USEPA 2000 Risk Assessment Guidance for Superfund (RAGS) (https://www.epa.gov/sites/default/files/2015-09/documents/rags_a.pdf

> of PFAS that share one or more similar characteristics. Characteristics of interest could include, but are not limited to, chemical structure (e.g., carbon chain length, functional group), physical and chemical properties, mode of toxicological action, precursors or degradants, or co-occurrence.

EPA also gives an example of the TCSA Significant New User Rule (SNUR) where grouping was based on chemical structure.

> In the TSCA program, EPA has developed Draft Principles for Cumulative Risk Assessment (CRA). In that document, EPA bases additivity on toxicological similarity: "Deciding, based on their toxicological similarity, which chemical substances to include in a cumulative chemical group that subsequently would be evaluated using dose additive models is an important element of a CRA."[7]

These four additional PFAS are not toxicologically similar, so EPA grouping them under the MCL proposed rulemaking is inconsistent with how EPA would group chemicals under TSCA and CERCLA.

In light of the evidence that critical health endpoints for individual PFAS, including those listed under the HI approach in the proposed rulemaking, are unique and diverse the assumption of dose additivity is not valid and therefore the use of the Hazard Index as a risk management approach is not appropriate.

Feel free to contact me regarding these comments.

Respectfully submitted,

Giffe Johnson, PhD
Program Manager, Chemical Management and Health Effects
NCASI

[7] Draft Principles for Cumulative Risk Assessment, EPA Document# EPA-740-P-23-001, Feb. 2023 United States Office of Chemical Safety and Environmental Protection Agency, Pollution Prevention, lines 458-460.

Message

From: McLain, Jennifer L. [McLain.Jennifer@epa.gov]
Sent: 4/11/2025 1:29:12 PM
To: Owscheduling [Owscheduling@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Risley, David [Risley.David@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Albert, Ryan [Albert.Ryan@epa.gov]; Mottley, Tanya [Mottley.Tanya@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Damico, Brian [Damico.Brian@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Donahue, Sean [donahue.sean@epa.gov]; Payne, James (Jim) [payne.james@epa.gov]; Huff, Lisa [Huff.Lisa@epa.gov]
CC: Tiago, Joseph [Tiago.Joseph@epa.gov]; Tisa, Nathaniel [Tisa.Nathaniel@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Swetland-Johnson, Karen [Swetland-Johnson.Karen@epa.gov]
Subject: RE: PFAS Pre-Brief
Attachments: [redacted] Ex. 5 Deliberative Process (DP)

Here is the briefing paper

Regulatory Options for Revising the PFAS National Primary Drinking Water Regulations (NPDWR) Compliance Deadlines

Purpose: Provide policy-based potential rule revision options to extend the compliance deadlines for the Maximum Contaminant Levels (MCLs) in the PFAS NPDWR.

Relevant Statutory Requirements

- Compliance deadlines: SDWA § 1412(b)(10)" A national primary drinking water regulation promulgated under this section (and any amendment thereto) shall take effect on the date that is 3 years after the date on which the regulation is promulgated unless the Administrator determines that an earlier date is practicable, except that the [HYPERLINK "https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=42-USC-146731693-1306907254&term_occur=999&term_src="], or a State (in the case of an individual system), may allow up to 2 additional years to comply with a [HYPERLINK "https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=42-Ex. 6 - Personal Privacy (PP) Ex. 6 - Personal Privacy (PP) XII:part:B:section:300g%E2%80%931"] or treatment technique if the[HYPERLINK "https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=42-USC-146731693-1306907254&term_occur=999&term_src="]or State (in the case of an individual system) determines that additional time is necessary for capital improvements."
- Anti-Backsliding: SDWA § 1412(b)(9) requires that "[any] revision of a national primary drinking water regulation shall…maintain, or provide for greater, protection of the health of persons."
- EPA authority where states do not have primacy: SDWA § 1416(f) "If a State does not have primary enforcement responsibility for public water systems, the Administrator shall have the same authority to exempt public water systems in such State from maximum contaminant level requirements and treatment technique requirements under the same conditions and in the same manner as the State would be authorized to grant exemptions under this section if it had primary enforcement responsibility."

Background: The rule was effective on June 25, 2024. The rule authorizes states to allow UCMR 5 data to meet the initial monitoring requirements and provides an extension for the MCLs under § 1412(b)(10). Rule compliance deadlines include:

- **Until April 26, 2027**: Systems conduct initial monitoring, and report results to primacy agencies.
- **April 26, 2027**: Systems begin compliance monitoring, reporting, and recordkeeping. Compliance determinations begin and public notices are issued for monitoring and testing procedure violations. Community water systems report PFAS on CCR.
- **April 26, 2029**: MCL compliance deadline, MCL compliance determinations begin, and public notices are issued for violations.
- **April 26, 2029**: State primacy

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Message

From: Ana Condulet [A.Condulet@americanconference.com]
Sent: 4/14/2025 7:21:25 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
Subject: FW: Invitation to Speak: 2nd Annual Summit on PFAS Regulation, Compliance and Litigation (May 29-30 2025, NYC)
Attachments: PFAS NYC Draft Agenda External 2025.docx

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Hi Jessica,

Hope your week is off to a good start. I wanted to send a quick follow up note and see if you might be available to join us.

Thank you!
Ana

From: Ana Condulet
Sent: Tuesday, April 1, 2025 10:27 AM
To: kramer.jessical@epa.gov
Subject: Invitation to Speak: 2nd Annual Summit on PFAS Regulation, Compliance and Litigation (May 29-30 2025, NYC)

Hi Jessica,

I hope things are going well! I'm reaching out as we are getting ready for the 2nd Annual Summit on PFAS Regulation, Compliance and Litigation **(May 29-30, 2025, NYC)** and it is my pleasure to formally invite you to speak at the upcoming May conference.

I'm reaching out at the recommendation of our co-chair- **Matt Leopold with Hunton Andrews Kurth.**

This is an annual conference that provides a comprehensive overview of the latest developments in PFAS-related legislation, regulatory compliance, and legal challenges. The event features insights from government officials, industry experts, and legal professionals.

We'd be honored to have you join our speaker faculty! I have attached the current draft agenda for your consideration and would like to propose the following panel session but please let me know if something else is of interest:

May 29th, 10:45
A Guide to the Anticipated Federal Reporting Requirements under TSCA (Toxic Substances Control Act) and more EPA Oversight: EPCRA, SDWA

To allow manufacturers and affected entities more time to comply with the final reporting requirements, EPA moved the reporting deadline from May 2025 to July 2026 with an effective date of January 2026.

- Understanding EPA's use of TSCA authority for PFAS testing and enforcement
- Assessing the implications for manufacturers

- Addressing PFAS reporting under the Emergency Planning and Community Right-to-Know Act, including the evolving TRI (Toxic Release Inventory) reporting thresholds and additional PFAS listings
    - What strategies can facilities employ to ensure compliance with these evolving regulations?
    - How are industries adapting to the expanded TRI reporting requirements for PFAS?
- Reviewing EPA's newly imposed MCLs (Maximum Contaminant Levels) under the Safe Drinking Water Act (SDWA)
    - Exploration of the implications for water utilities and public health protection
- Highlighting 'New Use Rule' developments that target future uses of PFAS

Speakers:

- Martha E., Marrapese, Partner, **Wiley Rein**
- Anna Willett, PE, Senior Project Manager, **LANGAN**

Thank you very much for considering this and look forward to hearing from you,

Kind regards,
Ana Condulet
Conference Producer
American Conference Institute
A C5 Group Company

T: (+1) 347-964-4941
E: a.condulet@americanconference.com
W: www.americanconference.com

May 28th,9:00 – 12:30
Workshop A: Environmental Law Fundamentals 101: A Comprehensive Guide to the EPA Laws Impacting the Regulation of PFAS in the United States

Kickstart your PFAS journey with this essential primer!

Join us for an engaging session designed to equip you with a clear understanding of the core environmental laws shaping the rapidly evolving landscape of PFAS regulation in the U.S: **CERCLA, TSCA, EPCRA, RCRA and Beyond.** This master class sets the tone for the main conference by demystifying the foundational policies driving the future governance of PFAS chemicals.

Topics to be covered will include:

- An overview of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
  - Assessing significant legal, legislative and regulatory developments since the Act's inception
  - Comparing Biden-Harris PFAS Roadmap priorities to Trump administration policies
  - Understanding the recent designation of PFOS and PFOA under CERCLA, classes as hazardous substances
  - What authority does CERCLA provide to the EPA in terms of holding Potentially Responsible Parties (PRPs) liable for environmental contamination?
- A comprehensive analysis of the Emergency Planning and Community Right-to-Know Act (EPCRA)
  - Understanding PFAS reporting under the Emergency Planning and Community Right-to-Know Act, including changes to TRI (Toxic Release Inventory) reporting thresholds and the addition of new PFAS listings
  - Assessing the challenges and implications for facilities now subject to reporting
- A comprehensive analysis of the Toxic Substances Control Act (TSCA)
  - Understanding the full scope of authorities that the TSCA provides to the EPA with regard to the governing of chemical substances in the U.S.
  - Examining significant compliance and enforcement developments under the Act
  - Understanding the recent developments under TSCA, with respect to reporting and removal of several exemptions' thresholds
- Understanding the fundamentals of the Resource Conservation and Recovery Act (RCRA)
  - Analyzing the implications of including a substance on the RCRA list of hazardous constituents
  - Under RCRA, PFAS-containing waste could potentially be classified as hazardous, which would subject it to stringent handling, storage, and disposal requirements

Speakers:

- Timothy J., Bergère, Partner, **Armstrong Teasdale**
- John Gilmour, Partner, **Kelley Drye & Warren LLP**

May 28th, 1:30 – 5:00
Workshop B: The Science Behind PFAS: A Deep Dive into Testing Methodologies, Remediation, and Regulatory Impacts

Join us for an in-depth exploration of the science behind Per- and Polyfluoroalkyl Substances (PFAS). This workshop delves into the latest advancements in understanding PFAS lifecycles, toxicity, and testing methods. Our workshop leaders will look at the real impact of these chemicals, the most reliable testing practices for your products, and the broader implications for your organization.

Topics of discussion will include:

- Understanding PFAS: What are they, and do they truly last "forever"?
- Analyzing different PFAS exposure pathways and exposure levels by life stage
- Exposure pathways and toxicology:
  - Examining exposure levels across life stages and different pathways
  - Assessing health effects studies on PFOA, PFOS, and other PFAS in animals and humans
- Navigating the challenges of PFAS testing—what methods are required by current regulations, and how do they differ across jurisdictions?
  - Reviewing validation technologies available
  - Discerning environmental release levels, product contamination, and choosing the right testing strategies
  - Managing test results—what to do when PFAS are detected and how to integrate findings into your litigation or regulatory response strategy
  - Managing third parties doing the testing
  - Guidance on selecting contract labs and ensuring alignment on testing methodologies and sensitivity thresholds
- Advances in Remediation:
  - Examining the latest PFAS treatment and destruction technologies, and how to translate research into actionable remediation plans
- Understanding how technical and scientific data influence agency rulemaking and enforcement
- Managing results and crafting responses that align with regulatory, litigation, and public relations strategies
- Navigating the challenge of proving causation in PFAS cases
  - Assessing the role of scientific evidence, testing for fluorine levels, and how these findings impact litigation strategies

Speakers:

- Owen P. Jappen, Director, Chemical Products and Technology, **American Chemistry Council**
- Tarek Saba, Ph. D. | Principal Scientist & Office Director, **Exponent**

MAIN DAY ONE: Thursday, May 29th, 2025

7:45

Continental Networking Breakfast and Registration

9:00

Co-Chairs' Welcome Remarks

Matthew Leopold
Partner
Hunton Andrews Kurth LLP

Gwendolyn R. Keyes
Partner
DLA Piper LLP (US)

PFAS in the Era of Trump 2.0

9:15

The Future of PFAS Policy Under a New Administration: Shifting Agendas and Emerging Challenges

With the shift to a new administration, the regulatory landscape surrounding PFAS is poised for significant change. From the expansive PFAS Roadmap built under the Biden administration, to the conservative recommendations outlined in Project 2025, the future of PFAS policy will have far-reaching implications for environmental regulation, corporate compliance, and litigation.

This panel will explore the trajectory of PFAS regulation and enforcement, the potential rollback or intensification of key policies, and the consequences for stakeholders navigating these uncertainties.

- Analyzing the Biden administration's PFAS agenda legacy
  - Understanding the impact of the PFAS Roadmap on regulations under major environmental laws like CERCLA, TSCA, and the Safe Drinking Water Act
  - Evaluating enforcement priorities under the Biden EPA and their influence on PFAS compliance
- Anticipating the Trump Administration's key environmental priorities and how they will impact PFAS
  - Assessing the possibility of reversing CERCLA PFAS designations and federal rollbacks on other PFAS rules, as per Project 2025 recommendations
  - Anticipating potential changes under a new EPA leadership and their impact on TSCA reporting deadlines and requirements

Speakers:

- Adam G. Sowatzka, Partner, **McGuireWoods LLP**
- Gwendolyn R. Keyes, Partner, **DLA Piper LLP (US)**

9:45

Understanding the Role of Administrative Law in the PFAS Landscape: Predictions for *Loper Bright*

The Administrative Procedure Act (APA) is foundational in shaping how federal agencies regulate and enforce PFAS policies. This panel will explore the APA's critical role in driving PFAS regulatory frameworks and how a rollback of *Chevron* deference could open the door to challenges to perceived overly broad or ambiguous EPA regulations.

- Evaluating the potential consequences of *Loper Bright v. Raimondo* on EPA rulemaking and regulatory oversight involving PFAS
- Understanding how the *Loper Bright* fallout may impact federal APA cases, including those in Michigan and the D.C. Circuit
- Examining the administrative landscape under a new administration:
  - Assessing how the new administration's first five months may reshape PFAS regulatory approaches
  - Comparing strategies of Trump 2.0 to those of prior administrations and the implications for industry and enforcement

Speakers:

- Stacey L. VanBelleghem, Partner, **Latham & Watkins LLP**
- Michael K. Murphy, Partner, **Gibson Dunn & Crutcher LLP**

10:15

Morning Networking Coffee Break

Breaking Down EPA's PFAS Roadmap: What It Means for You

These sessions reflect policies during the transition from the Biden-Harris administration to the Trump-Vance Administration. They will be updated over the next several months once more information on the New Administration's plans becomes available.

10:45

A Guide to the Anticipated Federal Reporting Requirements under TSCA (Toxic Substances Control Act) and more EPA Oversight: EPCRA, SDWA

To allow manufacturers and affected entities more time to comply with the final reporting requirements, EPA moved the reporting deadline from May 2025 to July 2026 with an effective date of January 2026.

- Understanding EPA's use of TSCA authority for PFAS testing and enforcement

- Assessing the implications for manufacturers
- Addressing PFAS reporting under the Emergency Planning and Community Right-to-Know Act, including the evolving TRI (Toxic Release Inventory) reporting thresholds and additional PFAS listings
  - What strategies can facilities employ to ensure compliance with these evolving regulations?
  - How are industries adapting to the expanded TRI reporting requirements for PFAS?
- Reviewing EPA's newly imposed MCLs (Maximum Contaminant Levels) under the Safe Drinking Water Act (SDWA)
  - Exploration of the implications for water utilities and public health protection
- Highlighting 'New Use Rule' developments that target future uses of PFAS

Speakers:

- Martha E., Marrapese, Partner, **Wiley Rein**
- Anna Willett, PE, Senior Project Manager, **LANGAN**

11:30

Where Are We Now? EPA's Final CERCLA (Superfund) Hazardous Substances Designations for PFOA and PFOS

EPA's recent developments in CERCLA designations, federal-state dynamics, and strategies for managing contamination and liability risks all set the stage for the overall PFAS Roadmap. Join our panelists as they look at potential changes under the current administration, and the challenges you could face in complying with these new designations.

- How does CERCLA liability impact industries, property owners, and municipalities?
- Analyzing the potential for litigation as parties navigate liability for remediation and natural resource damages
  - Understanding how CERCLA listings enable EPA to mandate cleanup and cost recovery
  - What do CERCLA designations mean for ongoing and future remediation efforts?
  - Reviewing potential liabilities for manufacturers with detectable PFAS discharges during product use or production
- What are the implications of federal CERCLA designations or other PFAS rules being rolled back under a new administration?
- Reviewing how expanding PFAS definitions and lists influence site investigations and remediation strategies

Speakers:

- Lindsay Ann Brown, Partner, **Duane Morris LLP**
- Meaghan G. Boyd, Partner, **Alston & Bird LLP**

- Greg Wall, Partner, **Hunton Andrews Kurth LLP**

12:45
Networking Luncheon

2:00
States Regulators Roundtable: Inside Scoop on PFAS Initiatives from Key State Environmental Agencies

Confirmed:

- Shawn M. LaTourette, Commissioner, **New Jersey Department of Environmental Protection**
- Susanne Miller, Bureau Director, **Maine Department of Environmental Protection**
- Katrina Kessler, Commissioner, **Minnesota Pollution Control Agency**
- Joaquin Esquivel, Board Chair, **California State Water Resources Control Board**
- Amy Rousseau, PFAS Response Coordinator, MtBE Remediation Bureau, **New Hampshire Department of Environmental Services**

Moderator:

David H. Quigley, Partner, **Akin Gump Strauss Hauer & Feld LLP**

3:15
Afternoon Break

3:30
State-Level PFAS Bans Unveiled: Your Essential Guide to Navigating the Patchwork of PFAS Laws Across the Country

Imagine this: you're manufacturing, distributing, or selling products today, but tomorrow, you're in violation of a state's PFAS law you didn't see coming.

State-by-state bans and restrictions are no longer just proposals; they're becoming law. Each state has its own rules, its own deadlines, and its own economic implications. If you operate in multiple jurisdictions or rely on products sold across state lines, your compliance plan must be airtight—or your bottom line will pay the price.

- **California's (AB 1817)**
  - Prohibiting the manufacture, distribution, or sale of textiles with intentionally added PFAS starting January 1, 2025
- **Washington's (Safer Products for Washington Act)**
  - Restricting PFAS in consumer products, particularly textiles, to be implemented by 2025
- **Maine's (LD 1503)**

- Requiring reporting of PFAS in products and phases out intentionally added PFAS in all products by January 1, 2030, unless deemed unavoidable
- **Colorado's (HB 22-1345)**
  - Ban on PFAS in consumer products such as carpets, furniture, and cosmetics starting January 1, 2025
- **Oregon (Toxics-Free Kids Act)**
  - Anticipating PFAS restrictions aligned with Washington and California, emphasizing children's products and environmental safety measures
- **New York's (S 8817A/A 4739C)**
  - Ban on PFAS in apparel and textiles effective January 1, 2025
- **New Jersey's** expanding stringent PFAS monitoring and adopting of drinking water standards under existing legislation

Speakers:

- Marchello Gray, Partner, **Hollingsworth LLP**
- Chris W., Rich, Partner, **Perkins Coie**
- Joo Cha Webb, Partner, **Venable LLP**
- Libby Stennes, Shareholder, **Greenberg Traurig LLP**

4:15

Developing an Environmental Due Diligence Check List for PFAS-Related Transactions: Strategies for Managing Risks, Liability, and Coverage in High-Stakes Deals

Gain practical insights into navigating PFAS challenges in complex transactions, including deal structuring and liability transfer. This panel will explore the latest trends in environmental due diligence, the impact of evolving PFAS regulations on the transactional process, and effective strategies for securing PFAS insurance coverage or mitigating risks when insurance isn't an option.

- Explore how PFAS concerns are impacting mergers, acquisitions, and financing, particularly for cross-border and large-scale transactions
- The importance of environmental due diligence and assessing compliance liabilities, contaminated properties, and the potential costs of cleanup
- The emergence of PFAS-specific insurance policies: What's available, and what steps companies must take to secure coverage
  - Managing liability when insurance options are limited or unavailable
  - Exploring alternative strategies to mitigate PFAS risks in the absence of adequate insurance coverage
- Taking the right steps to enhance insurability and reduce exposure to PFAS-related liabilities before closing a deal
- Understanding the critical role of ASTM (American Society for Testing and Materials) standards in guiding industries through regulatory compliance in environmental assessments

Speakers:

- ~~Scott Carr, PhD, Senior Managing Director,~~ **~~Ankura Consulting~~**

5:15
Closing Remarks – Conference Adjourns
Cocktail Reception

MAIN DAY TWO: Friday, May 30th , 2025

7:45
Continental Networking Breakfast and Registration

9:00
Co-Chairs' Opening Remarks and Recap of Day One

Matthew Leopold
Partner
Hunton Andrews Kurth LLP

Gwendolyn R. Keyes
Partner
DLA Piper LLP (US)

9:15
Navigating The Ongoing Battle with PFAS in Consumer Products and Highlighting Compliance Challenges and Emerging Trends

PFAS use in consumer products—such as food packaging, textiles, cosmetics, and children's goods—continues to present significant compliance and litigation challenges for companies. This session will explore its wide-ranging implications, focusing on evolving regulations, enforcement actions, and emerging trends.

- Addressing PFAS contamination in food packaging- a sector under scrutiny
  - Reviewing FDA efforts to restrict its use in food contact materials
- Navigating stricter state-level restrictions on PFAS in consumer products and the impact on compliance strategies
- How does PFAS complicates compliance with EPR (Extended Producer Responsibility) frameworks?
  - Particularly for products like food packaging and textiles that may unintentionally contain PFAS

- Considering global supply chain considerations and the challenges of managing PFAS in products manufactured abroad
  - ➢ How can companies address gaps in their knowledge about PFAS presence in packaging or textiles?
- Managing variations in state PFAS testing standards, compliance deadlines, and enforcement penalties

Speakers:

- James Pollack, Partner, **Marten Law**
- Guy Temple, Shareholder, **Reinhart Boerner Van Deuren s.c**
- Steven Siros, Partner, **Jenner & Block LLP**
- Bob DeMott, Principal Toxicologist, **Ramboll**

10:15
Morning Networking Break

10:45
The Evolving PFAS Litigation Scene: Trends, Targets, and Emerging Challenges

This session will provide a comprehensive update on key trends in PFAS-related litigation, including groundbreaking cases, the expanding scope of liability, and new legal challenges tied to regulatory developments. Join our panelists, as they review this high-stakes environment and explain the broader implications for risk management and compliance.

- Overview of ongoing class actions and product liability cases (non- AFFF)
  - Identifying key outcomes from landmark PFAS cases and their implications for downstream users of PFAS
- What's coming down the pike in PFAS litigation and how are these cases reshaping industry obligations?
  - Biosolids and air emissions
  - Medical monitoring claims
  - Lawsuits targeting non-users for environmental contamination
- Reviewing third-party testing from a litigation perspective
- Examining successful defenses and whether preemption played a role

Speakers:

- John E. Galvin, Partner, **Thomson Coburn LLP**
- Kegan A. Brown, Partner, **Lowenstein Sandler LLP**
- Benedict Lenhart, Partner, **Covington & Burling LLP**
- Mary Rose-Alexander, **Latham & Watkins LLP**

11:45
PFAS MDL Uncovered: Breaking News, Strategic Insights, and Industry Impacts

Join us for a case study on the evolving multidistrict litigation (MDL) landscape surrounding PFAS contamination and firefighting foam (AFFF). This session will explore settlement trends and the far-reaching impacts on industries, from economic damage suits to complex personal injury claims.

- Updates on the AFFF MDL, including recent settlements and pending claims
  - The progression from water utility cases to personal injury claims and the complexities of proving personal injury related to PFAS exposure
  - Litigation in local jurisdictions and efforts to move cases into MDL
- Analyzing the strategic use of MDL by defense lawyers and its impact on the timeline and outcomes of litigation
- Reviewing the growing trend of economic damage cases as a precursor to more complex personal injury claims

Speakers:

- Jacqueline Harrington, **Dechert LLP**

12:45
Networking Lunch

1:45
Industry Roundtable on PFAS Compliance-How are Companies Responding to Evolving PFAS Legal and Regulatory Landscape While Safeguarding Business Interests

In the ever-evolving regulatory landscape surrounding PFAS, companies are grappling with the complexities of managing a patchwork of state reporting requirements, prohibitions, and enforcement actions—often in the absence of cohesive federal guidelines. This panel brings together industry representatives to share practical insights, pain points, and strategies for navigating these competing regulatory demands.

- Federal vs. state dichotomy
  - How are companies balancing state-specific mandates with federal regulatory frameworks?
- Highlighting strategies for managing reporting requirements, prohibitions, and water-related concerns while maintaining operational efficiency
- How do you weigh all competing interests, as a company and strive to make good business decisions?

Speakers:

- Sozi Pedro Tulante, **Dechert LLP**

2:30
International Outlook on PFAS: Contrasting Developments in Canada, the EU, and Beyond

With PFAS regulations advancing across the globe, understanding the latest developments in key jurisdictions is essential. This panel will provide an in-depth look at how Canada and the EU are shaping their approaches to reporting, restrictions, and enforcement. We'll also explore emerging trends in Australia and New Zealand, shedding light on their initiatives and the potential implications for global compliance.

- A review of Canada's approach to reporting requirements for PFAS substances
  - Exploring the unique features of Canada's regulatory framework, including its focus on 2023 data, finite substance lists, and obligations covering manufacturing, import, and use
  - Is compliance more straightforward than in other regions?
  - How are Canadian authorities handling exemption requests or extension requests, and how do the penalties compare to U.S?
- Updates on the EU's progress toward banning PFAS substances as per ECHA (European Chemicals Agency)'s proposal, regulatory timelines, and how these efforts align with global initiatives
- Insights into emerging PFAS regulations in the Asia-Pacific (particularly Australia and New Zealand) region and their implications for international supply chains
- Highlighting the challenges and opportunities in aligning regulatory frameworks and industry compliance efforts across jurisdictions

Speakers:

- Grant Worden, Partner, **Torys LLP**

3:30
Co-Chairs Closing Remarks and Recap of Day Two
Conference Adjourns

Message

From: Spraul, Greg [Spraul.Greg@epa.gov]
Sent: 4/15/2025 1:52:29 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]
CC: McLain, Jennifer L. [McLain.Jennifer@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Risley, David [Risley.David@epa.gov]; Lanier, Lynsey [Lanier.Lynsey@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; McMiller, Nettie [McMiller.Nettie@epa.gov]
Subject: FYSA - Letters from Alabama communities on PFAS MCLs
Attachments: Public_Officials_Letter_02_17_2025_muscleshoalsApril2025.pdf; ColbertCountyCommission_AL_April12025.pdf

Jess and Peggy,

Sharing these letters from Alabama communities for your awareness.

1. Letter from Colbert County Commission (Alabama) - asking the Agency to not reverse or relax PFOA/PFOS MCLs
2. Letter from City of Muscle Shoals/ Muscle Shoals Utilities Board (Alabama) - asking the Agency to not reverse or relax PFOA/PFOS MCLs

We met with these communities as well as several other Northwest Alabama communities in person on Wednesday last week to hear their concerns. There were some communities who wanted to revisit the MCL, but most wanted to keep it (similar to what is expressed in these letters).

The communities appreciated having the opportunity to be heard.

We gave them a very brief update on the status of the PFAS drinking water rule litigation, that a request had been made the day before (April 8) to extend the abeyance.

Please let me know if you have any questions or if you would like any additional information.

Greg

From: Piziali, Jamie <Piziali.Jamie@epa.gov>
Sent: Monday, April 14, 2025 3:38 PM
To: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; McMiller, Nettie <McMiller.Nettie@epa.gov>; Spraul, Greg <Spraul.Greg@epa.gov>; Garcia Reyero Vinas, Natalia <GarciaReyeroVinas.Natalia@epa.gov>; Bergman, Ronald <Bergman.Ronald@epa.gov>
Cc: Tiago, Joseph <Tiago.Joseph@epa.gov>; McLaughlin, Julie <McLaughlin.Julie@epa.gov>; Christensen, Claude <Christensen.Claude@epa.gov>; Hanson, Alicia <Hanson.Alicia@epa.gov>; Barnes, Edlynzia <Barnes.Edlynzia@epa.gov>; Albert, Ryan <Albert.Ryan@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; O'Brien, Jack <OBrien.Jack@epa.gov>
Subject: FW: Letters from Alabama communities on PFAS MCLs

Greetings:

Thank you all for joining us last week in greeting 37 local officials from Northern Alabama! Whew. It was a big crowd.

I was told they would send a third letter, so I was waiting for that (but I haven't seen one yet) so I'm sharing the two we got in-person.

The letters are focused on the Agency NOT reversing or relaxing drinking water standards (MCLs) for PFAS

1. Letter from Colbert County Commission (Alabama) - asking the Agency to not reverse or relax PFOA/PFOS MCLs

2. Letter from City of Muscle Shoals/ Muscle Shoals Utilities Board (Alabama) - asking the Agency to not reverse or relax PFOA/PFOS MCLs

I've requested they be uploaded to CMS but wanted to make sure to share with the folks who joined us in the room who may not have received a copy and their relevant teams.

Thanks again!
Jamie

Jamie Piziali
Municipal Ombudsman
Office of the Municipal Ombudsman
U.S. Environmental Protection Agency
202-564-1709 piziali.jamie@epa.gov
www.epa.gov/ocir/municipal-ombudsman

The Utilities Board

City of Muscle Shoals

Phone (256) 386-9260 | P.O. Box 2648, 2001 Wildwood, MUSCLE SHOALS, ALABAMA 35662 | Fax (256) 386-9261

www.muscleshoalswater.org

February 17, 2025

RE: *Northwest Alabama Council of Local Governments*
Washington, D.C. Meetings
April 2025

Dear Public Officials:

I submit this correspondence on behalf of the Muscle Shoals, Alabama Utilities Board. Like many North Alabama cities, Muscle Shoals depends on water from the Tennessee River. We are permitted by the Tennessee Valley Authority to access the river for our city's water usage needs. Our water is polluted with "forever chemicals" and our treatment plant will have to be reworked in order to filter these dangerous pollutants from the City's drinking water.

Over the years, Health Advisories have been issued by the EPA placing us on notice of potential problems caused by the man-made pollutants discharged into the river at chemical manufacturing facilities operated by 3M and others in Decatur, Alabama. After years of study through several administrations, the EPA set a Maximum Contaminant Level ("MCL") on the amounts of PFOS and PFOA that should be in drinking water.

The Tennessee River has been designated as an EPA "impaired waterway" from decades of industrial chemical waste poured into the river. This problem is of particular concern to Muscle Shoals and other communities downstream from Decatur, Alabama because that is the location where 3M Company made the most toxic forever chemical which is known as PFOS. 3M Company has known that its discharges have created environmental and human health problems for many decades, yet they refused to offer assistance to North Alabama water utilities unless they pursued litigation.

A settlement was reached with West Morgan East Lawrence ("WMEL") Water Authority which used the settlement money to build a state-of-the-art Reverse Osmosis ("RO") water treatment plant on the banks of the Tennessee River in Lawrence County. A settlement was also reached with the City of

Decatur, Alabama. When we were informed that a new water treatment plant would have to be built in order to comply with safe drinking water standards, Muscle Shoals considered entering into a class action settlement, but the money offered was only 10% of the cost that we are going to have to spend to remove the forever chemical pollutants from our water.

We have heard from some groups that we should be seeking the suspension or elimination of PFOS and PFOA contamination limits. This shortsighted approach comes primarily from the chemical manufacturing sector and from water treatment operators that are not interested in coming into compliance in order to filter the forever chemical toxins from the water supply. The truth is that the public does not want man-made "forever chemicals" in their drinking water because they have been proven to be persistent, bioaccumulative and toxic ("PBT"). Any water treatment authority that fails to take reasonable steps to remove these chemicals from the public water supply will expose their utility to legal liability from their own citizens for not taking action.

It is our position that reversing or relaxing the EPA's MCLs on PFOS and PFOA will be a step backwards. It will take pressure off the Chemical Manufacturers to address the harm to public health and to the environment that they caused. Reversing or relaxing the EPA's MCLs on PFOS and PFOA will damage those water authorities like ours that face legal liability for failing to remove the "forever chemicals" from their drinking water supply.

Thank you for hearing our concerns about our community's water quality and forever chemical pollution problem. We were told during the election that President Trump wants clean and pristine water for all Americans. The people of North Alabama who live downstream from the plant that made the most hazardous of all forever-chemicals welcomed the President's promise. We were excited to see that EPA Chairman Lee Zeldin strongly supported the establishment of MCLs for PFOS when he was a congressman. We hope the support for clean water

continues and companies like 3M Company, DuPont and Daikin are not allowed to escape environmental enforcement.

Sincerely:

James Vance

James Vance, PE
General Manager
Muscle Shoals Utilities Board

cc:
United States Senator Tommy Tuberville
BB&T Centre
41 West I-65
Service Road North, Suite 2300-A
Mobile, AL 36608

United States Senator Katie Britt
United States Federal Courthouse
One Church Street
Suite F-401
Montgomery, AL 36104

United States Representative Robert Aderholt
1011 George Wallace Blvd.
Suite 146
Tuscumbia, AL 35674

COLBERT COUNTY COMMISSION
201 N. MAIN STREET, COURTHOUSE
TUSCUMBIA, AL 35674
PHONE (256) 386-8501
FAX (256) 386-8510

MEMBERS
TOMMY BARNES, DIST. 1
W. TYRUS MANSELL, DIST. 2
JIMMY GARDINER, DIST. 3
TORI BAILEY, DIST. 4
DAROL BENDALL, DIST. 5
DAVID C. ISOM, DIST. 6

April 1, 2025

RE: *North Alabama Council on Local Governments*
Washington, D.C. Meetings
April 2025

Dear Public Officials:

Thank you for hearing our concerns about our community's water quality and forever chemical pollution. We were told during the election that President Trump wants clean and pristine water for all Americans. This letter is written to help accomplish that goal by providing information, and to request your support for the citizens of Colbert County.

Our county depends on the Tennessee River for 100% of its drinking water. The river has been polluted with a chemical known as PFOS which 3M Company manufactured upriver in Decatur, Alabama. PFOS is known as one of the most toxic of all the "forever chemicals," and the EPA has designated the Tennessee River as an impaired waterway because of this pollution. Colbert County has litigation pending against the chemical polluters to recover the cost for making the necessary upgrades to our water treatment plant to filter out PFOS from our drinking water.

There are those, primarily from the chemical manufacturing sector and from water treatment operators, who are not interested in becoming compliant in filtering forever chemical toxins from the water supply. They feel that Counties should actually support the suspension or elimination of contamination limits of PFOS and PFOA ("MCLs"). As Commissioners, however, we have a responsibility to protect our county's residents from these lab created substances. These are man-made "forever chemicals" that have been proven to be persistent, bio-accumulative and toxic ("PBT"). As we've learned, they should not be in the drinking water consumed by our residents. Any failure by a water treatment authority to take reasonable steps to remove these chemicals from the public water supply could result in legal liability from our own citizens for failure to have taken action, regardless of any EPA regulatory rollback.

If the EPA's MCLs on PFOS and PFOA are reversed or relaxed, the Chemical Manufacturers will no longer feel pressure to address threats or mitigate the damage to public

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health and harm to the environment that they caused. Further, reversing or relaxing the EPA's MCLs on PFOS and PFOA will harm water authorities like ours who face legal liability for failing to remove the "forever chemicals" from their drinking water supply. Any attempt to relax the EPA's standards will benefit the polluters and cause harm to our citizens.

The people of Colbert County who live downstream from the plant that made the most hazardous of all forever chemicals (PFOS) welcomed the President's promise. We appreciate your help in working to make his promise a reality.

On behalf of the Colbert County Commission,

Jeremy Robison, P.E.
County Engineer
Colbert County Rural Water System

cc:
United States Senator Tommy Tuberville
BB&T Centre
41 West I-65
Service Road North, Suite 2300-A
Mobile, AL 36608

United States Senator Katie Britt
United States Federal Courthouse
One Church Street
Suite F-401
Montgomery, AL 36104

United States Representative Robert Aderholt
1011 George Wallace Blvd.
Suite 146
Tuscumbia, AL 35674

Colbert County Commission

ED_018877_00000253-00002

Message

From: Haga, Ellie [Haga.Ellie@epa.gov]
Sent: 4/15/2025 7:46:30 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Risley, David [Risley.David@epa.gov]; Lanier, Lynsey [Lanier.Lynsey@epa.gov]
Subject: OW Meeting Materials: Wednesday, April 16, 2025
Attachments: Ex. 5 Deliberative Process (DP)
Ex. 5 Deliberative Process (DP) Briefing on PFAS in Drinking Water Toolkit_Administrator_4.16.25.pptx; Ex. 5 Deliberative Process (DP)

Hi Jess,
Here are your materials for tomorrow, **Wednesday, April 16, 2025**, along with one item currently for a quick turnaround review/approval.

For review/approval by tomorrow:

Ex. 5 Deliberative Process (DP)

Meeting Materials:

Ex. 5 Deliberative Process (DP)

- **Meeting on Final PFAS Drinking Water Regulations (Part 2)**
  - Briefing on PFAS in Drinking Water Toolkit

Ex. 5 Deliberative Process (DP)

Ellie Haga
Special Assistant
Office of Water
U.S. Environmental Protection Agency
WJC East 3219-D
Desk Phone: 202-564-3854
Mobile Phone: 771-242-0793
Haga.ellie@epa.gov

Message

From: McLain, Jennifer L. [McLain.Jennifer@epa.gov]
Sent: 4/21/2025 5:22:27 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
Subject: FW: 04-16-2025 Meeting on Final PFAS Drinking Water Regulations (Part 2) - Materials
Attachments: Briefing on PFAS in Drinking Water Toolkit_Administrator_4.16.25.pptx

Jess – the potential CWA/SDWA actions are on slide 6

From: Tiago, Joseph <Tiago.Joseph@epa.gov>
Sent: Tuesday, April 15, 2025 11:18 AM
To: Risley, David <Risley.David@epa.gov>; Lanier, Lynsey <Lanier.Lynsey@epa.gov>; Haga, Ellie <Haga.Ellie@epa.gov>; Eng, Connie <Eng.Connie@epa.gov>
Cc: McLain, Jennifer L. <McLain.Jennifer@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>; Bergman, Ronald <Bergman.Ronald@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Moriarty, Edward <Moriarty.EdwardJ@epa.gov>; Albert, Ryan <Albert.Ryan@epa.gov>; Hogan, James <hogan.james@epa.gov>; Messier, Dawn <Messier.Dawn@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Tiago, Joseph <Tiago.Joseph@epa.gov>
Subject: 04-16-2025 Meeting on Final PFAS Drinking Water Regulations (Part 2) - Materials

Team OW – Please find attached materials for tomorrow's briefing with Administrator Zeldin. Thanks for sharing with meeting participants and please let us know if you have any questions or need additional information.

Best Regards,

Joe.

Message

From: Vaseliou, Molly [Vaseliou.Molly@epa.gov]
Sent: 4/24/2025 1:06:28 PM
To: Amidon, Eric [Amidon.Eric@epa.gov]; Voyles, Travis [voyles.travis@epa.gov]
CC: Mandy, Cora [Mandy.Cora@epa.gov]; Weiner, Ben [Weiner.Ben@epa.gov]; Gall, Daniel [Gall.Daniel@epa.gov]; Skala, Grant [Skala.Grant@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]; Cook, Steven [cook.steven@epa.gov]; Busterud, John [Busterud.John@epa.gov]; Hall, Jeffrey [Hall.Jeffrey.A@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Beck, Nancy [beck.nancy@epa.gov]; Corlett, Thomas [Corlett.Thomas@epa.gov]; Szabo, Aaron [Szabo.Aaron@epa.gov]; Tardif, Abigale (Abbie) [Tardif.Abigale@epa.gov]; Tisa, Nathaniel [Tisa.Nathaniel@epa.gov]; Donahue, Sean [donahue.sean@epa.gov]
Subject: FOR REVIEW: Draft on PFAS Release

Hey team,

Please do a review of the draft below and let us know if there's anything missing from your program and provide edits as you see fit. Travis – Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Message

From: Amidon, Eric [Amidon.Eric@epa.gov]
Sent: 4/24/2025 3:45:27 PM
To: Vaseliou, Molly [Vaseliou.Molly@epa.gov]; Voyles, Travis [voyles.travis@epa.gov]
CC: Mandy, Cora [Mandy.Cora@epa.gov]; Weiner, Ben [Weiner.Ben@epa.gov]; Gall, Daniel [Gall.Daniel@epa.gov]; Skala, Grant [Skala.Grant@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]; Cook, Steven [cook.steven@epa.gov]; Busterud, John [Busterud.John@epa.gov]; Hall, Jeffrey [Hall.Jeffrey.A@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Beck, Nancy [beck.nancy@epa.gov]; Corlett, Thomas [Corlett.Thomas@epa.gov]; Szabo, Aaron [Szabo.Aaron@epa.gov]; Tardif, Abigale (Abbie) [Tardif.Abigale@epa.gov]; Tisa, Nathaniel [Tisa.Nathaniel@epa.gov]; Donahue, Sean [donahue.sean@epa.gov]
Subject: RE: FOR REVIEW: Draft on PFAS Release

Made a suggested Ex. 5 Deliberative Process (DP)

Eric Amidon
Chief of Staff
Environmental Protection Agency

From: Vaseliou, Molly <Vaseliou.Molly@epa.gov>
Sent: Thursday, April 24, 2025 9:06 AM
To: Amidon, Eric <Amidon.Eric@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
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Message

From: Vaseliou, Molly [Vaseliou.Molly@epa.gov]
Sent: 4/24/2025 4:03:37 PM
To: Amidon, Eric [Amidon.Eric@epa.gov]; Voyles, Travis [voyles.travis@epa.gov]
CC: Mandy, Cora [Mandy.Cora@epa.gov]; Weiner, Ben [Weiner.Ben@epa.gov]; Gall, Daniel [Gall.Daniel@epa.gov]; Skala, Grant [Skala.Grant@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]; Cook, Steven [cook.steven@epa.gov]; Busterud, John [Busterud.John@epa.gov]; Hall, Jeffrey [Hall.Jeffrey.A@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Beck, Nancy [beck.nancy@epa.gov]; Corlett, Thomas [Corlett.Thomas@epa.gov]; Szabo, Aaron [Szabo.Aaron@epa.gov]; Tardif, Abigale (Abbie) [Tardif.Abigale@epa.gov]; Tisa, Nathaniel [Tisa.Nathaniel@epa.gov]; Donahue, Sean [donahue.sean@epa.gov]
Subject: RE: FOR REVIEW: Draft on PFAS Release

Added in testing methods below.

From: Amidon, Eric <Amidon.Eric@epa.gov>
Sent: Thursday, April 24, 2025 11:45 AM
To: Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
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Message

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Sent: 4/24/2025 5:03:18 PM
To: Cook, Steven [cook.steven@epa.gov]; Tardif, Abigale (Abbie) [Tardif.Abigale@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Amidon, Eric [Amidon.Eric@epa.gov]; Voyles, Travis [voyles.travis@epa.gov]
CC: Mandy, Cora [Mandy.Cora@epa.gov]; Weiner, Ben [Weiner.Ben@epa.gov]; Gall, Daniel [Gall.Daniel@epa.gov]; Skala, Grant [Skala.Grant@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]; Busterud, John [Busterud.John@epa.gov]; Hall, Jeffrey [Hall.Jeffrey.A@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Beck, Nancy [beck.nancy@epa.gov]; Corlett, Thomas [Corlett.Thomas@epa.gov]; Szabo, Aaron [Szabo.Aaron@epa.gov]; Tisa, Nathaniel [Tisa.Nathaniel@epa.gov]; Donahue, Sean [donahue.sean@epa.gov]
Subject: RE: FOR REVIEW: Draft on PFAS Release

Thanks team! I will clean up and send to LZ for approval.

From: Cook, Steven <cook.steven@epa.gov>
Sent: Thursday, April 24, 2025 12:55 PM
To: Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Amidon, Eric <Amidon.Eric@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
Subject: RE: FOR REVIEW: Draft on PFAS Release

No substantive change from OLEM – one minor typo change made in teal

Steven Cook
Deputy Assistant Administrator
Office of Land and Emergency Management
U.S. Environmental Protection Agency
Email: cook.steven@epa.gov
Phone: 202-564-7038

From: Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>
Sent: Thursday, April 24, 2025 12:42 PM
To: Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Amidon, Eric <Amidon.Eric@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
Subject: RE: FOR REVIEW: Draft on PFAS Release

No edits on my end!

-Abbie

Abigale Tardif
Principal Deputy Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
Office: (202) 564-7017

From: Vaseliou, Molly <Vaseliou.Molly@epa.gov>
Sent: Thursday, April 24, 2025 12:40 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>; Amidon, Eric <Amidon.Eric@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
Subject: RE: FOR REVIEW: Draft on PFAS Release

Thanks!!

From: Kramer, Jessica L. <kramer.jessical@epa.gov>
Sent: Thursday, April 24, 2025 12:35 PM
To: Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Amidon, Eric <Amidon.Eric@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
Subject: RE: FOR REVIEW: Draft on PFAS Release

A few edits from me in red. Thanks!

From: Vaseliou, Molly <Vaseliou.Molly@epa.gov>
Sent: Thursday, April 24, 2025 12:04 PM
To: Amidon, Eric <Amidon.Eric@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
Subject: RE: FOR REVIEW: Draft on PFAS Release

Added in testing methods below.

From: Amidon, Eric <Amidon.Eric@epa.gov>
Sent: Thursday, April 24, 2025 11:45 AM
To: Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>

Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
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Eric Amidon
Chief of Staff
Environmental Protection Agency

From: Vaseliou, Molly <Vaseliou.Molly@epa.gov>
Sent: Thursday, April 24, 2025 9:06 AM
To: Amidon, Eric <Amidon.Eric@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
Subject: FOR REVIEW: Draft on PFAS Release

Hey team,

Please do a review of the draft below and let us know if there's anything missing from your program and provide edits as you see fit. Travis – Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

DRAFT – INTERNAL – DELIBERATIVE – NOT FOR PUBLIC DISTRIBUTION

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Message

From: Risley, David [Risley.David@epa.gov]
Sent: 4/26/2025 3:31:06 AM
To: Spraul, Greg [Spraul.Greg@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Aguirre, Janita [Aguirre.Janita@epa.gov]
Subject: RE: One pager, budget briefing, administrator
Attachments:

Ex. 5 Deliberative Process (DP)

+ Jess

Thanks Greg! As he mentions, these in a shared folder linked below. I'm attaching the static copies just incase there are connection challenges.

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

From: Spraul, Greg <Spraul.Greg@epa.gov>
Sent: Friday, April 25, 2025 8:19 PM
To: Browne, Peggy <Browne.Peggy@epa.gov>; Risley, David <Risley.David@epa.gov>; Best-Wong, Benita <Best-Wong.Benita@epa.gov>
Cc: Aguirre, Janita <Aguirre.Janita@epa.gov>
Subject: RE: One pager, budget briefing, administrator

Peggy,

I let OCIR know to hold.

The fact sheets below with "final" at the end of the file name are ones that David has reviewed in the hearing prep folder and are ready for your review.

Ex. 5 Deliberative Process (DP)

Coming to us for review next week:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

From: Browne, Peggy <Browne.Peggy@epa.gov>
Sent: Friday, April 25, 2025 7:10 PM
To: Risley, David <Risley.David@epa.gov>; Best-Wong, Benita <Best-Wong.Benita@epa.gov>; Spraul, Greg <Spraul.Greg@epa.gov>
Subject: One pager, budget briefing, administrator

Ex. 5 Deliberative Process (DP)

Peggy

Get Outlook for iOS

PFAS Drinking Water Rule
Prepared by: Office of Water

BACKGROUND:

- Under the first Trump Administration, EPA began the process to address PFAS in drinking water. At that time, the agency engaged directly with communities impacted by PFAS as it developed the determination to regulate PFAS under the Safe Drinking Water Act.
- EPA issued a final drinking water rule in April last year.
- The American Water Works Association and others filed a lawsuit against the rule.
- 17 states (CA,CT,NJ,AZ,CO,DE,DC,HI,IL,MD,MA,MI,MN,NY,NC,OR,RI,WI) filed an amicus brief supporting the rule.
- The litigation is currently held in abeyance until May 12 to allow the new Administration to review the issues presented in the case and develop a path forward.

ISSUE:

Ex. 5 Deliberative Process (DP)

TALKING POINTS:

Ex. 5 Deliberative Process (DP)

KNOWN CONGRESSSIONAL INQUIRIES

- The Administrator was asked about this issue during his confirmation hearing by the following Senators: Capito, Lummis, Curtis, Wicker, Kelly.
- Jess Kramer was asked about this issue during her confirmation hearing by the following Senators: Capito, Kelly.

Message

From: Vaseliou, Molly [Vaseliou.Molly@epa.gov]
Sent: 4/27/2025 11:01:30 PM
To: Dekleva, Lynn [dekleva.lynn@epa.gov]; Amidon, Eric [Amidon.Eric@epa.gov]; Voyles, Travis [voyles.travis@epa.gov]
CC: Mandy, Cora [Mandy.Cora@epa.gov]; Weiner, Ben [Weiner.Ben@epa.gov]; Gall, Daniel [Gall.Daniel@epa.gov]; Skala, Grant [Skala.Grant@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]; Cook, Steven [cook.steven@epa.gov]; Busterud, John [Busterud.John@epa.gov]; Hall, Jeffrey [Hall.Jeffrey.A@epa.gov]; Beck, Nancy [beck.nancy@epa.gov]; Corlett, Thomas [Corlett.Thomas@epa.gov]; Szabo, Aaron [Szabo.Aaron@epa.gov]; Tardif, Abigale (Abbie) [Tardif.Abigale@epa.gov]; Tisa, Nathaniel [Tisa.Nathaniel@epa.gov]; Donahue, Sean [donahue.sean@epa.gov]
Subject: RE: FOR REVIEW: Draft on PFAS Release

Hey all! E Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

From: Dekleva, Lynn <dekleva.lynn@epa.gov>
Sent: Thursday, April 24, 2025 12:35 PM
To: Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Amidon, Eric <Amidon.Eric@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
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Could this work • Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

From: Vaseliou, Molly <Vaseliou.Molly@epa.gov>
Sent: Thursday, April 24, 2025 12:04 PM
To: Amidon, Eric <Amidon.Eric@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
Subject: RE: FOR REVIEW: Draft on PFAS Release

Added in testing methods below.

From: Amidon, Eric <Amidon.Eric@epa.gov>
Sent: Thursday, April 24, 2025 11:45 AM
To: Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
Subject: RE: FOR REVIEW: Draft on PFAS Release

Made a suggested Ex. 5 Deliberative Process (DP)

Eric Amidon
Chief of Staff
Environmental Protection Agency

From: Vaseliou, Molly <Vaseliou.Molly@epa.gov>
Sent: Thursday, April 24, 2025 9:06 AM
To: Amidon, Eric <Amidon.Eric@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy

<Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
Subject: FOR REVIEW: Draft on PFAS Release

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Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Message

From: Vaseliou, Molly [Vaseliou.Molly@epa.gov]
Sent: 4/28/2025 2:52:10 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]
Subject: FW: Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

Ex. 5 Deliberative Process (DP)

From: Hiroko Tabuchi <hiroko.tabuchi@nytimes.com>
Sent: Monday, April 28, 2025 10:47 AM
To: Vaseliou, Molly <Vaseliou.Molly@epa.gov>; EPA Press Office <Press@epa.gov>; Daguillard, Robert <Daguillard.Robert@epa.gov>
Subject: Fwd: Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Good morning Molly, Robert --

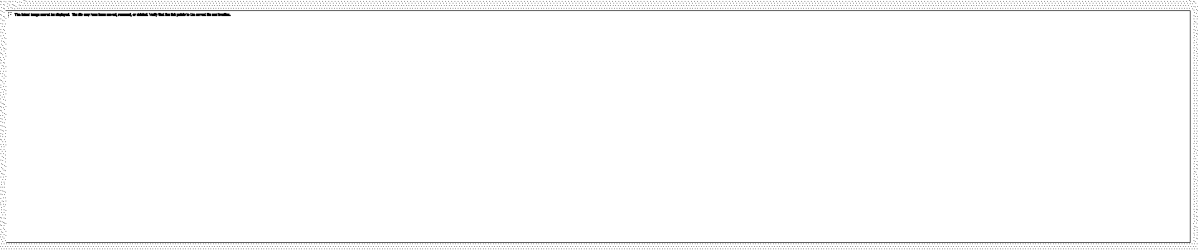
We are planning to write on this announcement -- but just wanted to circle back on the administration's plans re: the PFAS drinking water MCLs. Are these measures meant to replace the MCLs? Let me know if you can provide any further context/clarity?

All the best, Hiroko

Hiroko Tabuchi | Reporter | The New York Times | Phone 917-615-4180 | hiroko.tabuchi@nytimes.com | http://www.nytimes.com/by/hiroko-tabuchi

---------- Forwarded message ---------
From: **EPA Press** <EPAPress@govdelivery.epa.gov>
Date: Mon, Apr 28, 2025 at 9:31 AM
Subject: Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination
To: <hiroko.tabuchi@nytimes.com>

View as a webpage / Share



Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

April 28, 2025

Contact Information

EPA Press Office (press@epa.gov)

WASHINGTON – U.S. Environmental Protection Agency (EPA) Administrator Lee Zeldin outlined upcoming agency action to address Per- and Polyfluoroalkyl Substances (PFAS). In this suite of actions, Administrator Zeldin announced a long list that included in part the designation of an agency lead for PFAS, the creation of effluent limitations guidelines (ELGs) for certain PFAS to stop these forever chemicals from entering drinking water systems, and initiatives to engage with Congress and industry to establish a clear liability framework that ensures the polluter pays and passive receivers are protected. In line with Administrator Zeldin's Powering the Great American Comeback initiative, EPA's work in this space will advance Pillar 1: Clean Air, Land, and Water for Every American, and Pillar 3: Permitting Reform, Cooperative Federalism, and Cross-Agency Partnership.

> *"I have long been concerned about PFAS and the efforts to help states and communities dealing with legacy contamination in their backyards. With today's announcement, we are tackling PFAS from all of EPA's program offices, advancing research and testing, stopping PFAS from getting into drinking water systems, holding polluters accountable, and providing certainty for passive receivers. This is just a start of the work we will do on PFAS to ensure Americans have the cleanest air, land, and water,"* ***said EPA Administrator Zeldin.***

These actions are guided by the following principles: strengthening the science, fulfilling statutory obligations and enhancing communication, and building partnerships. With this approach, EPA will provide the foundation and investment necessary for a toolbox that will help states and communities dealing with PFAS contamination. This list is the first, not the last, of all decisions and actions EPA will be taking to address PFAS over the course of the Trump Administration. There will be more to come in the future across EPA's program offices to help communities impacted by PFAS contamination.

Strengthening the Science

- Designate an agency lead for PFAS to better align and manage PFAS efforts across agency programs
- Implement a PFAS testing strategy under Toxic Substances Control Act (TSCA) Section 4 to seek scientific information informed by hazard characteristics and exposure pathways
- Launch additional efforts on air related PFAS information collection and measurement techniques related to air emissions
- Identify and address available information gaps where not all PFAS can be measured and controlled
- Provide more frequent updates to the PFAS Destruction and Disposal Guidance—changing from every three years to annually—as EPA continues to assess the effectiveness of available treatment technologies
- Ramp up the development of testing methods to improve detection and strategies to address PFAS

Fulfilling Statutory Obligations and Enhancing Communication

- Develop effluent limitations guidelines (ELGs) for PFAS manufacturers and metal finishers and evaluate other ELGs necessary for reduction of PFAS discharges

- Address the most significant compliance challenges and requests from Congress and drinking water systems related to national primary drinking water regulations for certain PFAS
- Determine how to better use RCRA authorities to address releases from manufacturing operations of both producers and users of PFAS
- Add PFAS to the Toxic Release Inventory (TRI) in line with Congressional direction from the 2020 National Defense Authorization Act
- Enforce Clean Water Act and TSCA limitations on PFAS use and release to prevent further contamination
- Use Safe Drinking Water Act authority to investigate and address immediate endangerment
- Achieve more effective outcomes by prioritizing risk-based review of new and existing PFAS chemicals
- Implement section 8(a)7 to smartly collect necessary information, as Congress envisioned and consistent with TSCA, without overburdening small businesses and article importers.
- Work with Congress and industry to establish a clear liability framework that operates on polluter pays and protects passive receivers

Building Partnerships

- Advance remediation and cleanup efforts where drinking water supplies are impacted by PFAS contamination
- Work with states to assess risks from PFAS contamination and the development of analytical and risk assessment tools
- Finish public comment period for biosolids risk assessment and determine path forward based on comments
- Provide assistance to states and tribes on enforcement efforts
- Review and evaluate any pending state air petitions
- Resource and support investigations into violations to hold polluters accountable

A Record of Leadership

Administrator Zeldin's leadership on PFAS dates back to his time in Congress, where he was a founding member of the PFAS Congressional Taskforce and a strong supporter of the PFAS Action Act, legislation to provide funding to support local communities cleaning up PFAS-contaminated water systems. He was, and remains, a staunch advocate for protecting Long Islanders and all Americans from contaminated drinking water.

In the process of developing and taking action on a number of these items, Administrator Zeldin personally heard from Members of Congress on passive receiver issues where local water utilities will foot the bill for contamination and pass those costs onto consumers. This mindset and the need for a polluter pays model has guided a lot of the work to be done at EPA in the future.

Background

During President Trump's first term, EPA convened a two-day National Leadership Summit on PFAS in Washington, D.C. that brought together more than 200 federal, state, and local leaders from across the country to discuss steps to address PFAS. Following the Summit, the agency hosted a series of visits during the summer of 2018 in communities directly impacted by PFAS. EPA interacted with more than 1,000 Americans during community engagement events in Exeter, New Hampshire, Horsham, Pennsylvania, Colorado Springs,

Colorado, Fayetteville, North Carolina, and Leavenworth, Kansas, as well as through a roundtable in Kalamazoo, Michigan, and events with tribal representatives in Spokane, Washington.

In 2019, the Trump EPA announced the PFAS Action Plan. This historic Plan responded to extensive public interest and input the agency received and represented the first time EPA built a multi-media, multi-program, national communication and research plan to address an emerging environmental challenge like PFAS. EPA's Action Plan identified both short-term solutions for addressing these chemicals and long-term strategies that will help provide the tools and technologies states, tribes, and local communities need to provide clean and safe drinking water to their residents and to address PFAS at the source—even before it gets into the water.

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This email was sent to hiroko.tabuchi@nytimes.com using govDelivery Communications Cloud on behalf of: EPA Office of the Administrator · 1200 Pennsylvania Ave NW, Washington, DC 20460

Message

From: Flaherty, Colleen [Flaherty.Colleen@epa.gov]
Sent: 4/28/2025 7:28:30 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Mottley, Tanya [Mottley.Tanya@epa.gov]
Subject: PFAS science briefing papers
Attachments: 032725 TK bullets.docx; 040325 Use of tox values under CERCLA.docx; 0402025 PFOA PFOS RfDs vs ATSDR MRLs.docx; 032725 human health epi bullets .docx; 032725 immune bullets.docx; Topline messages PFAS health assessments Feb 2025.docx

Jess,

As discussed, attached are the PFAS science briefing papers that we previously sent to you. We're happy to answer any additional questions you may have.

Best,
Colleen

Colleen Flaherty
Director, Health and Ecological Criteria Division
Office of Water, U.S. EPA
1200 Pennsylvania Ave., NW
WJC Connecting Wing, Mail Code 4304T
Washington, DC 20460
Phone: (202) 564-5939| flaherty.colleen@epa.gov

Message

From: Haga, Ellie [Haga.Ellie@epa.gov]
Sent: 4/28/2025 7:49:26 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Risley, David [Risley.David@epa.gov]; Lanier, Lynsey [Lanier.Lynsey@epa.gov]
Subject: ACTION ITEM INCLUDED: OW meeting materials for Tuesday, April 29, 2025
Attachments: Ex. 5 Deliberative Process (DP)

Hi Jess,
Here are your materials for tomorrow's meetings including:

Ex. 5 Deliberative Process (DP)

Also, attaching one item for urgent review/approval – PFAS Media Inquiries

Best,
Ellie

Ellie Haga
Special Assistant
Office of Water
U.S. Environmental Protection Agency
WJC East 3219-D
Desk Phone: 202-564-3854
Mobile Phone: 771-242-0793
Haga.ellie@epa.gov

Message

From: Lanier, Lynsey [Lanier.Lynsey@epa.gov]
Sent: 4/28/2025 7:40:24 PM
To: Haga, Ellie [Haga.Ellie@epa.gov]
Subject: FW: FOR REVIEW: PFAS MEDIA INQUIRIES - DEADLINE ASAP: QUESTIONS REG: Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

Hey Ellie – can you add this to Peggy and Jess' binder? For Review and Approval?

Lynsey Lanier
Deputy Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Lanier.Lynsey@epa.gov
202-566-1951

From: Bender, Emily <Bender.Emily@epa.gov>
Sent: Monday, April 28, 2025 3:35 PM
To: Lanier, Lynsey <Lanier.Lynsey@epa.gov>
Subject: FW: FOR REVIEW: PFAS MEDIA INQUIRIES - DEADLINE ASAP: QUESTIONS REG: Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

Hi Lynsey-

Here are the media inquiries OPA is pinging on. Wondering if you might be able to help us get them reviewed?

Thanks so much,

Emily

Emily Bender
Associate Communications Director
U.S. EPA Office of Water
Bender.Emily@epa.gov
857-366-0397

From: Bender, Emily
Sent: Monday, April 28, 2025 2:57 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>
Cc: Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>; Risley, David <Risley.David@epa.gov>
Subject: FOR REVIEW: PFAS MEDIA INQUIRIES - DEADLINE ASAP: QUESTIONS REG: Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

Hi Jess and Peggy-

We have three media inquiries following up on this morning's PFAS announcement. See the inquiries and proposed responses for your review and approval.

We look forward to your feedback.

Thanks

Emily

Inquiries PFAS MCL (NYT; EE News)

- We are planning to write on this announcement -- but just wanted to circle back on the administration's plans re: the PFAS drinking water MCLs. Are these measures meant to replace the MCLs? Let me know if you can provide any further context/clarity? (NYT)

- Under this plan, will EPA keep in place and enforce the rules on PFAS drinking water MCLs and CERCLA hazardous designations finalized under the Biden administration? (EE News)

Draft Response

Ex. 5 Deliberative Process (DP)

Background
EPA issued a final drinking water rule in April last year. In February 2025, the court granted a request by DOJ, on behalf of the agency, to briefly suspend the current litigation of the PFAS drinking water rule. On April 8, 2025, DOJ submitted a motion for additional time.

Inquiry PFAS ELG (Bloomberg)

- Can you offer a timeline for any of the actions below, especially effluent limits, the lack of which are affecting the NPDES permits water utilities can use for upstream polluters? (Bloomberg)

Draft Response

Ex. 5 Deliberative Process (DP)

Emily Bender
Associate Communications Director
U.S. EPA Office of Water
Bender.Emily@epa.gov
857-366-0397

From: EPA Press <EPAPress@govdelivery.epa.gov>
Sent: Monday, April 28, 2025 9:31 AM
To: Rizzuto, Pat <prizzuto@bloombergenvironment.com>
Subject: Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

[redacted]

Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

April 28, 2025

Contact Information

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In the process of developing and taking action on a number of these items, Administrator Zeldin personally heard from Members of Congress on passive receiver issues where local water utilities will foot the bill for contamination and pass those costs onto consumers. This mindset and the need for a polluter pays model has guided a lot of the work to be done at EPA in the future.

Background

During President Trump's first term, EPA convened a two-day National Leadership Summit on PFAS in Washington, D.C. that brought together more than 200 federal, state, and local leaders from across the country to discuss steps to address PFAS. Following the Summit, the agency hosted a series of visits during the summer of 2018 in communities directly impacted by PFAS. EPA interacted with more than 1,000 Americans during community engagement events in Exeter, New Hampshire, Horsham, Pennsylvania, Colorado Springs, Colorado, Fayetteville, North Carolina, and Leavenworth, Kansas, as well as through a roundtable in Kalamazoo, Michigan, and events with tribal representatives in Spokane, Washington.

In 2019, the Trump EPA announced the PFAS Action Plan. This historic Plan responded to extensive public interest and input the agency received and represented the first time EPA built a multi-media, multi-program, national communication and research plan to address an emerging environmental challenge like PFAS. EPA's Action Plan identified both short-term solutions for addressing these chemicals and long-term strategies that will help provide the tools and technologies states, tribes, and local communities need to provide clean and safe drinking water to their residents and to address PFAS at the source—even before it gets into the water.

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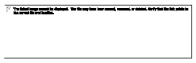

Message

From: Bender, Emily [Bender.Emily@epa.gov]
Sent: 4/28/2025 9:24:42 PM
To: Browne, Peggy [Browne.Peggy@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Guzda-Struck, Kathleen [GuzdaStruck.Mary@epa.gov]; Risley, David [Risley.David@epa.gov]
Subject: RE: FOR REVIEW: PFAS MEDIA INQUIRIES - DEADLINE ASAP: QUESTIONS REG: Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

Thank you!

Emily Bender
Associate Communications Director
U.S. EPA Office of Water
Bender.Emily@epa.gov
857-366-0397

From: Browne, Peggy <Browne.Peggy@epa.gov>
Sent: Monday, April 28, 2025 5:24 PM
To: Bender, Emily <Bender.Emily@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>; Risley, David <Risley.David@epa.gov>
Subject: RE: FOR REVIEW: PFAS MEDIA INQUIRIES - DEADLINE ASAP: QUESTIONS REG: Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

I approve, this looks good.

Peggy S. Browne

From: Bender, Emily <Bender.Emily@epa.gov>
Sent: Monday, April 28, 2025 4:39 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>
Cc: Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>; Risley, David <Risley.David@epa.gov>
Subject: FOR REVIEW: PFAS MEDIA INQUIRIES - DEADLINE ASAP: QUESTIONS REG: Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

Hi Jess and Peggy-

Just wanted to let you know that we have received a number of inquiries on the PFAS announcement this morning. See below for the latest list and the draft response for your review and approval.

We look forward to your feedback on the proposed statements. FYI- OPA is hoping to get back to the reporters ASAP on this.

Thanks so much,

Emily

Inquiries PFAS MCL (NYT; EE News; Inside Climate)

- We are planning to write on this announcement -- but just wanted to circle back on the administration's plans re: the PFAS drinking water MCLs. Are these measures meant to replace the MCLs? Let me know if you can provide any further context/clarity? (NYT)

- Under this plan, will EPA keep in place and enforce the rules on PFAS drinking water MCLs and CERCLA hazardous designations finalized under the Biden administration? (EE News)

- How does the April 2024 rule on PFAS in drinking water fit into the EPA's current approach to PFAS? As the May 12 deadline approaches on litigation concerning the rule, will the administration defend the 2024 standards in court? (Inside Climate)

Draft Response

Ex. 5 Deliberative Process (DP)

Background
EPA issued a final drinking water rule in April last year. In February 2025, the court granted a request by DOJ, on behalf of the agency, to briefly suspend the current litigation of the PFAS drinking water rule. On April 8, 2025, DOJ submitted a motion for additional time.

Inquiry PFAS ELG (Bloomberg)

- Can you offer a timeline for any of the actions below, especially effluent limits, the lack of which are affecting the NPDES permits water utilities can use for upstream polluters? (Bloomberg)

Emily Bender
Associate Communications Director
U.S. EPA Office of Water
Bender.Emily@epa.gov
857-366-0397

From: Bender, Emily
Sent: Monday, April 28, 2025 2:57 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>
Cc: Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>; Risley, David <Risley.David@epa.gov>
Subject: FOR REVIEW: PFAS MEDIA INQUIRIES - DEADLINE ASAP: QUESTIONS REG: Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

Hi Jess and Peggy-

We have three media inquiries following up on this morning's PFAS announcement. See the inquiries and proposed responses for your review and approval.

We look forward to your feedback.

Thanks

Emily

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Draft Response

Ex. 5 Deliberative Process (DP)

Emily Bender
Associate Communications Director
U.S. EPA Office of Water
Bender.Emily@epa.gov
857-366-0397

From: EPA Press <EPAPress@govdelivery.epa.gov>
Sent: Monday, April 28, 2025 9:31 AM
To: Rizzuto, Pat <prizzuto@bloombergenvironment.com>
Subject: Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

[redacted]

Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination

April 28, 2025

Contact Information

EPA Press Office (press@epa.gov)

WASHINGTON – U.S. Environmental Protection Agency (EPA) Administrator Lee Zeldin outlined upcoming agency action to address Per- and Polyfluoroalkyl Substances (PFAS). In this suite of actions, Administrator Zeldin announced a long list that included in part the designation of an agency lead for PFAS, the creation of effluent limitations guidelines (ELGs) for certain PFAS to stop these forever chemicals from entering drinking water systems, and initiatives to engage with Congress and industry to establish a clear liability framework that ensures the polluter pays and passive receivers are protected. In line with Administrator Zeldin's Powering the Great American Comeback initiative, EPA's work in this space will advance Pillar 1: Clean Air, Land, and Water for Every American, and Pillar 3: Permitting Reform, Cooperative Federalism, and Cross-Agency Partnership.

> *"I have long been concerned about PFAS and the efforts to help states and communities dealing with legacy contamination in their backyards. With today's announcement, we are tackling PFAS from all of EPA's program offices, advancing research and testing, stopping PFAS from getting into drinking water systems, holding polluters accountable, and providing certainty for passive receivers. This is just a start of the work we will do on PFAS to ensure Americans have the cleanest air, land, and water,"* ***said EPA Administrator Zeldin.***

These actions are guided by the following principles: strengthening the science, fulfilling statutory obligations and enhancing communication, and building partnerships. With this approach, EPA will provide the foundation and investment necessary for a toolbox that will help states and communities dealing with PFAS contamination. This list is the first, not the last, of all decisions and actions EPA will be taking to address PFAS over the course of the Trump Administration. There will be more to come in the future across EPA's program offices to help communities impacted by PFAS contamination.

Strengthening the Science

- Designate an agency lead for PFAS to better align and manage PFAS efforts across agency programs
- Implement a PFAS testing strategy under Toxic Substances Control Act (TSCA) Section 4 to seek scientific information informed by hazard characteristics and exposure pathways
- Launch additional efforts on air related PFAS information collection and measurement techniques related to air emissions
- Identify and address available information gaps where not all PFAS can be measured and controlled
- Provide more frequent updates to the PFAS Destruction and Disposal Guidance—changing from every three years to annually—as EPA continues to assess the effectiveness of available treatment technologies
- Ramp up the development of testing methods to improve detection and strategies to address PFAS

Fulfilling Statutory Obligations and Enhancing Communication

- Develop effluent limitations guidelines (ELGs) for PFAS manufacturers and metal finishers and evaluate other ELGs necessary for reduction of PFAS discharges
- Address the most significant compliance challenges and requests from Congress and drinking water systems related to national primary drinking water regulations for certain PFAS
- Determine how to better use RCRA authorities to address releases from manufacturing operations of both producers and users of PFAS
- Add PFAS to the Toxic Release Inventory (TRI) in line with Congressional direction from the 2020 National Defense Authorization Act
- Enforce Clean Water Act and TSCA limitations on PFAS use and release to prevent further contamination
- Use Safe Drinking Water Act authority to investigate and address immediate endangerment
- Achieve more effective outcomes by prioritizing risk-based review of new and existing PFAS chemicals
- Implement section 8(a)7 to smartly collect necessary information, as Congress envisioned and consistent with TSCA, without overburdening small businesses and article importers.
- Work with Congress and industry to establish a clear liability framework that operates on polluter pays and protects passive receivers

Building Partnerships

- Advance remediation and cleanup efforts where drinking water supplies are impacted by PFAS contamination

- Work with states to assess risks from PFAS contamination and the development of analytical and risk assessment tools
- Finish public comment period for biosolids risk assessment and determine path forward based on comments
- Provide assistance to states and tribes on enforcement efforts
- Review and evaluate any pending state air petitions
- Resource and support investigations into violations to hold polluters accountable

A Record of Leadership

Administrator Zeldin's leadership on PFAS dates back to his time in Congress, where he was a founding member of the PFAS Congressional Taskforce and a strong supporter of the PFAS Action Act, legislation to provide funding to support local communities cleaning up PFAS-contaminated water systems. He was, and remains, a staunch advocate for protecting Long Islanders and all Americans from contaminated drinking water.

In the process of developing and taking action on a number of these items, Administrator Zeldin personally heard from Members of Congress on passive receiver issues where local water utilities will foot the bill for contamination and pass those costs onto consumers. This mindset and the need for a polluter pays model has guided a lot of the work to be done at EPA in the future.

Background

During President Trump's first term, EPA convened a two-day National Leadership Summit on PFAS in Washington, D.C. that brought together more than 200 federal, state, and local leaders from across the country to discuss steps to address PFAS. Following the Summit, the agency hosted a series of visits during the summer of 2018 in communities directly impacted by PFAS. EPA interacted with more than 1,000 Americans during community engagement events in Exeter, New Hampshire, Horsham, Pennsylvania, Colorado Springs, Colorado, Fayetteville, North Carolina, and Leavenworth, Kansas, as well as through a roundtable in Kalamazoo, Michigan, and events with tribal representatives in Spokane, Washington.

In 2019, the Trump EPA announced the PFAS Action Plan. This historic Plan responded to extensive public interest and input the agency received and represented the first time EPA built a multi-media, multi-program, national communication and research plan to address an emerging environmental challenge like PFAS. EPA's Action Plan identified both short-term solutions for addressing these chemicals and long-term strategies that will help provide the tools and technologies states, tribes, and local communities need to provide clean and safe drinking water to their residents and to address PFAS at the source—even before it gets into the water.

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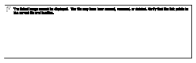

Message

From: Ana Condulet [A.Condulet@americanconference.com]
Sent: 4/1/2025 2:27:29 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
Subject: Invitation to Speak: 2nd Annual Summit on PFAS Regulation, Compliance and Litigation (May 29-30 2025, NYC)
Attachments: PFAS NYC Draft Agenda External 2025.docx

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Hi Jessica,

I hope things are going well! I'm reaching out as we are getting ready for the 2nd Annual Summit on PFAS Regulation, Compliance and Litigation **(May 29-30, 2025, NYC)** and it is my pleasure to formally invite you to speak at the upcoming May conference.

I'm reaching out at the recommendation of our co-chair- **Matt Leopold with Hunton Andrews Kurth.**

This is an annual conference that provides a comprehensive overview of the latest developments in PFAS-related legislation, regulatory compliance, and legal challenges. The event features insights from government officials, industry experts, and legal professionals.

We'd be honored to have you join our speaker faculty! I have attached the current draft agenda for your consideration and would like to propose the following panel session but please let me know if something else is of interest:

May 29th, 10:45
A Guide to the Anticipated Federal Reporting Requirements under TSCA (Toxic Substances Control Act) and more EPA Oversight: EPCRA, SDWA

To allow manufacturers and affected entities more time to comply with the final reporting requirements, EPA moved the reporting deadline from May 2025 to July 2026 with an effective date of January 2026.

- Understanding EPA's use of TSCA authority for PFAS testing and enforcement
  - Assessing the implications for manufacturers
- Addressing PFAS reporting under the Emergency Planning and Community Right-to-Know Act, including the evolving TRI (Toxic Release Inventory) reporting thresholds and additional PFAS listings
  - What strategies can facilities employ to ensure compliance with these evolving regulations?
  - How are industries adapting to the expanded TRI reporting requirements for PFAS?
- Reviewing EPA's newly imposed MCLs (Maximum Contaminant Levels) under the Safe Drinking Water Act (SDWA)
  - Exploration of the implications for water utilities and public health protection
- Highlighting 'New Use Rule' developments that target future uses of PFAS

Speakers:

- Martha E., Marrapese, Partner, **Wiley Rein**
- Anna Willett, PE, Senior Project Manager, **LANGAN**

Thank you very much for considering this and look forward to hearing from you,

Kind regards,
Ana Condulet
Conference Producer
American Conference Institute
A C5 Group Company

T: (+1) 347-964-4941
E: a.condulet@americanconference.com
W: www.americanconference.com

Message

From: Vaseliou, Molly [Vaseliou.Molly@epa.gov]
Sent: 5/7/2025 6:00:14 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]; Abboud, Michael [abboud.michael@epa.gov]; Voyles, Travis [voyles.travis@epa.gov]; Amidon, Eric [Amidon.Eric@epa.gov]
Subject: FW: EPA Recap & Week Ahead

FYI – what went to WH Comms

From: Vaseliou, Molly
Sent: Friday, May 2, 2025 2:22 PM
To: Persing, Johanna E. EOP/WHO Ex. 6 - Personal Privacy (PP)
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>
Subject: EPA Recap & Week Ahead

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Ex. 5 Deliberative Process (DP)

Message

From: Amidon, Eric [Amidon.Eric@epa.gov]
Sent: 5/7/2025 5:20:54 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
Subject: FW: MOCK UP: EPA Announces It Will Keep Maximum Contaminant Levels for PFAS

Eric Amidon
Chief of Staff
Environmental Protection Agency

From: Vaseliou, Molly <Vaseliou.Molly@epa.gov>
Sent: Wednesday, May 7, 2025 1:17 PM
To: Amidon, Eric <Amidon.Eric@epa.gov>
Subject: MOCK UP: EPA Announces It Will Keep Maximum Contaminant Levels for PFAS

Mock up below:

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Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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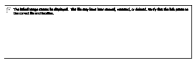

Message

From: Vaseliou, Molly [Vaseliou.Molly@epa.gov]
Sent: 5/7/2025 2:14:12 PM
To: Tisa, Nathaniel [Tisa.Nathaniel@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]; Donahue, Sean [donahue.sean@epa.gov]
CC: Mandy, Cora [Mandy.Cora@epa.gov]; Weiner, Ben [Weiner.Ben@epa.gov]; Gall, Daniel [Gall.Daniel@epa.gov]; Skala, Grant [Skala.Grant@epa.gov]; Bastasch, Mike [Bastasch.Mike@epa.gov]; Talmage, Sarah [Talmage.Sarah@epa.gov]
Subject: Updated DRAFT PFAS Release

Ex. 5 Deliberative Process (DP)

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Message

From: Risley, David [Risley.David@epa.gov]
Sent: 5/9/2025 4:58:55 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
Subject: FW: Letter from 50+ NGOs concerning EPA compliance dates for Lead and PFAS
Attachments: NGO PFAS_Lead Compliance Letter - May 9.pdf

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

From: Julian Gonzalez <jgonzalez@earthjustice.org>
Sent: Friday, May 9, 2025 12:43 PM
To: Zeldin, Lee <Zeldin.Lee@epa.gov>; Amidon, Eric <Amidon.Eric@epa.gov>; kramer.jessica@epa.gov; Risley, David <Risley.David@epa.gov>
Cc: Olson, Erik <eolson@nrdc.org>; Suzanne Novak <snovak@earthjustice.org>; Marissa Lieberman-Klein <mlieberman-klein@earthjustice.org>; Suzanne Novak <snovak@earthjustice.org>; Thompson, Jared <jared.thompson@nrdc.org>; Jonathan Kalmuss-Katz <jkalmusskatz@earthjustice.org>; Chen, Karen <kchen@nrdc.org>; Hobbs, Katie <kathrynhobbs@nrdc.org>; Christine Santillana <csantillana@earthjustice.org>; Hillary Aidun <haidun@earthjustice.org>; Molly Prothero <mprothero@earthjustice.org>
Subject: Letter from 50+ NGOs concerning EPA compliance dates for Lead and PFAS

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Dear Administrator Zeldin and Assistant Administrator for Water designee Kramer,

Good afternoon, I hope this email finds you well. Please see the attached letter from over 50 public health, community action, and environmental organizations concerning the compliance dates for three critical public protections: the "PFAS National Primary Drinking Water Regulation , the "National Primary Drinking Water Regulations for Lead and Copper: Improvements", and the rule listing two forever chemicals (PFOA and PFOS) as hazardous under the Superfund law.

It is our hope that EPA will vigorously defend, and not delay, these important public protections designed to help families protect themselves from lead and PFAS forever chemicals in our drinking water and environment.

Sincerely,
Julian Gonzalez
(On behalf of Earthjustice and the organizations listed on the attached letter)

Julián González *(he/him/his)*
Senior Legislative Counsel

EARTHJUSTICE | EARTHJUSTICE ACTION

1001 G St NW, Suite 1000

Washington, DC 20001
T: 646.316.5035
earthjustice.org
earthjusticeaction.org
facebook.com/earthjustice
twitter.com/earthjustice

Dear Administrator Zeldin,

On behalf of the many undersigned community-based organizations, public health organizations, and environmental organizations, we urge you to prioritize public health by vigorously defending and *not* delaying compliance dates for three critically important public health regulations: the "PFAS National Primary Drinking Water Regulation "("the PFAS drinking water standards"), the "National Primary Drinking Water Regulations for Lead and Copper: Improvements" ("the LCRI"), and the rule listing two forever chemicals (PFOA and PFOS) as hazardous under the Superfund law (the "PFAS Superfund listing."). Industry is challenging all three of these rules in court, and you must decide in the coming days whether the agency will continue to defend and carry out these crucial public health protections, or will retreat in the face of industry pressure.

Water utilities will soon be required to take action to comply with the new drinking water standards for good reason: people across the country have waited for decades for our federal government to take PFAS and lead contamination seriously. As many as 105 million people in America have PFAS in their drinking water at health-threatening levels exceeding the agency's new standards for six of these forever chemicals. Also, we know that exposure to any level of lead presents health risks, and EPA data show that over the past four years, 44 million people across the nation got their drinking water from systems that had lead 90th percentile levels of 10 parts per billion or more, posing significant health threats. About 13 million people drank from systems that had health-based violations of EPA's existing lead standard. Similarly, there are hundreds or even thousands of sites contaminated with PFAS, threatening the health of hundreds of millions of people. The PFAS Superfund listing rule is crucial to help ensure polluters pay for cleanup of these sites.

After waiting years, the last thing communities need is further delays and more broken promises. The current White House and Administration have publicly discussed the health risks from PFAS, writing that "the EPA has determined that many PFAS are harmful to human health, and they have been linked to harms affecting reproductive health, developmental delays in children, cancer, hormone imbalance, obesity, and other dangerous health conditions", and that PFAS "are often referred to as 'forever chemicals' because of their extremely long lifespans." Of course you visited Flint, Michigan, highlighting one of the more public epicenters of our national crisis regarding lead-contaminated drinking water. You noted that, "Our experiences during the Flint water crisis underscore the important role that each one of us can play in ensuring that EPA identifies and appropriately addresses human health and environmental risks…." What community members are asking for is to pair these words and public visits with strong action: vigorously defend and do not delay the very public protections designed to help families protect themselves from lead and PFAS forever chemicals in our drinking water and environment.

Sincerely,

A2 (Anthropocene Alliance)
Alabama Rivers Alliance
Alliance of Nurses for Healthy Environments
Bayou City Waterkeeper
Buxmont Coalition for Safer Water
Center for Environmental Health
Chesapeake Climate Action Network
Citizens for Safe Water Around Badger (CSWAB)
Clean Air Action Network of Glens Falls
Clean Cape Fear
Clean Water Action
Clean Wisconsin
Coastal Carolina Riverwatch
Committee on the Middle Fork Vermilion River
Community Water Center
Consumer Reports
Defend Our Health
Earthjustice
Environment America Research & Policy Center
Environmental Law and Policy Center
Environmental Protection Network
Environmental Working Group
Fight For Zero, Inc
Food & Water Watch
For Love of Water
Freshwater Future
Great Lakes PFAS Action Network
Green & Healthy Homes Initiative
Iowa Environmental Council
Kentucky Waterways Alliance
League of Conservation Voters
Little Village Environmental Justice Organization

Memphis & Shelby County Lead safe Collaborative
Merrimack Citizens for Clean Water
Midwest Environmental Advocates
Milwaukee Riverkeeper
Natural Resources Defense Council
Need Our Water
Newburgh Clean Water Project
Oscoda Citizens for Clean Water
Portland Advocates for Leadfree Drinking Water
River Network
S.O.H2O Save Our Water
Shelby County Lead Prevention & Sustainability Commission
Sierra Club
Testing for Pease
The Water Collaborative of Greater New Orleans
Town of Campbell, WI - resident
U.S. PIRG
Unleaded Kids
Vessel Project of Louisiana
Waterkeepers Chesapeake
Weequahic Park Association
Wisconsin's Green Fire, Inc.
Young, Gifted & Green

Cc: Jessica Kramer, Assistant Administrator for Water Designee

Message

From: Vaseliou, Molly [Vaseliou.Molly@epa.gov]
Sent: 5/13/2025 7:57:58 PM
To: Risley, David [Risley.David@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Drinkard, Andrea [Drinkard.Andrea@epa.gov]; Donahue, Sean [donahue.sean@epa.gov]; Tisa, Nathaniel [Tisa.Nathaniel@epa.gov]; Talmage, Sarah [Talmage.Sarah@epa.gov]; Levine, Carolyn [Levine.Carolyn@epa.gov]
CC: Guzda-Struck, Kathleen [GuzdaStruck.Mary@epa.gov]; Bender, Emily [Bender.Emily@epa.gov]; McLain, Jennifer L. [McLain.Jennifer@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Re: Wednesday PFAS Announcement

Thank you!

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From: Risley, David <Risley.David@epa.gov>
Sent: Tuesday, May 13, 2025 3:49:47 PM
To: Wadlington, Christina <Wadlington.Christina@epa.gov>; Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Drinkard, Andrea <Drinkard.Andrea@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Talmage, Sarah <Talmage.Sarah@epa.gov>; Levine, Carolyn <Levine.Carolyn@epa.gov>
Cc: Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>; Bender, Emily <Bender.Emily@epa.gov>; McLain, Jennifer L. <McLain.Jennifer@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: Wednesday PFAS Announcement

Ex. 5 Deliberative Process (DP)

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

From: Wadlington, Christina <Wadlington.Christina@epa.gov>
Sent: Tuesday, May 13, 2025 3:45 PM
To: Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Risley, David <Risley.David@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Drinkard, Andrea <Drinkard.Andrea@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Talmage, Sarah <Talmage.Sarah@epa.gov>; Levine, Carolyn <Levine.Carolyn@epa.gov>
Cc: Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>; Bender, Emily <Bender.Emily@epa.gov>; McLain, Jennifer L. <McLain.Jennifer@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: Wednesday PFAS Announcement

Adding OGWDW due to timing.

From: Vaseliou, Molly <Vaseliou.Molly@epa.gov>
Sent: Tuesday, May 13, 2025 3:44 PM
To: Risley, David <Risley.David@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Drinkard, Andrea <Drinkard.Andrea@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Talmage, Sarah <Talmage.Sarah@epa.gov>;

Levine, Carolyn <Levine.Carolyn@epa.gov>
Cc: Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>; Bender, Emily <Bender.Emily@epa.gov>
Subject: RE: Wednesday PFAS Announcement

Ex. 5 Deliberative Process (DP)

From: Vaseliou, Molly
Sent: Tuesday, May 13, 2025 2:16 PM
To: Risley, David <Risley.David@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Drinkard, Andrea <Drinkard.Andrea@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Talmage, Sarah <Talmage.Sarah@epa.gov>; Levine, Carolyn <Levine.Carolyn@epa.gov>
Cc: Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>; Bender, Emily <Bender.Emily@epa.gov>
Subject: RE: Wednesday PFAS Announcement

Thanks team! Looking through this now. Will try to get this in front of the Administrator for approval before the end of day.

From: Risley, David <Risley.David@epa.gov>
Sent: Tuesday, May 13, 2025 1:38 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>; Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Drinkard, Andrea <Drinkard.Andrea@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Talmage, Sarah <Talmage.Sarah@epa.gov>; Levine, Carolyn <Levine.Carolyn@epa.gov>
Cc: Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>; Bender, Emily <Bender.Emily@epa.gov>
Subject: Wednesday PFAS Announcement

Hi all –
Here is an updated PFAS rollout (press release and notification plan) reflecting updated policy direction. This has been

Ex. 5 Deliberative Process (DP)

Best,
David

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

Message

From: Amidon, Eric [Amidon.Eric@epa.gov]
Sent: 5/13/2025 11:08:39 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
Subject: FW: PFAS PFOS PFOA
Attachments: Overview 5-6-25.pdf; PFAS Directive 5-6-25.pdf

Look at that.

Eric Amidon
Chief of Staff
Environmental Protection Agency

From: Russo, Edward <Russo.Edward@epa.gov>
Sent: Thursday, May 8, 2025 10:17 AM
To: Amidon, Eric <Amidon.Eric@epa.gov>
Subject: PFAS PFOS PFOA

Good morning, Eric,

Great seeing you again yesterday.

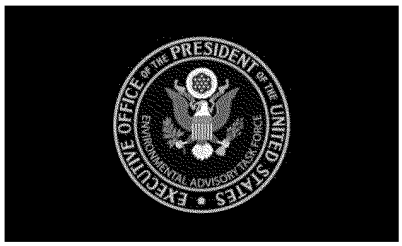
Toward the end of our meeting I made a few comments regarding PFAS, PFOS, and PFOA.

I thought it important to back that up with a perspective/opinion on the matter.

If you can forward this to the appropriate person for consideration, that could be helpful and of course if they have any concerns or comments, they can always reach out to me.

All the best.

Edward Russo
Chairman
Russo.Edward@epa.gov
202-438-6907



Message

From: Bender, Emily [Bender.Emily@epa.gov]
Sent: 5/14/2025 5:25:18 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]
CC: Risley, David [Risley.David@epa.gov]; Guzda-Struck, Kathleen [GuzdaStruck.Mary@epa.gov]
Subject: RE: FOR ASAP REVIEW: PFAS Statement

Thank you so much

Emily Bender
Associate Communications Director
U.S. EPA Office of Water
Bender.Emily@epa.gov
857-366-0397

From: Kramer, Jessica L. <kramer.jessical@epa.gov>
Sent: Wednesday, May 14, 2025 1:17 PM
To: Bender, Emily <Bender.Emily@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>
Cc: Risley, David <Risley.David@epa.gov>; Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>
Subject: Re: FOR ASAP REVIEW: PFAS Statement

Edits at the end of the first paragraph and also in the first Q/A response. Otherwise nothing else from me. Thanks!

Get Outlook for iOS

From: Bender, Emily <Bender.Emily@epa.gov>
Sent: Wednesday, May 14, 2025 1:02 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>
Cc: Risley, David <Risley.David@epa.gov>; Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>
Subject: FOR ASAP REVIEW: PFAS Statement

Hi Jess and Peggy-

As you know we are getting incoming on today's PFAS MCL announcement and we have prepared a draft overarching statement, and a few QA's for your consideration and approval. See the suggested statement and QA below to help with the incoming.

Also note: I included the talking points Jess used in her script yesterday that we would like to share with the regions and OPA.

This language has all gone through OGWDW and OGC career staff. We look forward to your feedback.

Thanks so much,

Emily

Draft Statement

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

From: Joseph, Dominique <Joseph.Dominique@epa.gov>
Sent: Wednesday, May 14, 2025 8:24 AM
To: Bender, Emily <Bender.Emily@epa.gov>; Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>
Subject: RE: OW Releases This Week
Importance: High

Good morning,

Following up on this. I am hearing that the PFAS MCL press release is going out this morning. Please provide a statement we can share with reporters to address queries we're already getting and will continue to receive.

This is the last statement I have from April 28:

Ex. 5 Deliberative Process (DP)

Dominique Joseph
Office of Public Affairs (OPA)
U.S. Environmental Protection Agency
202-805-3635 (cell)
joseph.dominique@epa.gov

From: Joseph, Dominique
Sent: Monday, May 12, 2025 10:25 AM
To: Bender, Emily <Bender.Emily@epa.gov>; Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>
Subject: OW Releases This Week

Good morning,

I know there are several OW releases planned for this week and, although the final timing in still in flux, I wanted to reach out in advance to ask for a statement and/or Q&A that I can use in response to the influx of queries that are expected. As the program experts, you usually know what media will ask (or what's missing or not elaborated upon in the press release), so it's just a matter of being prepared for it and I'm sure it will be helpful for all involved.

Dominique Joseph
Office of Public Affairs (OPA)
U.S. Environmental Protection Agency
202-805-3635 (cell)
joseph.dominique@epa.gov

Message

From: Risley, David [Risley.David@epa.gov]
Sent: 5/13/2025 6:51:24 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]; Talmage, Sarah [Talmage.Sarah@epa.gov]; Levine, Carolyn [Levine.Carolyn@epa.gov]; McLain, Jennifer L. [McLain.Jennifer@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]
CC: Guzda-Struck, Kathleen [GuzdaStruck.Mary@epa.gov]; Bender, Emily [Bender.Emily@epa.gov]
Subject: RE: Talking Points for PFAS MCL Briefing
Attachments: Script_PFAS NPDWR Update_5.13.25 DRAFT.docx

Jess – I'm attaching updated talking points for today's embargoed notification on PFAS.

Sarah and Carolyn – Do we know who will facilitate the calls?

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

From: Risley, David
Sent: Wednesday, May 7, 2025 1:19 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>; McLain, Jennifer L. <Mclain.Jennifer@epa.gov>
Cc: Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>; Bender, Emily <Bender.Emily@epa.gov>
Subject: Talking Points for PFAS MCL Briefing

Jess –
Here are talking points for this afternoon's embargoed briefings for the hill followed by state and local associations.

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

SCRIPT: Actions to support the PFAS Drinking Water Rule

May 13, 2025

Facilitator: Thank you all for joining us on today's embargoed call on EPA's work to address PFAS in drinking water while following the law and supporting water systems. My name is [NAME OF FACILIATOR AND TITLE]. This call is intended for [AUDIENCE]. If there are any press on the call, please hang up and email [HYPERLINK "mailto:press@epa.gov"] with your questions. The information that will be shared on this all **is embargoed until early tomorrow, May 14, when we will issue a press release.** With that, I will turn the call over to **Jessica Kramer, Senior Advisor for Water to Administrator Lee Zeldin**.

Jess Kramer

Intro/Overview

- **Thank you** all for joining today's call.
- **I'm Jess Kramer and I am a Senior Advisor to Administrator Zeldin.**
- I want to reiterate that the **information shared today is embargoed until we issue our press release tomorrow**.
    - By upholding this embargo, you will help EPA hold briefings like this in the future.
- I'm going to **preview a decision the Administrator has made** regarding our path forward for addressing PFAS in drinking water.
- As you know, the Trump Administration has been **reviewing the 2024 National Primary Drinking Water Regulation for PFAS that established standards for six PFAS**.
- This has been a **holistic review—including the science**, the monitoring data, statutory authority, Safe Drinking Water Act process, implementation flexibilities, etc.
- **When it comes to the science, especially when it comes to PFOA and PFOS, the agency's underpinning of the rule is robust and interconnected.**
    - We have found that its **not based on one study or one factor** that if changed, would change the outcome.

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    - Rather, if you **pull one string, the web of scientific underpinning remains substantial and compelling**.
- With that said, the Administrator's direction will **provide significant relief to drinking water systems, ensure that water systems can stay in business, and protect American families from water rate hikes.**
- I will talk about the Administrator's intent to
    - **Keep the current regulations for PFOA and PFOS and un-pause litigation** while
    - **Extending compliance deadlines**
    - Establishing a **federal exemption framework**
    - Pursuing **proactive technical assistance to water systems**—especially in rural and small communities
    - Using the tools available to **hold polluters accountable**
- **At the same time, we intend to rescind the regulations with respect to four additional PFAS.**
    - Specifically, we are announcing the agency's intent to **rescind the regulations and reconsider the regulatory determinations** for PFHxS, PFNA, HFPO-DA (commonly known as GenX), and the Hazard Index mixture of these three PFAS plus PFBS.
    - This action will ensure that the determinations and any resulting drinking water regulation **follow the legal process laid out in the Safe Drinking Water Act**.

<u>Compliance Deadlines</u>

- In terms of the compliance deadlines for PFOA and PFOS, as you are likely aware the 2024 regulation **gave public water systems until 2029** to comply with the maximum contaminant levels, or MCLs.
- Water systems, associations, elected officials, and others have shared with us that **the compliance schedule is one of the biggest challenges for implementation**.
- The Administrator agrees with this, **especially in light of stacking requirements** on PFOA and PFOS and the Lead and Copper Rule.
- To that end, EPA plans to **develop a rulemaking** to provide additional time for compliance, including proposing an **extension of the compliance date to 2031**.
- EPA plans to issue a **proposed rule this fall** and finalize this rule in the Spring of 2026.

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- In addition, in light of this extra time, **EPA encourages states seeking primacy for implementing the PFAS drinking water regulation to request additional time** for developing their applications.

Federal Exemption Framework

- We will also be announcing our **intent to establish a federal exemption framework for PFOA and PFOS**.

Technical Assistance (PFAS Out)

- We know that exposure to PFAS poses a threat to people's health, and the Trump Administration started the ball rolling on addressing PFAS in drinking water.
- With this announcement, we are continuing this important work, and **also announcing our new PFAS OUT initiative**.
- PFAS OUT will enhance engagement on addressing PFAS by **proactively connecting with every public water utility** known to need capital improvements to address PFAS in their systems.
- EPA will **share resources, tools, funding and technical assistance** opportunities to help utilities meet the federal drinking water standards.
- PFAS OUT will ensure that **no community is left behind** as we work to protect public health and bring utilities into compliance with federal drinking water standards.

Broader Actions and Holding Polluters Accountable

- It is critical to underscore that drinking water systems are **passive receivers of PFAS into their source waters, including PFOA and PFOS**.
- Polluters can **contaminate surface waters or aquifers** that water systems rely on as sources for drinking water.
- **As Administrator Zeldin announced on April 28, EPA intends to take a number of actions to reduce the prevalence of PFAS in the environment.**
- By **reducing PFAS at the source**, we can substantially **reduce the costs for water systems and family water bills**.

Close

- Again, **thank you** for taking your time to join this call and for **upholding the embargo**.

- I'll turn it back over to [FACILITATOR].

Facilitator: I will now call on people with questions as their hands are raised.

Facilitator: Thank you for joining today's call. Just a reminder, this information is embargoed until EPA's announcement tomorrow, May 14.

ED_018877_00000421-00004

Message

From: Bender, Emily [Bender.Emily@epa.gov]
Sent: 5/14/2025 5:02:16 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]
CC: Risley, David [Risley.David@epa.gov]; Guzda-Struck, Kathleen [GuzdaStruck.Mary@epa.gov]
Subject: FOR ASAP REVIEW: PFAS Statement

Importance: High

Hi Jess and Peggy-

As you know we are getting incoming on today's PFAS MCL announcement and we have prepared a draft overarching statement, and a few QA's for your consideration and approval. See the suggested statement and QA below to help with the incoming.

Also note: I included the talking points Jess used in her script yesterday that we would like to share with the regions and OPA.

This language has all gone through OGWDW and OGC career staff. We look forward to your feedback.

Thanks so much,

Emily

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

From: Joseph, Dominique <Joseph.Dominique@epa.gov>
Sent: Wednesday, May 14, 2025 8:24 AM
To: Bender, Emily <Bender.Emily@epa.gov>; Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>
Subject: RE: OW Releases This Week
Importance: High

Good morning,

Following up on this. I am hearing that the PFAS MCL press release is going out this morning. Please provide a statement we can share with reporters to address queries we're already getting and will continue to receive.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Dominique Joseph
Office of Public Affairs (OPA)
U.S. Environmental Protection Agency
202-805-3635 (cell)
joseph.dominique@epa.gov

From: Joseph, Dominique
Sent: Monday, May 12, 2025 10:25 AM
To: Bender, Emily <Bender.Emily@epa.gov>; Guzda-Struck, Kathleen <GuzdaStruck.Mary@epa.gov>
Subject: OW Releases This Week

Good morning,

I know there are several OW releases planned for this week and, although the final timing in still in flux, I wanted to reach out in advance to ask for a statement and/or Q&A that I can use in response to the influx of queries that are expected. As the program experts, you usually know what media will ask (or what's missing or not elaborated upon in the press release), so it's just a matter of being prepared for it and I'm sure it will be helpful for all involved.

Dominique Joseph
Office of Public Affairs (OPA)
U.S. Environmental Protection Agency
202-805-3635 (cell)
joseph.dominique@epa.gov

Message

From: KEVIN DOWLING [kdowling@mmm.com]
Sent: 5/13/2025 5:28:36 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Elise Maheu [emaheu@mmm.com]; Todd Weiss [tweiss@crshq.com]; Mat Lapinski [mlapinski@crshq.com]
Subject: RE: Meeting request: 3M Chief Technology Officer
Attachments: PFOA PFOS information.docx; Bibliography for PFOA PFOS discussion.docx; 2023-05-30 - 3M Comments on EPA NPDWR.pdf; Appendix B to 3M Comments on EPA Proposed National Primary Drinking Water Standard.pdf

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Hi Jesscia,

Following up on this request, we'd love to bring in some folks from our scientific team next week to walk through the attached information we shared with ACC and I believe they transmitted to you.

Please let us know if there are any times that work for you next week on Wednesday 5/21 or Friday 5/23? We would like to bring some experts from 3M who can brief you on the attached information. Some of our scientists will be in town for a meeting with the DOD on Thursday so will be in town.

Thanks, and looking forward to it,

-Kevin

3M Science. Applied to Life.™

Kevin Dowling
Head of Government Affairs, United States
Global Government Affairs
3M Company, 1425 K Street NW Suite 300 | Washington, DC 20005 | United States
Time: UTC -5:00 / EST
Mobile: +1 202.963.9089 kdowling@mmm.com

From: KEVIN DOWLING <kdowling@mmm.com>
Sent: Thursday, May 1, 2025 1:35 PM

To: kramer.JessicaL@epa.gov
Cc: Elise Maheu <emaheu@mmm.com>; Todd Weiss <tweiss@crshq.com>; Mat Lapinski <mlapinski@crshq.com>
Subject: Re: Meeting request: 3M Chief Technology Officer

Hi Jessica,

Checking back on this request for you and John Banovetz our EVP/CTO to connect as follow up from the water quality summit. Does May 14th or 15th work for you in DC?

Thanks, and looking forward to it,

Kevin

Kevin Dowling
Head of Government Affairs, United States
Global Government Affairs
3M Company, 1425 K Street NW Suite 300 | Washington, DC 20005 | United States
Time: UTC -5:00 / EST
Mobile: +1 202.963.9089 kdowling@mmm.com

From: KEVIN DOWLING <kdowling@mmm.com>
Sent: Wednesday, April 23, 2025 1:03 PM
To: kramer.JessicaL@epa.gov <kramer.JessicaL@epa.gov>
Cc: Elise Maheu <emaheu@mmm.com>; Todd Weiss <tweiss@crshq.com>; Mat Lapinski <mlapinski@crshq.com>
Subject: RE: Meeting request: 3M Chief Technology Officer

Hi Jessica,

Bumping this up. Can we find a time for you to connect with our CTO John Banovetz next week or in early May?

Looking forward to it,

Kevin

3M Science. Applied to Life.™

Kevin Dowling
Head of Government Affairs, United States
Global Government Affairs
3M Company, 1425 K Street NW Suite 300 | Washington, DC 20005 | United States
Time: UTC -5:00 / EST
Mobile: +1 202.963.9089 kdowling@mmm.com

From: KEVIN DOWLING <kdowling@mmm.com>
Sent: Thursday, April 10, 2025 6:08 PM
To: kramer.JessicaL@epa.gov
Cc: Elise Maheu <emaheu@mmm.com>; Todd Weiss <tweiss@crshq.com>; Mat Lapinski <mlapinski@crshq.com>
Subject: Meeting request: 3M Chief Technology Officer

Hi Jessica:
It was great hearing you @ the Chamber water quality summit last week and we really appreciated your offer to connect with stakeholders. Reaching out to set up a meeting between you and your team with your fellow panelist from last week Dr. John Banovetz, 3M's EVP & Chief Technology Officer, Environmental Responsibility. My colleague Elise Maheu is cc'd and will follow up with some times and we can make whenever / wherever works for you in the coming weeks.

Also, I am sorry I didn't get a chance to say hello last week. I am a Team Zeldin alumn from his House office and my family is in his former district. I am envious that you get to work with Eric and Sarah, I miss them!

Really looking forward to connecting soon. Talk to you soon and thanks,

-Kevin Dowling

Kevin Dowling
Head of Government Affairs, United States
Global Government Affairs
3M Company, 1425 K Street NW Suite 300 | Washington, DC 20005 | United States
Time: UTC -5:00 / EST
Mobile: +1 202.963.9089 kdowling@mmm.com

PFOA Carcinogenicity Designation

- EPA improperly relied on evidence of liver, pancreas acinar cell, and Leydig cell tumors in rats exposed to PFOA and a few selective and unrepresentative citations to associations observed between PFOA concentrations and kidney and testicular cancer in humans, placing particular emphasis on a nested case-control study of renal cell carcinoma conducted by the National Cancer Institute involving the Prostate, Lung, Colorectal and Ovarian (PLCO) cancer screening trial. Shearer et al. (2021).

- As explained in 3M's May 30, 2023 comments to EPA on PFAS National Primary Drinking Water Regulation; Docket No. EPA-HQ-TRI-OW-2022-0114 ("3M's 2023 Comments," attached hereto), EPA incorrectly excluded several occupational exposure studies from their analyses (Steenland and Woskie et al. (2012); Raleigh et al. (2014); Barry et al. (2013)), which collectively demonstrate limited or no association with kidney cancers among workers with 10- to 1000-fold greater exposure to PFOA than seen in the general population.

    - These studies should have been considered by EPA as strong evidence against carcinogenicity. Indeed, Steenland et al. (2022) concluded that the kidney cancer data from Barry et al. (2013), which included both occupational and community-exposed subjects, was statistically inconsistent with Shearer et al. (2021), which included lower-exposed general population subjects. And an effort to combine the two datasets showed that serum levels above approximately 13 ug/L did not present any additional significant risk of kidney cancer – a finding that undermines the generalizability of Shearer et al. (2021). Importantly, occupational cohorts such as followed in Raleigh et al. (2014) included workers with geometric mean serum levels of PFOA as high as 6,800 µg/L. Olsen et al. (2000).
    - Yet, EPA used Shearer et al. (2021), which had very little contrast in exposures among study participants (<4-27 µg/L), to derive a cancer slope factor (CSF) for PFOA of 0.00352 per µg/L PFOA in serum. Applying that slope factor to the occupational exposures in a cohort such as Raleigh would predict an enormous increase in kidney cancer among workers. In contrast, Raleigh et al. (2014) found no association between kidney cancer incidence risk and PFOA exposures among the highest two quartiles of workers, either individually or combined, compared with the referent non-occupationally exposed worker population. Q3 HR = 0.98 (95% CI: 0.33-2.92); Q4 HR = 0.73 (95% CI: 0.21-2.48); Q3 & Q4 Combined HR = 0.85 (95% CI: 0.36-2.06). Likewise, Barry et al. (2013) found no increased risk among the occupationally exposed cohort members who had median estimated annual PFOA serum levels of 174.4 ug/L (range: 5.2-3683 ug/L): HR (no lag) = 0.95 (95% CI: 0.59-1.52); HR (10-year lag) = 0.99 (95% CI: 0.67-1.46).

- As explained more fully in 3M's 2023 Comments, EPA's derivation of the PFOA CSF from Shearer et al. (2021) also appears to be flawed (failed to properly include the mid-points of the exposure categories in the derivation) and EPA used inconsistent methods for deriving candidate CFSs from different studies. EPA offers no explanation for these discrepancies, which appear to be arbitrary.

- As explained in 3M's 2023 Comments, EPA did not properly assess Shearer et al. (2021) for flaws that undermine its reliability, including use of a single serum measurement, inadequate control for confounding by key risk factors such as smoking, body mass index, and history of hypertension, and the potential for reverse causation given that serum PFOA measurements (the exposure variable) can be impacted by kidney function (which can be impacted by the cancer outcome being studied). As noted by Burgoon et al. (2023), "[w]hile Shearer et al. (2021) adjusted their results for estimated glomerular filtration rate (eGFR), adjusting for eGFR alone would not adequately control for potential confounding due to the extensive role of renal transporters in the clearance of PFOA."

- EPA also did not consider the impact of the case/control design of Shearer et al. (2021) on the reliability of the results. As explained in 3M's 2023 comments, the lowest exposure category in Shearer et al. (2021), which served as the reference group for the study, had fewer cases (47) than controls (81), which could have biased the statistical comparisons with the other exposure categories.

- EPA's assessment also improperly failed to account for Rhee et al. (2023) and Purdue et al. (2023), which were published after EPA promulgated its proposed rule for notice and comment but before EPA published its final rule. Rhee et al. (2023) was conducted by the same researchers at the National Cancer Institute that conducted Shearer et al. (2021) and used a similar design with general population subjects. But it involved a larger and more diverse study population derived from the Multiethnic Cohort. Contradicting Shearer et al.'s findings, it reported a non-significant *decrease* in renal cell carcinoma risk with doubling of PFOA serum level: $OR_{continuous} = 0.89$ (95% CI: 0.67, 1.18). Purdue involved a nested case-control design of U.S. Air Force servicemen and it found no associations between PFOA and testicular germ cells tumors either before or after adjustment for other PFAS exposures. Without further comment, in documentation accompanying the final rule EPA inexplicably indicates these study warrant "no change" in its cancer assessment. USEPA (2024).

- EPA's reliance on rodent chronic toxicity studies demonstrating liver, Leydig cell, and pancreas acinar cell tumors as supporting its human carcinogenicity designation for

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PFOA is also unsupported. It is well known that these types of tumors in rats are associate with peroxisomal proliferation, a response of limited relevance to human exposures. Burgoon et al. (2023); Corton et al. (2018); Klaunig et al. (2012); ATSDR (2021). As explained further in 3M's 2023 Comments, EPA researchers have previously acknowledged that the peroxisomal proliferation mechanism observed in rodents is not relevant to humans in a peer-reviewed article entitled "The PPARα-dependent rodent liver tumor response is **not** relevant to humans" (Corton et al. (2018) (emphasis added)). The agency failed to acknowledge its own scientists' findings. As further evidence of the irrelevance of these rat findings, fibrate drugs, which are also peroxisome proliferators, are widely prescribed for managing blood lipids. In rodents, similar to PFOA, they produce these same triad of tumors. Cook et al. (1999); Biegel et al. (2001). Yet they have not been shown to result in cancer in humans. Bonvas et al. (2012).

- The animal and mechanistic evidence relied on by EPA to support its PFOA carcinogenicity classification also fail to justify its myopic reliance on the kidney cancer association observed in Shearer et al. (2021) for its cancer slope factor derivation. Burgoon et al. (2023) note that if PFOA were a genuine kidney carcinogen, "one might expect that the massive doses of PFOA used in the rodent (and monkey) bioassays would have also induced kidney tumors. Yet, they did not." Excess renal tumors were seen in the three available PFOA chronic rat studies (NTP (2020); Butenhoff et al. (2012a); Biegel et al. (2001)).

PFOS Carcinogenicity Designation

- EPA improperly relied on the observation of liver tumors and pancreas tumors in PFOS-exposed rats (Thomford (2002); Butenhoff et al. (2012b)), and selective and unrepresentative citations to associations observed between PFOS and cancer outcomes in humans to conclude that PFOS satisfied its classification criteria for "likely to be carcinogenic to humans."

- The epidemiological literature regarding PFOS does not support EPA's designation. As described more fully in 3M's 2023 Comments, the majority of the studies identified by EPA as relevant for assessing whether PFOS is carcinogenic found no increased risk, or in one case, even a reduced risk of cancer from PFOS exposure.

    - In particular, the EPA's failure to give proper consideration to Eriksen et al. (2009), a study with the same methodology as Shearer et al. (2021) on which EPA heavily relies for its PFOA assessment, is arbitrary and unsupported. Notably, while EPA relies on liver and pancreas tumor findings in rats to support its PFOS classification, Ericksen et al. (2009) did not find a significantly significant

association by quartile of PFOS exposure or trend across quartiles for either cancer type.

- Further, while EPA references a significant association with liver cancer reported in Goodrich et al. (2022) above an arbitrarily 54.9 µg/L PFOS serum cut off, numerous other studies, including occupational cohorts with much higher exposure contrasts, do not report significant associations with PFOS. Olsen et al. (2004); Grice et al. (2007); Eriksen et al. (2009); Alexander et al. (2024); Moon et al. (2024); Li et al. (2022).

- Notably, in its most recent hazard assessment of the carcinogenicity of PFOS, IARC found the human epidemiological evidence supporting inadequate to support an association with any type of cancer. IARC (2025).

- As explained further in 3M's 2023 Comments, similar to its assessment of PFOA rat studies, EPA did not consider the biological plausibility and human relevance of the rat liver and pancreas tumor findings in Thomford (2002)/Butenhoff et al. (2012b). Receptor-mediated liver tumors in rats, whether mediated by activation of the chimeric antigen receptor (CAR) or PPARα receptor, are not relevant to humans. Corton et al. (2018); Hall et al. (2012). Nor are the other potential modes identified by EPA – hepatocyte nuclear factor 4 alpha (HNF4α) suppression, cytotoxicity, genotoxicity, oxidative stress, and immunosuppression – biologically plausible in humans. With respect to the pancreas tumor findings, it has been well-documented that there are substantial differences in pancreatic islet cells between rodents and humans in terms of anatomy, cellular components, gene expressions, and functional aspect of insulin secretion. Brissova et al. (2015); Steiner et al. (2010). EPA did not take these differences into account in considering human relevance.

- As further explained in 3M's 2023 Comments, EPA also improperly used two different models to interpret the liver tumor findings, which violates its own *Guidelines for Carcinogenic Risk Assessment.* USEPA (2005)

- EPA also improperly recalculated the statistical significance of pancreas tumor trends in Thomford (2002)/Butenhoff et al. (2012) by using a non-standard approach of eliminating animals who were sacrificed before the appearance of the first pancreas tumor from the analysis. EPA clearly did this to manufacture a significant outcome *post hoc* to justify their pre-determined classification decision. As explained in 3M's 2023 Comments, traditional statistical methods used by the authors adequately accounted for survival.

- The science does not support EPA's classification of PFOS based on its alleged "structural similarity" to PFOA. As outlined in 3M's 2023 Comments, the structural differences between PFOA and PFOS – carboxylic vs. sulfonic acid functional groups – impart significantly different physical-chemical properties to these compounds, which explains their different technical applications as well as differences in biological disposition and receptor site dynamics. Notably, while the PFOA and PFOS chronic toxicology studies in rats both show increased incidences of liver tumors, other sites differ. Further, EPA did not follow its own best practices for applying read across, including failing to follow its seven key workflow steps for evaluating read across or otherwise use its Generalized Read Across Tool.

EPA's Setting of PFOA/PFOS MCLgs To Zero

- EPA improperly set the MCLgs for both PFOA and PFOS to zero. In reaching this decision, EPA assumed a linear-no threshold model of carcinogenicity based on default assumptions of EPA's Guidelines for Carcinogenic Risk Assessment (USEPA (2005)), rather than analysis of the weight of evidence. As detailed in 3M's 2023 Comments, however, the weight of evidence does not support a mutagenic/genotoxic mode of action for either PFOA or PFOS. And the receptor-mediated and cytotoxic modes of action postulated by EPA display non-linear, threshold effects – effects that have not been shown to occur at human relevant exposure levels. See, *e.g.*, Evans et al. (2022); Hall et al. (2012); Beggs (2016). To the extent that EPA relies on these modes of action to support its PFOA and PFOS carcinogenicity classification, it should not assume PFOA/PFOS have no threshold for carcinogenic effects. It is inappropriate for EPA to set a MCLg at zero based on carcinogenicity when a substance does not have a linear mode of carcinogenic action. *Chemistry Council v. EPA*, 206 F.3d 1285, 1287 (D.C. Cir. 2000).

Non-Cancer Endpoints

- EPA identified four critical endpoints from non-cancer outcomes for which it derived reference doses (RfDs) for PFOA and PFOS: developmental effects (decreased birthweight); cardiovascular effects (total cholesterol); liver effects (alanine transaminase (ALT)); immune effects (vaccine antibody response). EPA's approach to assessing the overall weight of evidence for non-cancer health effects of PFOA and PFOS is not consistent with its guidance, and EPA's methods were neither transparent nor reproduceable.

- In addition, as explained in 3M's 2023 Comments, across all of these endpoints EPA relied on studies that used outdated and uncorrected NHANES data and EPA did nothing to verify the accuracy of the data or account for these discrepancies.

- ***Developmental Effects (Decreased Birth Weight)***

  - Overall, the available evidence relating to developmental outcomes was limited and inconsistent for any effects from PFOA or PFOS exposure. As explained in 3M's 2023 Comments, EPA failed to properly consider and account for potential bias in the birth outcomes evaluated in the studies due to pregnancy hemodynamics and PFOA/PFOS sample timing; mixed evidence for gestation duration, measured as gestational age or preterm birth; inconsistent evidence with rapid growth measures, including postnatal height and adiposity up to age 2; little evidence for increased fetal loss; no evidence for increased birth defects; and limited dose-response evidence in birth weight deficit studies.

  - In particular, EPA failed to demonstrate that the studies it relied on for the critical effect of decreases in birth weight were free from bias. As explained in 3M's 2023 Comments, studies show that serum volume increases by about 50% and glomerular filtration rate (GFR) on the same order (40-50%) during pregnancy (Salas et al. (2006); Cheung and Lafayette (2013)). These increases lead to a commiserate decrease in maternal serum PFAS concentration during pregnancy (Monroy et al. 2008; Steenland et al. 2018; Kato et al. 2014) and the magnitude of serum volume and eGFR increases can be correlated with birth weight. This makes the timing of serum sampling in birthweight studies critical in evaluating any association with PFOA/PFOS serum levels. Two meta-analyses by Dzierlenga et al. (2020) and Steenland et al. (2018) found that when PFOA and PFOS were measured in early pregnancy, there was little to no association with decreased birth weight, suggesting that the timing of serum measurement is critical for accurate interpretation of study results. Even though the study EPA relied on for its RfD derivation involved sampling in the first trimester (Wikstrom et al. (2020)), its findings were inconsistent with others with similar sample timing, and it did not attempt to adjust for estimate GFR (unlike other studies). EPA did not demonstrate that Wikstrom et al. 2020 was free from pharmacokinetic bias.

  - As discussed in 3M's 2023 Comments, EPA failed to show that decreases in birthweight observed in studies, even if due to PFOA/PFOS exposure and not pregnancy hemodynamics and PFOA/PFOS sample timing, represent adverse effects or lead to any other clinically meaningful health outcomes.

- ***Cardiovascular Effects (Cholesterol)***

  - EPA did not justify its selection of studies to evaluate for cardiovascular disease RfD derivation. As described in 3M's 2023 Comments, EPA considered only three studies

(Dong et al. 2019; Lin et al. 2019; Steenland et al. 2009), but there were numerous additional medium (Averina et al. 2021; Christensen et al. 2019; Domazet et al. 2016; Donat-Vargas et al. 2019; Fan et al. 2020; Han et al. 2021; Jain and Ducatman 2018; Jain 2019; Kang et al. 2018; Kobayashi et al. 2022; Lin et al. 2009, 2019, 2020; Liu et al. 2018, 2020; Mora et al. 2018; Papadopoulou et al. 2021; Skuladottir et al. 2015; Spratlen et al. 2020; Tian et al. 2021; Zare Jeddi et al. 2021; Eriksen et al. 2013; Fisher et al. 2013; Geiger et al. 2014; Nelson et al. 2010; Sakr et al. 2007; Timmermann et al. 2014; Winquist and Steenland 2014) and high confidence (Gardener et al. 2021; Li et al. 2021) studies it did not consider.

- The cardiovascular disease endpoint was not an appropriate critical effect choice. As noted in 3M's 2023 Comments, EPA acknowledges that the evidence for most cardiovascular-related endpoints such as changes in blood pressure, hypertension, coronary heart disease, and stroke is inconsistent. See also ATSDR (2021); Steenland et al. (2020).

- EPA did not properly consider confounding in selecting the studies evaluating total cholesterol for PFOS/PFOA RfD derivation. As explained in 3M's 2023 comments, dietary habits, family history, and even exercise can have effects on cardiovascular outcomes, including cholesterol measurements. Vincent et al. (2019); Allen et al. (2016); Mensink et al. (2003); Lin et al. (2019). Because of potential confounding due to enterohepatic circulation of both PFOA/PFOS and bile acids *in vivo*, the European Food Safety Authority (EFSA) decided not to use cholesterol as a critical effect for derivation of its tolerable weekly intake values for PFOA and PFOS. EFSA (2020).

- **Liver Effects (alanine transaminase (ALT))**

  - For both PFOA and PFOS, EPA selected increases in ALT as a critical effect for derivation of RfDs. However, as described in 3M's 2023 Comments, EPA failed to characterize the biological relevance of changes in ALT or other liver biomarkers in the context of quantitative clinical outcomes. As EFSA (2020) pointed out, while there is evidence for elevated ALT due to PFOA exposure, the adversity of this effect is uncertain because of the low magnitude of increases and no associations with liver disease.

  - As explained in 3M's 2024 Comments, EPA's reliance on animal studies involving rodents as support for liver affects is also misplaced, as these liver effects involve mechanisms of action with questionable relevance to humans, such as pathways moderated by peroxisome proliferator-activated receptor-alpha ("PPARα").

- EPA also used inappropriate studies to derive its RfD values. As explained in 3M's 2023 Comments, EPA derived its candidate PFOS RfD for elevated ALT from Nian et al. (2019), which was a cross-sectional study from China that reported a 4.1 percent change (95% CI: 0.6, 7.7) in ALT for every 1 ng-mL increase in PFOS. But the change became non-significant when participants taking medications were excluded. And confounding variables, such as alcohol, smoking and diet, were not adequately controlled.

- ***Immune Effects (Vaccine Antibody Response)***

  - EPA determined that there was moderate evidence for an association between PFOA/PFOS exposure and immunosuppressive effects in human studies relying on decreases in antibody responses to various vaccination types observed in children in several studies. However, as described in 3M's 2023 Comments, there were significant uncertainties in the potential immune effects of PFOA and PFOS across studies, including: (1) inconsistent findings of decreased vaccine response in adult populations; (2) Inconsistent and/or imprecise findings of increased infectious disease; (3) mixed findings of hypersensitivity, including allergy, asthma, and eczema; and (4) mixed findings for autoimmune disease.

  - Even with respect to antibody response to diphtheria and tetanus vaccines in children, the results have been inconsistent. As explained in 3M's 2023 comments, the associations between vaccine response for tetanus or diphtheria with PFOA or PFOS exposures in cohorts from the Faroe Islands were not consistent either by age or by vaccine type across several studies (Grandjean et al. (2012); Grandjean et al. (2017a,b); Mogensen et al. (2015); Shih et al. (2021)). The alternate candidate study selected by EPA involving Greenlandic children also had critical limitations that should have been identified as part of a proper systematic review. Timmerman et al. (2021).

  - Deficiencies in the epidemiological evidence relating to vaccine antibody response make it an inappropriate critical endpoint for use in EPA's PFOA/PFOS risk assessment. As described in 3M's 2023 Comments, ToxStrategies conducted an independent assessment of studies examining vaccine response and PFOA exposure using the same IRIS framework for systematic review and critical appraisal of studies used by the EPA in the draft toxicity assessment for PFOA. See 3M's 2023 Comments, Appendix A.

- After identification and critical appraisal of studies examining vaccine response and PFOA exposure in the independent assessment, all studies received an overall rating of "deficient" or "critically deficient." Each study had deficiencies in participant selection, timing of exposure and outcome measures, or confounding, which resulted in a body of evidence that was of low quality with a high risk of bias.

- Based on these findings, vaccine response was not considered appropriate as a critical endpoint for PFOA exposure, and no studies qualified for POD development. Garvey et al. (2023) also conducted an independent review of the evidence and concluded that: "the Faroe Islands cohort data should not be used as the primary basis for deriving PFAS risk assessment values. The panel agreed that vaccine antibody titer is not useful as a stand-alone metric for risk assessment. Instead, PFOA and PFOS toxicity values should rely on multiple high-quality studies, which are currently not available for immune suppression."

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May 30, 2023

Submitted electronically via Regulations.gov

Mr. Alexis Lan
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Re: 3M Comments on PFAS National Primary Drinking Water Regulation; Docket No. EPA-HQ-TRI-OW-2022-0114

Dear Mr. Lan:

The 3M Company (3M) appreciates the opportunity to provide comments on the U. S. Environmental Protection Agency's (EPA) March 23, 2023 proposed rule (the Proposed Rule) to establish National Primary Drinking Water Standards (NPDWRs) for certain per- and polyfluoroalkyl substances (PFAS). 3M has included two appendices containing extensive technical information supporting and in addition to the comments below for EPA's consideration during this public comment period.

3M supports proactive management of PFAS and the goal of using science-based regulatory standards, based on a complete review of the best available scientific information, to provide communities with high-quality drinking water. More than 20 years ago, in 2000, 3M announced its exit from the manufacture of perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), two of the PFAS that are the subject of the proposed NPDWRs. Late in 2022, 3M announced that it would cease all PFAS manufacturing by the end of 2025 and work to eliminate the use of PFAS across its product portfolio by the end of 2025. As it works toward its exit from all PFAS chemistries, and even following that exit, 3M will remain committed to working together with all stakeholders to develop reasonable, science-based actions that address PFAS in the environment in view of the continued uses of PFAS in critical industries across our modern economy.

To that end, the proposed NPDWRs are not a science-based response to the presence of the specified PFAS in drinking water. The proposed standards do not reflect the findings of important scientific literature that should help inform the establishment of drinking water standards for PFAS, nor do they sufficiently address the pointed criticisms and recommendations of EPA's own Science Advisory Board (SAB), which is tasked with ensuring the Agency's actions are supported by sound science. EPA should reconsider its proposal and work with all stakeholders to ensure that the full range of scientific evidence is appropriately considered and incorporated into the regulatory process.

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In short, a science-based approach to this issue would have resulted in a proposal to improve water quality that met statutory requirements. Regrettably, that is not what happened here because, as we explain below, the process that EPA used to develop its NPDWRs was deeply flawed and has resulted in proposed NPDWRs that exceed the agency's authority and can only be characterized as arbitrary and capricious. 3M encourages EPA to revise its proposed standards to reflect the collective body of best available science, which has not been reflected in the rulemaking process to date. This will help ensure that water treatment technologies are deployed where doing so will provide meaningful benefits. 3M remains ready and eager to partner with EPA in that effort.

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I. EXECUTIVE SUMMARY

As discussed below, EPA's proposed NPDWRs violate the Safe Drinking Water Act (SDWA) because they are not based on the "best available, peer-reviewed science,"[1] and because EPA did not follow statutorily defined procedures and, in many cases, its own well-established guidance in promulgating them. EPA did not appropriately establish and follow processes designed to help ensure its rulemaking reflects the weight of the evidence-based conclusions about potential consequences of exposure to the PFAS at issue, and the levels at which such consequences could be observed. The processes for collecting and evaluating scientific research are not matters of interpretation or preferred approach. They are foundational scientific practices and guidance, including, in many cases, the Agency's own guidance. Here, EPA has significantly deviated from those foundational practices. This has resulted in a proposal for incredibly low regulatory limits for PFOA, PFOS, and the Hazard Index (HI) substances (perfluorohexanesulfonic acid [PFHxS], perfluorobutane sulfonic acid [PFBS], perfluorononanoic acid [PFNA], and hexafluoropropylene oxide dimer acid [HPFO-DA]) in drinking water without showing that any benefits of such low limits are justified by their significant costs. The agency's flawed process has resulted in proposed NPDWRs that are arbitrary and capricious as they do not achieve the goal of appropriately balancing the costs of compliance against the expected benefits.

EPA Did Not Establish and Follow Required Procedures Designed to Ensure SDWA Compliance and Promote Regulation Based on the Best Available Science

EPA did not follow established best practices, including its own long-standing guidance, to conduct a systematic review of the relevant scientific literature. A proper systematic review is important to ensure that the Agency's conclusions are driven by science and are transparent to the public. Although EPA has long-standing guidance on how to conduct a systematic review, it did not follow it. Here, EPA's own SAB, in its *Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS*, "identified multiple inconsistencies and deficiencies in both the description and execution of the systematic review process utilized in the evaluation of both PFOA and PFOS." (USEPA SAB 2022, p. 3.)[2] SAB also noted that EPA did not publish a pre-defined review protocol, did not have transparent criteria for study inclusion and exclusion, omitted studies that should have been considered, and improperly categorized studies, resulting in a review with "major deficiencies." (USEPA SAB 2022, p. 3.) These issues were so significant that at least one SAB member indicated EPA's systematic review did not "represent the state of practice."

As discussed herein, EPA did not meaningfully implement SAB's feedback. This resulted in an after-the-fact systematic review protocol that is contrary to the SAB's feedback and the Agency's own guidance. *See e.g., ORD Staff Handbook for Developing IRIS*

[1] 42 U.S.C.A. § 300g-1(b)(3)(A).

[2] A complete list of references is available at the end of this document and each of the appendices. Each reference list is specific to the document it accompanies and may have different lettering or other designations when referring to the same document. Those designations may also be different than those in the EPA docket. Refer to the reference list for complete document identification.

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Assessments, (USEPA ORD 2022, pp. xiv-xvii) ("The transparency and scientific rigor of the IRIS process is enhanced through the application of systematic review . . . The IRIS process applies a systematic review approach from the literature identification stage through the selection of studies for dose-response assessment"); USEPA SAB 2022 p. 3 ("***Before*** initiating a systematic review process, it is essential to clearly define the study question to be addressed and to develop a protocol.") (emphasis added).

The absence of a rigorous, prescribed systematic review has had a serious impact on the rulemaking process. For example, the lack of a pre-defined review protocol led to outsized weight being placed on studies that have highly material deficiencies while underweighting higher-quality studies that do not support the proposed limits. Further, EPA reliance on cancer endpoints as the basis for a maximum contaminant level goal (MCLG) of zero for PFOA and PFOS is not consistent with the evidence EPA presents nor with its own guidance. Similarly, EPA did not establish review processes designed to ensure that the weight of evidence supports its new classification of PFOS as "likely" to be carcinogenic to humans.

EPA's derivation of its alternate, non-cancer reference doses (RfDs) for PFOA and PFOS are similarly in need of reconsideration and revision. In calculating the RfDs, EPA did not follow its own guidance documents including EPA's *ORD Staff Handbook for Developing IRIS Assessments* (USEPA ORD 2022). These procedures are important for transparency and reproducibility in study evaluation. An appropriate evaluation of the existing literature, consistent with EPA guidance, would have found many of the studies that EPA relied on to calculate the extremely low RfDs for these PFAS were low quality and at high risk of bias, therefore leading EPA to reach different conclusions.

The Proposed Rule is also based on profound uncertainty and assumptions, which EPA did not properly quantify and explain in its rulemaking documents. EPA defines "uncertainty" as "a lack of knowledge about factors affecting exposure or risk" (USEPA 2019, p. 1-7).. "Uncertainty factors" are "used in noncancer risk assessments when insufficient data are available to support the use of chemical-specific and species-specific extrapolation factors" (OEHHA 2008). Because uncertainty factors are used to address a lack of data, the higher the total uncertainty factors, the lower the confidence in the accuracy of the analysis. For its evaluations of HFPO-DA and PFHxS, EPA has assigned "uncertainty factors" totaling 3,000—the maximum that could be considered as the basis of a reference value according to EPA's IRIS Handbook. Had the uncertainty factors been any higher, EPA's own guidance would have precluded it from setting a reference value for those substances. In adopting a total uncertainty factor of 3,000, EPA implicitly acknowledges that its proposed RfDs for those substances are, at best, on the very edge of acceptability. This is important because "uncertainty factors" only account for specific sources of uncertainty in the Proposed Rule. They do not account for significant additional uncertainties, including uncertainties resulting from EPA's poor systematic review, inconsistent and non-transparent study quality evaluations, lack of an independent verification of underlying analyses of the selected points of departure, and the absence of peer review of the proposed hazard index MCLG. Accordingly, EPA's uncertainty factor of 3,000—already at the margins of acceptability—significantly understates the actual uncertainties inherent in EPA's proposal for those substances.

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EPA Did Not Follow SDWA Best Practices in Calculating the Benefits of the Proposed Regulations

The SDWA requires EPA to show that the benefits of its proposed regulations justify the costs. EPA did not comply with that requirement in several important respects.

As an initial matter, EPA's analysis of estimated benefits related to its proposed standards for PFOA and PFOS violates the SDWA's requirement that it analyze separately the benefits of each proposed regulatory standard because EPA improperly conflated its benefits analysis for the two separate regulations. *See* SDWA §1412(b)(3)(C)(i)(I) (stating that EPA "shall" publish and seek public comment on certain considerations including anticipated benefits of regulation at alternative levels for "a maximum contaminant level that is being considered."). For example, EPA's estimated impact on total cholesterol from reducing PFOS is nearly two orders of magnitude less than the reduction in total cholesterol that EPA calculated for PFOA, but EPA combined those levels in its benefits analysis. It did not analyze separately the benefits for PFOA and PFOS individually, as required by the SDWA.

EPA also has not provided enough information in the record to allow the public to understand how EPA conducted its benefits analysis, which precludes meaningful peer review and comment. EPA's benefits analysis is not reproducible or adequately transparent to the public because EPA has not made important inputs and models available for public or peer review.

From the available information, EPA's benefits analysis appears unreliable. EPA purports to distinguish between the benefits of alternative drinking water exposure concentrations of 4.0 ppt, 5.0 ppt, and 10.0 ppt. However, foundational toxicological principles demonstrate that those levels are so similar that there is likely no way to discern changes in benefits between them (and EPA has not provided the information in the record to explain how it purported to do so).

Similarly, EPA did not provide the pharmacokinetics models underlying its estimates of blood serum PFOA and PFOS concentrations on which it based its benefits analysis. *See* (USEPA 2023a,b,c,d). The serum data estimate is a foundational conclusion supporting EPA's entire benefits analysis. It is the first value input in a sequence that is ultimately used to estimate the health risk reduction benefits for the proposed maximum contaminant level (MCL) and the regulatory alternatives. Without access to the models underpinning the input, the public and scientific experts cannot meaningfully understand and evaluate the scientific validity of EPA's conclusions about the relative benefits of a 4.0 ppt MCL versus a 5.0 ppt or 10.0 ppt alternative.

EPA's benefits analysis also does not consistently take alternative exposure considerations into account and improperly combines estimated benefits for PFOA and PFOS. This results in inflated estimates of the anticipated individual benefit calculation for each proposed regulatory standard and flawed human equivalent internal dose responses that introduce significant uncertainty about EPA's ultimate conclusions.

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EPA's Proposed Hazard Index-Based MCL for PFHxS, PFBS, PFNA, and HFPO-DA Does Not Comply with the SDWA

EPA's proposed Hazard Index-based Maximum Contaminant Level (HI-MCL) for PFHxS, PFBS, PFNA and HFPO-DA is procedurally improper and substantively incorrect, for several reasons.

As an initial matter, the SDWA does not permit the Agency to simultaneously issue a notice of intent to regulate and a proposed MCLG and MCL. EPA may issue a *decision to regulate* at the same time that it proposes an MCLG and MCL, but it may not provide initial public notice that it is contemplating regulation at the same time it proposes the regulation. The failure to undertake the statutorily required two-step process undermines the validity of the EPA's proposals.

In addition to being procedurally improper, EPA's development of the HI-MCL is also substantively flawed. EPA's approach assumes co-occurrence of the four PFAS included in the hazard index, but EPA has not provided meaningful occurrence data showing substantial likelihood that those substances co-occur. Further, EPA's discussion of potential co-occurrence is replete with examples of EPA relying on data from sources that EPA claims supports its argument while ignoring sources that clearly undermine it. For example, the co-occurrence data presented at the system level for detection of any relevant PFAS shows wide variability among states (USEPA 2023h, p. 197), and states with the most systems tested show much lower frequency of co-occurrence detections.

EPA's interpretation of the data it selected is also flawed and has not been peer-reviewed, in violation of the SDWA. EPA created the HI-MCL after SAB review, and based it on Health-Based Water Concentrations (HBWC) for the four HI substances that were not submitted to SAB. This violates the SDWA, which requires that EPA request comments from the SAB "prior to proposal of a maximum contaminant level goal and national primary drinking water standard."[3]

The absence of necessary peer review resulted in EPA making substantive errors that could have been identified and addressed before publication of the Proposed Rule. For example, EPA's selection of reference values for the four PFAS for which it is now issuing a preliminary regulatory determination contains important technical errors, including reliance on standards or studies that have been discredited and fail to account for numerous uncertainty factors. The proposed NPDWR also contains a math error in calculating the HBWC for PFHxS that resulted in EPA proposing an HBWC of 9 ppt instead of 10 ppt.

Finally, EPA also violated the SDWA when it did not consider any alternatives for the HI-MCL itself, or for the HBWCs that underpin it. Consideration of a reasonable range of

[3] SDWA §§ 1412(b)(3)(A)(i) and (g)

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alternatives is required by both the SDWA, and the Unfunded Mandates Reform Act.[4] It also meant that EPA did not adequately consider the point at which benefits expected to result from the proposed HI-MCL outweigh its costs, as required by the SDWA.

[4] SDWA § 1412(b)(3)(C)(i); 2 U.S.C. § 1535.

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II. LEGAL FRAMEWORK

The SDWA regulates public water systems by limiting the allowable level of substances in drinking water.[5] Prior to promulgating an MCLG or MCL, EPA must (1) identify substances for listing on the Contaminant Candidate List ("CCL"), and (2) determine which of those substances it will regulate under the SDWA.[6] At each step, EPA must follow specific procedures, consider information prescribed by the SDWA, and offer opportunities for public engagement.

When considering which substances from the CCL to regulate, the SDWA requires EPA to consider:

(1) Whether the substance may have an adverse effect on the health of persons;

(2) Whether the substance is known to occur, or there is a substantial likelihood that the substance will occur, in public water systems with a frequency and at levels of public health concern; and

(3) Whether the regulation of such substance presents a meaningful opportunity for health risk reduction for persons served by public water systems.[7]

The decision to regulate "is the beginning of the Agency's regulatory development process, not the end."[8] As EPA continues the analyses required by the SDWA, it may determine that a chemical does not meet the statutory criteria for finalizing a NPDWR.[9] If EPA determines the three statutory criteria are met, it may make a final determination that an NPDWR is needed. That determination to regulate triggers a 24-month statutory period to publish a proposed MCLG and NPDWR, and 18 months after that to promulgate a final standard.[10] Importantly, EPA may only promulgate an NPDWR for a substance that it has determined to regulate through the public notice and comment process.[11]

After determining to regulate a substance, EPA must set an MCLG for each identified substance at a level at which no known adverse health consequences will occur.[12] EPA must then set an MCL for each substance as close to the MCLG as is feasible.[13] Under the statute,

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[5] *City of Portland, Oregon v. EPA*, 507 F.3d 706 (2007).
[6] *Id.* § 300g-1(b)(1)(B).
[7] 42 U.S.C.A. § 300g-1(b)(1)(A).
[8] 85 Fed. Reg. 14098, 14100 (Mar. 10, 2020).
[9] *Id.*
[10] *Id.* § 300g-1(b)(1)(E)I.
[11] *See* 85 Fed. Reg. at 14100 ("The development of the CCL, regulatory determinations, and any subsequent rulemaking should be viewed as a progression where each process builds upon the previous process, including the collection of data and analyses conducted.").
[12] 42 U.S.C.A. § 300g–1(b)(4)(A).
[13] *Id.* § 300g–1(b)(4)(B).

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"feasible" means "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds ... are available (taking cost into consideration)."[14]

The SDWA requires that, when undertaking this process, EPA base its decisions on the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices, and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).[15] The legislative history of the 1996 SDWA Amendments makes clear that Congress intended to ensure that drinking water standards regulations promulgated under the SDWA are meaningful and science-based:

> Our intent was simple. Drinking water standards should not be set just because they are technologically feasible as they are under current law; they must also be justifiable. If we are going to demand that our states, counties and towns spend billions of dollars to comply with new chlorine standards, for example, at the very least, we owe them the assurance that these are dollars well spent. [16]

III. FACTUAL BACKGROUND

a. EPA Has a Clearly Established Process to Set a NPDWR

The process for setting an MCL begins with a determination of which chemicals should be considered for regulation. As discussed above, under the SDWA, EPA is required to publish a list of chemicals (the CCL) that are currently not subject to any proposed or promulgated NDPWRs but are known or anticipated to occur in public water systems. SDWA §1412(b)(1)(B)(i). EPA must publish this list every five years. The list is used to identify priority chemicals for regulatory decision making and information collection.

During the regulatory determination process, EPA selects a minimum of five chemicals from the CCL to evaluate for regulation.[17] Based on the criteria in § 1412(b)(1)(A)(i)-(iii), EPA must make a regulatory determination for whether the chemical ought to be regulated under the SDWA. Once EPA makes a determination to regulate the chemical, EPA must then propose an MCLG and MCL or treatment technique.

The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on human health would occur, allowing an adequate margin of

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[14] *Id.* § 300g–1(b)(4)(D).
[15] *Id.* at § 300g-1(b)(3)(A).
[16] Congressional Record Vol. 141, No. 189, Nov. 29, 1995; S177723; Statement of Sen. Kempthorne. *See also* Congressional Record Vol. 140, No. 62, May 18, 1994, S55929; Statement of Sen. Breaux ("…only contaminants which present a significant threat to public health will be regulated. EPA will also have to base its analysis on sound science and risk assessment when determining whether or not a contaminant poses a significant enough threat to merit regulation.").
[17] SDWA § 1412(b)(1)(B)(ii).

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safety.[18] MCLGs are not enforceable but they are meant to guide public health goals. MCLGs do not take into consideration the limits of detection and treatment technology effectiveness; therefore, they are sometimes set at levels that water systems cannot meet. The way EPA determines MCLGs depends on the type of contaminant targeted for regulation. All microbial contaminants have an MCLG of zero because even one microbial contaminant can cause adverse health effects. The MCLG is also set at zero for chemicals where there is no dose at which the chemical is considered safe, including some chemicals that may cause cancer. Finally, for chemicals that are non-carcinogens but can cause adverse non-cancer health effects, the MCLG is based on a reference dose.[19]

A reference dose (RfD) is defined as an estimate of human daily exposure that is likely to be without an appreciable risk of adverse effects during a lifetime.[20] RfDs are derived using a point of departure (POD). The POD is a dose that represents the low or no effect level derived from dose-response relationships in experimental or observational studies.[21] The most common PODs used to derive RfDs are the no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or statistical benchmark dose (BMD). The BMD, currently EPA's preferred POD, is the dose or concentration that produces a predetermined change in the response rate of an adverse effect.[22] In other words, the BMD is the minimum dose expected to produce a low-level health impact. EPA takes the POD (typically the BMD) and divides that number by uncertainty factors, which are used to account for potential differences between the experimental data and real life (such as the existence of sensitive populations or lack of information). The RfD is then multiplied by body weight and divided by expected daily water consumption to provide a Drinking Water Equivalent Level (DWEL). The DWEL is then multiplied by the relative source contribution (also called the RSC), which is the portion of the total exposure that comes from the ingestion of water. The value at the end of those calculations is the MCLG.

EPA often uses several types of modeling to extrapolate from known data to support risk analyses. Physiologically Based Pharmacokinetic (PBPK) models are mathematical models that can be used to predict absorption, distribution, metabolism, and excretion (ADME) of substances in humans or animal species. Models are built using compartments that correspond to different tissues in the body and describe the relationship between the external exposure dose and the internal plasma or tissue concentration of a compound over a period of time.

Once the MCLG is calculated, EPA then crafts an enforceable standard. Typically, and at issue here, that standard is the MCL. The MCL is the maximum amount of a chemical allowed in water delivered to any user of a public water system. MCLs are set as close to the

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[18] *Id.* § 1412(b)(4)(A).
[19] *See* https://www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants.
[20] *See* https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system
[21] *See* EPA's IRIS Program Glossary: https://sor.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS%20Glossary
[22] *See* https://www.epa.gov/sites/default/files/2015-01/documents/benchmark_dose_guidance.pdf at 6.

MCLG as feasible. Feasible here means taking into consideration cost and the technical limitations of available treatments.

EPA must submit its draft MCLG and MCL for technical peer review to EPA's Science Advisory Board before they are proposed as regulations.[23]

b. History of this Rulemaking Process

EPA began the process of setting this NPDWR in March 2020, when EPA solicited public comment on the preliminary regulatory determinations for contaminants on the fourth CCL. This publication included a preliminary determination to regulate PFOA and PFOS in drinking water. The following year, in March 2021, EPA published its final determination to regulate PFOA and PFOS.[24] In November 2021, EPA requested feedback from the Science Advisory Board (SAB) [25] on four draft documents related to this rulemaking:

- *EPA's Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water*
- *EPA's Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water*
- *EPA's Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water*
- *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)*

In the first two of these documents, EPA proposed an approach to calculating MCLGs for PFOA and PFOS based on an immune effects endpoint. In other words, EPA's proposed MCLGs were based on the exposure to PFOA and PFOS that the Agency determined was expected to result in negative impacts to immune system function. In its *Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS* (the "SAB Final Report"), the SAB strongly criticized many of EPA's approaches and requested EPA provide significant clarification. SAB's criticisms included:

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[23] *See* SDWA §1412(e).

[24] *See* 86 FR 12282.

[25] The Scientific Advisory Board (SAB) is a Federal Advisory Committee made up of subject matter experts. SAB reviews technical information used by EPA for quality and relevance. The board provides advice on EPA proposed regulations and on specific questions posed by the EPA Administrator. SAB's Drinking Water Committee formed a PFAS Review Panel of 16 experts on the scientific and technical aspects of PFAS. As subject matter experts, specifically chosen to provide guidance on the scientific aspects of EPA regulations, their recommendations and analysis should have been taken seriously by EPA when it received feedback on this proposed rule.

- "EPA should provide additional transparency and completeness in its evidence identification methodology, including development of a protocol with clear inclusion/exclusion criteria and study evaluation approaches."

- "Studies, particularly human studies, that were included in the 2016 health effects summary documents (HESDs) should be considered in the same manner as the more recent studies."

- "EPA needs to provide additional details and transparency for all quantitative modeling, including that used for CSF [cancer slope factor] development, toxicokinetic modeling, and benchmark dose modeling for POD derivation. It is essential that details of the Benchmark Dose (BMD) modeling that forms the basis of the PODs are transparently available for evaluation of the methods, approaches, and results."

- "EPA should provide a stronger and more transparent justification for the choice of benchmark responses (BMRs)"

When EPA ultimately published its proposed PFAS NPDWR in March 2023, EPA shifted from relying on the immune effects endpoint to cancer endpoints for PFOA and PFOS in the proposed NPDWR.

EPA also submitted to the SAB in November 2021 its *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances* for SAB review which would, according to EPA, "inform development of the MCLGs and NPDWR **for PFOA and PFOS**." (emphasis added). This Draft Mixture Framework did not present an MCL framework for the four Hazard Index (HI) PFAS, nor did it set proposed health-based water concentrations (HBWCs) for the HI PFAS. In this draft document, EPA acknowledged that HBWCs "would need to be calculated in order to develop component HQs [hazard quotients] and an overall PFAS mixture HI," but made no such calculation. In other words, EPA never submitted draft HBWCs to SAB for review.[26]

In March 2023, EPA proposed this NPDWR regulating PFOS, PFOA, PFHxS, HFPO-DA, PFNA, and PFBS, including HBWCs for the HI PFAS.

IV. EPA's FLAWED SYSTEMATIC REVIEW UNDERMINES THE SOUNDNESS OF EPA'S ANALYSIS FOR ALL SIX SUBSTANCES

A proper systematic review of the relevant scientific literature is the foundation for the agency to reach scientifically sound conclusions. As described by EPA's IRIS Handbook, EPA must review the full body of available scientific information, identify the subset of that information that is the best available, explain the basis for that decision, and then analyze that

[26] Moreover, EPA "emphasized" to the SAB "that the draft mixtures document is not a regulation, does not impose legally binding requirements on EPA, states, tribes, or the regulated community, and might not apply to a particular situation based on the circumstances." (USEPA SAB 2023, p. 1-2.)

information to come to an ultimate conclusion (USEPA ORD 2022, EPA 2012). The agency cannot make its regulatory decision and selectively cite scientific studies that support the decision while ignoring equally valid but contradictory scientific information. For two of the six substances—PFHxS and PFNA—EPA did not conduct a systematic review and instead relied on the conclusions of the Agency for Toxic Substances and Disease Registry (ATSDR). For the remaining four substances, EPA has selectively cited studies to support its decision.

In reviewing EPA's draft documents, EPA's own SAB and numerous other commenters pointed out several major failings, including that EPA failed to publish a pre-defined review protocol. The SAB noted

> Significant concerns that the reviews for PFOA and PFOS do not appear to have established a predefined protocol. The lack of a protocol led to a lack of clarity across each of the major systematic review steps for both chemicals and was seen as a major deficiency of the reviews. (USEPA SAB 2022, p. 3)

For example, the SAB "found that the inclusion and exclusion of epidemiologic and animal studies was inconsistent across endpoints, leading to confusion about the criteria being used." Similarly, the SAB found that EPA's literature review ignored studies that should have been considered, including some of those EPA relied on for its 2016 health advisory levels (HALs) for PFOA and PFOS, and some of which may have changed EPA's conclusions regarding the potential hazard of exposure to PFOA and PFOS at low levels.[27] Indeed, the SAB concluded that "[t]he rationale for not considering studies, particularly human studies, that were included in the [2016 HALs] is not clear or supportable. There is no reason to conclude that the earlier studies are less relevant or of lesser quality than the newer studies." (USEPA SAB 2022, p. 5; *see also* p. 14-15.) The SAB also "concluded that the decision to exclude literature published within the timeframe of the development of the 2016 health effects support document in the current literature search was unjustified." (USEPA SAB 2022, p. 5)

EPA's lack of a review protocol raises serious questions about the integrity of EPA's systematic review. It precludes clarity into how EPA decided which studies to review, how to weigh the studies it did review and, ultimately, how it decided which studies would form the foundation for its proposed levels. EPA also did not follow the same protocol across the multiple reviews it conducted, another major failure that the SAB identified (EPA SAB 2022).

EPA has not sufficiently addressed these and the SAB's other foundational concerns in the Proposed Rule. Instead, and as discussed below, EPA continues to pick and choose scientific studies based on unknown and non-transparent conditions (violating EPA's own procedures on conducting systematic reviews) which appears to have biased EPA's review to favor studies that support the low regulatory levels EPA has proposed and omit discussion of studies that do not

[27] During review hearings, SAB Board members expressed significant concern about the draft approach documents, with at least one noting they do not "represent the state of practice" around information gathering. Another Board member said there were "significant problems that really can't be fixed," and said he would reject the papers if they were being peer-reviewed for publication purposes.

support those levels. In short, EPA's systematic review was not grounded in "sound and objective scientific practices," a flaw it has not remedied.[28] These classification and review protocol errors are identified throughout the comments herein as they relate to specific topics in the rulemaking.

a. EPA's systematic review methods continue to lack transparency and consistency in evaluation of study quality.

EPA's methodology for study identification and inclusion lacks integrity and transparency. In response to SAB comments, EPA expanded its assessment to include epidemiological and animal studies identified in EPA's 2016 Health Effects Support Documents for PFOA and PFOS. However, it is unclear whether these studies were incorporated into the literature screening process applied to other citations or included based on subjective judgement. It is also unclear why 15 studies identified in the 2016 Health Effects Support Documents were not accounted for in the review.[29] EPA also implemented the use of SWIFT-Review[30] for a portion of study identification, which has yet to be validated for this purpose. This may have resulted in inadvertently excluding relevant studies. Additional study types that may have been inappropriately excluded from the review according to the reported methodology include erratums, corrections, and corrigendums. This issue is discussed in detail in Appendix A, *Detailed Technical Comments on the Non-cancer Reference Doses (RFDs) and Economic Analysis for PFOA and PFOS.*

Increased transparency in reporting is needed. The SAB recommended changes to the evidence identification step of the PFOA and PFOS systematic reviews, including providing a more transparent reporting of output. EPA responded by providing a publicly accessible interactive flow diagram. That diagram, however, does not give insight into the specific Population, Exposure, Comparator, and Outcomes (PECO) criteria that EPA decided certain studies did not meet. PECO criteria define the objectives of the review and inform the "inclusion and exclusion criteria for a review, as well as facilitating the interpretation of the directness of the findings based on how well the actual research findings represent the original question."(Morgan et al. 2018) EPA's failure to identify the PECO criteria that excluded studies did not meet precludes independent appraisal of why those studies were excluded. This issue is discussed in detail in Appendix A.

EPA did not refine study quality criteria to the topic per standard IRIS systematic review guidelines. To evaluate study quality and risk of bias in the PFOA and PFOS assessments, EPA said it used its IRIS assessment tool. EPA IRIS Handbook (USEPA ORD 2022) guidance states that to evaluate studies, chemical-, outcome- or exposure-specific considerations should be developed as needed to identify issues expected to result in critical biases and that should reduce the confidence rating of a study (ORD Handbook, p. 4-2).

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[28] 42 U.S.C. § 300g-1(i).

[29] *See* Tables A-6 and A-7 of the 2016 HESD summary tables and Interactive Reference Flow Diagram for PFOA & PFOS | Tableau Public.

[30] "SWIFT" is an acronym for Sciome Workbench for Interactive computer-Facilitated Text-mining. It is software that uses statistical modeling and machine learning to conduct automated document prioritization. *See* https://www.epa.gov/sites/default/files/2018-02/documents/d-4_swift_demo_abstract_-_nas_2018.pdf.

Contrary to EPA's own guidance, the only apparent modification EPA made to its IRIS assessment tool for study evaluation in this rulemaking was to the exposure assessment domain criteria. This modification is insufficient in that it fails to account for critical issues that could render studies unreliable for dose-response assessment – a critical part of EPA's analysis here. Critical omissions include lack of consideration of factors that are specific to exposure, outcome ascertainment, confounding factors that affect the association of interest, and sensitivity issues such as external validity and study construct. This issue is discussed in detail in Appendix A.

The study quality evaluation protocol used in EPA's assessments of PFOA and PFOS generated inconsistent study confidence ratings. EPA did not correctly evaluate and rate studies for reverse causality, which is a type of bias where the health outcome affects physiological factors that moderate exposure measurement. (Andersen et al. 2021). If reverse causality is not accounted for in a study, the observed effects may not result from the exposure and could be mischaracterized as adverse. Although guidance provided for PFAS-Specific Exposure Measures states that concern for potential bias due to reverse causality with no direct evidence should be rated as 'deficient,' EPA did not consistently rate study design aspects that may impact reverse causality in the body of evidence it considered. In a review of cross-sectional studies that fall into the category of "potential reverse causality," the Exposure Methods ratings were inconsistent and generally rated as adequate or good rather than deficient. Further, subjectivity introduced by the Guidance allows reviewers to increase confidence in studies reporting an effect if its confidence was reduced due to sensitivity only. How and when this was applied by EPA in its review here is not readily transparent. Lastly, the lack of transparency and objectivity in the study quality evaluation guidance also contributes vague overall study confidence ratings that do not appear to take the individual domain metric ratings into consideration. This issue is discussed in detail in Appendix A.

EPA's inconsistent systematic review methods violated its own guidance and resulted in exclusion of relevant studies and reliance on low-confidence studies that may be unsuitable for regulatory decision-making.

V. EPA'S PROPOSED STANDARDS FOR PFHxS, PFBA, PFNA, AND HFPO-DA ARE PROCEDURALLY AND TECHNICALLY FLAWED

a. The SDWA Does Not Permit Publication of a Preliminary Determination to Regulate at the Same Time as a Proposed NPDWR.

EPA issued its proposed NPDWRs for PFHxS, PFBA, PFNA, and HFPO-DA (the HI MCL) without adhering to the Congressionally prescribed procedure for setting MCLs under the SDWA. The Proposed Rule is therefore arbitrary and capricious and violates the SDWA. *See Chevron USA Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984) ("[i]f the intent of Congress is clear… the agency… must give effect to the unambiguously expressed intent of Congress").

The SDWA requires EPA to make a "preliminary determination" to regulate a substance and provide notice and an opportunity for public comment on that preliminary determination.[31] The independent step of issuing notice of a preliminary determination reflects an intentional, discrete step in the regulatory process sanctioned by Congress. Once EPA has solicited and considered comment on that preliminary determination, EPA can make a final "determination to regulate." This two-step process is clearly reflected in the language of 42 USC § 300g-1 (b)(1)(B)(ii)(I)-(b)(1)(B)(ii)(III). Section (b)(1)(B)(ii)(I) states a "determination" to regulate a substance on the CCL "shall" only be issued "after notice of the preliminary determination and opportunity for public comment."

While the SDWA allows EPA to publish a proposed regulation "concurrent with the determination to regulate," *id.* at § (b)(1)(E), it does not permit the EPA to skip the "preliminary determination to regulate" step, as it did here. To the contrary, the SDWA distinguishes between the process of issuing a "preliminary determination" that is subject to public comment (i.e., a proposed rule) and the "mak[ing of]" a final determination (i.e., a final rule). *Id.* Similarly, SDWA Section (b)(1)(B)(ii)(2) lists factors that must support the final "determination," not the "preliminary determination." Further, section (b)(1)(B)(ii)(III) states the same "determination" can be made even if the substance does not appear on the CCL, as required by (b)(1)(B)(ii)(I). These distinctions confirm that Congress intended a "determination to regulate" under the SDWA to mean a final determination and not a preliminary determination. Stated differently, EPA has the authority to promulgate a final decision to regulate in the same rulemaking as a proposal for additional drinking water standards. However, the SDWA does not give EPA the authority to issue a proposed NPDWR and a preliminary regulatory determination at the same time – but this is precisely what EPA did in this rulemaking.

EPA has recognized that "[t]he development of the CCL, regulatory determinations, and any subsequent rulemaking should be viewed as a progression where each process builds upon the previous process, including the collection of data and analyses conducted."[32] EPA's truncated regulatory determination in this case minimizes time for public-review and violates the plain language of the SDWA.

b. EPA Has No Meaningful or Sound Occurrence Data for the HI MCL Substances

The SDWA requires that before it can promulgate an NPDWR, EPA must determine that, among other things, the substance is "known to occur or there is substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern."[33] Alleged co-occurrence of the four HI-PFAS is the basis for EPA's HI MCL. EPA's justification for the HI approach depends in part on the four HI-PFAS substances most frequently

[31] 42 USC § 300g-1(b)(1)(B)(ii)(I).
[32] 85 Fed. Reg. at 14100.
[33] SDWA §1412(b)(1)(A)(i) and (ii).

co-occurring as a mixture, rather than individually.[34] But EPA's analysis does not demonstrate that there is substantial likelihood that the four HI-PFAS co-occur *with each other*. Instead, EPA analyzed where any of the four HI-PFAS individual and either PFOA or PFOS co-occur.

Exhibit 6-3 summarizes co-occurrence of combinations of PFAS in the UCMR3 data. The combination of the four HI-PFAS is not listed.[35] Importantly, **it appears there were no records in the UCMR3 data of the four HI-PFAS co-occurring**.

Section 6 of the Background Support Document (USEPA 2023h) presents analyses of the co-occurrence rate of PFOA, PFOS and any of the four HI-PFAS, but does not specifically address co-occurrence of the four HI-PFAS proposed for regulation as a mixture using the HI approach. The analyses, discussion, and Exhibits 6-2, 6-4 and 6-5 also focus on co-occurrence of PFOA and PFOS with the four HI-PFAS, rather than co-occurrence of the four HI-PFAS with each other. That analysis is irrelevant to the decision to regulate the four HI-PFAS as a mixture, since neither PFOA nor PFOS is included in the group to be regulated as a mixture.

There are also significant issues with the sampling on which EPA relies that call into question the reliability of the data. Data are evaluated at the sample and PWS level, though it is not clear if sample counts represent unique locations or include multiple samples from the same location. Evaluating multiple samples from the same location within a system could overestimate the frequency of co-occurrence. The co-occurrence data presented at the system level for detection of any HI-PFAS show wide variability among states (USEPA 2023h, p. 197). And the states with the most systems tested, Michigan and Ohio, show much lower frequency of detection of any HI-PFAS (i.e., 6.5 percent and 3.9 percent respectively) than states with fewer system tested (USEPA 2023h, p. 197). This observation suggests that data from states with fewer systems sampled may not be representative of occurrence in those states.

EPA's failure to include all states' data violates the fundamental scientific principle that one cannot selectively use data to generate a preferred outcome. The data set used covers 11 states and is described as "limited to samples from non-targeted monitoring efforts where at least one HI PFAS was analyzed and PFOS and PFOA were analyzed sufficiently to determine whether one was present." Although the state of Alabama analyzed for all four HI-PFAS and PFOA and PFOS, data from Alabama are not presented and no explanation for the omission is provided (USEPA 2023h, p. 11). Sampling efforts are ongoing in 6 of the 11 states presented (Illinois, Massachusetts, Michigan, New Hampshire, New Jersey, and Vermont); for these states, data collected after May 2021 are available but are not used by EPA for the co-occurrence analysis (USEPA 2023h, p. 11). EPA's PFAS Analytical Tools webpage

[34] For PFHxS, the median sample concentrations range from 2.14 to 11.3 ppt. The HRL for this substance is 9.0 ppt. For HFPO-DA, the median sample concentrations range from 1.7 to 9.7 ppt. The HRL for this substance is 10.0 ppt. For PFNA, the median sample concentrations range from 2.1 to 7.46 ppt. The HRL for this substance is 10.0 ppt. For PFBS, the median sample concentrations range from 1.99 to 7.26 ppt. The HRL for this substance is 2000.0 ppt. The maximum sample did not even exceed the HRL for PFBS.

[35] Many of the combinations included in Exhibit 6-3 indicate PFHpA is detected, which is irrelevant to the proposed regulation of the four HI-PFAS as a mixture, given that PFHpA is not one of the four HI-PFAS.

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(https://echo.epa.gov/trends/pfas-tools) lists data for several additional states (e.g., Oregon, Rhode Island) also not considered in EPA's co-occurrence analysis.

EPA also uses different data sets for the evaluations of co-occurrence and of affected systems, creating a fundamental disconnect such that one analysis cannot be used to inform the other. For example, in estimating the number of systems affected by the proposed MCLs, EPA uses an occurrence model that incorporates data from 17 states (USEPA 2023f, p. 18678). The 17 states include Arizona, California, Delaware, Georgia, Maine, and Pennsylvania (Cadwallader 2022). For these states, EPA considers the sampling "targeted" and omits them from the co-occurrence evaluation (USEPA 2023h, p. 11). Conversely, data from the state of Colorado are included in the co-occurrence evaluation but are not included in this modeling of affected systems. Different and unstated rationale for including state data for these two purposes suggest that those criteria were arbitrary.

EPA failed to include more recent samples that would improve the representativeness of the analysis. Specifically, EPA's analysis of co-occurrence does not include samples collected after May 2021 and uses different data sets than are used for EPA's occurrence modeling. The data set used to evaluate co-occurrence is limited to data available on public state websites through August 2021, which was limited to samples collected through May 2021.

c. EPA's Interpretation of the Data It Uses as the Basis of the MCLGs and MCLs is Flawed and Has Not Undergone Peer Review in Violation of the SDWA

The HI MCL also violates the SDWA's mandate that EPA solicit peer review from its SAB prior to issuing a proposed MCL.[36] In 2021, EPA provided SAB with its *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)* (USEPA 2021c). That document was an external peer review draft, which was not revised and published for public review until March 2023 (USEPA 2023e). This means that the Proposed Rule employs techniques regarding data requirements for mixture Health-Based Water Concentrations" but never sets out proposed HBWCs for the HI PFAS or for EPA's currently proposed HI-based MCL for those substances. In the mixtures framework document, EPA itself said that "because there are no EPA-published HBWCs (e.g., Health Advisories, MCLGs) at this time for other PFAS with federal or state assessments/RfVs (e.g., PFBS (EPA), GenX chemicals (EPA), PFHxS (ATSDR), and PFNA (ATSDR)) or chemicals categorized under PFAS 1 or PFAS 2, these values would need to be calculated in order to develop component HQs and an overall PFAS mixture HI."[37] In other words, EPA expressly did not submit its "mixtures" document as a potential MCL for public review prior to the publication of the Proposed Rule. Indeed, EPA proposed the HBWCs only after SAB reviewed its proposed mixtures framework. As a result, neither the HBWCs that form the basis for the HI-MC, nor the

[36] SDWA §§ 1412(b)(3)(A)(i) and (g).
[37] Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS), 35 (November 2021)

HI-MCL itself have been properly submitted to the SAB or peer-reviewed as required by the SDWA.[38]

The lack of peer review and submission to the SAB is significant. As noted above, it expressly violates the SDWA. The lack of peer review has even resulted in EPA making basic errors that would have been identified during the peer review process. For example, EPA makes an arithmetic error in its derivation of the HBWC for PFHxS (USEPA 2023l). Using EPA's inputs in Table 4 of the Hazard Index document (USEPA 2023l), the HBWC would be 12 ppt, and applying one significant figure, the final HWBC should be 10 ppt, not 9 ppt. This error must be corrected. This error also signals an absence of even basic quality assurance. All of EPA's calculations require comprehensive peer review before the NPDWR is finalized, and EPA must submit its proposed MCLG and NPDWR for the HI PFAS, including the HBWCs, to SAB for comment.

i. EPA's selection of reference values for the four PFAS for which it seeks to issue preliminary regulatory determinations (PFHxS, HFPO-DA, PFNA, and PFBS) is erroneous.

Putting aside EPA's violations of SDWA-mandated processes for public notice and peer review, the proposed standards for the HI PFAS are not consistent with EPA processes designed to ensure reliability and sound scientific practices. EPA relies on ATSDR for the PFHxS and PFNA reference values, and there is no evidence that EPA conducted an independent systematic review of the evidence base or assessed study quality for these compounds as recommended by the IRIS Handbook. Furthermore, because these four PFAS are considered together under the HI, EPA has not sufficiently discussed, as recommended in EPA's own RfD process recommendations (USEPA 2002), the implications of the collective uncertainty underlying all four reference values.

PFHxS. EPA's proposed reference value of 0.000002 mg/kg/day for PFHxS is based on ATSDR's (2021) Minimum Risk Level (MRL)[39], which is derived from Butenhoff et al. (2009). Butenhoff et al. (2009) observed that adult male rats exposed to PFHxS at 3 mg/kg-day exhibited thyroid follicular cell hyperplasia that may have been due to increased liver hypertrophy and induction of liver enzymes, which could in turn impact thyroid hormone metabolism. However, the authors did not measure thyroid hormones; therefore, the clinical significance of thyroid cell hyperplasia is unclear. Furthermore, in contrast to Butenhoff et al.'s (2009) findings, ATSDR (2021) concluded that liver effects in mice after exposure to PFHxS were not adverse. Had EPA evaluated Butenhoff et al. (2009) per systematic review guidance, that lack of adversity may have been identified and the study excluded.

In contrast, Chang et al. (2018), did measure thyroid stimulating hormone (TSH), and observed changes in neither TSH levels nor thyroid histopathology in mice at doses up to 3 mg/kg-day. Had EPA conducted an appropriate systematic review and assessed study quality per its IRIS Handbook, it may have considered this study, which is more reliable than Butenhoff et

[38] *See* SDWA § 1412(g).
[39] An MRL is a screening value used to identify potential environmental risk and is not a regulatory standard.

al. (2009) because it measured relevant endpoints. In other words, if EPA had conducted a truly independent systematic review of PFHxS toxicity studies, rather than rely on ATSDR's (2021) evaluation, it likely would have selected a different critical effect for PFHxS and therefore derived a different HBWC.

EPA also failed to comply with its guidance related to the application of uncertainty factors (USEPA 2002; USEPA ORD 2022). To derive the reference value for PFHxS, EPA applied a 10-fold uncertainty factor to ATSDR's MRL of 0.00002 mg/kg/day to extrapolate from subchronic to chronic exposure. This 10-fold uncertainty factor is in addition to the 30-fold uncertainty factor and 10-fold modifying factor that ATSDR applied its derivation of the MRL. The resultant combined uncertainty factor is 3,000, which highlights the substantial uncertainty of the evidence for the reference value. EPA's IRIS Handbook and EPA's recommendations on the RfD process (USEPA 2002) recommends that any composite uncertainty factor greater than 3,000 represents "excessive uncertainty" and should not be relied upon.

HFPO-DA. EPA's (2021b) selection of an RfD of 0.000003 mg/kg/day for HFPO-DA is likewise inconsistent with sound scientific process and guidance. Not only is the study it selected unpublished (DuPont 2010a), but EPA also selected a critical effect of "constellation of liver lesions." The study, which was a reproductive and developmental study in mice, indicated that the various hepatic effects were not consistently observed in male and female mice. However, EPA inappropriately combined these effects in order to consider it as a single critical effect, in violation of its own guidance. The resultant no-observed-adverse-effect level (NOAEL) and lowest-observed-adverse-effect level (LOAEL) values are 0.1 mg/kg-day and 0.5 mg/kg-day, respectively. EPA's IRIS Handbook states that common endpoints are "the same specific outcome measurement, not just any endpoint in a common target organ" indicating that to be combined, the observed effects have to be the same.

Combining the observed liver effects is inappropriate because some of the liver effects considered in the "critical effect" were not clearly adverse; the effects were either adaptive changes or unclear in their adversity (e.g., hepatocellular hypertrophy, enlargement of liver cells, changes in cytoplasm of liver cells) (USEPA 2021b). These effects could occur through different modes of action or were not actually adverse effects (Hall et al. 2012), which makes combining them inappropriate per EPA's IRIS Handbook. Because differences between exposed and unexposed animals were only observed when all observed liver effects were combined, EPA could not have established a NOAEL and LOAEL based on any individual effect.

EPA also violated proper systematic review processes when it inexplicably disregarded other studies that did not find such a "constellation" of hepatic effects in rodents exposed to HFPO-DA. For instance, DuPont (2010b) reported a NOAEL of 0.5 mg/kg-day in a separate unpublished mouse study, rather than a NOAEL of 0.1 mg/kg-day applied by EPA. DuPont (2010b) was unable to establish a dose-response in female mice in this study (USEPA 2021b). Similarly, hepatic effects were not observed at such low doses in a DuPont chronic rat study (DuPont 2013). These scientifically flawed practices result in a critically flawed RfD value. EPA (2021b) itself demonstrates its uncertainty in the overall evidence base with its RfD by applying an uncertainty factor of 3,000. In other words, the significant uncertainty inherent in EPA's RfD highlights its unsuitability as the basis of a regulatory value. As noted for PFHxS, an

uncertainty factor of 3,000 is the maximum that could be considered as the basis of reference value according to EPA's IRIS Handbook and USEPA (2002).

PFNA. EPA's reference value for PFNA is based on ATSDR's (2021) intermediate MRL of 0.000003 mg/kg-day and is overly conservative as a result of EPA's improper data review processes. ATSDR's (2021) MRL is derived from Das et al. (2015), in which mouse pups exposed to PFNA at 3 mg/kg-day were observed to have decreased body weight and delays in development. Importantly, most of the PFNA-induced effects, including developmental effects, are directly linked to the PPARα pathway (Rosen et al. 2017; Wolf et al. 2010). As demonstrated in Wolf et al. (2010), there is a clear association between PPARα and delayed eye opening and decreased body weight in exposed mouse pups. Because the PPARα has limited relevance to humans, the selection of Das et al. (2015) as the primary basis of the MRL is improper.

Additionally, ATSDR's (2021) application of an uncertainty factor of 3 for interspecies differences was overly conservative and in violation of EPA's own guidance. As previously discussed, the limited application of PPARα to humans indicates that mice are the more sensitive species to the observed effects in Das et al. (2015) (i.e., PPARα is less active in humans than it is in mice), such that an interspecies uncertainty factor of 1 would be consistent with guidance in EPA's IRIS handbook that allows for lower uncertainty factors considering differences in cross-species toxicokinetics and toxicodynamics are accounted for. Prior to the application of an interspecies uncertainty factor, the MRL was amply protective of human health. EPA (USEPA 2023l) also acknowledges that both ATSDR and EPA are reassessing the toxicity of PFNA via a revised MRL or new IRIS assessment, respectively. This further highlights the uncertainty in the reference value and lack of basis in the most up-to-date and systematically reviewed science.

Finally, another example of poor quality assurance in this proposed rulemaking, is in Section III.B.3 of the Federal Register Notice (USEPA 2023f), where EPA incorrectly refers to the HBWC for PFNA as both 100 ppt and 10.0 ppt.

PFBS. EPA relies on its RfD of 0.0003 mg/kg/day (USEPA 2021a) as the basis of the HBWC. EPA again failed to follow processes that would have ensured its RfD was properly supported. EPA relied on Feng et al. (2017), in which mouse pups exposed to PFBS were observed to have decreased serum thyroid hormone (thyroxine [T4]) levels compared to unexposed pups. The study's authors, however, expressed uncertainty as to whether the decreased serum T4 levels were toxicologically relevant; they further state that the decreased levels were not specifically related to development (Feng et al. 2017). A proper systematic review would have taken that uncertainty into account.

The selection of thyroid hormone changes in mice as the critical effect by EPA (USEPA 2021a) in and of itself is overly conservative but is further compounded by EPA's application of an uncertainty factor of 3 for interspecies differences. Multiple studies have shown that rodents are more sensitive to alterations in thyroid hormone compared to humans (NRC 2005; Bartsch et al. 2018; Parker and York 2014; Brown-Grant 1963). In other words, without the uncertainty factor, EPA's RfD may be protective of human health, but is made unduly conservative with it.

EPA also violates its own guidance when it does not discuss the critical implications of the collective application of the uncertainty factors when considering these four PFAS together in the HI. The uncertainty factors when compared across PFHxS, HFPO-DA, PFNA, and PFBS are 3,000, 3,000, 300, and 300, respectively. Though the uncertainty factors across the four PFAS may not be purely multiplicative, EPA's own guidance (USEPA 2002) clearly recommends "limiting the total UF applied for any particular chemical to no more than 3000 and avoiding the derivation of a reference value that involves application of the full 10-fold UF in four or more areas of extrapolation" because uncertainty in four or five areas "may also indicate that the database is insufficient to derive a reference value." As stated previously, USEPA (2002) recommends "justification for the individual factors selected for each chemical," guidance that should also apply when considering uncertainty across multiple reference values under the HI. Taken together, in proposing the HI, EPA has failed to follow its own guidance, which recommends that clear justification for the uncertainty factors, consideration of areas of overlapping uncertainty, and implications for the reliability of the reference values be provided.

ii. EPA's relative source contribution value for PFHxS, HFPO-DA, PFNS, and PFBS is not based on the best available science

The relative source contribution (RSC) term used to assign exposure contribution from drinking water is a key element of MCL derivation. The smaller the RSC, the more protective the drinking water regulatory limit is in order to account for other potential sources of exposure. EPA chose the 20 percent default RSC value for HFPO-DA, PFHxS, PFNA and PFBS to develop the HBWCs used in the HI-MCLG, citing insufficient data to calculate a substance-specific RSC. EPA guidance provides that the 20 percent default should only be used when data to characterize other exposure sources is insufficient(c).

In its comments on the PFOA and PFOS MCLG derivation, the SAB suggested EPA more clearly justify the 20 percent default value, yet in the documentation for PFOA, PFOS and PFAS mixture, EPA continues to stress that data are not sufficient to characterize exposures for individual substances (USEPA 2023j). While EPA states there are not sufficient data to calculate substance-specific RSC values for the various substances, the agency nonetheless presents several pages of scientific literature regarding substance occurrence in various media (e.g., dietary sources, indoor dust, soil, sediment) (USEPA 2023e, 2022a,b). The HFPO-DA RSC development documentation cites 52 studies, 14 "gray literature sources" and 3 additional references. For PFBS, 183 peer-reviewed and grey literature references were identified that characterized occurrence in drinking water, groundwater, surface water, dietary sources, consumer products, indoor dust, indoor air, ambient air, and soil (USEPA 2022b). For PFNA and PFHxS, 176 and 177 peer-reviewed studies, respectively, and at least 12 grey literature sources included occurrence data for ambient air, indoor air, consumer products, dust, food, groundwater, drinking water, surface water, sediment, soil, and human blood/serum/urine (USEPA 2023e). There is no clear explanation for why the numerous studies presented do not provide sufficient data to calculate substance-specific RSCs, as recommended by EPA's own guidance.

In addition to the studies presented by EPA for each of the four PFAS, other studies have directly characterized exposure sources for various PFAS. Ericson et al. (2008) determined that

drinking water exposure to PFCs (including PFNA and PFHxS) may be as important as the dietary pathway. Vestergren et al. (2012) found that drinking water intake contributed 36–53 percent of the total exposure for PFHxS, PFHpA, and PFHxA.

Given the number of studies and breadth of exposure sources evaluated, inferences can reasonably be made about exposure from various sources using occurrence and concentration data presented. When the currently available data cited by EPA and the studies that directly show water is a primary contributor to exposure for each of the four HI-PFAS are considered collectively, there is likely sufficient support for chemical-specific RSC terms, similar to the chemical-specific values developed for PFOA by several states (Lindborg et al. 2022). EPA suggests that there were insufficient US-based studies, but 47, 50, and 59 of the studies presented for PFNA, PFHxS, and PFBS, respectively, were US-based (USEPA 2023e, 2022b). There is also no evidence that EPA evaluated the RSC based on these studies. Rather, EPA presented a summarized table of the concentration ranges, with no indication or evaluation of how the study findings relate to exposure contribution. This directly contradicts the intended application of EPA's Exposure Decision Tree methodology (USEPA 2000b).

d. EPA Failed to Consider Any Alternatives to the HI-MCL, in Violation of SDWA §1412 (b)(3)(C)(i)

EPA must consider a range of alternative MCLs but did not do so here in violation of the SDWA and the Unfunded Mandates Reform Act (UMRA). SDWA §1412(b)(3)(C)(i) requires EPA to consider alternative MCLs. In promulgating other NPDWRs after the 1996 SDWA Amendments, EPA has routinely considered at least four alternatives.[40] Additionally, the Unfunded Mandates Reform Act of 1995 requires EPA to consider alternative MCLs.[41] The Unfunded Mandates Reform Act of 1995 (UMRA).[42] UMRA requires any agency promulgating a rule with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year to "identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule."[43]

Here, EPA did not consider a "reasonable number of regulatory alternatives." For PFHxS, HFPO-DA and its ammonium salts, PFNA, and PFBS, EPA considered a single HBWC, which effectively functions as substance-specific MCL. Nor did EPA consider any alternatives to the HI-MCL of 1.0 itself. Clearly, the analysis of only one regulatory option is not a

[40] *See* National Primary Drinking Water Regulations: Lead and Copper Rule Revisions, 84 Fed. Reg. 61684 (2019) (considering four alternative regulatory options); National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring 66 Fed. Reg. 6976 (2001) (considering four alternative MCL levels); National Primary Drinking Water Regulations; Radon-222, 60 Fed. Reg. 59246 (1999) (considering seven alternative MCL levels).
[41] EPA identified that this rule is subject to the UMRA, *see* 88 Fed.Reg. 18733 (Mar. 29, 2023) ("This action contains a Federal mandate under the Unfunded Mandates Reform Act").
[42] 2 USC § 1535 (1995)
[43] Id.

consideration of "alternatives." The lack of alternatives considered for the PFAS covered in the Hazard Index violates both the SDWA and UMRA.

Not only is the failure to consider any alternatives to the HI-MCL itself a direct violation of the SDWA, it also led to EPA's failure to identify the level at which the costs of the HI-MCL justify the benefits. The HBWCs are purely health-based and should be calculated to have a margin of safety, similar to an MCLG. But EPA effectively set MCLs for these four substances at the HBWC without considering whether the same benefits could be achieved for lower costs because it did not consider any alternatives to the HBWCs as required by the SDWA.[44]

e. EPA's Unprecedented Hazard Index Approach Violates the SDWA and is Arbitrary

EPA's proposal to regulate drinking water concentrations for the HI PFAS using the so-called "general HI approach" is arbitrary, not based on sound scientific principles, and does not conform with long-standing risk assessment practices and toxicological principles detailed in EPA's human health risk assessment guidance (USEPA 1986, 1989, 2000b). Further, the use of the general HI approach is at odds with methods currently employed in some EPA regulatory programs, and the adoption of this approach for use in National Primary Drinking Water Regulations (NPDWR) would introduce conflicting outcomes depending on PFAS present and their relative concentrations.

Moreover, EPA's decision to regulate the HI substances as a mixture led to an inflated sense of the opportunity for risk reduction. In the section on this criterion, the only factors considered discussed the substances as a group. There was no analysis of how, individually, the substances presented a meaningful opportunity to reduce risk to the public (Section VII). This omission violates the requirements for regulating new substances under the SDWA.

i. The hazard index approach is not appropriate in the regulatory context

The use of the general HI approach as proposed by EPA is contingent on potential exposure information, compound toxicology, and an acceptable noncancer hazard. In short, the general HI method applies principles of human health risk assessment, but in an inherently flawed manner. The science of cumulative risk assessment of chemical mixtures has been the topic of research and policy making for decades, and as it pertains to PFAS, even EPA acknowledged that "there is currently no consensus on whether or how PFAS should be combined for risk assessment purposes" (USEPA 2023, p. 3) as also discussed in Section V.C of the proposed rule. Nonetheless, EPA arbitrarily employs the proposed general HI approach even though, by its own admission, it is not a consensus method and is contrary to EPA's long-standing guidance and policy related to the application of risk assessment of chemical mixtures.

The general HI method is intended for "screening level" assessments that determine the need for further evaluation, rather than the basis for an expensive and complex NPDWR. In no fewer than threeEPA risk assessment guidance documents, EPA refers to the general HI

[44] *See* SDWA §1412(b)(3)(C)(i).

approach as "screening level," including: EPA's *Guidelines for Health Risk Assessment of Mixtures* (USEPA 1986), *Risk Assessment Guidance for Superfund – Part A* (USEPA 1989), *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA 2000a).

ii. The hazard index approach is based entirely on unscientific assumptions of dose additivity

EPA's proposed general HI method is inconsistent with long-standing policy and science regarding chemical hazard additivity. As described below, EPA has not established that the HI-PFAS share a mode of action (MoA) that is relevant for humans, which is required to regulate groups of chemicals.[45] MoA information is critical to grouping PFAS and "[o]nly those PFAS that affect the same target organ/tissue/system should be grouped and assessed for dose additive or response additive approaches."[46] This is consistent with long-standing EPA guidance stating that multi-chemical cumulative non-cancer hazards should only be assessed for chemicals with RfDs that are based on an effect on the same target organ (USEPA 1986, 1989, 2000b.

EPA admits that the HI MCL lacks evidence of a common MoA.[47] To the contrary, the reference value for PFHxS and the RfD for PFBS are based on different thyroid effects, the HFPO-DA RfD is based on a "constellation" of liver effects, and the PFNA reference value is based on changes to body weight and development. For PFHxS and PFBS, the same thyroid endpoints are not used as the critical effects – for PFHxS the critical effect is based on thyroid follicular epithelial hypertrophy/hyperplasia in parental male rats and for PFBS the critical effect is based on decreased serum total thyroxine in newborn mice after gestational exposure to the mother. These effects are likely occurring via different MoAs due to the different life-stages affected (parental versus offspring, respectively). EPA has also not established a shared MoA or considered relative potencies of the HI-PFAS. Because the HI-PFAS lack a common toxicity endpoint, summing potential hazards (as measured with a hazard quotient or HQ), contradicts long-standing EPA guidance and widely held scientific opinion.

These differences in target organs[48] and critical effects for the four HI-PFAS are precisely why EPA did not use a target organ-specific HI approach and instead opted for the screening-level HI approach, despite its inability to accurately characterize the additivity of the four HI-PFAS. EPA guidance (USEPA 1989) recommends the use of the general HI approach as an initial screening to assess potential adverse effects and not for binding regulatory purposes. The approach assumes that simultaneous exposures to several chemicals occurring below their respective health-based thresholds could result in an adverse health effect, regardless of the chemicals' target organs or mechanisms of action. The HI is calculated as the sum of the ratios of each chemical's exposure relative to that chemical's respective health-based threshold. If the resulting general HI is less than 1, then an unacceptable hazard does not exist, and no further evaluation is needed. However, if the general HI exceeds 1, the guidance then recommends

[45] *See, e.g.,* (Anderson et al. 2022).
[46] *Id.* at 5.
[47] *See* 88 FR 18668.
[48] A target organ is an organ in the body most affected by a specific substance.

conducting a refined assessment by separating the HI evaluation by target organ and/or mechanism of action. EPA's proposed HI MCL omits the critical consideration for shared target organs and/or mechanism of action to determine potential hazard.

Because the four HI-PFAS do not share the same target organ, potential hazards calculated via the general HI method are not toxicologically accurate. EPA's proposed general HI method fails to use the target organ-specific RfDs in the most appropriate manner, resulting in a screening-level assessment when a refined target organ HI approach is available and is far more appropriate.[49] This flaw results in inaccurate and overly conservative MCLs, combined with problematic risk communication due to their flawed scientific foundation and lack of transparency.

In short, EPA's reliance on the general HI method for PFHxS, HFPO-DA, PFNA, and PFBS is contrary to long-standing practices employed in human health risk assessments, well established and scientifically sound principles of toxicology, and EPA guidance. Further, the proposed general HI approach cannot be claimed as a more health protective method. Rather, it is an inaccurate method for assessing exposures and risks to compounds with different toxicological endpoints, and because of the method's inaccuracy, cannot be used to determine health protectiveness or margin of safety. Considering these fundamental shortcomings, the use of the general HI method in the proposed NPDWR is arbitrary.

f. The Hazard Index Fails to Provide Regulatory Certainty

The unprecedented HI-MCL "standard" is not actually a fixed standard. Instead, the "standard" is based on an unlimited combination of detections of the four HI-MCL substances, all of which can be below their respective HBWC, and still be considered a violation of MCL. Similar results where all four substances are below their HBWCs can have different regulatory outcomes. EPA has not set a single MCL for the HI-PFAS. Instead, the proposed HI-MCL is actually thousands of fluid standards.

Such unpredictable and inconsistent regulatory outcomes raise a host of issues, including fundamental issues regarding fairness, equity, and regulatory certainty. There is no evidence in the Proposed Rule or supporting materials that EPA considered these issues before proposing the HI-MCL. That lack of reasoned consideration is the hallmark of arbitrary agency action.

[49] EPA wrongly refers to the general HI method as a more health protective indicator of risk and the target organ-specific HI approach as less health protective estimate of risk. Noncancer evaluations are based on threshold effects and, as a result, are either health protective or not. The contention that the general HI is "more" health protective stems from the misapplication of the long-standing approach for assessing the potential hazards associated with exposure to more than one noncarcinogen. The general HI method results in an inaccurate potential hazard calculation that unnecessarily increases uncertainty, reduces transparency, and hinders the risk communication process.

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g. EPA Has Not Conducted a Benefits Analysis for the HI MCL, in Violation of the SDWA

SDWA §1412(b)(3)(C)(i) requires that EPA "shall" for each alternative MCL considered, publish and seek comment on an analysis of the quantifiable and nonquantifiable health risk reduction benefits and costs of the proposed rule. As described above in Section IV.d, EPA did not consider any alternatives for either the HBWCs or the HI MCL itself, contrary to the SDWA requirements. In addition, EPA failed to conduct any analysis of the benefits or costs of the HI-MCL, also in violation of the SDWA. EPA acknowledged in its Proposed Rule that it "has not separately presented changes in quantified costs and benefits" for the "HI approach". 88 FR 18638, 18671. Similarly EPA stated that it "has not separately quantified the benefits and costs for the alternative approach to regulate PFHxS, PFNA, PFBS, and HFPO-DA with individual MCLs instead of the HI."[50] *Id.*

Given that the HI MCL can be exceeded by a vanishingly small amount over the non-peer reviewed HBWCs (for example, 2001 ppt PFBS, where the HBWC is 2000 ppt), and that the HI MCL can be exceeded by a combination of the HI-PFAS all below HBWCs, EPA's failure to engage in SDWA-required analysis of the benefits of the proposed HI MCL leaves the public entirely without information as to the potential benefits and costs of the Proposed Rule. Moreover, any assumption by EPA of a measurable benefit related to the HI MCL is implausible. EPA proposes setting the HI MCL at the same level as the HI MCLG. EPA admits in the Proposed Rule that the MCLG represents "a level at which no known or anticipated adverse effects on the health of persons is expected to occur and which allows for an adequate margin of safety." 87 FR 36848 (March 29, 2023). Similarly, EPA set the PFBS HBWC at the same level as its lifetime health advisory for PFBS. EPA states that its "lifetime health advisories identify levels to protect all people, including sensitive populations and life stages, from adverse health effects resulting from exposure throughout their lives to…PFBS in drinking water."[51] EPA goes on to state that "the health advisory levels were calculated to offer a margin of protection against adverse health effects." In other words, EPA's Proposed Rule would set an enforceable standard at levels it concluded is protective against potential risks, with an adequate margin of safety, rather than determining an appropriate regulatory level based on the considerations enumerated in the SDWA.

EPA's failure to prepare any analysis of the benefits or costs of the HI MCL not only violates the SDWA, but also violates the APA's requirement that the Agency engage in notice and comment rulemaking. Without providing the analysis required by the SDWA for the HI MCL, the public is precluded from meaningfully commenting on the potential benefits and costs of the Proposed Rule.

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[50] Because the individual HBWCs for the HI substances function as individual MCLs (because an exceedance of one HBWC would exceed the HI MCL), establishing individual MCLs for the HI-PFAS is not an "alternative approach" but rather a description of the proposed action.

[51] *See* https://www.epa.gov/sdwa/questions-and-answers-drinking-water-health-advisories-pfoa-pfos-genx-chemicals-and-pfbs#:~:text=4.-,What%20is%20a%20lifetime%20health%20advisory%3F,or%20PFBS%20in%20drinking%20water.

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VI. EPA's PROPOSED MCLGS AND MCLS FOR PFOA AND PFOS ARE NOT BASED ON BEST AVAILABLE SCIENCE

EPA's process flaws have resulted in a proposed NPDWR that does not comply with the SDWA's statutory requirement to rely only on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices," rendering the proposed rule arbitrary, capricious, and in excess of statutory authority.[52] An agency must be prepared to provide a "full analytical defense" of its approach.[53] As many courts have noted, "[t]he deference accorded an agency's scientific or technical expertise is not unlimited."[54]

First, as explained in Section III, EPA's evaluation of relevant scientific literature has serious procedural issues that raise significant questions regarding the Agency's scientific conclusions. For example, EPA did not follow basic principles or even its own guidance in conducting its review and evaluation analysis of studies, which resulted in the use of low-quality papers and datasets that cannot be reproduced. Flaws in EPA's scientific approach that forms the basis of the standards proposed in this rulemaking are described in detail below.

EPA acknowledges significant uncertainty in the scientific literature, to the point that it incorporated uncertainty factors so high as to be the maximum that could be considered as the basis of reference value according to EPA's IRIS Handbook. EPA cannot cite scientific uncertainty as a basis for relying on subpar studies that fit its predetermined conclusion.[55] Nor can EPA simply default to caution when scientific evidence directs the agency otherwise.[56] (EPA cannot "reject '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.")

As described in the sections below, EPA's proposed NPDWRs violate numerous foundational scientific practices such that it cannot represent the "best available, peer-reviewed science," in violation of both the SDWA and the Administrative Procedures Act's requirement that an agency's actions not be arbitrary.

a. EPA Did Not Follow Best Practice and Its Own Guidelines for Data Quality Control

EPA has published a series of quality control (QC) and best practice guidelines for program development and project development (USEPA 1992,2002a), data quality objectives (USEPA 2003, 2006), and good statistical practice (USEPA, 2006). EPA has also published approved methods and software for calculating benchmark doses (BMD) and their uncertainty (USEPA 2012, 2022c) which have been developed into an interactive web site. These guidelines are intended to ensure that the resulting decisions made by EPA meet the highest scientific

[52] 42 U.S.C. § 300g-1(i).
[53] *Chemical Manufacturers Association v. EPA*, 28 F.3d 1259, 1265 (D.C. Cir. 1994)
[54] *Brower v. Evans*, 257 F.3d 1058, 1067 (9th Cir.2001).
[55] *See City of Waukesha*, 320 F.3d at 254.
[56] See *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290-91 (D.C. Cir. 2000)

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standards, including reproducibility of results, appropriate data treatment, ensuring representative data, and accurate identification and quantification of true risk to human populations and environmental metrics. The IRIS Handbook and USEPA (2012) provide criteria for how to review literature studies and categorize them based on availability of data, study design, testing procedures, statistical methods, and deficiencies.

The methods and procedures EPA used to support the Proposed Rule did not follow these established procedures, and lack good data practice, sound statistical analysis practice, consistency of methods and models, and the ability to replicate analytical results. EPA has not proposed data quality objectives (DQOs) or Quality Assurance Project Plans (QAPP) for any data source chosen for the Proposed Rule, and/or associated findings used to establish the MCLG. DQOs are required for any research initiative in order to document and ensure that data are collected properly, data are treated using good statistical practice, and any findings can be replicated by scientists and data analysts not working at EPA. EPA's own documents provide guidance on DQOs, program planning, good data practice, and good statistical practice (USEPA 2003, 2006, 2014).

Nor has EPA followed its own requirements and guidance (as listed in the foregoing paragraph) for collecting and analyzing data. Rather, for the MCLG and associated analyses, EPA has largely relied on previously published studies conducted by non-EPA employees for which EPA has not verified data collection, data treatment, outlier detection, variance estimation, elimination of records, or good statistical practice. For example, EPA has selected papers where the data used to calculate BMDs and other measures of risk were not publicly available or were difficult and time-consuming to obtain (e.g., Budtz-Jørgensen and Grandjean, 2018; Shearer et al., 2021). The inability to replicate study findings violates a key principle of the scientific method.[57] This action also is in direct violation of the IRIS Handbook (USEPA ORD 2022), which states that studies with no original data are "tracked for potential use in identifying missing studies, background information, or current scientific opinions," meaning they are not included in the quantitative IRIS assessment. Further, EPA's guidance for considering literature toxicity studies (USEPA ORD 2022) lists specific criteria for invalidation of studies, including "inadequate or missing analytical data," "deficiencies in reporting of study data," and "lack of appropriate statistical methodology." Had EPA's analysis comported with its guidance, many of the studies that EPA relied upon would have been categorized as invalid and therefore presumably not appropriate for use. Exclusion of significant studies, such as Budtz-Jorgensen and Grandjean (2018) and Shearer et al. (2021) would alter EPA's findings.

b. EPA Did Not Follow Its Own Guidelines on Good Statistical Practice

Throughout the technical documents supporting the rule, EPA's statistical and modeling analyses conflict with guidance (USEPA 1992, 2002, 2003, 2006a, 2006b). This failure to

[57] This is a critical and highly relevant topic given that peer review is only as good as the information provided. Lack of transparency in publications and other related issues may limit the effectiveness of peer review and the ability to replicate results of the study. *See, e.g.,* https://www.news-medical.net/life-sciences/What-is-the-Replication-Crisis.aspx; *see also* Improving transparency and scientific rigor in academic publishing (Prager et al. 2019) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6346653/.

follow the practices specified in EPA's guidance results in very low to negligible confidence in the quantitative findings on a consistent basis. Below are a few of the many examples of EPA's practices that are counter to the guidance on statistical and modeling practices cited above. Appendix A and Appendix B, *EcoStat Comments on the United States Environmental Protection Agency's Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation*, include more fulsome explanation of each of these issues.

- Frequently, EPA does not have the original data sets used by the authors in papers EPA considers of high quality. This directly contradicts the IRIS Handbook literature screening steps that exclude studies without provided data. Therefore, EPA and other scientists cannot replicate the results of the original authors, nor can EPA evaluate the authors' consideration of non-detects, outlier detection, sensitivity studies, or data transformations.

- When building statistical models, EPA often ignores fundamental covariates like gender, ethnicity, age, body weight, geographic region, etc. Papers selected by EPA may consider these variables and provide graphics, but the factors are not considered as fundamental covariates within the models that are used to estimate BMDs or to estimate public health risk When models are incorrectly built (e.g., leaving out key variables), the effect is to generate incorrect model error estimates for hypothesis testing, which has the effect of overestimating the significance of PFAS concentrations in the model (Heinze et al 2018).

Because EPA frequently lacks the source data used in outside publications, and because these data are frequently unavailable to the public, EPA attempts to infer the statistical properties of the unavailable data for the purpose of model building. This approach is clearly a violation of EPA's QC guidelines (USEPA 1992, 2002). For example, EPA attempts to generate a "pooled variance" having only the 25^{th} and 75^{th} percentiles of a data set to infer the median and mean values. EPA states that "[i]f access to data and methods cannot occur, EPA should, to the extent practicable, apply especially rigorous robustness checks to analytical results and carefully document all checks that were undertaken." (USEPA 2002) Sound statistical practice recognizes that there are many (if not hundreds) of empirical distributions with the same 25^{th} and 75^{th} percentiles that result in different median and mean values. Accordingly, assuming any single distribution, without the ability to assess the original data, is inappropriate, unreliable, and subjective and does not adhere to the "rigorous robust checks" recommended in EPA's own guidance (USEPA 2002).

- EPA has selected papers and data sources to support the rule without establishing that the information is representative of national US populations. Therefore, findings from these papers cannot be inferred to the entire US population. Regional data, data from the Faroe Islands, data collected without a sampling frame, or data collected where sampling weights cannot be determined should not be used for setting a national standard.

- EPA has not included time-based effects in the models used to support the rule. 3M's assessment of NHANES data clearly demonstrates that changes in serum levels of PFOA

and PFOS over time highly influence the modeling results and should be considered in models for all human risk endpoints evaluated in the technical support documents.

c. EPA's Process Failures Render Its Carcinogenicity Determinations for PFOA and PFOS Unreliable

i. PFOA

The MCLG of zero for PFOA is based on EPA's determination that PFOA is "likely to be carcinogenic to humans." EPA's conclusion is reportedly based on evidence of kidney and testicular cancer in humans and testicular Leydig cell tumors ("LCTs"), pancreatic acinar cell tumors, and hepatocellular adenomas in rats. As discussed below, as a result of process failures, EPA's analysis of the evidence on which it relies is fundamentally flawed, rendering EPA's conclusion unreliable.

In determining whether a substance is a likely carcinogen, EPA follows its Guidelines for Carcinogen Risk Assessment (USEPA 2005). That Guidance directs EPA to evaluate relevant studies and make a "weight of evidence" determination, by "weighing all of the evidence in reaching conclusions about the human carcinogenic potential of agents" based on considerations of animal and human evidence, mechanisms of action and dose-response relationships (USEPA 2005, p. 1-11). Here, EPA's systematic review and evidence synthesis failures led it to inaccurately assess the weight of the evidence as it relates to PFOA. For example, tumors identified in animals have questionable relevance to humans because they have been shown to occur through the PPARα pathway, a mode of action with limited relevance to humans (Biegel et al., 2001; Corton et al., 2018). In addition, the LCT tumors observed in animals do not have a common mode of action with testicular germ cell tumors seen in humans (Klaunig et al. 2012). Additionally, an excess of renal tumors has not been reported in three rat studies (NTP 2020; Butenhoff et al. 2012; Biegel et al. 2001). Despite the limited supporting evidence for renal carcinogenicity in animal studies, EPA relied primarily on the matched case-control study on kidney cancer (Shearer et al. 2021), even though other studies on humans evaluating associations between kidney cancer and PFOA exposure also have yielded inconsistent results and do not demonstrate consistent dose-response (Steenland and Woskie 2012; Barry et al. 2013; Raleigh et al. 2014).

Moreover, the study by Shearer et al. (2021) relied upon by EPA to derive the cancer slope factor (CSF)[58] for PFOA is undermined by the study's reliance on PFOA exposure measured at a single point in time almost a decade before cancer diagnosis. This discrepancy adds uncertainty to the associations of exposure and cancer outcomes, as discussed in more detail below. Furthermore, Shearer et al. (2021) insufficiently adjusts for confounding by key risk factors, including the very limited categorical data on smoking history, body mass index, and history of hypertension. EPA's *Guidelines for Carcinogen Risk Assessment* (2005) specifically discusses the importance of confounding factors and states, "[c]ommon examples include age, socioeconomic status, smoking habits, and diet" and further "[s]tatistical analyses of the bias,

[58] A cancer slope factor is a value representing a relationship between increases in exposure dose and cancer risk.

confounding, and interaction are part of addressing the significance of an association and the power of a study to detect an effect." EPA failed to follow its guidance when using Shearer et al. (2021) without consideration of these important variables.

Contrasts in PFOA levels in this study cohort were also modest—comparing the upper quartile of >7.3 μg/L PFOA to a lower quartile of <4.0 μg/L PFOA—and substantially smaller than exposure contrasts in more highly exposed populations that showed no significant difference in kidney cancer risk (e.g., Raleigh et al. 2014). The reference group (i.e., the least exposed group) in Shearer et al. (2021) also had fewer cases (47 cases) than the control group (81 controls), which may have biased the statistical comparisons for the other exposure categories. This distribution of 81 controls and only 47 cases in the referent group is counterintuitive because one would expect a more similar distribution among the least exposed. Neither Shearer et al. nor EPA commented on this referent group, which becomes the main driver in the subsequent calculations for the other three exposure categories. This shortcoming another example of EPA's attempts to infer statistical properties as discussed in Section IV.b. Other scientific literature indicates no association between PFOA exposure and kidney cancer risk; for example, a significant association or exposure-response trend was not observed between PFOA exposure and kidney cancer incidence or mortality in several other human epidemiological studies, including those from highly exposed occupational cohorts (e.g., Barry et al. 2013; Raleigh et al. 2014). The fact that there was little to no association between exposure to PFOA in workers with occupational exposure to high levels of PFAS and kidney cancer should have been considered by EPA as strong evidence against carcinogenicity, but , as a result of its deficient review processes, EPA appears to have largely disregarded this evidence.

Finally, the mechanistic weight of evidence for carcinogenicity indicates that PFOA is more likely to act via a threshold mode of action. EPA concludes that "most of the evidence for mutagenicity is consistently negative." This means that best practice would be for EPA to identify a dose below which toxicity does not occur (the threshold) and, accordingly, set an MCLG based on that dose (rather than assuming a zero MCLG). EPA's overall conclusions, however, assume a linear-no threshold model of carcinogenicity based on default assumptions of EPA's Cancer Guidelines (USEPA 2005) rather than analysis of the weight of evidence. As detailed in the section below on evidence of PFOS carcinogenicity, many of the modes of action for carcinogenicity of PFOA identified in animals do not apply to humans (e.g., PPARα pathways) and best practice dictates that EPA's assessment of carcinogenic mode of action should be revised to reflect its conclusion that most of the evidence for mutagenicity is consistently negative, indicating the linear no-threshold model of carcinogenicity is not appropriate for PFOA.

1. Evidence for PFOA Carcinogenicity and Derivation of the Cancer Slope Factor

EPA failed to apply applicable guidance in evaluating the evidence of carcinogenicity and deriving a CSF for PFOA. EPA's IRIS Handbook indicates that "consistency across studies or experiment" should be considered as part of the evidence synthesis step. Additionally, EPA's Cancer Risk Assessment Guidelines (USEPA 2005) recommend that, "[w]hen multiple estimates

[of cancer risk] can be developed, all datasets should be considered, and a judgment made about how best to represent the human cancer risk."

Contrary to this guidance, the proposed rule makes clear that EPA failed to consider all datasets relevant to potential cancer risk. As discussed below, in evaluating carcinogenicity, EPA incorrectly excluded several occupational exposure studies (Steenland and Woskie et al. 2012; Raleigh et al. 2014; Barry et al. 2013) which collectively demonstrate limited or no association with kidney cancers among workers with 10- to 100-fold greater exposure to PFOA than seen in the general population. Instead, EPA relies on Shearer et al. (2021), a matched case-control study on kidney cancer (324 cases, 324 matched controls) from the Prostate, Lung, Colorectal, and Ovarian Screening Trial (PLCO), which has critical flaws, as detailed below (*e.g.* a single serum measurement, potential reverse causation), that undermine the integrity of EPA's conclusion.

a. EPA incorrectly excluded occupational studies with greater exposures than Shearer et al. (2021)

Steenland and Woskie (2012) is an occupational cohort mortality study of DuPont workers (n = 5,791) with PFOA exposures, which reported a total of 12 kidney cancer deaths. This study observed significant elevated risk of kidney cancer death only in the highest exposure quartile. EPA identified this as a medium confidence study but stated that it did not consider it further because of the small number of observed cancer cases and because "information on a range of exposures more relevant to the general population were available from Shearer et al. (2021)" (USEPA 2023a). However, the range of exposures in Steenland and Woskie (2012) was actually 10 to 100 times higher than the general population, an indication that kidney cancer is not associated with general population-levels of exposure to PFOA.[59]

EPA also improperly excluded Barry et al. (2013), which is a community/worker cohort study of 32,254 residents (28,285 community members and 3,713 DuPont workers) with residential exposure to PFOA in their drinking water for which there were a total of 105 kidney cancer cases (87 from the community and 18 from the DuPont workers). This study also did not find a significant association of kidney cancer cases among workers who had serum concentrations that were 10-fold greater than the community population in Shearer et al. (2021). EPA stated Barry et al. (2013) was not suitable for dose-response analysis because it was performed in the same study area as Vieira et al. (2013) and may involve a number of the same participants. In addition, EPA stated that Barry et al. (2013) lacked the necessary exposure measurements for CSF calculation. However, a later study, Bartell and Vieria (2021), reports the necessary exposure data from Barry et al. (2013), which EPA did not acknowledge or explain

[59] EPA did not acknowledge that the observed kidney cancer cases could have been confounded by occupational exposure to tetrafluoroethylene (TFE), a known rodent renal carcinogen. EPA also failed to address that Steenland communicated in a recent publication (Bartell and Vieira 2021) that there was a major error in the cumulative ppm-years quartile analyses where the quartile PFOA exposure categories should have been defined as cumulative ng/mL-years (ppb-years) and not ppm-years. Therefore, the exposures in this study were actually lower (i.e., more relevant to the general population) and the reported cancers may have been due to TFE exposures and not PFOA.

why these data did not make this study appropriate for inclusion in its analysis, and thus arbitrarily excluded Barry et al. (2013).

EPA also incorrectly excluded Raleigh et al. (2014), reportedly based on concerns of exposure assessment methods and study quality as well as the small number of cases (USEPA 2023a). Raleigh et al. (2014) is an occupational cohort mortality and cancer incidence study of 3M workers (n= 4,668) with exposure to the manufacture of the ammonium salt of PFOA (i.e., APFO) that reported 16 kidney cancer cases and was not confounded by TFE exposure. The authors did not find an excess of kidney cancer cases beyond what would be expected in the general population. EPA stated that it excluded this study because it used modeled estimates of PFOA air concentrations in the workplace rather than biomonitoring measurements and because of concerns about absorption of inhaled PFOA. However, EPA did not appropriately consider the totality of other studies that found that these workers did likely have high PFOA exposures consistent with the higher PFOA serum concentrations (Olsen et al. 2000, 2003; Raleigh et al. 2013, 2014). Other studies have also concluded that PFOA is efficiently absorbed in rodents following inhalation of PFOA (Griffith and Long 1980; Kennedy et al. 2004). Therefore, EPA mischaracterized the quality of the data from Raleigh et al. (2014), resulting in the arbitrary exclusion of this study.

EPA's failure to collectively synthesize evidence from the occupational exposure studies resulted in a misinterpretation of the weight of evidence. Though individually the three occupational studies may not have been suitable to calculate a CSF, EPA failed to consider that, collectively the PFOA exposures in these three worker studies were one to two orders of magnitude greater than the general population serum PFOA concentrations reported in Shearer et al. (2021) yet showed little to no association with kidney cancer.[60] In Shearer et al. (2021), 324 kidney cancer cases originated from a cohort of 150,000 adults aged 55 – 74 with kidney cancer cases representing 0.22% of the cohort. In the three occupational cohorts by Steenland and Woskie (2012), Raleigh et al. (2014), and Barry et al. (2013) which had cohorts of 5,791, 4,668, and 3,713 (total = 14,172) workers respectively, there were a total of 52 kidney cancer deaths and cases representing 0.37% of the combined three cohorts. Though EPA labels each of these as small studies, they are collectively comparable to Shearer et al. (2021) in the percentage of kidney cancer cases.[61]

Therefore, among these three occupational analyses, which likely represent the highest exposed individuals based on overall reported biomonitoring data, only one analysis (Steenland and Woskie 2012) showed a statistically signficant associaton with kidney cancer, but this was confounded by the authors' decision to not adjust for TFE exposure. EPA did not synthesize the evidence across these studies, as is recommended by the IRIS Handbook and Cancer Guidelines,

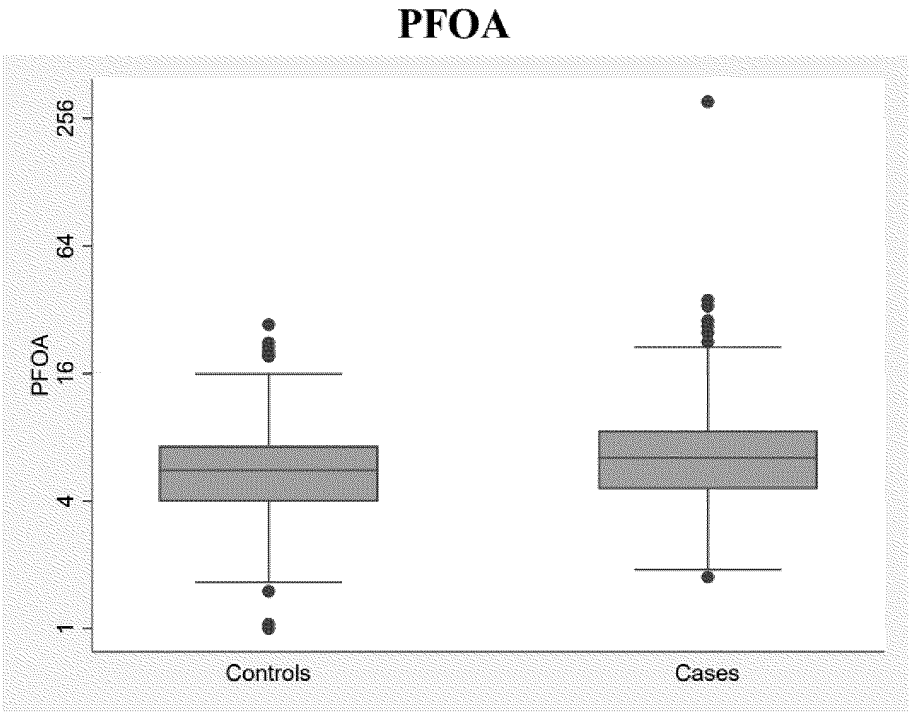
[60] In fact, Steenland et al. (2022) found that the risk of kidney cancer demonstrated in Shearer et al. (2021) decreased above 13 ng/mL serum PFOA. Combining Shearer et al. and Barry et al. together showed essentially no additional risk of kidney cancer above 10-13 ng/mL.

[61] The ability to collectively compare studies is the reason to do a systematic review, and demonstrates the value gained from such meta-analyses.

to inform its approach to the CSF and as a result did not appropriately assess the overall weight of evidence for carcinogenicity.

b. EPA did not properly assess Shearer et al. (2021) for flaws that undermine its reliability

Because EPA excluded the above occupational studies from consideration for the CSF, it instead inappropriately relied solely on Shearer et al. (2021) where a single measurement of serum PFOA was used to calculate the CSF.



Both EPA and Shearer et al. state the long half-life of elimination of PFOA indicates that a single serum measurement could be sufficient to provide an accurate and precise measurement of a person's long-term PFOA exposure. This assertion ignores the considerable uncertainty regarding the distribution, calculation, and measurement biases associated with the serum elimination half-lives of PFOA in humans as discussed in a series of publications (Dourson and Gadagbui 2021; Campbell et al. 2022a,b; Post et al. 2022). Shearer et al.'s (2021) conclusion that a single PFOA measurement is sufficient based on PFOA's long-half life in humans contradicts fundamental considerations of the connection between toxicodynamics, toxicokinetics, and time (Rozman et al. 1996). This highlights the limitations of using serum concentrations measured 2 to 18 years prior to the diagnosis of the disease. If the serum elimination half-life ranges from 0.5 to less than 3.0 years, then a PFOA measurement taken, on average, 8.8 years prior to the diagnosis of kidney cancer could be anywhere from 3 to greater than 5 half-lives from the diagnosis of kidney cancer. This discrepancy limits the accuracy of the reported serum concentrations in Shearer et al. (2021).

Shearer et al. (2021) also did not appropriately address reverse causation, which is a type of pharmacokinetic bias (Andersen et al. 2021) and occurs when a physiological outcome (e.g., estimated glomerular filtration rate [eGFR]), which affects the exposure assessment, has been *moderated by the health outcome itself*. The pharmacokinetic bias occurs when there is a sufficient window of time for the disease state to influence physiological factors that can bias the exposure assessment. EPA's IRIS Handbook recommends evaluating epidemiological studies for reverse causality and if reverse causality is a concern in the observed association of the exposure and health outcome, then a study should be labelled as deficient or critically deficient. In Shearer et al. (2021), the lack of an association between eGFR, PFOA, and kidney cancer does not conclusively demonstrate a lack of reverse causation, but it should have been considered as a factor because the eGFR was measured, on average, 8.8 years *prior to* the diagnosis of kidney cancer. There is the possibility of pre-diagnostic conditions that result in declining renal function. EPA therefore violated its own guidance in suggesting the lack of an association between a single eGFR measurement, and the diagnosis of kidney cancer eliminates the concern about this type of pharmacokinetic bias in the association between the exposure to PFOA and kidney cancer.

c. EPA uses inconsistent methods to calculate the cancer slope factor resulting in an overly conservative value

The cancer slope factor (CSF) describes the relationship between dose and cancer risk. EPA considers the slope factor as the upper-bound estimate of risk per increment of dose that can be used to estimate risk of cancer for different exposure levels (USEPA 2005). Thus, a steeper slope, or greater CSF, indicates that cancer risks are expected to increase more per each unit increase in dose. EPA's Cancer Guidelines (USEPA 2005) state that CSFs are derived for substances that are assumed to have a linear no-threshold mode of action or as a default if a different mode of action cannot be identified. This means that EPA assumes that even at doses below a carcinogenic point of departure, there is a nonzero risk of cancer. CSFs can be derived from either animal or human studies but should be derived based on the best practices in EPA's Cancer Guidelines.

EPA's derivation of the CSF lacks transparency and EPA inconsistently selects studies and analysis techniques, resulting in a CSF that is not based on the best available data. EPA relied solely on the relative risk of renal cell carcinoma from Shearer et al. (2021) to calculate the CSF, which as described above has critical limitations that make it unreliable. EPA's CSF derivation is based on a simple regression model originally used by the California Office of Environmental Health Hazard Assessment (OEHHA) (CalEPA 2021; OEHHA 2004), which is used to estimate the dose-response between PFOA and renal cell carcinoma risk. The CSF is then calculated as the excess cancer risk associated with each ng/mL increase in serum PFOA (internal CSF).

Results of EPA's analysis of Shearer et al. (2021) are reported in Table E-42 in the PFOA MCLG Appendix excerpted below. PFOA dose levels in each quartile of exposure (represented as x_i) were supposedly calculated as the midpoint of the reported PFOA range in ng/mL from Shearer et al. (2021). However, as seen in the second and third rows of excerpted Table E-42

below, the x_i values of 2.75 and 4.4 are not within their respective PFOA ranges in the leftmost column. Thus, these values do not actually represent the midpoint of the categories used by Shearer et al. (2021).

Table E-42 from the PFOA MCLG Appendix demonstrating the odds ratios for PFOA serum concentrations and renal cell carcinoma from Shearer et al. (2021).

Table E-42. ORs for the association between PFOA serum concentrations and RCC in Shearer et al. (2021, 7161466) and data used for CSF calculations

PFOA Range (ng/mL)	x_i	OR_i	LCI_i	UCI_i	$Var(OR_i)$	w_i	w_ix_i	$w_ix_i^2$	$w_ix_iOR_i$	cases	controls
< 4	0 (reference)	1	-	-						47	81
4.0–5.5	2.75	1.47	0.77	2.80	0.234	4.267	11.734	32.267	17.248	83	79
5.5–7.3	4.4	1.24	0.64	2.41	0.176	5.685	25.012	110.053	31.015	69	83
7.3–27.2	15.25	2.63	1.33	5.20	0.837	1.195	18.224	277.909	47.928	125	81

Based on the analysis outputs in Table E-43 of the PFOA MLCG Appendix, EPA calculates the CSF of 0.00352 $(ng/mL)^{-1}$ which represents the upper 95th percentile of the slope.

EPA also calculated CSFs based on Vieira et al. (2013) which is a study based on 58 kidney cancer cases exposed via drinking water and compared to greater than 7,000 controls. EPA calculates CSFs by either including or excluding the highest exposure level from that study (Table E-43 PFOA MCLG Appendix). EPA failed to explain why it chose not to use the regression model provided by California's Office of Environmental Health Hazard Assessment (OEHHA) and instead used the midpoint ranges of the Vieira et al. (2013) categorical data. This practice is inconsistent with the approach EPA applied to Shearer et al. (2021) to derive the CSF. This inconsistency of methods to derive a CSF from these two studies is arbitrary, lacks sufficient justification, and in the absence of a sensitivity analysis, prevents understanding of the ramifications of this arbitrary choice.

It is important to note that EPA's and OEHHA's approach to the derivation of the CSF are distinctly different and when followed with the same datasets, will result in different CSFs. OEHHA chose to use the central estimate of the slopes (i.e., the slopes themselves). This is because OEHHA combined the results of two separate studies (i.e., Shearer et al. 2021 and Vieira et al. 2013) to develop its final overall CSF. OEHHA determined this combination of different studies and different study sites would account for much of the variance likely to occur across different PFOA-kidney cancer sites and therefore using the geometric mean of the two slopes was a better representation of potential cancer risks across the general population. In contrast, because EPA did not appropriately synthesize the evidence, it only relied on Shearer et al. (2021) and instead based its estimate of the slope on the upper 95th percent confidence interval. Thus, California's CSF of 0.00178 $(ng/mL)^{-1}$ is approximately half that of EPA's CSF of 0.00352 $(ng/mL)^{-1}$. Notably, the California CSF is nearly identical to the CSF derived from the pooled data analysis of the Shearer et al. (2021) and Barry et al. (2013) as published in

Steenland et al. (2022).[62] Additionally, EPA's Cancer Guidelines allow for "combining data from different datasets in a joint analysis" (USEPA 2005, p. 3-25). Therefore, EPA should have considered this approach, which may better reflect the overall evidence base.

ii. PFOS

The agency's conclusion that PFOS is likely to be carcinogenic to humans is likewise undermined by the lack of a reliable process for identifying and evaluating available evidence. As a result, EPA's conclusion is inconsistent with the evidence that EPA presents, as well as with fundamental scientific principles.[63] The vast majority of the studies that EPA produced and analyzed reported no effects, no effects of statistical significance, or effects that are inapplicable for human risk assessment because of species differences. EPA's conclusion that the weight of evidence supports the classification that PFOS is likely to be carcinogenic to humans is inconsistent with the weight of the evidence to the contrary, as further detailed in this section. Of critical importance, the PFOS cancer assessment as written was not reviewed by the SAB, counter to the Cancer Guidelines (USEPA 2005) that state, "[g]enerally, cancer risk decisions strive to be "scientifically defensible, consistent with the agency's statutory mission, and responsive to the needs of decision-makers" (NRC, 1994). Scientific defensibility would be evaluated through use of EPA's Science Advisory Board, EPA's Office of Pesticide Programs' Scientific Advisory Panel, or other independent expert peer review panels to determine whether a consensus among scientific experts exists." EPA's conclusions on the carcinogenicity of PFOS have been proposed without sufficient peer review, in violation of EPA's own Cancer Guidelines.

1. Epidemiological Evidence

EPA is inconsistent in its presentation of epidemiological data regarding PFOS (USEPA 2023c).[64] EPA summarized epidemiological studies regarding PFOS and their reliability in USEPA (2023c). In a previous assessment that EPA conducted of pre-2016 epidemiology studies of PFOS for its 2016 Health Effects Support Document for PFOS (USEPA 2016),[65] EPA concluded that Jørgensen (2011), Eriksen (2009) and Grice (2007) did not support EPA's new conclusion in the proposed NPDWR regarding PFOS carcinogenicity.[66] Nonetheless, in EPA's weight-of-evidence conclusion for carcinogenicity, the agency misleadingly stated that Grice (2007) "observed that prostate cancers were among the most frequently reported malignancies."

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[62] Steenland et al. (2022), which calculated a CSF from pooled data from Shearer et al. (2021) and Barry et al. (2013), recognized that the CSF derivations from Shearer et al. and Barry et al. were statistically different due to differences in the dose-response relationship at different exposure levels.

[63] In its November 2021 draft PFOS MCLG document submitted to SAB, EPA said there was "suggestive evidence of carcinogenic potential" of PFOS in humans. Now, without providing adequate justification, the Agency has switched its carcinogenicity determination for PFOS despite no new evidence and came to different conclusions about studies it had previously reviewed.

[64] EPA stated that it "identified 15 epidemiological" studies, of which "8 were classified as medium confidence, 6 as low confidence, and 1 was considered uninformative" (p. 3-260). In another section (p. 3-263), the agency states that, "of the 15 studies identified since the 2016 assessment (Figure 3-73), seven were considered medium confidence and six were low confidence," and that figure shows two studies as critically deficient.

[65] See (USEPA 2023c at Figure 3-72, p. 3-262).

[66] See (USEPA 2023c at 3-260-261).

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This directly contradicts the original authors' conclusions that they "observed no association between working in a PFOS-exposed job and several cancers, common health conditions, and birth weight" (Grice 2007).

The majority of the studies identified by EPA as relevant for assessing whether PFOS is carcinogenic concluded no, or in one case, even a reduced risk of cancer from PFOS exposure, as follows:

- Bonefeld-Jørgensen et al. (2011): "the association was of a low magnitude and could not be separated from the effects of other perfluorosulfonated compound exposures" (p. 3-283).
- Cohn et al. (2020):" maternal PFOS was associated with a decreased daughters' breast cancers risk" (p. 3-265).
- Ducatman et al. (2015): "No association between PFOS exposure and prostate cancer was reported […] in a study of the association between PFOS serum concentrations and prostate specific antigen (a biomarker of prostate cancer)" (p. 3-282).
- Eriksen et al. (2009): "No elevated bladder cancer risk was observed in a nested case-control study in a Danish cohort" (p. 3-261).
- Fry and Power (2017): "Cancer mortality based on Public-use Linked Mortality Files was not associated with PFOS exposure" (p. 3-266).
- Grice et al. (2007): "they did not reach statistical significance" (p. 3-261).
- Hurley et al. (2018):" A nested case-control study did not observe an association between breast cancer identified through California cancer registry and PFOS concentrations in serum" (p. 3-265).
- Shearer et al. (2021): "reported a statistically significant positive trend in risk of renal cell carcinoma" but "the association with PFOS was attenuated after adjusting for other PFAS […]. There was no association when evaluated on a per doubling of PFOS after adjusting for other PFAS" (p. 3-265).

In particular, there is a lack of confidence in EPA's review methodology, especially as it relates the Eriksen et al. (2009) study when compared to the Shearer et al. (2021) study. Both studies used the same methodology during the same time period. Both studies were published in the Journal of the National Cancer Institute. The Shearer et al. study originated from the PLCO screening trial study that enrolled approximately 150,000 individuals. These participants were enrolled between 1993 – 2001. Single measurement blood (serum) samples were collected at enrollment. At a later date, these samples were measured for PFOA and PFOS. A case control study was much later conducted of those who subsequently were diagnosed with kidney cancer (324 cases, 324 controls) and their archived serum sample for PFOS and PFOA. The Eriksen study originated from the prospective cohort Danish Diet, Cancer, and Health Study which had a cohort of 57,053 individuals aged 50 -65 years, born in Denmark with no previous cancer diagnoses. These participants were enrolled between 1993 – 1997. As with Shearer et al., there was only a single measure of blood (plasma) taken for each participant. Eriksen et al. followed the cancer experience in this cohort through mid-2006. Cases were ascertained through the

Danish National Cancer Registry. A total of 713 prostate cancer cases, 332 bladder cancer cases, 128 pancreatic cancer cases, and 67 liver cancer cases were identified in this follow-up time period. A total of 772 noncancer cases were selected as controls. Archived plasma samples were measured for PFOA and PFOS. Eriksen concluded there was no clear differences in risk for these cancers in relation to plasma concentrations of PFOA and PFOS.

Unlike Shearer et al. (who assert that a single measurement can be used), however, Eriksen et al. wrote, "Consequently, misclassification may have occurred because the concentration may have occurred because the concentration at one moment in time may not reliably reflect the relevant plasma concentrations decades ago or at other times." Eriksen is the largest study, to date, to examine prostate, pancreas, and especially liver cancer, in the general population with PFOS exposure. (The Eriksen et al. study also analyzed for serum PFOA concentrations).

EPA judged both studies by Shearer et al. and Eriksen et al. to result in overall "adequate" confidence with confounding to be deficient in both studies (i.e., both had the same qualitative measurements for cigarette smoking). Given the same methodology, EPA considered Shearer et al. to have good metric scores for participant selection, exposure measurement, outcome, and analysis, whereas Eriksen et al. only received one good metric for participant selection. The mere fact that the EPA has considered PFOS to be likely carcinogenic (based on liver cancer in rats) but utterly failed to mention the Eriksen et al. study for its null liver cancer results in the PFOS final report illustrates inconsistency and apparent arbitrariness EPA's carcinogenicity assessment process.

In conclusion, EPA's process errors led it to reach a carcinogenicity determination that is contrary to the weight of epidemiological evidence in violation of EPA's own Cancer Guidelines.

2. Animal Evidence

EPA made similar process errors in determining that PFOS is "*likely to be carcinogenic to humans*" based on the results of neoplastic tumor data for the liver and pancreatic islet cells from a 2-year chronic dietary study (cited as Thomford, 2002 and Butenhoff et al. 2012, for the original study report and published peer-reviewed manuscript, respectively). While the original study data (by Thomford 2002) reported statistically significant increases in liver adenoma incidences in both male and female rats at the highest dose, it did not conclude such for the pancreatic islet cell tumors.

With regards to the hepatocellular tumor data observed in rats, EPA did not take the known biological plausibility into consideration as it related to human health and used two different models to interpret animal studies regarding PFOS carcinogenicity, which violates its own *Guidelines for Carcinogenic Risk Assessment*. In the draft PFOS appendix (USEPA 2023d), EPA states about data on hepatocellular adenomas and carcinomas in female rats, "the best fitting model was the Multistage Degree 1 model based on adequate p-values" (p. E-55 and p. E-58). It based its selection of a BMDL10[67] on this model. For data for hepatocellular

[67] BMDL10 is the benchmark dose level corresponding to the 95% lower confidence limit of a 10% change.

adenomas in male rats, EPA stated "the best fitting model was the Multistage Degree 4 model based on adequate p-values" (p.E-47). EPA fails to explain the use of different models for studies involving male and female rats in evaluating the evidence of carcinogenicity. In doing so, EPA violates its 2005 *Guidelines for Carcinogen Risk Assessment*, which states, "goodness-of-fit to the experimental observations is not by itself an effective means of discriminating among models that adequately fit the data."

EPA deemed the study by Butenhoff et al (2012) a "high confidence study" (USEPA 2023c, p. 3-260), which should add to the importance of its correct interpretation and the representation of the study's result. However, EPA over-interpreted the importance of a "statistically significant trend of increased incidence of pancreatic islet cell carcinomas with increased PFOS dose" in male rats in the cancer classification section (USEPA 2023c, p. 3-296). It is important to understand that a trend, even if it is statistically significant, simply indicates a non-zero slope among data points. A trend is non-quantitative and does not imply that the magnitude of the increase in effect over increasing dose ever reaches biological significance, or that it would result in the observation of statistically significant increase in effects. A trend simply means that there is a consistent change within the observed parameters across the doses that were investigated. This does not necessarily mean that it continues to persist when additional experimental data is introduced, or that it ever reaches statistical or biological significance before reaching a physiological maximum dose limit such as stomach capacity for dosing, or the natural lifetime of rats.

With regards to the pancreatic islet cells tumors, the EPA improperly employed an alternative statistical approach which led to a statistical significance in trend for the pancreatic islet cell carcinoma. Specifically, the original study report by Thomford (2002) calculated the total tumor incidence rate based on the total number of the tissues examined per specific dose group upon study termination at the end of two years. Given that age-related mortality is quite common among rodents in long-term studies, it is worth noting that the original statistical trend analysis (reported in Thomford 2002) did adjust for survival and survival was taken into account for the logistic regression of tumor prevalence and binary regression analyses. The EPA, on the other hand, calculated the tumor incidence rate based on the number of animals alive at the time when the tumor first occurred, which was an attempt to adjust for survival as well as excluding a subset of rats from control (n=10) and the highest dose group (n=10) that were sacrificed at week 52. While the EPA does not have any specific publication on how to analyze tumor incidence data, the guidance document from U.S. FDA Center for Drug Evaluation and Research (Lin 2007) summarizes various ways of analyzing tumor data in rodents by adjusting for intercurrent mortality, it did not, however, mention this particular approach taken by the EPA.

It was also not best practice to exclude subsets of rats from control (n=10) and the highest dose group (n=10) that were sacrificed at week 52 from the overall trend analysis for tumors, given that the trend test was adjusted for survival. All the animals in these two subgroups were subject to the same rigor in terms of specimen collections and pathology evaluations for potential presence or progression of tumor formations, if any. This was the ultimate purpose of the 2-year cancer study hence if anything, the interim evaluations (with proper survival time adjustment) did not "dilute", but rather, reflect additional statistical power to ascertain the likeliness of tumor

outcome. Furthermore, in accordance with the guidance from the American Statistical Association (Wasserstein and Lazar 2016), a hard cut-off for statistical significance on its own should not be used to make scientific conclusions – "Scientific conclusions and business or policy decisions should not be based only on whether a p-value passes a specific threshold." Therefore, the interpretation should not be based on whether a p-value is above or below 0.05. On that note, the relationship between pancreatic islet cell carcinoma and PFOS treatment is further called into question because there was no increased incidence of pancreatic islet cell hyperplasia (Thomford 2002). This is important because an increase in islet cell hyperplasia is typically viewed as a continuum to develop islet cell neoplasm.

Lastly, best practice required consideration that it has been well-documented that there are substantial differences in pancreatic islet cells between rodents and humans in terms of anatomy, cellular components, gene expressions, and functional aspect of insulin secretion (Brissova et al. 2015; Steiner et al. 2010). For instance, human islet cells contain less β-cells and more α-cells relative to rodents; and the pancreas tissue in rats are highly vascular. The species difference in pancreatic islet architecture and composition begs the question regarding the interpretation and extrapolation of rodent data finding to humans.

3. Mechanistic Evidence

EPA's processes also undermine its conclusion that PFOS is likely to be carcinogenic to humans based on mechanistic evidence. Mechanistic evidence is critical to support the relevance of data to carcinogenicity, with specific focus on relevance to carcinogenicity in humans. Mechanistic information is relevant to assess the applicability of findings in animals to human cancer risk. EPA (USEPA 2005) specifically emphasizes the importance of making "decisions about potential modes of action and the relevance of animal tumor findings to humans." As discussed below, profound uncertainties compromise the agency's following statement about hepatic tumors in animals: "the available studies provide varying levels of support for the role of several plausible MoAs: PPARα activation, chimeric antigen receptor (CAR) activation, hepatocyte nuclear factor 4 alpha (HNF4α) suppression, cytotoxicity, genotoxicity, oxidative stress, and immunosuppression." (USEPA 2023c, p.3-284). Each of these modes of action is discussed below.

PPARα Activation. EPA's treatment of PPARα as a viable theory for carcinogenicity applicable to humans directly contradicts its own scientists' conclusions. EPA scientists previously published a peer-reviewed article with the title "The PPARα-dependent rodent liver tumor response is **not** relevant to humans" (Corton 2018) (emphasis added), which EPA cites in the proposed NPDWR. The agency failed to acknowledge its own scientists' key finding that "[t]he PPARα-dependent rodent liver tumor response is **not** relevant to humans." EPA's insistence on the relevance of this pathway with respect to PFOA and PFOS is further drawn into question by findings from EPA scientists who demonstrated last year (Evans et al. 2022) that the endogenous fatty acid oleic acid, which is also ubiquitous in the diet, is a more potent PPARα activator than are PFOA (by more than 1 order of magnitude) and PFOS (by more than 2 orders of magnitude). If PPARα activation were a relevant pathway to human liver tumors, that disease state presumably would be at epidemic levels, based on oleic acid alone.

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In addition, EPA (Evans et al. 2022) reported concentrations of PFOS and PFOA that did not induce PPARα activity, which demonstrates that this alleged key MOA for carcinogenicity is, if anything, a proven threshold effect. Best practice would be to apply those insights to the carcinogenicity assessment of PFOS and PFOA and abandon the principle of a linear non-threshold dose response.

CAR Activation. In 2016, EPA referenced Hall et al.'s (2012) conclusion that, "CAR activation can lead to hepatocyte proliferation and hepatocarcinogenesis in animals. The human CAR receptor is relatively resistant to mitogenic effects and less likely to induce cancers through this mechanism." EPA referenced the same publication elsewhere in the 2023 draft proposal for PFOS but neglected to report the same conclusion regarding the implausibility of CAR as MoA for PFOS carcinogenicity. EPA vaguely alluded to Hall's conclusion on CAR in the PFOA draft proposal but failed to acknowledge its fundamental implications for human cancer risk.

Every event that is elicited by receptor binding is a threshold effect. A zero-effect threshold is inevitable at concentrations where insufficient numbers of activating molecules are present to trigger a biological signaling cascade and, thus, a response. Receptor-mediated theories warrant dismissal if proven inapplicable for human risk assessment; otherwise, they should be considered threshold effects. EPA did neither.

HNF4*a* Suppression. Beggs (2016) reported that concentrations of 10,000 nanomolar (nM) PFOA and PFOS had statistically significant impacts on HNF4α expression in primary human hepatocytes—and lower concentrations (i.e., 10, 100, 500, 1,000 nM) did not. This observation demonstrates the existence of a threshold below which no effect was observed. Best practice is to discontinue the use of a non-threshold approach for both PFOS and PFOA and instead use PBPK modeling based on concentrations in drinking water to compare *in vitro* no-effect concentrations to expected concentration within human hepatocytes.

Cytotoxicity. In the draft document for PFOS (USEPA 2023c, p. 3-292), EPA states, "the available data indicate a parallel dose response for cytotoxicity and the formation of liver tumors as evidence in Table 3-24 and Table 3-25." It is unclear how EPA reached this conclusion from data that only show statistical significance for hepatocellular adenomas and combined hepatocellular adenomas and carcinomas, and for none of the other (cytotoxicity) endpoints. Variations on a cellular level cannot cause statistically significant tumor formation at a dose where those cellular changes are not also statistically significantly increased. A molecular event cannot be responsible for a pathological response if the dose-response curves are parallel and not intersecting. For PFOA, EPA presents evidence of cytotoxicity *in vivo* (i.e., "significantly increased single cell (hepatocyte) death and in necrosis in male and female was reported in Sprague-Dawley rats, with a significant dose-response trend"), but fails to conduct a dose-response assessment. Only effect concentrations of *in vitro* assays are mentioned in the draft document, none of which are lower than 10 μM. EPA lists non-cytotoxic concentrations but fails to use them as demonstrable no-effect levels to justify a threshold assessment of carcinogenicity.

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The assessment of cytotoxicity lacks the diligence that is warranted if it is considered a key event in carcinogenesis.[68]

Genotoxicity. EPA concluded based on the available in vivo mutagenicity study (Wang et al. 2015) that "the evidence for mutagenicity of PFOS in vivo is negative" (USEPA 2023c, p. 3-269). Addressing DNA damage, the agency stated, "it is important to note that rat models could be ineffective for determining micronucleus formation if study authors do not use appropriate methodologies because the spleen will remove micronucleated cells" (USEPA 2023c, p.3-269). This draws the biological relevance of other models and findings into question because an effective removal of micronucleated cells implies the neutralization of this hazard. EPA should explain why said findings in other models are applicable for assessing potential human carcinogenicity.

Immunosuppression. EPA (USEPA 2023c, p.3-295) states that "the only available study in Sprague-Dawley rats [...] does not indicate that immunosuppressive effects are occurring at or below doses that result in tumorigenesis." This finding demonstrates that there is no toxicological evidence that immunosuppression is a plausible MoA on the organism level because a mechanism that supposedly underlies a carcinogenic effect should occur at the same doses that cause tumors. EPA ignores the fundamental logic that a response (e.g., cancer) that occurs at doses below the no-observable-effect-level (NOEL) of another response (e.g., immunosuppressive effects) cannot be linked to or caused by the latter. By insisting that both are linked, EPA violates the basic principle of dose-response. According to EPA's Vocabulary Catalog for Drinking Water Technical & Legal Terms (see https://sor.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=Drink%20Water%20Tech%2FLegal%202009), the NOEL is defined as a "dose level at which no effects are noted" and dose response is defined as "the quantitative relationship between the amount of exposure to a substance and the extent of toxic injury produced". If the extent of toxic injury from immunosuppression is zero, then it cannot be in a quantitative relationship with cancer that allegedly occurs below the NOEL of immunosuppression.

The perpetual inconsistency of EPA's findings and interpretations warrants a detailed analysis to compare and contrast reported dose-responses and clinical relevance of experimental models.

4. Structural Similarities

EPA inappropriately attempts to rely on the structural similarity between PFOA and PFOS to conclude that its carcinogenicity determination PFOA applies to PFOS. EPA's

[68] It is inappropriate for EPA to set a MCLG at zero based on carcinogenicity when a substance does not have a linear mode of carcinogenic action. *Chemistry Council v. EPA*, 206 F.3d 1285, 1287 (D.C. Cir. 2000). When a substance exhibits a "cytotoxic" mode of action, no carcinogenic effects at low doses, a zero MCLG based on carcinogenicity is not in line with the goals of the SDWA. While there is uncertainty in the range at which no known or anticipated adverse effects on the health of persons occur, this does not mean that EPA can simply default to zero. Uncertainty allows EPA to choose the lowest MCLG within the window of uncertainty but it does not justify choosing an MCLG outside of the range of uncertainty. *Id.* at 1290.

reasoning of structural similarity for cancer risk read-across (USEPA 2023c, p. 3-296) between PFOA and PFOS is also not supported by evidence. EPA states in its publication by Patlewicz et al. (2019) that "the Environmental Protection Agency had the greatest experience in using read-across" but failed to apply any of the best practices – or even apply its own Generalized Read-Across Tool (https://www.epa.gov/chemical-research/generalized-read-across-genra#:~:text=Chemical%20read%2Dacross%20is%20a,(e.g.%2C%20structural%20similarity). EPA also did not follow the seven key steps in the workflow: 1. Decision context 2. Data gap analysis 3. Overarching similarity rationale 4. Analog identification 5. Analog evaluation 6. Data gap filling 7. Uncertainty assessment. The two PFAS substances differ in a key functional group, in that PFOA is a perfluoroalkyl carboxylic acid and PFOS is a perfluoroalkyl sulfonic acid. Carboxylic acids and sulfonic acids possess different physical-chemical properties, which not only explains their different technical applications but also suggests differences in disposition and dynamics on biological receptor sites. The agency stated that a "similar set of non-cancer effects have been observed after exposure to either PFOA or PFOS in humans and animal toxicological studies," implying that those effects were of relevance for cancer risk assessment, when in fact, only the consideration of key events that actually lead to cancer is of relevance. By definition, non-cancer events are not applicable for cancer risk assessment.

d. EPA's Approach to Assessing the Overall Weight of Evidence for Non-Cancer Health Effects of PFOA and PFOS is Not Consistent with Guidance and Methods are Neither Transparent nor Reproducible

EPA likewise did not follow its own guidance in determining that PFOA and PFOS exposure is associated with numerous noncancer health effects including, but not limited to: "effects on the liver (e.g., liver cell death), growth and development (e.g., low birth weight), hormone levels, kidney, immune system, lipid levels (e.g., high cholesterol), the nervous system, and reproduction." For each type of health effect listed, EPA has not followed its own guidance (i.e., the IRIS Handbook) in evaluating the weight of evidence of the science, which shows, at most, inconsistent associations of the effects with PFOS and PFOA exposures. For several endpoints, EPA improperly conflates changes in biomarkers (e.g., antibody response, cholesterol, liver enzymes) with increased risk of adverse disease outcomes in humans.

Agencies cannot disregard available scientific evidence that is better than the evidence on which it relies.[69] However, this is exactly what EPA did in this Proposed Rule. As summarized below, EPA disregarded legitimate studies for reasons that are unclear or not justified in its Proposed Rule.[70] Key scientific evidence and uncertainties for each health endpoint as well as EPA's failure to properly review and evaluate the evidence are summarized below, using immune system effects as an example.

In EPA's draft toxicity assessments for PFOA and PFOS (USEPA 2023a,b), EPA derived multiple candidate RfDs across four non-cancer health outcomes comprising four endpoints (i.e.,

[69] *Kern County Farm Bureau v. Allen*, 450 F.3d 1072, 1080 (9th Cir.2006).
[70] Ultimately, "[t]he presumption of agency expertise may be rebutted if the agency's decisions, although based on scientific experience, are not reasoned." *Greenpeace v. NMFS*, 80 F.Supp.2d 1137, 1147 (W.D. Wash. 2000).

decreased antibody response, low birth weight, increased total cholesterol, and elevated alanine transaminase (ALT)[71]) from both epidemiological and animal toxicological studies that EPA deemed to have the "strongest weight of evidence" (USEPA 2023a,b). However, as described in Sections V.d – V.f above, EPA's process failures mean that none of these endpoints are, in fact, supported by the weight of evidence. Nonetheless, EPA determined that *"candidate RfDs derived from epidemiological studies were all within 1 order of magnitude of each other (10^{-7} to 10^{-8} mg/kg/day), regardless of endpoint, health outcome, or study population . . . In fact, [for PFOA] candidate RfDs within the immune, developmental, and cardiovascular outcomes are the same value"* (USEPA 2023a). EPA made similar conclusions for PFOS, as the candidate RfDs based on epidemiological studies *"within the developmental and cardiovascular outcomes are the same value"* (USEPA 2023b). As a result, EPA selected an overall RfD of 3×10^{-8} mg/kg/day for PFOA and 1×10^{-7} for PFOS.

As described in the following discussion, the range of estimated RfD values for PFOA that account for uncertainty is quite large. If uncertainties in each step of RfD derivation were estimated for each of the "co-critical endpoints" identified by EPA, it is unlikely that the resulting range of RfD values for each co-critical endpoint would be the same. To further increase confidence in the overall RfD, best practice would be to calculate ranges of RfD values that account for uncertainties within each of the endpoints identified as co-critical.

i. EPA relied on studies that used outdated and uncorrected NHANES data and did not conduct its own analysis or verify data accuracy

Many of EPA's conclusions related to non-cancer health impacts rely on previously published papers that used data sets that were ultimately rejected by the National Health and Nutrition Examination Survey (NHANES), the reporting entity, because they did not meet NHANES data quality requirements. EPA has largely relied on previously published statistical relationships between PFAS compounds and health outcomes that rely on NHANES data. NHANES regularly updates all its datasets, which in turn affects any previous quantitative analyses.[72] In 2021 and 2022, the NHANES Biospecimen Program processes were reevaluated to monitor quality control after a procedural error was identified. Following a comprehensive review of all surplus sample datasets generated between 1999 and 2018, NHANES modified certain data files to remove 15-20% of PFAS records that were initially included in error because it said that data did not meet program standards. Revised files were released in April 2022 (CDC 2022).[73]

While EPA notes the possibility of NHANES data updates, without conducting additional analyses, EPA cannot understand the ramification of these updates. EPA has not provided details on the data used in its analyses, or the year class of the data and it is thus very likely that

[71] ALT is an enzyme found primarily in the liver that can be used to assess liver health.
[72] *See* https://www.cdc.gov/nchs/nhanes/new_nhanes.htm and https://www.cdc.gov/nchs/nhanes/archive_new_nhanes.htm
[73] 3M queries to the Biospecimen Program email address were not answered so 3M cannot determine exactly which records were removed.

EPA findings using NHANES are based on uncorrected data. Best practice is for EPA to provide details on the data updates incorporated into its models.

In short, any and all previously published analyses EPA relies on that use NHANES PFAS data contain an unknown number of errors, which invalidates the published statistical relationships.

ii. EPA's assessment of developmental effects is flawed

In evaluating the impacts of PFOA/PFOS on development effects (namely, low birth weight), EPA did not appropriately employ methods described in the IRIS Guidance for evaluation of study quality and risk of bias.

EPA (USEPA 2023a,b) considered associations between PFOA and PFOS exposures and multiple developmental outcomes, including birth weight, birth length, head circumference, diagnosed condition of low birth weight,[74] or small for gestational age,[75] gestational duration, or diagnosed conditions such as preterm birth.[76] EPA determined that there was **moderate** evidence of an association between PFOA or PFOS and developmental effects based on epidemiologic literature. As discussed below, this determination was not supported by the underlying evidence and appears to be based primarily on inconsistently observed decreases in birth weight.

EPA also did not appropriately consider uncertainties – most of which directly implicate bias in studies' results. These uncertainties include:

- Potential bias due to pregnancy hemodynamics and sample timing
- Mixed evidence for gestational duration, measured as gestational age or preterm birth
- Inconsistent evidence with rapid growth measures, including postnatal height and adiposity up to age 2
- Little evidence for increased fetal loss
- No evidence for increased birth defects
- Limited dose-response evidence in birth weight deficit studies

Additional details regarding the strength of evidence related to developmental outcomes are described in the EPA Evidence Stream and Summary Judgments (USEPA 2023a Table 3-10; USEPA 2023b, Table 3-12). EPA's determination of a "moderate" level of evidence is not supported by the findings presented. Decreases in birth weight have not been shown to represent adverse effects or other clinically meaningful health effects. In the appraisal of study quality and risk of bias, EPA did not evaluate studies consistently, which led to the selection of candidate studies for POD development with critical limitations. PODs are estimates of the dose levels at which an adverse response is not expected; they are typically derived near the low end of the

[74] LBW- defined as a birth weight less than 5 pounds, 8 ounces, or <2500g; (Cutland et al. 2017)
[75] SGA - birth weight <10th percentile for gestational age; (Osuchukwu and Reed 2023)
[76] Gestational age < 37 weeks

observable range of data by using dose-response analyses within the selected studies. The PODs are then used as the basis for toxicity value calculations. Selection of reliable studies with limited bias is critically important for limiting the uncertainty in the derived POD and subsequent toxicity values.

1. Evidence integration of developmental outcomes demonstrated inconsistent evidence for an effect from PFOA/PFOS exposure.

EPA's categorization of the evidence regarding developmental outcomes is inconsistent with EPA's own criteria for an evidence synthesis judgement of "moderate" evidence in human studies. In order for evidence to be characterized as "moderate," the IRIS Handbook states that the evidence "*includes at least one high or medium confidence study reporting an association and additional information increasing certainty in the evidence. For multiple studies, there is primarily consistent evidence of an association with reasonable support for adversity, but there might be some uncertainty due to potential chance, bias, or confounding or because of the indirectness of some measures"* (USEPA ORD 2022, Table 6-4). IRIS guidance also states that supplementary evidence may address some of the uncertainty factors and raise a set of studies from "slight" to "moderate" evidence rating. Given the lack of consistency in the scientific literature, it is unclear how EPA concluded that there is "moderate" evidence that PFOA/PFOS affect developmental outcomes.

Moreover, EPA's determination of "moderate" evidence for developmental outcomes is a broad judgement that obscures the fact that such a designation is not consistent with EPA guidance for specific categories such as birth weight, birth length, head circumference, LBW, SGA, gestational duration, fetal loss, post-natal growth, and birth defects (USEPA 2023a Table 3-10; USEPA 2023a Table 3-12). EPA presented inconsistent or limited evidence of associations between PFOA/PFOS and each of the specific developmental outcomes, and did not provide judgements for any one of the specific developmental outcomes separately. Therefore, the strength of each evidence base is unclear.

In reviewing EPA's draft documents, the SAB stated that it was "not aware of evidence for associations of PFOA and PFOS with adverse consequences such as developmental delays in low birth weight/small for gestational age infants." (USEPA SAB 2023, p. 21). In short, EPA did not show consistent evidence that met the criteria for "moderate" evidence of an association between PFOA or PFOS exposure and developmental outcomes. Yet despite the uncertainties in the evidence of a relationship between PFOA or PFOS exposure and developmental outcomes, as acknowledged by EPA's own SAB, EPA selected decreases in birth weight as a critical endpoint and used it in POD derivation. Best practice is for EPA to follow its own guidance and determine evidence judgements for specific outcomes to select appropriate critical endpoints.

2. EPA did not appropriately consider the lack of consistency or plausibility demonstrated within the evidence base for decreased birth weight and incidence of adverse effects such as small for gestational age or low birth weight.

In reviewing EPA's draft documents, SAB recommended that EPA "*clearly demonstrate that the endpoints selected for POD development are well established, sensitive, adverse or precursor to adverse"* (USEPA 2023c, p. 20). Due to the lack of evidence for associations between PFOA and PFOS exposure and developmental outcomes (e.g., fetal loss or birth defects), lack of consistency in evidence for outcomes of LBW or SGA, and lack of evidence that measured decreases in birth weight are clinically relevant developmental outcomes, EPA has failed to meet the standard SAB deemed appropriate.

Two thirds of the studies (6 of 9) for PFOA showed some increased risk of either SGA or LBW, but did not have statistically significant results, meaning those studies are not reliable predictors of developmental effects. Critically, only 5 of the 11 examined PFOA in early pregnancy, which is the only period of exposure timing that is considered a lower risk of bias due to changes in pregnancy hemodynamics (Meng et al. 2018; Hjermitslev et al. 2020; Manzano-Salgado et al. 2017; Wikstrom et al. 2020; Chang et al. 2022). Of these 5 studies, only 2 identified statistically significant associations (Wikstrom et al. 2020; Chang et al. 2022). Of those, EPA selected one as a candidate study (Wikstrom et al. 2020). However, serum volume increases by about 50% during pregnancy, peaking at 30-35 weeks gestation (Salas et al. 2006), and glomerular filtration rate (GFR) increases similarly (40-50%) (Cheung and Lafayette 2013). These increases lead to a decrease in maternal serum PFAS concentration during pregnancy (Monroy et al. 2008; Steenland et al. 2018; Kato et al. 2014) and the magnitude of increases can be inversely correlated with birth weight. First trimester serum PFAS measures have less chance for bias from sample timing (USEPA 2023a, p. 3-212). Additionally, two meta-analyses by Dzierlenga et al. (2020) and Steenland et al. (2018) found that when PFOA was measured in early pregnancy, there was little to no association with LBW, suggesting that the timing of serum measurement is critical for accurate interpretation of study results.

While EPA described the collective evidence as "supportive" of an increased risk of LBW or SGA with PFOA/PFOS exposure, this is inconsistent with the fact that less than half of the studies reported statistically significant results, demonstrating that there was not consistent evidence of an association between PFOA/PFOS and these outcomes. Among the studies for PFOS, 5 of 10 studies examined PFAS measured in early pregnancy (Meng et al. 2018; Hjermitslev et al. 2019; Manzano-Salgado et al. 2017; Wikstrom et al. 2020; Chang et al. 2022), one of which was selected as a candidate study. Of the 5 studies, 2 reported statistically significant associations. Of the 7 high- or medium confidence studies, 2 reported statistically significant increased risks of SGA and only 2 of the 4 high- or medium-confidence studies reported increased risks of LBW (USEPA 2023b, p. 3-206-210).

EPA considered 6 high confidence studies of PFOA for POD development (Chu et al. 2020; Govarts et al. 2016; Sagiv et al. 2018; Starling et al. 2017; Wikstrom et al. 2020; Yao et al. 2021) (USEPA 2023a, p. 4-9). 2 of those were used for RfD determination because serum PFAS

was measured in the first trimester (Sagiv et al. 2018; Wikstrom et al. 2020) (USEPA 2023a, p. 4-43). The agency also considered 6 high confidence studies of PFOS for POD development (Chu et al. 2020; Darrow et al. 2013; Sagiv et al. 2018; Starling et al. 2017; Wikstrom et al. 2020; Yao et al. 2021) (USEPA 2023b, p. 4-9), and the 2 that were used for RfD determination were the same as those chosen for PFOA (USEPA 2023b, p. 4-39).

For 5 of the studies, it is unknown if the study populations had clinically relevant changes in birth weights with PFOA or PFOS exposure (Sagiv et al. 2018; Starling et al. 2017; Wikstrom et al. 2020; Yao et al. 2021), because only mean or median birth weights were reported, none of which were <2500g. Among a Belgian birth cohort of 248 mother-infant pairs, the number of LBW infants was not reported, nor was the risk of LBW with PFOA or PFOS exposure examined, so it is unknown if there was an increased risk of an adverse effect in this population (Govarts et al. 2016).

The remaining 2 studies reported the risk of an LBW birth in the population. A study of the births among women in the C8 population of highly exposed individuals observed no significant associations between LBW births and PFOA or PFOS exposure (Darrow et al. 2013). In a study of 372 births in Guangzhou between July and October 2013 observed no significant associations between LBW and PFOA exposure. A statistically significant association was observed between LBW and PFOS (OR=2.43, 95% CI: 1.09-5.147), but not by quartiles of PFOS exposure. Authors also noted that the relationship between PFAS and birth outcomes was controversial due to concerns regarding effective dose, reverse causality, and sample timing. Based on the limited reporting on birth weights and inconsistent evidence of increased risk of LBW in the candidate studies, the evidence for an adverse effect with PFOA or PFOS exposure in that study is not clear.

3. Candidate study selection for developmental effects was not transparent

In reviewing EPA's draft documents, the SAB recommended "that additional clarification and detail be included to support the selection of the critical effect and why this effect, beyond having the lowest POD_{HED}, is the most scientifically appropriate choice as well as being the most protective of public health." (USEPA 2023j, p. 38). In other words, SAB told EPA that it needed to show why critical studies were selected beyond simply having the lowest POD. EPA failed to do so with respect to its analysis of developmental effects.

The IRIS Handbook recommends that only well conducted high or medium confidence human and animal toxicological studies be considered for POD derivation (USEPA ORD 2022). EPA chose 6 studies for POD development for PFOA (Chu et al. 2020; Govarts et al. 2016; Sagiv et al. 2018; Starling et al. 2017; Wikstrom et al. 2020; Yao et al. 2021), and six for PFOS (Chu et al. 2020; Sagiv et al. 2018; Starling et al. 2017; Wikstrom et al. 2020; Darrow et al. 2013; Yao et al. 2021). EPA ultimately chose Wikstrom et al. (2020) for RfD derivation for both compounds. EPA did not describe why these studies were chosen among the multiple medium and high-quality studies for POD derivation, as the SAB requested. Over 30 medium or high confidence studies of birth weight and PFOA were available, and nearly 40 medium or high

confidence studies of PFOS and birth weight. All of the studies selected as candidates were rated high confidence, though 4 of the studies measured PFAS later in pregnancy or after delivery, making them subject to biases from pregnancy hemodynamics (Chu et al. 2020; Darrow et al. 2013; Govarts et al. 2016; Starling et al. 2017; Yao et al. 2021). Had EPA's critical appraisal been conducted consistent with recommendations of the SAB and the IRIS Handbook and taken factors specific to PFAS measurement (like timing) into consideration, these studies likely would not have been considered high confidence due to this bias alone.

Both candidate studies selected for the derivation of the RfD for developmental effects measured PFAS in maternal serum taken in early pregnancy – Wikstrom et al. (2020) measured serum PFAS at a median of 10 weeks (range 3-27 weeks), and Sagiv et al. (2018) measured PFAS in a comparable time frame (median 9 weeks; range 5-19 weeks). The Sagiv study also adjusted for estimated glomerular filtration rate (eGFR) to account for blood volume increase and higher flow rate in pregnancy. Despite the additional adjustments for eGFR by Sagiv et al. (2018), Wikstrom et al. (2020) was ultimately used for RfD derivation instead. EPA's rationale for choosing the Wikstrom study over Sagiv is not clear. EPA stated: "The RfD for low birth weight from Wikström et al. (2020) was selected as the basis for the health outcome-specific RfD for developmental effects as it was the lowest and therefore most health protective candidate RfD from these two studies" (USEPA 2023a, p. 4-52, USEPA 2023b, p. 4-48). EPA offered this rationale despite the SAB's recommendation, "that additional clarification and detail be included to support the selection of the critical effect and why this effect, beyond having the lowest PODHED, is the most scientifically appropriate choice as well as being the most protective of public health" (USEPA 2023j, p. 38).

EPA selected Wikstrom et al. (2020) as "the most scientifically appropriate choice," yet it is unclear whether there were clinically significant birth weight changes, and neither co-exposures to other PFAS nor eGFR levels were accounted for in the study's analyses. Thus, EPA failed to follow the SAB's recommendation to provide additional clarification and detail in its justification for outcome-specific study selection other than having the lowest candidate RfD.

iii. EPA's assessment of cholesterol[77] is inconsistent with best practice

EPA similarly did not adequately address the SAB request for transparency in its selection of outcome-specific studies for cardiovascular disease POD derivation. EPA acknowledges that the evidence for most cardiovascular-related endpoints such as changes in blood pressure, hypertension, coronary heart disease, and stroke is inconsistent (USEPA 2023a, b). Despite this limited evidence, however, EPA selects total cholesterol as the basis of the POD for cardiovascular effects. A complete and rigorous risk of bias assessment is needed to address underlying uncertainties and limitations in the available evidence base for changes in serum lipids, such as cholesterol. Contrary to SAB recommendations, the IRIS Handbook, and its own statements, for cardiovascular disease (CVD) outcomes, EPA failed to consider high-confidence and medium-confidence studies, including those that did not support an association between PFOA and PFOS exposure and CVD. EPA states that "*only well-conducted high or medium*

[77] EPA's conclusions regarding cardiovascular disease appear to be driven by its finding of an association between cardiovascular disease and cholesterol, which was the result of a flawed process, as discussed herein.

confidence human and animal toxicological studies were considered for POD derivation, as recommended in the IRIS Handbook {U.S. EPA, 2022, 10476098}" (USEPA 2023a,b; p. 4-1). EPA's statement misleadingly suggests that it considered both high-confidence and medium-confidence studies. In fact, EPA considered three studies for derivation of a cardiovascular POD for PFOA and PFOS (Dong et al. 2019; Lin et al. 2019; Steenland et al. 2009); these three studies are all described as "medium-confidence" in the draft assessment (USEPA 2023a,b; p. 4-7). However, EPA identified additional medium and high confidence studies but did not consider them for POD derivation.

Although EPA provides some information regarding evidence integration, the agency does not address the SAB's request for explanation of why a specific study was selected for POD derivation among multiple comparable choices for CVD outcome evaluation. Specifically, EPA does not explicitly describe why the high-confidence (Gardener et al. 2021; Li et al. 2021) and other medium-confidence studies (Averina et al. 2021; Christensen et al. 2019; Domazet et al. 2016; Donat-Vargas et al. 2019; Fan et al. 2020; Han et al. 2021; Jain and Ducatman 2018; Jain 2019; Kang et al. 2018; Kobayashi et al. 2022; Lin et al. 2009, 2019, 2020; Liu et al. 2018, 2020; Mora et al. 2018; Papadopoulou et al. 2021; Skuladottir et al. 2015; Spratlen et al. 2020; Tian et al. 2021; Zare Jeddi et al. 2021; Eriksen et al. 2013; Fisher et al. 2013; Geiger et al. 2014; Nelson et al. 2010; Sakr et al. 2007; Timmermann et al. 2014; Winquist and Steenland 2014) were not further considered for POD derivation.

Specific information on the selection criteria used by EPA to pare down the list of medium- and high-quality studies described in the Study Evaluations is necessary to provide confidence in the CVD POD derivation and toxicity assessment. Some studies not considered for POD derivation have study design components that may provide more confidence in the observed exposure-response relationships, including longitudinal designs or collection of multiple serum measurements (e.g., Donat-Vargas et al. 2019, Convertino et al. 2018). EPA did not provide justification and transparently describe the process used to select the three studies that were considered for dose-response evaluation (Dong et al., 2019; Lin et al. 2019; Steenland et al. 2009). Further, additional clarification on how to interpret "multiple judgments" within the findings of the study evaluation process is needed. For example, Steenland et al. (2009) was considered deficient (or "Low Confidence") in some EPA judgments (USEPA 2023a,b; see Figure 3-33), but EPA ultimately treated it as having adequate or "Medium Confidence."

Another deficiency that is contrary to the IRIS Handbook's guidance for study evaluation is EPA's inadequate control for confounding or correlated exposures (e.g., diet, family history, or co-exposure to other PFAS). EPA did not follow best practice as described in the IRIS handbook in that it heavily weighted studies that failed to consider confounding factors, such as family history and dietary factors, which are established contributors to CVD and serum lipids. However, none of the three studies considered by the USEPA for CVD POD derivation (Dong et al. 2019; Lin et al. 2019; Steenland et al. 2009) adjusted analyses to account for family history. Additionally, Dong et al. (2019) and Steenland et al. (2009) do not adjust for dietary habits or cholesterol intake. Intake of saturated fats, trans-fats, polyunsaturated fats, and monounsaturated fats are typically controlled for in randomized controlled trials evaluating impacts of cholesterol intake on TC, LDL-C and HDL-C, as intake is known to affect serum lipoprotein levels (Vincent

et al. 2019; Allen et al. 2016; Mensink et al. 2003). Cholesterol intake has also been shown to affect serum lipoproteins (Vincent et al. 2019). Because of these relationships between dietary patterns and circulating lipoproteins, the National Academies and USDA Dietary Guidelines recommend limiting trans and saturated fats and dietary cholesterol (while maintaining a healthy diet) as a major focus for reducing TC and LDL concentrations (USDA and HHS 2020). Lin et al. (2019) adjusted for "*percent of daily calories from fat*" and daily fiber intake from a "*semi-quantitative food frequency questionnaire with 177 items that measured dietary habits over the previous year.*" In their longitudinal analysis, Lin et al. (2019) found that associations between baseline PFAS and TC did not translate to an increased risk of hypercholesterolemia or hypertriglyceridemia in the lifestyle intervention group, indicating an effect of diet and exercise. Through use of poorly controlled cross-sectional analyses as the basis for RfD development, EPA failed to account for the effects of diet and exercise, well known contributors to CVD outcomes, in its assessment.

1. Contrary to EPA's best practices for systematic review and guidance, EPA did not evaluate study quality consistently for CVD

EPA did not transparently document risk of bias in each domain for each endpoint to ensure that the study quality evaluations are relevant to the endpoint being evaluated, as requested by the SAB. The SAB noted that:

> a protocol for risk of bias assessment and, more importantly, how that approach was used in the synthesis of evidence for each particular health endpoint is not clearly presented; and therefore, the results cannot be confidently evaluated for accuracy or transparency, or for consistency across health endpoints. This is especially important when a proposed systematic review protocol has not been previously registered or published. (USEPA SAB 2022, p. 6)

EPA's own best practices, as described in the IRIS Handbook, require that individual studies be evaluated for risk of bias and rated according to the Health Assessment Workplace Collaborative (HAWC) database. Here, EPA failed to comply with that guidance and best practice by failing to evaluate the risk of bias for each endpoint within a study that evaluated multiple endpoints. EPA presents Study Quality Evaluation results for each study with CVD outcomes, including serum lipid changes (see USEPA 2023a,b Figures 3-30 to 3-36). According to EPA, each study was evaluated for risk of bias using multiple study domains, including participant selection, exposure measurement, outcome ascertainment, confounding, analysis, selective reporting, and sensitivity. Results from each of these domains are synthesized into a characterization of the overall confidence in the individual study. Although individual studies were evaluated for risk of bias within each of these domains, review of the justifications supporting the risk of bias ratings provided in the HAWC database indicates that the risk of bias ratings for each domain are not necessarily determined relative to each individual endpoint considered in a study.

For example, EPA rated the domains for outcome ascertainment and results in Lin et al. (2019) as "Good" for serum lipids because "*blood samples were collected at baseline, annual, and semi-annual follow-visits*" (see USEPA 2023d for details). However, Lin et al. (2019) only collected PFOA and PFOS concentrations at baseline and the TC measurements considered as

the basis for POD derivation were also collected only at baseline. Therefore, this rating is misleading for the TC measurements considered by EPA if repeated measurements are part of the justification for a "Good" rating.

In another example, EPA rated the domains for participant selection, exposure measurement, outcome, and analysis in Gardener et al. (2021) as "Good," and these individual domain ratings contributed to the overall confidence categorization as a "High Confidence" study. However, as described within EPA's HAWC documentation, Gardener et al. (2021) is a pilot study that uses a non-nationally representative sample of pregnant women in the Vanguard Pilot Study of the National Children's Study. Although Gardener et al. (2021) evaluated serum lipid concentrations in pregnant women, the EPA's justifications regarding the quality of the outcome, confounding adjustments, and endpoint analysis specifically refer to the gestational age and birth weight endpoints only. Justifications for the confidence ratings of serum lipids as an endpoint in Gardener et al. (2021) are not provided in EPA's HAWC documentation.

By not properly conducting a systematic review and assessing studies for bias within individual endpoints, EPA did not correctly determine which endpoints were suitable for further evaluation. Thus, relevant endpoints and data may have been excluded or unreliable endpoints were included because EPA rated the study overall instead of refining its rating based on a specific endpoint of interest.

iv. EPA's assessment of liver effects is was not performed consistent with best practices.

EPA's assessment of liver effects of exposure to PFOA and PFOS is inconsistent with its own scientists' and the SAB's conclusions and again reflects EPA's failure to engage in a proper systematic review and evidence assessment process. As part of the hazard characterization and dose-response step, the IRIS Handbook states that EPA should consider the dose-response pattern in the relevant dose range and relevance of specific health outcomes in humans. In contrast to this recommendation, EPA cites animal studies showing liver effects which involve mechanisms of action with questionable relevance to humans, such as pathways moderated by peroxisome proliferator-activated receptor-alpha ("PPARα"). EPA also did not consider EFSA (2020), which noted there is evidence for elevated ALT due to PFOA exposure, but the adversity of this effect is uncertain because of the low magnitude of increases and no associations with liver disease. EPA even acknowledges that studies "have questioned the biological significance of relatively small increases in serum ALT (i.e., less than 2-fold) reported in animal toxicological studies (Hall. et al. 2012)." For PFOA and PFOS, EPA fails to characterize the biological relevance of changes in ALT or other liver biomarkers in the context of quantitative clinical outcomes. SAB similarly noted that "the limited available information does not demonstrate an increase in liver disease" (USEPA SAB 2022).

As an example of its failures in conducting systematic review and assessing study quality, EPA inappropriately based its candidate PFOS RfD for elevated ALT on a study by Nian et al., (2019). This was a cross-sectional study from China that reported a 4.1 percent change (95% CI: 0.6, 7.7) in ALT for every 1 ng-mL increase in PFOS. Excluding individuals who were taking medications, this percent change was reduced to 3.8 which was not statistically significant (95%

CI: -0.2, 7.8). Confounding variables were also not adequately controlled as most were described as binary (yes/no) which included alcohol, smoking and diet, which limits quantitative assessment. In addition, confounding from other PFAS were not adjusted for in the analysis of PFOS and PFOA. In EPA's section on Study Evaluation for Epidemiology Studies of PFOS and Hepatic Effects (page 3-25), EPA states that the Nian et al., (2019) approach to study participant selection and recruitment was not described in the paper. However, EPA still rates participant selection as "adequate." Given this information was not provided, EPA should have rated participant selection as "inadequate" based on its own criteria.

v. EPA's assessment of immunotoxicology is inconsistent with agency guidance.

In assessing immune efforts, EPA did not appropriately employ methods described in the IRIS Handbook for evaluation of study quality and risk of bias in evaluating vaccine repose. EPA did not evaluate evidence consistently across studies, nor did it synthesize evidence according to guidance. This omission again led to the selection of candidate studies for point of departure (POD) development with critical limitations. Selection of reliable studies with limited bias is critically important for limiting the uncertainty in the derived POD and subsequent toxicity values. If EPA had appropriately refined the study evaluation to the vaccine endpoint, thus accounting for aspects SAB recommended, a high level of uncertainty would have been found in the body of evidence. EPA failed to follow IRIS guidance to refine the study evaluation tool to the topic, including modifications to evaluation criteria to include factors specific to the exposure and outcome of interest, as well as potential confounders that specifically affect these associations. Such considerations would allow for the evaluation of specific factors critical to the overall study reliability conclusions. As a result of these process errors, the evidence presented does not support antibody response to vaccine as a critical endpoint and leads to a high level of uncertainty in the calculated toxicity values derived for this endpoint.

EPA (USEPA 2023a,b) considered multiple outcomes under the category of immune function, including vaccine response, infectious disease, immune hypersensitivity (allergy, asthma), and autoimmune disease. EPA determined that there was **moderate** evidence for an association between PFOA/PFOS exposure and immunosuppressive effects in human studies. This conclusion was based on its findings in PFOA studies of "*largely consistent decreases in antibody response following vaccinations (against two different infectious agents: tetanus and diphtheria) in multiple medium confidence studies in children*" (USEPA 2023a, p. 3-133), and a "*largely consistent decrease in antibody response following vaccinations (against three different infectious agents) in multiple medium confidence studies in children*" for PFOS (USEPA 2023b, p. 3-122). However, uncertainties in the conclusions for both PFOA and PFOS reflect:

- Inconsistent findings of decreased vaccine response in adult populations
- Inconsistent and/or imprecise findings of increased infectious disease
- Mixed findings of hypersensitivity, including allergy, asthma, and eczema
- Mixed findings for autoimmune disease

Additional details regarding the strength of evidence for outcomes related to immune function are described in the EPA Evidence Stream and Summary Judgments (USEPA 2023a, Table 3-7; USEPA 2023b, Table 3-10).

1. EPA's Selection of Candidate Studies Was Neither Transparent Nor Consistent

The SAB provided specific guidance to EPA that in selecting endpoints for POD development, "[*i*]*nternal inconsistencies in the criteria used for selection of endpoints for POD development should be addressed. It is also important to explain why a specific study of a health endpoint was selected when there are several possible choices*." This guidance from the SAB related to all PODs EPA considered. EPA's response was that it presented evidence integration judgments for each health outcome, including the rationale for the selection of a particular study for POD derivation (USEPA 2023c, p. 20-21). Although EPA provided some discussion of evidence integration, it did not explain the choice of study for POD derivation among multiple medium-confidence studies. The studies selected for POD development had critical deficiencies that should have excluded them from consideration.

First, the evidence base for vaccine response was not consistent. For example, the associations between vaccine response for tetanus or diphtheria with PFOA or PFOS exposures were not consistent either by age nor by vaccine type across several studies (Grandjean et al. 2012; Grandjean et al. 2017a,b; Mogensen et al. 2015; Shih et al. 2021). All of these studies were conducted based on cohorts from the Faroe Islands. Authors noted in 2012 that although negative associations were observed with vaccine antibodies, "*the overlapping confidence intervals and the lack of comparative toxicology studies prevent inference in regard to causal attribution*" (Grandjean et al. 2012). Similarly in 2017 they noted, "*inter-correlations between serum-PFAS concentrations prenatally and at different ages make it difficult to determine accurately the possible age-dependent roles of individual PFASs in regard to immune function outcomes"* (Grandjean et al. 2017b). The Agency did not adequately discuss the sporadic findings and uncertainties within the studies examining the Faroe Islands cohorts and to resolve those uncertainties before selecting a candidate study from this group of Faroe Islands cohorts (Butz-Jorgensen and Grandjean 2018).

The alternate candidate study selected by EPA also had critical limitations that should have been identified as part of a proper systematic review. Timmermann et al. (2021) was a cross-sectional analysis of vaccine response in Greenlandic children. Because the exposure and outcome are measured at the same time in a cross-sectional study, the study cannot determine if there is a temporal link between the exposure and the outcome. In addition, the timing of its exposure measurement is unclear compared to vaccination, as vaccination records were not available for nearly half (163/338 children) of the study population, which means the authors estimated the date of vaccination for purposes of evaluating antibody response. Notably, the

authors acknowledged that using an estimated date of vaccination likely caused information bias, possibly due to long and varied time intervals since the most recent vaccination. [78]

2. EPA did not appropriately employ methods described in the IRIS guidance for evaluation of study quality and risk of bias in evaluating vaccine response.

EPA's failure to follow its IRIS Handbook for evaluation of study quality and risk of bias led it to reach conclusions opposite those that would have been reached by an independent assessment of the evidence that did follow EPA's IRIS Guidance. According to IRIS guidance, additional chemical, outcome, or exposure-specific considerations for evaluating studies should be developed in order to identify issues that would be expected to result in critical biases and reduce the confidence rating of a study (USEPA ORD 2022, p. 4-2). Based on this guidance, the criteria for assessing bias in several of the evaluation domains (exposure assessment, outcome ascertainment, confounding, and sensitivity) should have accounted for factors specific to the exposure and outcome of interest, as well as potential confounders that specifically affect these associations. Such considerations would allow for the evaluation of specific factors critical to the overall study reliability conclusions.

An independent assessment was performed by ToxStrategies for studies examining vaccine response and PFOA exposure using the same IRIS framework for systematic review and critical appraisal of studies used by the EPA in the draft toxicity assessment for PFOA (USEPA 2023a, p. 1-10). *See* Appendix A. The independent assessment followed the IRIS guidance to modify several of the evaluation domains specific to the topic in order to identify critical issues regarding study quality and risk of bias, including consideration of factors that are specific to either the exposure, outcome ascertainment, confounding factors that affect the association of interest, and sensitivity issues including external validity and study construct. In contrast, the only apparent modification EPA made to its tool was to the exposure assessment domain criteria. This and missed critical issues that could render studies unreliable for dose-response assessment.

After identification and critical appraisal of studies examining vaccine response and PFOA exposure in the independent assessment, all studies received an overall rating of "deficient" or "critically deficient." Each study had deficiencies in participant selection, timing of exposure and outcome measures, or confounding, which resulted in a body of evidence that was of low quality with a high risk of bias. Based on these findings, vaccine response was not considered a critical endpoint for PFOA exposure, and no studies qualified for POD development.

Significant additional flaws and limitations in EPA's assessment of immunotoxicology, including EPA's failure to consider the conclusions of other agencies regarding immune effects

[78] Timmermann et al. (2022) is also a poor choice because the children examined in that study had very different chemical exposure levels than American children. They had high levels of mercury and PCB concentrations compared to American children, and PFOS concentrations that were twice as high as American or Faroese children.

as a critical endpoint (and the Grandjean et al. (2012) study in particular), are described in further detail in Appendix A.

e. Significant Uncertainty in Benchmark Dose (BMD) Derivation Approaches Preclude Confidence in the Risk Values Calculated by EPA for Non-Cancer Endpoints

EPA also violated best practices and its own guidance when it failed to independently model and verify the underlying analyses to increase confidence and transparency in the BMDL derivation of each co-critical effect. Properly conducting BMD analysis is critical because the points of departure derived from the BMD analysis are the basis of EPA's proposed non-cancer RfDs. EPA does not transparently describe its process for key study selection or the impact of uncertainties in BMDL derivation arising from 1) the lack of consideration of pooled analyses, 2) reliance upon modeling assumptions, 3) model selection; or 4) benchmark response (BMR)[79] selection. These issues are discussed below and in detail in Appendices A and B.

i. EPA was not transparent and consistent in selecting key studies and models for BMD derivation

EPA's IRIS handbook and risk assessment best practice requires that the process for selection of key studies for use in BMD and BMDL derivation be clearly described, including identifying data quality objectives to ensure consistency and transparency. But here EPA did not propose data quality objectives, and it did not follow requirements for data quality assurance. As EPA itself has noted "[t]he strength of the DQA is that it is designed to promote an understanding of how well the data satisfy their intended use by progressing in a logical and efficient manner." (USEPA 2000c, p. 0-3). As a result of this process failure, key studies had critical deficiencies that preclude confidence in their findings and the subsequently derived regression coefficients or BMD(L)s. Dose-response models and BMD(L)s derived from poor quality or limited studies may not accurately describe the true exposure-response relationship and will therefore lead to inaccurate PODs and uncertainty in RfD derivation.

Additionally, when provided with multiple models from a given study or dataset, EPA provides minimal and inconsistent justification for selection of a single model for POD derivation. For some endpoints, EPA does provide limited justification for selection of individual models within a study; however, these justifications (e.g., selection based on p-values) are not statistically defensible nor do they align with EPA guidance for model selection (USEPA 2012). Other justifications, such as stated confidence in the BMDL or potential for confounding, are not transparently defined or consistently applied. As the range of BMD(L)s both within and among studies for a given endpoint can be uncertain, it is critical for the EPA to show a transparent model selection process to increase confidence that the POD is representative of the exposure-response and not biased towards an overestimation of risk. In other words, EPA's lack of transparency in how it selected models could lead EPA to rely on models that overestimate risk or select PODs that are highly uncertain. In addition to the lack of transparent study and

[79] A benchmark response is a predetermined change in response. It is used in determining a benchmark dose, which is the dose that corresponds to a specific change in adverse response, i.e., the benchmark response.

model selection, EPA did not validate or compare BMD(L)s derived from individual studies with BMD(L)s derived from pooled regression coefficients (when available). This issue is discussed in detail in Appendix A.

ii. EPA's BMD values have a high level of uncertainty

For derivation of BMD(L)s, EPA used a non-standard approach and relied on previously developed models or pre-defined regression coefficients as presented in the published literature. The use of non-standard approaches violates EPA's own guidance and means that its analyses do not accurately reflect the true underlying dose-response relationships. Traditionally, benchmark dose modeling is conducted by fitting dose-response models to mean or proportional responses at given exposures; EPA's (2012) BMDS guidance is designed for these traditional dose-response models. EPA did not independently validate or verify the published regression coefficients, nor did it transparently report the details of BMD modeling from the candidate studies. Key modeling information, as recommended in EPA's benchmark dose modeling guidance (USEPA 2012), is consistently absent from the published models, including analyses of model shape, model fit, the distribution or variance of the regression coefficients, and background [P(0)] responses. EPA did not critically evaluate the underlying response data to fill gaps in reporting of the modeling approaches or results. Therefore, EPA relied on assumptions regarding model shape, model fit, coefficient variance, model distribution, confounding, and background (or "zero-exposure") responses. Without verification of these factors, EPA cannot confirm that its assumptions are reasonable approximations of the underlying data, nor can it confirm that the estimated BMD(L)s accurately describe the dose-response. Moreover, EPA derived BMD and BMDLs from models with non-significant exposure parameters and with no consideration of model fit. EPA's benchmark dose guidance (USEPA 2012) states that modeled datasets should, at minimum, have a statistically or biologically significant dose-response trend. This issue is discussed in detail in Appendices A and B.

iii. EPA failed to demonstrate that use of a non-standard BMD approach is biologically appropriate

EPA discusses uncertainties in the draft toxicity assessments for PFOA and PFOS introduced through the use of regression coefficients (a non-standard approach) instead of response data for BMD modeling of epidemiological data. As noted above, the use of non-standard approaches may have also led EPA to make erroneous conclusions about the relationships of exposure and effects observed in human epidemiological studies. EPA used the information from Steenland et al. (2009) to validate the use of regression coefficients; Steenland et al. (2009) was selected due to the accessibility of the mean response information underlying the regression coefficients. EPA states that the difference in BMDLs generated through use of regression coefficients instead of mean response information is less than 3-fold different and therefore acceptable; EPA has not, however, demonstrated that this relationship is consistent across PFAS compounds, endpoints, studies, or publicly available information such as NHANES. EPA did not evaluate additional datasets with the raw data or mean response information in order to quantitatively justify that the BMDLs generated through this non-traditional approach are comparable to those generated through use of mean response information. Some of the publications relied upon by EPA, including the key study for total

cholesterol (Dong et al. 2019), are based on NHANES or other publicly available information and, as such, further sensitivity analyses should have been performed using these additional studies and endpoints to provide confidence in the approach used to derive BMD(L)s for PFOA and PFOS. The uncertainty analysis conducted by EPA is not sufficient for validating its use of regression coefficients instead of response data. This issue is discussed in detail in Appendix A.

iv. EPA's BMR selections are neither adequately justified nor consistently applied

BMD modeling approaches used by EPA were non-standard and relied upon published regression coefficients. EPA did not address the inconsistency in methods and approaches used for BMD(L) calculation, nor did it thoroughly consider or evaluate the sensitivity of selected models to changes in biological cutoffs or alternative BMR assumptions. Each of the endpoints selected as critical effects by EPA (e.g., serum lipids, birth weight, and vaccine response) have widely accepted clinical cutoffs that are considered biologically significant. However, EPA did not establish that the underlying exposures are significantly associated with the measured outcomes, after accounting for confounding, or increased incidence of adverse responses such as infection or cardiovascular disease. EPA may be inappropriately applying BMRs to evaluate changes in adverse outcome probability for non-adverse effects. This means that EPA may be deriving MBDs based on arbitrary changes in responses that are not actually adverse. Additional transparency is needed in order to understand 1) the methods used by EPA to estimate background exposure and probability; 2) justifications for BMR selection; 3) the impact of using alternative BMRs based on clinical cut-points on BMD(L) derivation; and 4) consideration of the strength of association between exposure and response. Additionally, in order to derive study-specific BMRs for Extra Risk, EPA relied on estimations of the study-specific intercepts of the study-reported regression coefficients, or slopes, in order to estimate response in an unexposed population; these estimations of the outcome probability in unexposed populations does not account for model uncertainty, variance in regression coefficients, or consideration of US population responses. Differences in BMR type, BMR sensitivity, and estimations of model intercepts (or hypothetical responses in unexposed populations) impact the estimation of the BMD(L) and subsequently derived RfD. This issue is discussed in detail in Appendix A.

v. EPA did not estimate the impact of modeling assumptions on derived BMDLs or how changes in these assumptions affect BMDL sensitivity

EPA used many assumptions to estimate BMD(L)s for changes in birth weight, immune response, and serum total cholesterol. Each assumption adds some quantifiable uncertainty to the derived BMD(L)s used for POD derivation. **Using analyses of changes in birth weight as an example, variations in estimations of background exposure, BMR type, and background incidence of low birth weight may increase the derived BMDL by approximately 30% to 210%, depending on the study and assumptions.** Uncertainty in the derived BMDLs, based on assumptions required to conduct modeling, impacts confidence in the derived PODs. EPA did not quantify or discuss the potential uncertainty in the BMDLs used for POD derivation or the sensitivity of the BMDLs to changes in the underlying assumptions. This critical oversight means that the PODs EPA used to derive RfDs may have significant uncertainty making its

assessment of non-cancer health effects unreliable. This issue is discussed in detail in Appendix A.

f. EPA Did Not Follow SAB Recommendations to Address Lack of Transparency, Lack of Reproducibility, and High Levels of Uncertainty in its Use of PBPK Models

PBPK models were used to simulate dosimetry during pregnancy and lactation for endpoints in human neonates and children. The SAB considered EPA's use of compartment based PBPK models to be reasonable but requested that details and assumptions required to run the model be documented sufficiently to allow reproduction of the simulations. EPA failed to address SAB comments regarding clarity of the PBPK model and EPA's lack of evaluation of the PBPK model performance. EPA placed the PBPK model code on Github to allow reproduction of simulations but failed to provide sufficient documentation or a required header file ('linear_interp.h') needed to compile and run the code. As a result, the conversion of the point of departure (POD) to the POD human equivalent dose (POD_{HED}) could not be reproduced and remains uncertain. These issues are discussed below and in detail in Appendix A.

i. EPA failed to adequately perform sensitivity analysis for PBPK modeling and provide a quantitative assessment of model performance.

EPA also failed to address SAB's recommendation that EPA better characterize the uncertainty that results from different parameters/assumptions by considering sensitivity analyses or Monte Carlo simulations with a range or distribution of values. EPA did not perform a quantitative assessment of model performance and, as such, failed to address SAB's comment. Best practice frameworks recommend the use of global and local sensitivity analysis (Johnson et al. 2021). EPA only performed local one-at-a-time sensitivity analysis. The parameter(s) driving the output value (i.e., intake-based HED derived from a serum measurement) were not identified and sufficient quantification was not provided in EPA's one-at-a-time sensitivity analysis to fully assess the overall relative importance of all model parameters. This issue is discussed in detail in Appendix A.

ii. EPA did not follow SAB's recommendation to use the Goeden et al. (2019) model as a more 'fit for purpose' model for deriving MCLGs

SAB recommended that EPA consider its use of the Verner et al. (2016) models and whether the Goeden et al. (2019) model that incorporates age-specific toxicokinetic and exposure factors would be more appropriate for deriving drinking water MCLGs. EPA compared use of the Verner and Goeden models and concluded that there was no "substantial improvement" in the outcome when modeled using either method. This statement was not supported by a side-by-side comparison of results or sufficient information to allow for assessment and an understanding of whether the appropriate model was selected. Data should be presented to support how the decision to use constant daily dose versus age-specific toxicokinetic factors (e.g., volume of distribution) and exposure factors (milk and drinking water intake) affects the model outcome. This issue is discussed in detail in Appendix A.

iii. EPA failed to account for life stage-specific variables in the PBPK model that impact the resulting POD_{HED}

The PBPK model used by EPA does not account for life stage (maternal, fetal, infant) differences in parameters such as elimination and clearance rate, half-life, and volume of distribution (Vd), as recommended by the SAB. To clarify the uncertainty in life stage-specific variables, age-related differences in chemical-specific parameters should be considered to better explain the variability observed (i.e., lack of fit) in predicted child serum levels compared to reported child serum levels of PFOA and PFOS (see Figures F-15 and F-12 in draft Appendices for PFOA and PFOS, respectively). Consideration of life stage-specific variables may also impact the resulting POD_{HED}. This issue is discussed in detail in Appendix A.

iv. EPA failed to quantitatively characterize uncertainty for PBPK modeling and HED calculations

Monte Carlo simulations recommended by the SAB were not performed by EPA for PBPK modeling of co-critical endpoints including vaccine response and birth weight to inform the variability inherent in the modeling approach. In addition, the variability of chemical-specific parameters used to calculate the HED for total cholesterol was not quantified by EPA. Therefore, range of uncertainty in the resulting POD_{HED} estimations were also not considered by EPA. This issue is discussed in detail in Appendix A.

VII. THE PROPOSED MCLs ARE NOT "FEASIBLE"

After determining to regulate a substance, EPA must set a "maximum contaminant level goal" (MCLG) for each identified substance at a level at which no known adverse health consequences will occur.[80] EPA must then set a "maximum contaminant level" (MCL) for each substance as close to the MCLG as is feasible.[81] Under the statute, "feasible" means "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds... are available (taking cost into consideration)."[82] Some basic factors such as insufficient lab capacity and inability to reliably measure samples at the ultra-low levels in the proposed NPDWR render the proposed MCLs infeasible, contrary to SDWA requirements.

a. There is Insufficient Analytical Laboratory Capacity to Process the Quantity of Samples Required Under the Proposed Rule

EPA overstates the number of approved laboratories for the analysis of PFAS in drinking water and overestimates laboratory capacity. As of March 2023, there are 53 laboratories approved to support UCMR5, only 46 of which accept commercial samples (USEPA 2023g). As of April 21, 2023, the National Environmental Laboratory Accreditation Program (NELAP) Accreditation Management System lists only 38 total active laboratories certified to perform

[80] 42 U.S.C. § 300g–1(b)(4)(A).
[81] *Id.* § 300g–1(b)(4)(B).
[82] *Id.* § 300g–1(b)(4)(D).

either EPA Method 533, 537.1, or both, and that accept commercial samples for drinking water (NELAP 2023).

Moreover, analytical capacity varies by laboratory and, for that reason, the number of approved laboratories is a poor indicator of overall capacity. The larger laboratory networks are currently at or near capacity for PFAS analyses in non-drinking water matrices (e.g., non-potable waters, soils); as a result, customers are experiencing considerable delays in receiving analytical results. In the past year, 3M has experienced several commercial testing labs move from standard 10 business day turnaround times for analysis of PFAS in water to straining to achieve turnaround times of less than 30 business days, despite adding equipment and other resources. This has impacted the ability to meet required timelines for regulatory-related obligations, as well as the operation, installation, and optimization of water treatment processes. The current PFAS testing capacity constraint is occurring *prior* to finalization of the EPA 1633 method, a more resource intensive test method than is currently employed by commercial contract testing labs. Further capacity constraints are expected after finalization and implementation of the EPA 1633 method. In fact, Metropolitan Council Environmental Services, which administers industrial discharge permits in Minnesota, notified 3M that there are only a small number of laboratories in North American that can perform EPA draft method 1633, and that turnaround times for analytical results can be as long as 4 months. It is not realistic to expect that growth in laboratory services will keep pace with increased demand, given all that is required to construct, permit, and staff an analytical laboratory.

b. Testing Methods Do Not Provide the Analytical Capacity to Identify or Distinguish Between the Ultra-low Levels at Issue in the Proposed Rule

The proposed MCLs for PFOA and PFOS are set at the practical quantitation level (PQL) of 4.0 ng/L and EPA proposes setting a rule trigger level of one-third the MCL to determine compliance monitoring frequency (USEPA 2023f, p. 18681). The PQL is defined as "the lowest concentration that PFOA and PFOS can be reliably quantified" (USEPA 2023f, p. 18666). By definition, measurement results less than the PQL are not reliably quantified and therefore not suitable for quantitative comparison against a standard. EPA notes that most of the laboratories seeking UCMR 5 approval included a calibration standard below the 4.0 ng/L PQL, while also noting that, "measuring PFOA and PFOS results below the PQLs may not be achievable from all laboratories" (USEPA 2023f, p. 18867). EPA also assumes the laboratory market for PFAS analyses will expand (USEPA 2023f, p. 18867). It is not safe to assume that as the market grows, new laboratories will have the same proficiency as existing experienced laboratories that already may not be able to measure below the PQL.

VIII. EPA's BENEFITS ANALYSIS DOES NOT COMPLY WITH THE SDWA

The SDWA requires EPA to analyze the "[q]uantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of the treatment to comply" with each alternative

level the Agency considers.[83] As discussed below, EPA's benefits analysis fails to comply with this requirement and is arbitrary, opaque, and counter to fundamentals of toxicology.

a. EPA's Selection of Alternative MCLs for PFOA and PFOS is Arbitrary

In promulgating NPDWRs since the 1996 SDWA Amendments, which first require consideration of alternatives, EPA has routinely considered at least four regulatory alternatives.[84] As discussed below, in this rulemaking EPA considers only two theoretical alternatives to the proposed MCL of 4.0 ppt for PFOA and PFOS: 5.0 ppt and 10.0 ppt. EPA justifies its selection of regulatory alternatives not based on meaningful toxicological considerations, but instead on arbitrary comparisons to analytical levels and inapplicable state regulations. EPA states (USEPA 2023f) that it "considered an MCL of 5.0 ppt for PFOA and PFOS because it is 25 percent above the [practical quantitation limit] PQL of 4.0 ppt." EPA notes that this selection was based on input from a commenter in EPA's outreach consultations who "suggested the Agency consider a buffer of approximately 20 percent if the MCL is close to the quantitation level because water systems operate with a margin of safety and plan for performance that maintains water quality below quantitation levels." Thus, this value is intended to be a buffer between the PQL and MCL that could allow utilities to manage treatment approaches. EPA states that it disagrees that such a consideration is necessary but nonetheless applies the value yielded by the approach.

EPA (USEPA 2023f) also states that it "considered the MCL of 10.0 ppt to evaluate the national costs and benefits and whether the expected reduction in costs would change EPA's determination of the level at which the benefits would justify the costs (see Safe Drinking Water Act [SDWA] Section 1412(b)(6)(A))." The Agency maintains that this regulatory alternative level is consistent with State-enacted MCLs for certain PFAS, citing New York's PFOA and PFOS MCLs of 10 ppt.[85] There is no evidence that EPA considered different approaches nor the toxicological bases of various states' MCLs.

b. As a Matter of Toxicology, the "Alternatives" EPA Selected All Represent the Same Level of Exposure.

The alternatives EPA considered for PFOA and PFOS are meaningless, in violation of SDWA §1412 (b)(3)(C)(i). EPA prepared a health risk reduction and cost analysis and quantified health outcomes in the benefits analysis for the proposed NPDWR, where it purported to distinguish between national benefits at drinking water concentrations of PFOS and PFOA at 4.0 ppt, 5.0 ppt, and 10.0 ppt (USEPA 2023i). It is not possible to determine how EPA conducted its benefits analysis because EPA did not make its model or important inputs into the model available in the public docket. What is clear is that EPA failed to acknowledge that

[83] SDWA §1412(b)(3)(C)(i)(I).
[84] *See* National Primary Drinking Water Regulations: Lead and Copper Rule Revisions, 84 Fed. Reg. 61684 (2019) (considering four alternative regulatory options); National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring 66 Fed. Reg. 6976 (2001) (considering four alternative MCL levels); and National Primary Drinking Water Regulations; Radon-222, 60 Fed. Reg. 59246 (1999) (considering seven alternative MCL levels).
[85] EPA ignores that states have implemented a range of PFAS MCLs, some greater than 10 ppt., without further explanation for its use of 10ppt.

chemical exposures from drinking water at 4.0 ppt, 5.0 ppt, and 10.0 ppt are toxicologically indistinguishable based on fundamental principles of toxicology and dose-response (Waddell 2008, 2010) and further detailed below. The numerically quantified health outcomes for those concentrations are not meaningful for public health.

Toxicology at its most fundamental level is based on the chemical reaction of a substance with a biological receptor. The activity of such chemical reactions is measured based on a logarithmic scale (Waddell 2008). Thus, dose-response relationships which describe the relationship of the amount of a substance to the effects from these biological reactions are assessed using a logarithmic scale. Consequently, when considering a logarithmic scale, only doses that differ by an order of magnitude (*i.e.,* 10-fold) or more are biologically distinguishable.[86] EPA even incorporates this concept into its own definition of a reference dose (USEPA 1993) "is an estimate **(with uncertainty spanning perhaps an order of magnitude)** of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." [emphasis added]. This definition highlights that it is not meaningful to distinguish between exposure doses occurring within an order of magnitude (*i.e.,* 10-fold) of one another.

EPA's attempt to differentiate among health effects associated with the proposed MCL and the two regulatory alternatives—4.0 ppt, 5.0 ppt, and 10.0 ppt—is at best a theoretical exercise that lacks any toxicological relevance. This lack of relevance becomes obvious when human exposure doses are derived from the respective concentrations in drinking water and compared on a logarithmic scale.

However, the EPA (USEPA 2019) *Exposure Factors Handbook* provides information on drinking water intakes, and the following calculations can be conducted for any age group without yielding fundamentally different results. For this calculation (Table 7-1, Figure 7-2), the two-day average per capita estimates of combined direct and indirect water ingestion for all ages at the 95th percentile, which EPA listed as 37.1 ml/kg-d, was applied.

[86] The logarithmic nature of toxicology is also the reason why the dose selection for dose-response studies is generally advised to span two to four orders of magnitude (e.g., OECD, 2018 Test No. 408; USEPA, 2000 Health Effects Test Guidelines OPPTS 870.3050): it allows for an investigation of equidistant doses on the logarithmic scale in half-unit steps, e.g. log(1)=0, log(3.16)=0.5, log(10)=1, log(31.62)=1.5, log(100)=2, etc..

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Table VII-1. Calculation of Hypothetical Exposure Doses (pg/kg-d) at Each Regulatory Alternative.

Exposure Dose by Data Transformation	4.0 ppt	5.0 ppt	10.0 ppt
Dose pg/kg-d	148.4	185.5	371.0

And displayed graphically:

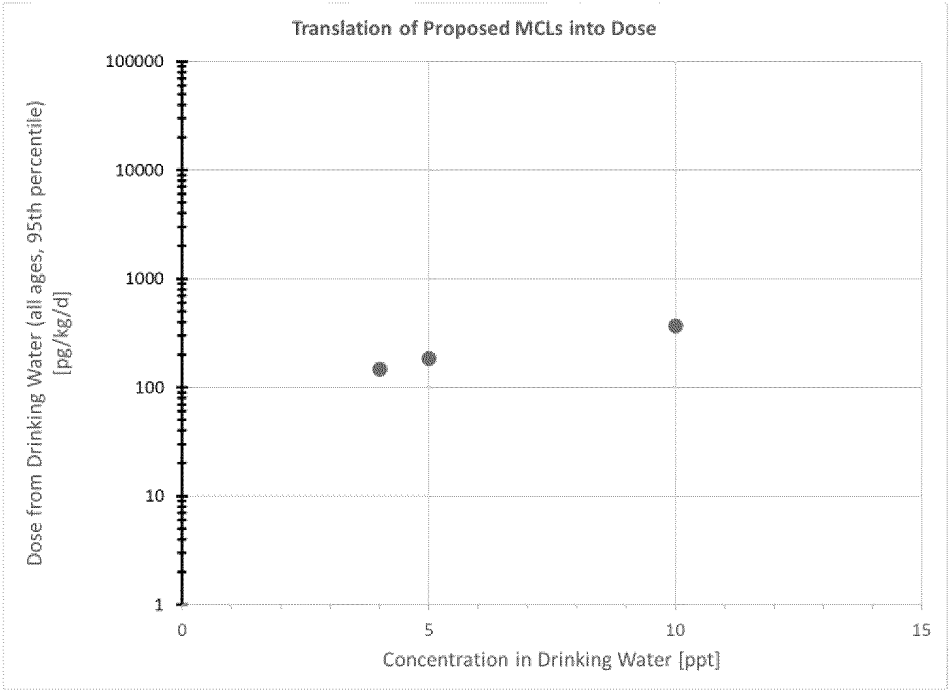

Figure. VII-1. Presentation of Exposure Doses Resulting from Proposed PFOA and PFOS Regulatory Alternatives.

The plots of daily exposures from drinking water that contains 4.0 ppt, 5.0 ppt, or 10.0 ppt of a substance (Figure 9-2) powerfully clarifies why dose should be considered on a logarithmic scale. In this figure, the y-axis is adjusted to a logarithmic scale to demonstrate that the three doses are actually all within one order of magnitude of each other (i.e., between 100 and 1000 pg/kg/d, a 10-fold range). In fact, the difference is within 2.5-fold. Accordingly, applying EPA's definition of a reference dose, there would be no discernable differences between exposures occurring at 4.0 ppt, 5.0 ppt, or 10.0 ppt. Therefore, when presented on a toxicologically accurate scale, these three exposures cannot be expected to be biologically different from one another. Any hypothesized health benefits from choosing one of the proposed concentrations over the other are just that: hypothetical and speculative.

c. The Uncertainties in Parameters Used by EPA Thwart the Ability to Accurately Distinguish Between 4.0, 5.0, and 10.0 ppt.

Even though EPA listed numerous uncertainties in its benefits analysis, it failed to acknowledge that these uncertainties make it impossible to practically distinguish effects at

concentrations of 4.0 ppt, 5.0 ppt, and 10.0 ppt. A slight change in assumptions within the spectrum of uncertainties might mathematically result in completely different concentrations in drinking water. In other words, the uncertainties in EPA's analysis are so great that they dwarf the difference between these toxicologically indistinct alternatives such that they are not true alternatives.

The calculations in Table 7-1 represent daily exposure doses. In contrast, EPA derived human equivalent internal doses using sophisticated models, which are based on numerous assumptions regarding intra- and interspecies variables in toxicokinetics (e.g., volume of distribution, half-life, tissue distribution), toxicodynamics (e.g., gender differences, age differences, susceptible life stages, differences in adverse outcome pathways), exposure (e.g., translation of concentration in rat chow into systemic exposure dose, relative source contribution assumptions, deterministic vs. probabilistic exposure modeling), and more. The six tables named "Limitations and Uncertainties" in the Economic Analysis draft (USEPA 2023i) further document the myriad assumptions that underpin EPA's analysis.

Every assumption used for these models and endpoints introduces uncertainty. Multiple uncertainties can have combinations of effects. Those effects can be additive, synergistic, potentiating, or antagonistic, which in turn introduces even higher levels of uncertainty regarding the accuracy of the predicted effects at the three alternative drinking water concentrations—without even considering the precision of said models. The compounding effects of multiple uncertainties far outweigh the *de minimis* differences of exposures on the logarithmic scale, which makes any attempt to distinguish between the health benefits of 4.0 ppt, 5.0 ppt, and 10.0 ppt not only futile but impossible.

d. EPA's Calculation of PFAS Serum Concentration Lacks Transparency

In the Economic Analysis, EPA (USEPA 2023i) states that it "developed single-compartment PK models for adult males and females to estimate blood serum PFOA and PFOS concentrations," noting that they are described in the MCLG documents. EPA then states that it compares the differences in serum concentrations at each regulatory alternative level to published coefficients of changes in serum concentrations that have been associated with health effects (e.g., reduced birth weight). Although EPA states the pharmacokinetics models are described in the PFOA and PFOS MCLG documents (USEPA 2023a,b,c,d), neither these specific models nor the blood serum predictions are provided in the referenced material.

EPA's documents describe other pharmacokinetics models used for cross-species dosimetry or predicting points of departure to derive reference doses, but the "single-compartment pharmacokinetics models" used for predicting serum concentrations from drinking water – and subsequently for calculating benefits – are not described. EPA's entire benefits analysis hinges on these predicted serum data. It is the first parameter entered into the sequence of analyses that are used to estimate the health risk reduction benefits for the proposed MCL and the regulatory alternatives (e.g., Figure 6.1 of USEPA 2023i). EPA failed to clearly provide its predictions of the serum concentrations expected in populations consuming drinking water at the proposed MCL of 4.0 ppt and each regulatory alternative (5.0 ppt and 10.0 ppt) and identify if there are meaningful differences between the steady-state serum concentrations at each

alternative. Importantly, there is no evidence that these pharmacokinetics models have been peer-reviewed. EPA's lack of transparency in model details, data outputs, assessment of uncertainty, and interpretation of results are underlying critical deficiencies. Such an analysis requires peer review before it is used to support regulatory decision-making. Moreover, EPA's lack of transparency is particularly important with respect to serum concentration calculations because the outputs of those calculations are used to determine difference in benefits at each regulatory alternative.

e. Demonstration of Overlap in Serum Concentrations at Each Regulatory Alternative

Though EPA does not make available either its model or its predictions of serum concentrations, EPA cites a first-order single-compartment model pharmacokinetics model (Bartell 2017; Lu and Bartell 2020) that it adapts to calculate PFNA serum concentrations from drinking water exposures (USEPA 2023k). To highlight the shortcomings in EPA's approach, this same model could be used to predict PFOA and PFOS steady state serum concentrations at the proposed MCL and each regulatory alternative. The following example analysis is intended to illustrate that the small, predicted differences in serum concentrations are not meaningful because they do not account for uncertainties and inherent variability in the model input parameters (e.g., half-life).

Table 7-2 demonstrates the model's outputs using NHANES geometric mean serum concentrations as the starting serum concentrations and assumes the model's defaults for other toxicokinetic and intake parameters. The half-life parameter was adjusted based on the range of half-lives reported by EPA to illustrate how altering only the half-life parameter impacts the modeled serum concentrations. EPA (USEPA 2023a,c) states that, in humans, the half-lives of PFOA can range from 1.7 years (Xu et al. 2020) to 4.4 years (Fu et al. 2016). For PFOS, half-lives can range from 1.04 (Xu et al. 2020) to 60.9 years (Fu et al. 2016). For the calculation of points of departure, EPA (USEPA 2023a,c) selected a half-life of 2.7 years for PFOA (Li et al. 2017) and a half-life of 3.4 years for PFOS (Li et al. 2018), which is consistent with the model default (Lu and Bartell 2020).

As illustrated in Table 7-2, there is significant overlap in potential serum concentrations when inputting a range of half-lives for each regulatory alternative. For example, for PFOA, the predicted serum concentration at the 10.0 ppt and the shortest half-life (1.7 years) is 2.54 ng/ml which is ***less than*** the serum concentration of 2.64 ng/ml predicted at the longest half-life (4.71 years) and the lowest regulatory level (4.0 ppt). When EPA's selected half-lives are applied to the comparison of 4.0 ppt and 10.0 ppt, there is less than a 0.82 ng/mL difference in the predicted PFOA and PFOS serum concentrations (Table 9-2). **These minimal differences in serum concentrations do not represent a meaningful difference in dose. Thus, there are likely not biologically relevant differences in effects between these regulatory alternatives.**

Table VII-2. Predicted Steady State Serum Concentrations (ng/mL) at Each Regulatory Alternative Using Lu and Bartell 2020.

PFAS	Half-life (years)	4.0 ppt	5.0 ppt	10.0 ppt	NHANES Geometric Mean (95% CI)	NHANES 95th Percentile (95% CI)
PFOA	1.7	2.02	2.11	2.54	1.42 (1.33-1.52)	3.77 (3.17-5.07)
	2.3 (model default)	2.14	2.26	2.85		
	2.7 (EPA)	2.23	2.36	3.06		
	4.7	2.64	2.88	4.09		
PFOS	1.04	5.36	5.40	5.60	4.25 (3.90-4.62)	14.6 (13.1-16.5)
	3.4 (model default and EPA)	5.72	5.85	6.49		
	60.9	14.46	16.78	28.36		

Notes:

Model Source: Lu S, Bartell SM. Serum PFAS Calculator for Adults, Version 1.2, 2020, www.ics.uci.edu/~sbartell/pfascalc.html.

Calculations assume a default starting serum concentration based on the NHANES geometric mean values for PFOA and PFOS (NHANES 2017-2018 Total Population https://www.cdc.gov/exposurereport/data_tables.html)

CI = confidence interval

Half-life Sources:

Model Default: PFOA is from Bartell et al. 2010 and PFOS is from Li et al. 2018

EPA: PFOA Li et al 2017 and PFOS Li et al 2018

The above analysis demonstrates that considerations of variability are critical in conducting an accurate scientific assessment of serum concentrations. EPA correctly notes that factors such as age and health status of individuals can impact toxicokinetic parameters such as half-lives (USEPA 2023a,c). However, it is not clear if or how such biological variability was accounted for in EPA's assessment of serum concentrations. EPA (USEPA 2023c) also states that "linear PFOS molecules exhibit longer half-lives than branched forms," but it is not clear if EPA considered those differences. Variability in other toxicokinetic parameters, such as volume of distribution or clearance rates, would add further uncertainty to the serum predictions. This inherent uncertainty in the alternatives analysis renders the overlap in serum concentrations at 4 ppt and the regulatory alternatives too great to be biologically distinct.

Additionally, EPA's apparent approach to predicting serum concentrations based on intake of drinking water contradicts its own statements in the MCLG documents (USEPA 2023a,c). In describing studies on half-lives for both PFOA and PFOS, EPA states, "**there is insufficient data to correlate PFOS [and PFOA] intake measurements to serum/plasma** and urine concentrations" [emphasis added]. Given this conclusion, it is unclear why EPA determined that predicting serum concentrations as the basis of the benefits analysis was appropriate, in light of the significant population and biological variability in the underlying estimates of exposure and toxicokinetics. EPA's approach is not scientifically supportable.

These critical flaws in EPA's prediction of serum concentrations are then propagated through its benefits analysis, where EPA attempts to apply exposure-response relationships to assess associations with adverse disease outcomes and other estimates of impacted populations.

There is simply no basis for distinguishing health outcomes across the regulatory alternative concentrations. Because there are no biologically meaningful differences between the serum concentrations at each regulatory alternative concentration (as explained above), the outputs of the benefits analysis also are neither meaningful nor valid. EPA has not chosen appropriate regulatory alternatives and there are likely no distinctly quantifiable health benefits at each of the alternatives.

f. Exposure-Response Relationships Were Improperly Selected

To calculate the health-risk reduction benefits based on serum concentrations, EPA extracts from literature or independently reanalyzes various exposure-response slope factors that are intended to demonstrate a quantitative relationship between a change in serum concentrations and a specific health effect. For both PFOA and PFOS, EPA evaluates the health effects of reductions in birth weight and increases in total cholesterol. EPA also considers increases in renal cell carcinoma risk for PFOA and increases in blood pressure for PFOS. For each endpoint, EPA selects relationships between serum levels and health effects that are not supported by the underlying studies or are based on uncertain reanalysis of data. These flawed analyses add to the misleading conclusions associated with basing the analysis on inappropriate and indistinguishable regulatory alternatives.

For reduced birth weight, EPA uses an exposure-response slope factor of –10.5 g per ng/mL for PFOS from Steenland et al. (2018), which is a random effects meta-analysis based on 24 studies. Contrary to EPA's assessment, however, Steenland et al (2018) concludes, "current human evidence provides only modest support for decreased birth weight with increasing PFOA. Studies with a wide range of exposure, and studies with blood sampled early in pregnancy, **showed little or no association of PFOA with birth weight**. These are studies in which confounding and reverse causality would be of less importance." (Emphasis added). In other words, EPA relies on an association for an endpoint that is not supported by the underlying publication. For PFOS, EPA conducts its own meta-analysis of data presented in Dzierlenga, Crawford et al. (2020) deriving an exposure-response slope factor of –3.0 g per ng/mL, even though Dzeirlenga et al. (2020) itself found that "when blood was drawn at the very beginning of pregnancy, there was essential no relation of birth weight to PFOS." This meta-analysis has not been peer reviewed, which calls into question the validity of EPA's reanalysis methods.

For the endpoints that EPA suggests are associated with cardiovascular disease (e.g., increased cholesterol), EPA also inappropriately derives exposure-response slope factors and ignores their biological relevance. For total cholesterol, EPA conducted its own meta-analysis and only included studies that had linear associations (6 studies for PFOA and 5 studies for PFOS) (USEPA 2023k). This selection criterion biases the results and misrepresents the overall weight of evidence, because other studies that did not show linear associations (6 studies for PFOA and 7 studies for PFOS) were ignored altogether in the calculation of the exposure-response slope factor. Like the birth weight analysis for PFOS, this analysis is not peer reviewed. EPA (USEPA 2023i) also states that it used "untransformed serum PFOA/PFOS," which means that it did not evaluate the relationship using a log scale. The importance of using a log scale is described in Section VII.b above. The associations with total cholesterol also are not biologically significant. For example, EPA derives an exposure-response slope factor for

PFOA equal to 0.08 mg/dL per ng/mL, which means that for every 1 ng/mL increase in serum PFOA, total cholesterol increases by 0.08 mg/dL. Based on the demonstration of serum concentrations described in Section VII.d above, the difference in serum concentrations between 4.0 ppt and 10.0 ppt was less than 1 ng/mL. A change of 0.08 mg/dL of total cholesterol is not biologically meaningful, since total cholesterol is typically reported in mg/dL as whole integers (e.g., 175 mg/dL or 200 mg/dL); cholesterol is not measured or reported to the hundredths of mg/dL. Thus, a potential change in total cholesterol going from a drinking water exposure at 4.0 ppt to 10.0 ppt would not likely be measurable. For PFOS, the exposure-response slope factor is 1.57 ng/dL per ng/mL, which also does not represent a biologically significant change in cholesterol, especially over small changes in serum concentrations.

The exposure-response slope factor of 0.00178 per ng/mL for PFOA and renal cell carcinoma risk is apparently derived from Shearer et al (2021). This publication and its supporting information, however, do not report this value. Shearer et al (2021) instead reports odds ratios, which are not linear associations. EPA should transparently describe how it generated this exposure-response slope factor. Additionally, as described previously (see Section V.c), this study is fundamentally flawed and did not show consistent dose-response relationships. Thus, deriving an exposure-response slope factor from a study that did not demonstrate a linear dose-response is not scientifically valid. Notably, EPA does not assess risks of cancer from PFOS exposure as part of the benefits analysis. This omission may indicate that there is not enough evidence to support a quantifiable association between PFOS exposure and cancer, which contradicts EPA's conclusions that PFOS is "likely to be carcinogenic."

EPA's approach to selection of exposure-response slope factors is scientifically flawed, lacks transparency, and disregards the biological relationship of exposure and effects. EPA should consider and discuss the exposure-response slope factors in the context of biologically relevant effects and obtain peer review for any novel analyses. EPA's analysis egregiously misrepresents any meaningful determination of health risk reduction benefits between the proposed MCL and regulatory alternatives.

g. EPA's Estimate of Decreased Cardiovascular Disease (CVD) Risk is Not Reproducible or Transparent

The estimated CVD risk reduction derived by EPA in the Economic Analysis for the proposed PFOA and PFOS NPDWR is systematically flawed. Issues with the estimated CVD risk reductions stem from deviations from EPA's guidance for study selection and dose-response analysis and are compounded by a lack of transparency and reproducibility in EPA's methods.

i. EPA's study quality evaluation and study selection process are not consistent and are not transparent

EPA used meta-analytic approaches to derive a pooled estimate of the slope of a linear function of exposure-response between serum PFOA and PFOS (ng/dL) and serum total cholesterol (TC) (mg/dL) for use in the Economic Analysis (USEPA 2023c). These pooled slope estimates are developed independently for PFOA and for PFOS. Pooling information across epidemiological literature through use of meta-analysis allows for incorporation of individual-

study uncertainty and consideration of the full range of observed exposure-response relationships across epidemiological studies; this allows EPA to use the full body of evidence in lieu of selecting an observed exposure-response slope from one single study. The first step of this process is identification of studies that meet inclusion criteria for the meta-analysis. EPA relied upon the literature review processes from the Agency for Toxic Substances and Disease Registry (ATSDR, 2021) and EPA risk assessments (USEPA 2023a,b). These approaches identified 80 studies on PFAS (see USEPA 2023c, Figure F-1). From those studies, EPA further limited the included studies by the following criteria: the study must 1) be conducted on adults in the general population; 2) quantitatively measure TC and high-density lipoprotein cholesterol (HDLC); 3) evaluate exposure of PFOA and PFOS. Additional exclusion criteria included: 1) pregnant women, infants, or children; 2) reporting of only relative risks or odds ratios for hyperlipidemia or hypercholesterolemia as these measurements of response could not be used. EPA also stated that "*studies performed on specific population subsets, such as occupational populations, were not considered for inclusion in the meta-analysis due to the potential for greater levels of exposure to PFOA and PFOS in these populations compared to the general population*" (USEPA 2023k, p. F-2). In other words, EPA excluded studies on members of the population expected to have higher-than-average concentrations of PFOA and PFOS in their blood.

In the Economic Analysis, EPA states that "*[a]ll studies were evaluated for risk of bias, selective reporting, and sensitivity as applied in developing EPA's Toxicity Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water (U.S. EPA, 2023a; U.S. EPA, 2023b)*" (USEPA 2023c, p. F-8). However as noted in Section V.d.iii, the risk of bias analyses presented by EPA and its systematic review methods lack transparency and consistency in the evaluation of study quality. Despite the lack of transparency and consistency in the process, EPA assigned a determination regarding its confidence in each study (based on EPA IRIS protocol for risk of bias, selective reporting, and sensitivity; *see* EPA 2023a,b, p. 3-147). However, the study quality ranking was not used as an exclusion criterion for the meta-analysis. Therefore, studies considered as "low confidence" by EPA (based on the study quality evaluation) were not excluded from the pooled analysis.

A total of 23 studies on PFAS and TC and HDLC in the general population were considered for inclusion in the meta-analysis (USEPA 2023c, p. F-2). Of the 23 studies considered for the Economic Analysis by EPA (USEPA 2023c), 14 total studies on adults in general populations met EPA's inclusion criteria. Eleven of the studies evaluated the relationship between serum TC and PFOA and 12 studies evaluated serum TC and PFOS. Each of these 14 studies are described in USEPA 2023c, Table F-1. This includes: **6 studies** on serum TC and PFOA/PFOS from NHANES[87] that represents the general US population (Dong et al. 2019; Fan et al. 2020; He et al. 2018; Jain 2019; Liu et al. 2018; Nelson et al. 2010); **2 studies** from other US populations, including prediabetic adults from a diabetes prevention program (Lin et al. 2019) and a potentially highly exposed population (Steenland et al. 2009); and **6 studies** on serum TC and PFOA/PFOS in other countries, including Canada (Fisher et al. 2013), a Canadian

[87] Studies based on NHANES are cross-sectional in nature, and therefore have limited utility for purposes of establishing causality (see discussion at the end of this section). Also see Section V.d.i noting significant concerns regarding studies using uncorrected NHANES data.

Inuit population (Château-Degat et al. 2010), Sweden (Li et al. 2020), Taiwan (Yang et al. 2018; C.Y. Lin et al. 2020) and China (Fu et al. 2014).

EPA does state reasons for exclusion of several additional general population studies that met its initial inclusion criteria (e.g., Eriksen et al. 2013; Fitz-Simon et al. 2013; Huang et al. 2018; Convertino et al. 2018). However, EPA does not clearly explain why other studies on adults in general populations (e.g., Donat-Vargas et al. 2019), clinical trials (e.g., Liu et al. 2020) or highly exposed populations (e.g., Canova et al. 2020; Zare Jeddi et al. 2021) were not considered. Despite being a clinical trial, in which exposure and response are typically known, Convertino et al. (2018) was judged "low confidence" or "uninformative" by EPA due to residual confounding by socioeconomic status (SES) and "*lack of information on allocation of participants to treatment levels*" (USEPA 2023a, p. C-23, C-44). However, other "low confidence" studies were included in the meta-analyses; in the Economic Analysis, four included studies were designated as "low confidence" due to deficiencies in participant selection, outcome assessment, or confounding domains (Fu et al. 2014; He et al. 2018; Yang et al. 2018; Y. Li et al. 2020). EPA conducted a sensitivity analysis to evaluate the impact of excluding all "low confidence", or higher risk of bias studies (reported in EPA 2023c, Tables F-2 and F-3), however EPA did not conduct sensitivity analyses to evaluate the impact of removing He et al. (2018), a low confidence study, from the "linear models only" pooled estimate or removal of all "low confidence" studies from the US/Canada only models. Inclusion of these low confidence studies may introduce bias into the pooled estimates. Additionally, this sensitivity analysis does not address studies not included in the "all studies" analysis. EPA should demonstrate that the pooled slope estimates are not biased through inclusion and exclusion of specific studies through 1) consistency in application of exclusion criteria; and 2) sensitivity analyses that quantify the impact of inclusion and exclusion of individual studies on the pooled slope estimates. Without additional sensitivity analyses, EPA cannot demonstrate that the pooled effects are not sensitive to (or driven by) one study, lower quality studies, or other specific populations that are not generalizable to the US.

Confidence in the sensitivity analyses that measure the impact of inclusion/exclusion of low confidence studies is further weakened by the lack of transparency and consistency in EPA's determinations of study quality (as noted in Section V.d.iii *supra*). Many of the studies considered "medium quality" by EPA have critical deficiencies, including inadequate control for confounding or correlated exposures and/or cross-sectional study designs. Without additional sensitivity analyses, including the exclusion of cross-sectional studies and further exclusion of "low confidence" studies, EPA cannot demonstrate that the meta-analyses are not sensitive to inclusion or exclusion of specific studies and improve confidence in the pooled slope estimates

Highly exposed populations include both occupational cohorts and communities that were exposed to elevated levels of PFAS in drinking water. Although EPA states that "*studies performed on specific population subsets, such as occupational populations, were not considered for inclusion in the meta-analysis due to the potential for greater levels of exposure to PFOA and PFOS in these populations compared to the general population*" (USEPA 2023k, p. F-2), this judgment is not consistently applied. For example, EPA included Steenland et al. (2009) in the meta-analysis despite the fact that "*Steenland et al. (2009) retained the results from a study of a highly exposed population in the United States (the C8 Health Project cohort)*" (USEPA 2023c, p. F-

4). Some of the studies **not** included in the meta-analysis (e.g., Eriksen et al. 2013; Fitz-Simon et al. 2013) **are** included as key studies in the PFOA (USEPA 2023a, Table A-6) or PFOS (USEPA 2023b, Table A-6) risk assessments. It is unclear why EPA would find those studies appropriate for use in risk assessments but not in derivation of a dose-response curve for its benefits analysis.[88] Exclusion of studies EPA itself identified as "key" or studies from highly exposed populations create substantial risk of biasing the results of the meta-analysis and limiting generalizability of the findings. These risks can only properly be addressed by EPA through inclusion in the meta-analysis and use of sensitivity analyses to measure the impact of omission.

Occupational exposures were excluded from the pooled analysis (e.g., Olsen et al., 2001, 2003; Olsen et al 2007; Costa et al. 2009). However, the estimated slopes used in the pooled assessment are an estimate of change in TC per ng/mL PFAS exposure, therefore information from these studies would be expected to be informative despite the expected difference in exposure levels. The models used in the meta-analysis are a continuous function of the relationship between exposure and TC outcomes (i.e., straight lines), and so the highly exposed, or occupational, groups should be just an extension of the same dose-response slope.

Further, occupational studies typically represent highly exposed populations and a lack of increased odds of CVD risk in these populations would indicate a potential lack of response in the general population with lower exposures. As noted by EPA (USEPA 2023a, p. 3-174), the occupational studies "*suggest no association between PFOA and TC in workers*", in part due to a lack of statistically significant associations for the observed increases in serum TC and the reported inverse association between changes in PFOA and serum TC reported by Olsen et al. (2012). EPA states that "*[c]ross-sectional occupational studies… reported positive associations between PFOS and increased serum TC…however, the association was not observed in longitudinal analyses*,"[89] which weakens the strength of the causal association as the significant associations were only observed in cross-sectional analyses that cannot establish a temporal relationship[90] between exposure and response (USEPA 2023b, p. 3-145). Findings from longitudinal analyses should hold greater weight in the evidence synthesis because they can establish that exposure precedes the observed response. Accordingly, best practice would be to benchmark the slopes of the pooled analyses against these occupational studies to ensure that the proposed exposure-response relationship is coherent across the full body of evidence. Additional sensitivity analyses should also be conducted with inclusion of these occupational populations. For example, EPA conducts a sensitivity analysis excluding "non-US/Canada and high exposure studies" but does not evaluate the pooled results from US/Canada populations including those high-exposure populations. These additional sensitivity analyses are necessary to ensure that the

[88] Although information required for incorporation of Erikson et al. (2013) and Fitz-Simon et al. (2013) into the pooled analyses were not available in the publications, EPA did not indicate that it attempted to contact the authors or to re-assess the underlying evidence to incorporate these study populations into the meta-analysis, which is recommended by Cochrane review processes to reduce bias from under-reporting in the primary literature.

[89] A longitudinal study is defined by repeated collections of sampling data in the same individuals over a period of time (typically years). A cohort study is a common example.

[90] Temporality is a criterion of the Bradford Hill criteria, an established and well-accepted list of criteria used to consider causal associations in epidemiology.

pooled slope used for the economic benefits analysis is representative of the reliable (or high-quality) studies from relevant populations.

EPA's reliance in its benefit analysis on cross-sectional studies is also in contradiction with its statement that "*the main considerations specific to evaluating the quality of studies on serum lipids included use of medications, fasting, and potential for reverse causality*." (USEPA 2023c, p. F-8). Cross-sectional studies, such as those based on NHANES data, cannot establish temporality and findings may be due to reverse causality. In other words, cross-sectional studies measure exposure and response simultaneously, and therefore cannot establish that the exposure occurred prior to onset of the measured disease or response outcome. When the exposure and response are measured simultaneously, it cannot be demonstrated that the measured exposure is not affected (or caused) by the response. As noted by Dong et al. (2019), "*The NHANES data are capable of examining the association but cannot address the issue of causality. Similar to other cross-sectional studies, this study* ***cannot answer*** *whether: 1) exposure to PFASs elevates the cholesterol level; 2) high cholesterol levels allow the storage of PFASs easier; or 3) joint factors simultaneously affect both PFASs and cholesterol*". *See also, e.g.,* Andersen et al. (2021); Fragki (2021). Therefore, inclusion of cross-sectional analyses in the meta-analyses is a limitation that must be addressed by EPA.

In summary, EPA does not clearly state the reasoning for inclusion or exclusion of all relevant studies from the meta-analyses. The studies selected for the economic benefits analysis are inconsistent with the studies included in the risk assessment for RfD derivation. This inconsistency limits confidence that that the meta-analyses for CVD risk include all applicable information, which then impacts confidence in the estimated economic benefits.

ii. EPA's dose-response model selection process is not transparent or consistent with generally accepted risk assessment and statistical approaches.

Of the pooled model options presented in EPA's Economic Analysis appendices (USEPA 2023c, Tables F-2 and F-3) EPA selected "linear models only" for use in its CVD risk reduction analysis. This means that EPA chose to include only models that describe a linear relationship (straight line) between exposure and response and excluded studies that fit a linear regression to logarithmically transformed data (i.e., log-linear models). Use of only studies with slope estimates based on linear models, instead of logarithmic or other transformations, limits analyses to 4 of the 14 studies on serum TC and PFOA and 5 of 15 studies on serum TC and PFOS (USEPA 2023c, Tables F-2 and F-3). In addition, studies considered "low confidence" by EPA are included in the limited numbers of studies included in the "linear models only" analyses. EPA's use of the "linear models only" resulted in the exclusion of higher-quality studies and could bias the analysis. Because of the significant likelihood that the "linear models only" approach omits critical information and biases the results, a proper analysis would require demonstration that the findings from the limited "linear models only" analyses are representative of the body of evidence and are not biased by the study selection criteria.

In other analyses in this rulemaking, EPA has relied on studies using logarithmically transformed data for estimating the slope of the exposure-response and BMD(L) derivation (e.g.,

Budtz-Jorgensen and Grandjean, 2018). However, EPA states that, for the economic benefits analysis, it "*selected the pooled slope estimate based on the studies using linear models to ease interpretability and to reduce bias due to backtransformations of effect estimates with log-transformed outcomes or exposures*" (USEPA 2023c, p. 6-55). EPA failed to show that its justification for use of the linear models was based on scientific accuracy; instead, the justification indicates that the selection of models was based on ease of use and not based on best science. Although conversion of non-linear studies into useable linear slope estimates requires mathematical assumptions that impart uncertainties in the backtransformed[91] estimates, EPA relied upon log-transformed evidence (e.g., Grandjean et al. 2012; Budtz-Jorgensen and Grandjean 2018) in support of derivation of PODs for RfD development and demonstrated a clear willingness to modify and make assumptions from the underlying evidence (see USEPA 2023a,b Appendix E for details of BMD modeling). For example, EPA estimated BMRs from Budtz-Jorgensen and Grandjean (2018) measured as the "*log2[tetanus antibody concentration]*" (p. USEPA 2023a, p.E-1). This means that EPA had to backtransform the evidence from Budtz-Jorgensen and Grandjean (2018) in derivation of the RfD. Therefore, the rationale to select the pooled slope estimate based only on linear models "*to reduce bias due to backtransformations of effect estimates*" is not consistent with approaches used by EPA in its risk assessments in the supporting documents for this Proposed Rule.

In addition, EPA's decision to base the pooled slop estimate only on linear models[92] removes a large portion of the complete body of evidence and does not integrate the findings from all studies. Critically, this approach likely biases the pooled estimate toward finding a statistically significant effect through 1) exclusion of higher quality studies; 2) exclusion of additional populations of interest; and 3) exclusion of non-linear models may better capture the observed dose-response relationship. As evidenced by the sensitivity and other meta-analytic models (e.g., Table F-2 and Figure F-4), inclusion of these additional studies results in a lack of a statistically significant dose-response between PFOA and TC. Meaning, overall, the full body of evidence indicates that there is likely no significant effect between PFOA/PFOS and serum TC. The fact that the "linear models only" analysis is the ***only*** pooled analysis of PFOA exposures that identified a statistically significant slope (p-value < 0.05) (see Table F-2) indicates that the "linear models only" analysis is not representative of the full body of evidence. For PFOS and TC, the pooled dose-response using *"linear models only"* was not statistically significant (p-value > 0.05). Inclusion of additional studies with non-linear models identified a statically significant (p-value < 0.05), albeit shallow, pooled slope estimate for some of the modeled relationships between PFOS and serum TC (Table F-3). The analyses presented in EPA's (2023c) Tables F-2 and F-3 show the meaningful impact that inclusion and exclusion of individual studies has on pooled slope estimates. Therefore, EPA must carefully evaluate its decision to use the "linear models only" slope estimates for the economic analysis and provide

[91] Backtransformation is defined as converting a transformed number (i.e., a log or square root of a measurement) to its untransformed equivalent (i.e., exponentiation or squaring of the log or square root).

[92] A linear (i.e., straight line) model is equivalent to a linear regression model with the function $y = mx + b$, where y = response; m = slope; x = dose; b = intercept. Non-linear models incorporate other parameters, such as exponential functions, or use transformation (e.g., logarithm) of the dose or response variable to improve description of the observed dose-response. Non-linear models allow for fitting either 1) a linear model to log-transformed dose and/or response data or 2) fitting a curve to the observed data, for which the slope is not constant and may be more steep or more shallow than the rest of the model in the exposure region of interest.

additional justification for the use of these models in lieu of models that incorporate more information. This justification is critical due to the differences between the "linear models only" and models with more complete information, both in terms of the magnitude and the significance of the pooled slope estimates.

Further, inclusion of linear-only models assumes that a linear dose-response best explains the observed dose-response relationships between PFAS exposures and serum TC changes. However, EPA has not clearly shown that linear assumptions are appropriate or consistent with underlying toxicological evidence, nor has it provided the information required for peer or public review. Non-linear models incorporate other parameters, such as exponential functions, or use transformation (e.g., logarithm) of the dose or response variable to improve description of the observed dose-response. Use of these non-linear models may allow for improved predictivity of the observed relationship between exposure and response.

Contrary to EPA guidance for dose-response analysis, EPA does not describe relative model fit for each of the included studies or the appropriateness or impact of linear assumptions. As stated by EPA BMDS guidance, "*an important criterion for selecting a fitted model is that the model provides an adequate description of the data, especially in the region of the BMR*" (USEPA 2012, p. 33).[93] Although EPA is not using a BMD to support this economic assessment, the model fitting criteria prescribed by EPA's BMDS guidance are generally accepted statistical practice. Evaluating the model's ability to predict the observed response (or "model fit") is a critical step in basic regression statistics. EPA's BMDS guidance also recommends visual inspection and plotting of residuals in order to evaluate deviations of the model predictions from the observed response. In selecting models, EPA recommends a stepwise process that 1) assesses the goodness-of-fit; 2) rejects models that do not adequately describe data in the dose-response region of interest; and 3) applies additional "*somewhat arbitrary*" defaults for model selection (EPA 2012, p. 39-40). Here, EPA has not shown that the linear models fit the observed TC responses from individual studies, nor that they accurately predict responses at exposures relevant to the general population. Moreover, EPA has not shown that the non-linear or logarithmically transformed models fail to more accurately describe the observed exposure-response. In the absence of causality information among the epidemiological literature, which is the case here, toxicological information could be used to inform on the expected model shape and the appropriateness of assuming linearity. EPA acknowledges this potential issue in its discussion of model limitations and uncertainties (EPA 2021; Table 7) when it states "*the derivation of PFOA/PFOS exposure-response functions for the relationship between PFOA/PFOS serum and TC assumes that there are no threshold serum concentrations below which effects do not occur.*" However, the impact of this uncertainty is described only as "uncertain" and not further addressed by EPA. Therefore, projecting economic impacts based on models that do not clearly demonstrate an exposure-response may overstate the predicted economic benefit.

For PFOA, when looking at the full body of evidence and pooled meta-analytic slope estimates (shown in Table F-2), EPA's pooled slope estimates are only statistically significant when using linear models only. The estimated slopes from the linear models, only, also indicate

[93] See Sections II.a and V.e for further explanation of BMDs and their import.

a steeper (or more potent) dose-response compared to slopes generated from pooled estimates of all studies and all lower risk of bias studies. This inconsistency indicates that the linear models likely are not adequately describing the full body of underlying evidence.

For PFOS, only two models from the studies EPA selected for determining the slope of the dose-response relationship have a statistically significant slope (p-value < 0.05): the serum PFOS and TC model including all lower risk of bias studies and the model excluding Jain et al. 2019 (shown in Table F-3). However, with little or no explanation, EPA changed its criteria for statistical significance (using and alpha value of 0.1 instead of 0.05) to support selection of the "linear models only" estimate that is not statistically significant (p=0.064). As stated by the USEPA, "*When including the five studies reporting linear associations, there was a positive increase in TC of 0.08 (95% CI: -0.01, 0.16) mg/dL per ng/mL serum PFOS (p-value=0.064, I2=84%) that was significant at the 0.10 level.*" (EPA 2023c, p. F-16). As stated in the Economic Analysis, the USEPA noted that "*While the association for PFOS and TC is not significant at the 0.05 confidence level, it is significant at the 0.10 confidence level (p = .064).*" (EPA 2023c, p. 6-55). No justification was provided for the change in the confidence level used to denote statistical significance. Notably, EPA also did not apply this change in criteria consistently, as evidenced by the statement "*When all studies were combined (12 studies, 15 results), EPA observed a* ***borderline statistically significant*** *positive increase in TC of 0.066 (95% CI: -0.001, 0.132) mg/dL per ng/mL serum PFOS* ***(p-value=0.055****, I2=100%) (Table F-3, Figure F-8).*" (p. F-16) [emphasis added]. The term "borderline statistically significant" is typically used when a study does not achieve statistical significance, but the p-value is close to the pre-determined cutoff. EPA does not explain why a p-value of 0.055 for the "all studies" model was considered "borderline" but the p-value of 0.064 for the "linear models only" is considered statistically significant. This illustrates that EPA is not consistently applying the criteria for statistical significance across models. Although changes in the criteria used for denoting statistical significance may be statistically and scientifically appropriate, these changes are typically made to make the criteria more stringent to adjust for multiple comparisons or reduce the risk of making a Type I error[94]. Any justification to change the criteria from the standard accepted value of a p-value of 0.05 should be done *a priori* and justified scientifically. EPA has failed to show that the change in p-value criteria to 0.10 was done prior to analyses, is consistently applied, or is supported by the underlying biology.

Based on the reported meta-analyses (Tables F-2 and F-3), it is not clear that there is a statistically significant dose-response relationship between PFOA/PFOS and serum TC when the full body of evidence is considered. Use of information with no significant change in response is not consistent with EPA guidance for dose-response modeling (USEPA 2012). Therefore, based on EPA's own guidance and widely accepted risk assessment practice, the available body of evidence indicates that use of changes in serum TC as the basis for EPA's CVD risk reduction model is not appropriate. Despite the lack of statistically significant slopes in the pooled analyses for PFOA and PFOS when all studies are included, or when only linear models were included for PFOS, EPA justifies its choice for use of serum TC in the CVD risk reduction

[94] A Type I Error is also called a "false-positive"; it is an error that occurs when a researcher identifies a statistically significant association when there is no true association. Criteria for defining statistical significance traditionally accept a Type I Error rate of 5% (or p < 0.05), or 95% confidence in the observed effect.

model by stating "*The literature provides sufficient support of a positive association (e.g., Château-Degat et al., 2010; Dong et al., 2019; U.S. EPA, 2023d; U.S. EPA, 2023e). The studies are large with more than 700 and 8,900 participants, respectively (Château-Degat et al., 2010; Dong et al., 2019) and have low risk of bias*." (USEPA 2023c, p. 6-55). However, as already described, EPA's literature review lacked guardrails designed to support the reliability of such conclusions. Had EPA followed appropriate systematic review processes, it likely would have found that the overall body of evidence (shown visually in Figures F-4 and F-8) is not clearly supportive of an exposure-response association and the sensitivity analyses (presented in Tables F-2 and F-3) do not support the conclusion of a significant relationship between PFOA or PFOS and serum TC across the pooled body of information. This indicates that the use of serum TC as the basis for the economic benefits analysis may overstate the expected reductions in serum TC with reductions in PFOA/PFOS, thereby also overstating the economic benefits. As a result of these process and analytical failures, EPA has not shown that the pooled dose-response functions are reliable or consistent with the underlying biology. Therefore, any use of these functions to estimate economic benefits from reduced health impacts is uncertain and unreliable.

Additional considerations of model applicability specific to meta-analyses, such as inter-study heterogeneity, must be addressed by EPA. In meta-analyses, the pooled estimate is intended to be derived from a body of comparable studies on similar populations. Inter-study heterogeneity, measured as I^2, describes the amount of variability in the response between studies and measures the probability that the pooled estimate contains information from populations that are ***not*** similar. This estimate reflects differences in study design, study population, and data analysis, among other study- and population-level differences. Increased inter-study heterogeneity decreases confidence in the generalizability and utility of the pooled estimate. For the analyses presented by EPA (2023c, Tables F-2 and F-3), the measured heterogeneity for the meta-analyses is relatively high (>75%) for most models. EPA does not discuss the impact this high level of heterogeneity has on its confidence in the meta-analytic models. Heterogeneity could be introduced into these models through differences in underlying population demographics, which is evidenced by the reduction in I^2 estimates for PFOA and PFOS when non-US/Canada and high exposure studies are excluded (see Tables F-2 and F-3). EPA uses "the large degree of heterogeneity in the pooled associations when all data were included" to justify use of the meta-analyses using linear models only (EPA 2023c, P. F-16). However, the I^2 is not meaningfully lower when comparing the PFOA "linear only" model with those for "all studies" or "all lower risk of bias studies" (I^2 range of 87.19 - 89.49; see EPA 2023c, Table F-2). Additionally, the PFOA and PFOS models that "exclude non-US/Canada and high exposure studies" have 1) more included studies, 2) a lower I^2 (or less heterogeneity) compared to the linear models only, and 3) are more representative of the US population that EPA is evaluating in its CVD risk reduction models. Based on these considerations, the model that uses only studies from the US/Canada, which do not show a statistically significant dose-response, are likely 1) more statistically appropriate and 2) generalizable to the United States population for whom this economic analysis is based. EPA should provide additional justification to explain its rationale for use of the "linear models only" in lieu of the US/Canada-based population studies.

In summary, EPA did not provide clear or consistent rationales for its selection of the "linear only" meta-analytic models for PFOA and PFOS for use in the CVD risk reduction analysis. Accordingly, the slopes selected for the CVD risk reduction analysis are unreliable and not consistent with EPA guidance.

iii. Dose-response slopes used by EPA for benefits analysis are different from those used in its risk assessment (i.e., RfD derivation).

As discussed in (USEPA 2023a,b), EPA uses the slope estimate from the exposure-response measured by Dong et al. (2019) as a basis for RfD derivation. EPA presents the slopes from Dong et al. (2019) in its sensitivity analyses, but fails to describe why the slope used in RfD derivation is different than that used for estimating the economic benefits. For example, EPA derives a benchmark dose (BMD) and benchmark dose lower limit (BMDL) based on the slopes, or regression coefficients, reported by Dong et al. (2019) (see USEPA 2023a, p. E-297 to E-300; USEPA 2023b, p. E-25 to E-29) and Steenland et al. (2019) (see USEPA 2023a, p. E-301 to E-306; USEPA 2023b, p. E- 29 to E-34), and the mean differences in serum TC by quartiles of exposure reported by Lin et al. (2019) (see USEPA 2023a, p. E-306 to E-307; USEPA 2023b, p. E-35 to E-36). Each of these individual studies are included in the meta-analysis. A summary of the derived BMD(L)s is presented in the main text (USEPA 2023a p. 4-33; USEPA 2023b. p. 4-29) and the appendices for the Proposed MCLGs for PFOA (USEPA 2023a, p. E-308, Table E-27) and PFOS (USEPA 2023b, p. E-37, Table E-25). The BMDLs from Dong et al. (2019) and Steenland et al. (2009) are used to derive candidate RfDs for PFOA (USEPA 2023a, p. 4-48) and PFOS (USEPA 2023b, p. 4-43). From the candidate RfDs, EPA chose the value of 3×10^{-8} mg/kg/day for PFOA and 1×10^{-7} mg/kg/day for PFOS derived from the BMDLs from Dong et al. (2019) as the basis for considering an RfD for CVD effects (USEPA 2023a, p. 4-52; USEPA 2023b, p. 4-48). Although EPA chose to use the slopes from a single study (Dong et al. 2019) to derive a BMDL and RfD for PFOA and PFOS, EPA used the pooled slope from the meta-analysis as the basis for the economic analysis. EPA does not provide justification for the lack of consistency in dose-response estimation between the risk assessments and the economic analysis. The difference in methodologies applied by EPA is unexplainable and there is no apparent reason as to why it is appropriate for EPA to use different dose-response slopes between the risk assessments and the economic analysis. As described in Section VII.g, the pooled slopes derived from the meta-analyses could be considered for RfD derivation, however EPA does not describe the meta-analyses in the Proposed MCLG risk assessment documentation. For PFOA, the slope estimates are relatively comparable (i.e., 1.48 mg/dL per ng/mL from Dong et al. 2019 and 1.57 mg/dL per ng/mL from the "linear models only" meta-analysis presented in the economic analysis; Table F-2). However, for PFOS, the slope estimates are drastically different (i.e., 0.40 mg/dL per ng/mL from Dong et al. 2019 and 0.079 mg/dL per ng/mL from the "linear models only" meta-analysis presented in the economic analysis; Table F-3). EPA must explain why Dong et al. (2019) was used as the basis for PFOA and PFOS RfDs, whereas a pooled slope estimate from studies using linear models was employed for estimating the economic benefit of reducing PFOA/PFOS levels to the RfDs.

iv. EPA does not transparently describe how the selected dose-response models inform the economic benefits analysis for CVD risk and fails to illuminate the impact on a benefit reduction analysis for PFOA and PFOS individually.

EPA states that it used the pooled slope estimates for PFOA and PFOS derived from the "linear models only" in order to inform the CVD risk reduction model. However, EPA does not transparently describe in its methods how these pooled slope estimates directly impact the models and estimated CVD risk. Outputs are reported as a pooled estimate of CVD benefits for PFOA and PFOS (see examples in USEPA 2021c, Table 6; USEPA 2023c Table 6-20). However, the estimated impact on serum TC per ng/mL PFOA (estimated at 1.574 mg/dL per ng/mL PFOA) is drastically steeper than that of the impact per ng/mL PFOS (estimated at 0.079 mg/dL per ng/mL PFOS). Even accepting that the dose-response slopes selected by EPA are appropriate, the slope for PFOA is nearly two orders-of-magnitude steeper, compared to PFOS, and therefore should have a larger impact on the estimated economic impact. EPA does not transparently describe its methods for integrating these disparate slope estimates for PFOA and PFOS or provide a description for how PFOA and PFOS exposures mixed to generate a single economic benefit model. The CVD risk reduction model is not described in a way that allows for transparent reproducibility of the approach or evaluation of sensitivity of the model to changes in estimated serum TC responses. It cannot be determined, based on the reported information, whether EPA is accurately accounting for the differences in exposure-response slopes for PFOA and PFOS. Moreover, it is impossible to determine from the record provided by EPA what benefit would be expected from the reduction of PFOA or PFOS alone. Sufficient information should be provided for the model to be independently verified.

Additionally, EPA does not evaluate the sensitivity of the CVD risk reduction model to changes in the estimated slope. As shown in Tables F-2 and F-3 of the Economic Analysis (USEPA 2023c), the estimated slopes for PFOA and PFOS are heavily dependent on the studies included in the meta-analytic models, with ranges changes in serum TC of 0.002 to 1.632 mg/dL per ng/mL PFOA and 0.0003 to 0.40 mg/dL per ng/mL PFOS. EPA acknowledges in its discussion of modeling limitations and uncertainties (USEPA 2021c; Table 7) that "*the derivation of PFOA/PFOS exposure-response functions for the relationship between PFOA/PFOS serum and TC levels assumes that the six studies used in meta-analysis capture the majority of PFOA/PFOS effects on serum TC levels*." EPA further states that the included studies "*may not represent all possible relationships between PFOA/PFOS and serum TC levels*" and describes the impact of this uncertainty as "uncertain." However, EPA does not further address or describe the potential impact of study inclusion or exclusion. EPA neither established that its selection of "linear models only" for meta-analysis was reasonable, nor did it evaluate the impact of other reasonable models (such as the US/Canada-population models) on CVD risk reduction estimates. It is best practice to consider a range of modeling options, especially given the uncertainties attributable to study inclusion and selection. Even if EPA were to select the linear models only, as a conservative estimate assuming a significant dose-response, the 95% CIs for the pooled estimate for PFOA are broad (e.g., 1.57 mg/dL per ng/mL PFOA [95% CI 0.0177, 3.13]) and the 95% lower limit for the pooled estimate for PFOS is negative (i.e. -0.005), indicating a reduction in serum TC (a beneficial effect) with increasing serum PFOS. Therefore,

the Economic Analysis may not be appropriately representing the accurate risk/benefit of reduction in PFOA/PFOS exposures. Uncertainties in the underlying slope estimates used as the basis for the economic benefits model translates into uncertainties in the estimated economic benefit for PFOA/PFOS reduction. Because the confidence interval produced by the studies chosen by EPA for PFOS includes both negative and positive slopes in the 95% confidence interval, the interpretation of the economic benefit is uncertain as to whether reductions in PFOS could be beneficial or harmful. Therefore, because of the uncertainties and lack of statistical significance, use of serum TC as the basis for Economic Benefit Analysis is likely not accurate, informative, or appropriate. EPA should provide uncertainty analyses to evaluate the range of impacts on CVD risk based on variations in slope assumptions and show its confidence in the underlying estimate of economic benefit.

In summary, the meta-analysis presented by EPA fails to follow best practice for meta-analyses (*e.g.* The Cochrane Handbook for Systematic Reviews of Interventions) and does not sufficiently account for underlying uncertainties in the dose-response relationships between serum PFOA/PFOS and serum TC. These uncertainties cannot be evaluated due to the complexity and lack of transparency in EPA's modeling documentation. Additional information regarding the impact of model selection and model uncertainty is needed to provide confidence in EPA's CVD risk reduction model.

IX. THE SDWA REQUIRES A COST-BENEFIT ANALYSIS FOR EACH MCL

The SDWA was amended in 1996 to specifically require cost-benefit analysis as part of the regulatory process. Id. § 300g-1(b)(3)(C), (4)(C). For each drinking water standard and each alternative standard being considered by EPA, § 1412(b)(3)(C)(i) provides that EPA must publish and seek public comment on an analysis of the health risk reduction benefits and costs associated with the proposed MCL. Id. § 300g-1(b)(3)(C)(i). The purpose of the cost-benefit analyses is to determine whether the benefits of the MCL justify, or do not justify, the costs of the proposed regulation.

EPA failed to determine whether the benefits of the HI-MCL justify the costs of the proposed regulation as it did not quantify benefits for any health point for PFHxS (USEPA 2023i). Because there is no quantitative benefit analysis for the HI portion of the rule, there cannot be a cost-benefit analysis for that portion of the rule. This violates the SDWA.

In the cost analysis EPA did conduct, documented in the *Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation* (USEPA 2023i), EPA uses opaque methodological approaches, fails to document the assumptions it applies, and fails to provide an adequate and transparent description of the analytical approaches, models, and tools that it uses to estimate costs. These omissions impose substantial uncertainty on many steps of this convoluted cost analysis. That uncertainty propagates and compounds throughout the analysis and imposes biases on various intermediate calculations. These biases subsequently yield potentially highly uncertain cost estimates of questionable accuracy.

EPA is missing critical data and is forced to use category-wide and/or nationwide estimates for baseline and compliance characteristics in the selection of treatment technology or non-treatment alternative. The absence of this data negates EPA's ability to present cost analysis results at the PWS-level. Instead, EPA collapses the more than 66,000 PWSs and summarizes nationwide cost and benefit estimates for 36 general PWS categories.[95] This generalization and reporting opacity prevent an evaluation of the potential distributional impacts of the proposed NPDWR.

a. EPA Did Not Account for the Fact that Costs Incurred are "Solely the Result of the" NPDWR, but Purported Benefits are Not.

EPA's analysis of the benefits of the proposed MCLs does not comply with SDWA §1412(b)(3)(C)(i)(I)'s requirement to analyze "[q]uantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits *are likely to occur as the result of treatment to comply with each level.*" And while the costs of the Proposed Rule are "solely as a result of compliance" with the Rule, the purported benefits are not.[96]

The first step in assessing the benefits of the Proposed Rule is to analyze the baseline conditions of the population in the United States. Average blood levels of PFOA and PFOS in the U.S. population have decreased by more than 70% and 85% respectively since 2000.[97] Moreover, based on the latest NHANES biomonitoring data from the 2017-2018 timeframe, average blood levels of PFAS such as PFHxS and PFNA also decreased significantly during that time.[98] In short, the baseline conditions of PFOA and PFOS exposure and blood serum levels, as well as PFAS subject to the HI, have decreased significantly in the past two decades, and there is no evidence indicating they will not continue to do so in the absence of the Proposed Rule.[99] The SDWA requires that EPA demonstrate the incremental decrease in illness or morbidity is meaningful and associated with the NPDWR itself, not other actions such as decreased exposure through voluntary cessation of manufacturing or use.[100]

The SDWA requires EPA to evaluate how the small fraction of any purported benefit of reduced PFOA and PFOS exposure would result from EPA establishing a NPDWR as opposed to

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[95] The Bayesian model EPA used to establish a national distribution of PFAS concentrations as part of the benefit-cost analysis did not include important covariates including distance from the PFAS source, topography, number of private drinking water wells in the area or state, climatology, distance to nearest large water and river systems, and other environmental factors. EPA's Bayesian model outputs are clearly not representative of the PFAS exposure distribution on a national level. Therefore, any benefit-cost conclusions drawn based on these data and model outputs do not represent the expected PWS concentrations across the US and cannot be used to support a MCLG. EPA does not provide details of the Bayesian model that are commonly included in the description by practicing statisticians. Therefore, evaluation of adequacy and believability of the model outputs cannot be understood, as required by EPA's QC practices.

[96] SDWA §1412(b)(3)(C)(i)(I).

[97] *See* https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html

[98] The CDC stopped analyzing for PFBS since 2014 as part of its NHANES monitoring program because of the lack of detection in general population blood.

[99] *See* Biomonitoring Data Tables for Environmental Chemicals | CDC

[100] *See* SDWA §1412(b)(3)(C)(i)(I).

the myriad other factors already greatly reducing exposure over time. Under the SDWA, EPA must also show that the small incremental reduction in exposure is meaningful or even measurable in terms of benefit as compared to reductions from other means. Unless EPA can demonstrate an incremental benefit based solely on a NPDWR that outweighs the associated cost, which in fact would derive from the NPDWR, then the proposed NPDWR does not comply with the mandates of the SDWA.

b. EPA Improperly Inflated the Purported Benefits of the Rule

i. EPA improperly quantified benefits of co-removed substances rather than co-occurring substances

EPA quantified benefits of a co-removed substance (THM4) (USEPA 2023i, p. 6-108). This is inappropriate as it artificially inflates the benefits of the MCL. The SDWA contemplates quantifying benefits from co-occurring substances but **not** quantifying the benefits of all co-removed substances.[101] If EPA were to weigh the benefits of all co-removed substances as a result of treatment, every NPDWR would have its benefits inflated because any treatment technique will remove more than the targeted substance. For example, THM4 is not a PFAS and EPA did not make a determination that it is a co-occurring substance. EPA's inclusion of the purported benefits of THM4's removal in the cost-benefit analysis violates the SDWA's clear direction on considerations to be included in that analysis.

1. EPA's failure to clearly analyze the benefits of the PFOA and PFOS proposed standards separately overstates the benefits of the PFOS standard and precludes appropriate analysis of the individual MCLs.

EPA's failure to separately analyze the benefits of the PFOA and PFOS MCLs violated the SDWA directive that EPA analyze "quantifiable and non-quantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each level."[102] For example, CVD reduction is a major element of EPA's benefit analysis for PFOA and PFOS. CVD reduction depends on EPA's calculation of the impact of reduction of total cholesterol (TC). There are numerous issues with EPA's calculation of a dose-response relationship between serum PFOS and TC, including that they do not demonstrate what is normally considered a statistically significant relationship between those two factors. Even ignoring those issues, and assuming the accuracy of EPA's analysis, the impact on TC from reducing PFOS is nearly two orders of magnitude less than the reduction in TC that EPA calculated for PFOA.[103]

EPA has not provided enough information in the record to allow for replication of the benefit analysis. This lack of transparency with respect to the benefits of the proposed standards prevents meaningful comment on an aspect of the proposed rule with a very significant impact

[101] See SDWA §1412(b)(3)(C).
[102] SDWA §1412(b)(3)(C)(i)(I).
[103] EPA stated that "[w]hen using studies reporting linear associations between total cholesterol and serum PFOA or PFOS, EPA estimated a positive increase in TC of 1.57 (95% CI: 0.02, 3.13) mg/dL per ng/mL serum PFOA (p-value=0.048), and of 0.08 (95% CI:-0/01, 0.16) mg/dL per ng/mL serum PFOS (p-value=0.064.)" 88 FR 18709.

on EPA's analysis of whether the proposed standards meet the SDWA requirements that the benefits outweigh the costs.

c. The Benefit-Cost Model is New and Unvalidated

EPA previously developed a generalized tool known as the SafeWater Cost-Benefit Model (CBX) analysis tool to automatically estimate costs and benefits of drinking water standards. EPA indicates that CBX was designed to evaluate the impacts of a single proposed MCL and incorporates uncertainty in both input and output values to generate best-guess estimates of the impacts of proposed drinking water regulations. The single MCL CBX model was peer-reviewed.

For the proposed NPDWR, EPA developed a new model called the SafeWater Multi-Contaminant Benefit Cost Model (MCBC), which can track multiple substances and compare those to proposed MCLs developed for individual substances or mixtures of substances. EPA states that MCBC modifies the "structure of the occurrence data input to the model…to not only handle multiple contaminants, but to incorporate all information from the PFAS occurrence model on the predicted co-occurrence of contaminants," allows the assignment of more than one compliance technology, and estimates the costs and benefits associated with estimated reductions in multiple contaminants (USEPA 2023i).

Unlike the CBX model, the MCBC model has not been validated, approved for use via a public review and comment process, or peer-reviewed by independent third-party experts. The absence of a peer review process casts doubts on the validity, reliability, and accuracy of the cost estimates derived from its use. Peer review is particularly necessary because the modifications of the MCBC model relative to CBX are significant. For example, the estimation of statistical uncertainty is calculated differently when two or more uncertain variables are considered simultaneously relative to just one uncertain variable. The resulting uncertainty propagates and compounds throughout the analysis. The impact of the modifications of the MCBC model relative to its CBX counterpart is unknown and is not explained in sufficient detail. This issue is further complicated by the opacity of the analysis, which does not allow stakeholders and members of the public to evaluate whether the uncertainty is being appropriately addressed. Without peer review, expert validation, and a public comment process allowing for input from stakeholders of the PWS community, the MCBC model and its resulting cost estimates cannot be considered validated, reliable, or accurate.

d. Significant Data are Missing and Insufficient Detail is Provided Regarding Imputation

EPA lacks complete PWS-specific data across the 49,193 community water systems (CWSs) and 17,337 non-transient non-community water systems (NTNCWSs) in the Safe Drinking Water Information System (SDWIS/Fed) for many of the baseline and compliance characteristics necessary to estimate costs and benefits. Data are incomplete for design, average daily flow rates, water quality characteristics, treatment in-place, and labor rates, among other factors. EPA does not explain 1) the number of CWSs for which data are missing, 2) the number of each baseline and compliance characteristic for CWSs that are missing by CWS category, 3)

the number of NTNCWSs for which data are missing, or 4) the number of each baseline and compliance characteristic for NTNCWSs that are missing by NTNCWS category. EPA states that "[i]n some cases, the categorical data are simple point estimates. In this case, every model PWS in a category is assigned the same value" (USEPA 2023f, p. 18691). Consequently, many characteristics necessary to estimate costs and benefits—such as design, daily flow rates, water quality characteristics, among others—may be simple category-wide or nationwide averages. It appears that, in estimating the costs and benefits of the proposed NPDWR, EPA makes assumptions that are themselves based on assumptions.

The baseline and compliance characteristics are critically important to the cost analysis. For example, the SafeWater Multi-Contaminant Benefit-Cost Model (MCBC) uses the baseline and compliance characteristics as input values for a decision tree model. The decision tree model then selects the treatment technology or non-treatment alternative in response to estimated occurrence/co-occurrence estimates. These treatment technologies or non-treatment alternatives form the foundation of all costs and benefits estimated in response to the proposed rule. As EPA notes, "there are nearly 3,500 individual cost equations across the categories of capital and operation and maintenance (O&M) cost, water source, component level, flow, bed life (for GAC and ion exchange), residuals management scenarios (for GAC and ion exchange), and design type (for GAC)" (USEPA 2023f, p. 18692). These assumptions and imputation processes have a significant impact on the overall cost estimates, and EPA fails to transparently adequately describe them in detail or justify their use.

X. THE PROPOSED RULE DOES NOT PERMIT MEANINGFUL NOTICE AND COMMENT IN VIOLATION OF THE SDWA AND THE APA

The APA requires notice-and-comment rulemaking for agency rules, 5 U.S.C. § 553(b)-(c). This notice-and-comment process is a "crucial" rulemaking requirement to ensure that "regulations are tested via exposure to diverse public comment" and "affected parties [have] an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review." *Daimler Trucks N. Am. LLC v. EPA*, 737 F.3d 95, 100 (D.C. Cir. 2013); *see Miami-Dade Cty. v. EPA*, 529 F.3d 1049, 1058 (11th Cir. 2008) (the purposes of notice requirements in notice-and-comment rulemaking under the APA are "(1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review"), quoting *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005).

The D.C. Circuit has explained that an agency must "allow for meaningful commentary" not only as to the requirements that a proposed rule adopts, but also on the "technical basis for a proposed rule." *N. Am.'s Bldg. Trades Unions v. OSHA*, 878 F.3d 271, 301 (D.C. Cir. 2017); *see also Owner-Operator Indep. Drivers Ass'n v. FMCSA*, 494 F.3d 188, 199 (D.C. Cir. 2007) (the notice-and-comment requirement applies not only to the text of a rule but also to the "technical basis for a proposed rule" and the "critical factual material that is used to support the agency's position"). And the methods relied on by the agency must be made "available during the rulemaking." *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008). An

agency cannot withhold key elements of its analysis—methods and data—until the final rule, because that defeats the purpose of the notice and comment process.

Unless the agency promulgates a revised proposal in which it fully discloses the data and methods on which it relies, so that interested parties may comment on them, the public will learn of that "uncommented upon data and calculations," *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008), only when the "final rule reveal[s]" them. *CSX Transp. v. STB*, 584 F.3d 1076, 1081 (D.C. Cir. 2009). That is not a permissible way to conduct rulemaking governed by the APA.

Here, basic transparency requirements have been blatantly violated, as demonstrated above. See Scientific Integrity Fast-Track Action Committee (2022), which states, "development of Federal regulations follows strict procedures that support transparency, e.g., through issuance of Notices of Proposed Rulemaking that solicit public input and establishment of regulatory dockets containing related information that are open for public inspection. Continued vigilance is necessary to ensure these procedures are followed and that all underlying documentation—including related scientific information—is made publicly available." The Agency's numerous failures to disclose underlying data and methods for its analysis are described throughout these comments.

3M has been prejudiced by the agency's non-disclosure of these key bases for the Proposed Rule. While it comments here on the errors in EPA's analysis, and on the gaps in the data and methods EPA used, what these comments cannot address is the substance of the missing material. *See Horsehead Res. Dev. Co. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994) ("While we have noted that insightful comments may be reflective of notice and may be adduced as evidence of its adequacy, we have rejected bootstrap arguments predicating notice on public comments alone. Ultimately, notice is the agency's duty because comments by members of the public would not in themselves constitute adequate notice. Under the standards of the APA, notice necessarily must come—if at all—from the Agency"). The only way to cure this serious procedural defect is for the agency to issue a new proposed rule in which it discloses all the data and methodology underlying its conclusions, on which interested parties may then comment.

XI. CONCLUSION

As detailed in the above comments and the attached appendices, EPA's Proposed Rule does not comply with either the SDWA or the APA. The Proposed Rule is not based on best available, peer-reviewed science, as required by the SDWA, nor does it comport with EPA's own guidance on how to conduct the analyses underlying the Proposed Rule. These numerous failures are identified in detail in 3M's comments.

3M appreciates the opportunity to comment on the Proposed Rule.

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Appendix B to 3M Comments on EPA Proposed National Primary Drinking Water Standard

EcoStat Comments on the United States Environmental Protection Agency's Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

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Introduction

The United States Environmental Protection Agency (EPA) has published a series of quality control (QC) and best practice guidelines for program development and project development (USEPA 1992, 2002), data quality objectives (USEPA 2003, 2006), and good statistical practice (USEPA 2006). EPA has also published approved methods and software for calculating benchmark doses (BMD) and their uncertainty (USEPA 2012, 2022) which have been developed into an interactive web site. These guidelines are intended to ensure that the resulting decisions made by EPA meet standards based on the best available science, including reproducibility of results, appropriate data treatment, ensuring representative data, and accurate identification and quantification of true risk to human populations and environmental metrics.

However, the methods and procedures used by EPA to support the National Primary Drinking Water Regulation Rulemaking (the "Proposed NPDWR") did not follow these established procedures, and lack good data practice, good statistical analysis practice, consistency of methods and models, and the ability to replicate analytical results.

In the following sections we provide specific examples of where EPA is lacking good practice in its selected quantitative approaches and provide examples of inappropriate practices and issues not addressed by EPA in the proposed rule.

Below, we demonstrate key statistical issues in the Proposed NPDWR using references to the rulemaking and supporting documents, describe how the issues impact the validity of the Maximum Contaminant Level (MCL), reference EPA support documents with examples, explain that EPA is required to meet its own guidance and specifications, and provide examples from National Health and Nutrition Examination Survey (NHANES) illustrating the issue.

Background on NHANES

NHANES is a program of studies administered by the Centers for Disease Control and Prevention (CDC) to produce vital and health statistics for the United States. Since 1999, this cross-sectional survey has been a continuous program that examines a nationally representative sample of about 5,000 different people each two-year sampling period (located in 15 counties across the country). NHANES collects demographic, socioeconomic, dietary, and health-related data and conducts a comprehensive medical examination which consists of blood work, dental, and physiological measurements. Beginning with NHANES 1999–2000, PFAS and associated compounds have been measured in some (but not all) NHANES participants. NHANES employs a multiyear, stratified, clustered design to create a nationally representative sample of the US civilian, noninstitutionalized US population; however, NHANES purposely oversamples certain demographic groups to increase the reliability and precision of health status indicator estimates for those groups. This survey design results in each sampled person not having an equal probability of selection and thus sample weighting is needed to produce correct population estimates of means, percentiles, and other descriptive statistics.

Lack of appropriate analytical techniques when using NHANES data

As described above, proper analysis of NHANES data requires the use of sample weighting variables to produce correct estimates of means, percentiles, and other descriptive statistics. EPA

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acknowledged in its supporting document "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Appendices" (see (USEPA 2023b), page F-23) that many of the papers forming the foundation of EPA's analysis of the relationship between PFAS and serum cholesterol did not clearly indicate whether the required sampling weights were used in their analyses. Despite acknowledging this fact, EPA did not give these publications appropriate classifications for study quality (*see e.g.* Figure 3-34 on pages 3-159 through 3-161 of (USEPA 2023d)). EPA chose studies where data analyses did not meet EPA guidance and good practice guidelines. Therefore, these studies were of low quality. Subsequent analyses by EPA in the support documents use the number of studies with study quality (high/medium/low) as a metric of certainty of the relationship (*see e.g.* Table 3-8 on pages 3-185 through 3-189 of (U.S, 2023d)), giving an incorrect sense of the relationship between PFOS concentrations and cholesterol.

We highlight these misclassification errors of study quality for cholesterol but the same issue applies to any and all analyses that include NHANES data without confirming use of appropriate sample weighting variables and must be corrected.

1. **Lack of consistent quality control practice by EPA in the Proposed Rule and supporting documents negates the validity of key findings.**

EPA has not proposed data quality objectives (DQOs) or Quality Assurance Project Plans (QAPP) for any data source chosen and associated findings used to establish the MCLG. EPA and National Institutes of Health (NIH) National Institute of Environmental Health Sciences (NIEHS) program offices, are required to generate quality assurance/quality control (QA/QC) plans that include the derivation of analysis-specific, and data-specific DQOs. Under standard quality control practices, DQOs are required for any research initiative in order to document and ensure that data are collected properly, data are treated using good statistical practice, and any findings can be replicated by scientists and data analysts not working at EPA. EPA's own documents provide guidance on DQOs, program planning, good data practice, and good statistical practice. (*See e.g.* USEPA 2003, 2006, 2014).

EPA has not followed its own requirements and guidance for collecting and analyzing data. Rather, for the MCLG and associated analyses, EPA has largely relied on previously published studies conducted by non-EPA employees for which EPA has no control over data collection, data treatment, outlier detection, variance estimation, elimination of records, or good statistical practice. For example, EPA has selected papers where the data used to calculate BMDs and other measures of risk, were not publicly available or difficult and time-consuming to obtain (*e.g.,* Budtz-Jørgensen & Grandjean, 2018; Shearer et al., 2021). EPA has violated a key principle of statistical analysis, which requires that all studies and findings be available to the outside public and the findings replicated.

EPA did not address the inconsistent methods and approaches to BMD calculation in the selected papers and documents used to support the MCLG. This lack of consistency severely limits EPA's ability to reliably and accurately assess potential risk. Note the calculation approach used in (Budtz-Jørgensen & Grandjean, 2018) is completely different than that used by (Dong et al., 2019) (which incorrectly references (Liu et al., 2016)). Different statistical models will, simply based on different mathematics, provide differing results. This uncertainty, and the possible inaccuracy it would cause in the final rule, was not addressed by EPA. For example, EPA has accepted the slope produced by (Dong et al., 2019) when rerunning its BMD calculations yet

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ignores the fact that the slope is calculated with an incomplete data set, and data weights are not consistent with NHANES guidance. This is clearly a violation of EPA's quality principles and guidance.

EPA has established guidance that it should use DQOs as an insurance to create analyses of high caliber that are scientifically defensible. Here, EPA failed to establish DQOs, contrary to its own guidance.

2. EPA does not provide evidence that the study data sets used for BMD calculation represent the US population and even when appropriate datasets are selected, they are improperly analyzed.

(2A) EPA did not verify the representational nature of datasets selected for its BMD calculation

The data underlying several key studies EPA relies as the basis for its Proposed NPDWR are unavailable for review and evaluation (see for example Budtz-Jørgensen & Grandjean, 2018). Moreover, even where data is available, EPA did not address the representativeness of the data with respect to US national level populations.

Unless individual study findings can translate directly to the US population at large, the findings cannot be used to anticipate the impact of the rulemaking on human health risk in the US. Also, without a clear and quantitative understanding of how studies based on various non-representative data sets were analyzed and treated, the costs and benefits of the proposed rule cannot be assessed properly.

(2B) Lack of appropriate analytical techniques when using NHANES to create population metrics

As described above, proper analysis of NHANES data requires the use of sample weights to produce correct estimates of means, percentiles, and other descriptive statistics. As acknowledged in an EPA supporting document (*see e.g.* page F-23 of USEPA 2023b) many of the papers forming the foundation of the potential association between PFOA/PFOS and serum cholesterol did not clearly indicate whether the required NHANES sampling weights were used in their analyses. Despite EPA acknowledging this fact, EPA did not appropriately classify these publications for study quality (*see e.g.,* Figure 3-34 on pages 3-159 through 3-161 of USEPA, 2023d). Subsequent analyses use a number of studies with study quality (high/medium/low) as a metric for the degree of confidence that can be attributed to the study finding (*see e.g.* Table 3-8 on pages 3-185 through 3-189 of USEPA 2023d). EPA, for example when reviewing the Dong et al. 2019 study, ignored good data and statistical practice when assigning quality scores. An independent analysis of Dong et al. indicates the analysis approaches and data practices used by Dong were flawed and the findings unsupportable. See Section 6.5).

(2C) EPA's removal of important modeling co-variates is not accepted practice and is inconsistent with study authors' conclusions.

EPA's improper analyses and lack of justification for alterations of previously published models lacks statistical rigor, are problematic, and leads to incorrect conclusions. An important modeling approach for assessing population phenotypes that aid in the assessment of representative models, is to include at least some basic population information like ethnicity, age, gender, socioeconomic status, and other components in the model. Here, EPA's failure to adjust BMD calculations for key co-variates results in incorrect BMD model generation which led to incorrect BMDL values.

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In fact, the Budtz-Jørgensen & Grandjean (2018) study reveals, both in the SAS output and as clearly stated in the original paper (at 7), when co-variates like gender, age, and type of booster are included in the model, the relationship of PFOS or PFOA blood concentrations are shown to have a non-significant relationship with antibody titer changes (see Table 1, below reproduced from Table 1 of Budtz-Jørgensen & Grandjean, 2022). We provide other examples where models are developed without inclusion of important statistically significant covariates arises later in the comments. For example, we will demonstrate that the PFOA and PFOS blood concentration relationships to selected response variables are very weak to non-existent when using US nationally representative data such as NHANES.

Table 1. PFOS Model Non-Adjusted Copied from Output Sent to EPA

PFOS Model Non-Adjusted	
Variable	Pr > t
Intercept	0.510
PFOS Parameter	*0.120*
sex	0.006
Age at 7 years	0.388
Booster type at age 5	0.860
From Table 1 of (Budtz-Jørgensen & Grandjean, 2022)	

In addition, EPA has not explained when or why co-variates are either included or excluded from the statistical models used by EPA to support the MCLG. This lack of scientific rigor in model development is clearly a violation of good statistical practices (Harrell 2016). When key population metrics are included in the model, these metrics dominate any relationship between the response variable and the model parameters. In such models, the parameter associated with either PFOA or PFOS is generally statistically insignificant.

3. NHANES data important to PFAS and Health Outcomes are frequently changed and/or modified.

NHANES regularly updates datasets which have PFAS concentration variables, changing the values or excluding data that do not meet program standards. Some of these changes occur relatively soon after the datasets have been released and are posted on the NHANES news website (see https://www.cdc.gov/nchs/nhanes/new_nhanes.htm and https://www.cdc.gov/nchs/nhanes/archive_new_nhanes.htm). In 2021 and 2022 the NHANES Biospecimen Program processes were reevaluated to monitor quality control after a procedural error was identified. Following a comprehensive review of all surplus sample datasets generated between 1999 and 2018, NHANES modified certain data files to remove records that were initially included in error and did not meet program standards and revised files were released in April 2022 (Source: Update to Tables Associated with Revised NHANES Biospecimen Program Data Files see https://www.cdc.gov/exposurereport/whats_new_121522_1.html)

> From https://wwwn.cdc.gov/Nchs/Nhanes/2013-2014/SSPFAC_H.htm
>
> Note: The NHANES Biospecimen Program processes were reevaluated in 2021 and 2022 to monitor quality control after a procedural error was identified. This error did not pose

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any risk of participant disclosure. Addressing this error resulted in the removal of some records from various stored biospecimen data files between 1999 and 2018 that did not meet program standards. After a comprehensive review of all stored specimen datasets, this data file was modified to remove records (15-<20% of records) that were initially included in error. No data values were altered. However, survey weights were adjusted. For each analyte included in this data file, it was determined that overall and for stratified sex, age, and race/Hispanic origin groups, the updated file using the new sample weights resulted in an estimate within the 95% confidence limit calculated using the original file and sample weights. However, not all possible analyses were performed. For any queries related to this dataset please email the Biospecimen Program at serumplasmaurine@cdc.gov.

While EPA notes the possibility of NHANES data updates, EPA does not provide details on the data used in its analyses, or the year class of the data. Additionally, EPA ignores that papers published prior to any updates must have used the incorrect values in their analyses and thus the conclusions are at a minimum inaccurate and at worst incorrect. EPA must provide details on whether and how data updates were incorporated into its models.

NHANES Cycle	PFAS Data First Published	PFAS Data Last Revised
1999-2000	Oct-06	Dec-22
2001-2002	-	-
2003-2004	Jul-07	Dec-22
2005-2006	Aug-09	Sep-12
2007-2008	Oct-10	Oct-13
2009-2010	Dec-11	Oct-13
2011-2012	Feb-14	Oct-14
2013-2014*	Jul-16	-
		Apr-22
2015-2016	Sep-18	-
2017-2018	Nov-20	-
*For 2013-2014, PFAS were in two different NHANES tables		

EPA does not provide sufficient detail on the data used in its analyses; therefore, it is difficult to know whether EPA is using outdated data. However, given the frequency of the updates in NHANES data, any and all publications that EPA is relying on and using NHANES PFAS data that have been previously published analyses contain an unknown number of errors. The ramification is that the analyses, the generated models, and conclusions based on uncorrected NHANES data are most certainly flawed. EPA must provide details on how the NHANES data updates were incorporated into its models, if they were incorporated at all and must update its analyses to use the most accurate datasets supplied by NHANES.

4. NHANES cholesterol values changed significantly due to non-PFAS factors

NHANES determined that a change in assay methods was most likely responsible for changes in HDL cholesterol values in the NHANES cycles from 1999-2008 (Source: National Health and

Nutrition Examination Survey, 1999-2000 Data Documentation, Codebook, and Frequencies Cholesterol - Total & HDL (Lab13) https://wwwn.cdc.gov/Nchs/Nhanes/1999-2000/LAB13.htm). NHANES developed a formula to correct HDL values and re-posted the corrected data. It is very rare that papers document when data extracts were downloaded but it is not uncommon for papers to take more than two years from publication to data analysis and papers published with data prior to corrections will have inaccurate findings. The following table shows the original dates of data published for cholesterol as well as prescription drugs.

NHANES Cycle	Prescription Drugs		TC & HDL		LDL	
	First Published	Last Revised	First Published	Last Revised	First Published	Last Revised
1999-2000	-	-	Jun-02	Apr-10	Jun-02	Mar-07
2001-2002	-	-	Sep-04	Apr-10	Jun-05	Mar-07
2003-2004	Aug-07	Jun-09	Jun-06	Apr-10	Sep-06	May-08
2005-2006	Sep-08	Jun-09	Nov-07	Apr-10	Mar-08	
2007-2008	Apr-10		Sep-09	Feb-10	May-10	Sep-10
2009-2010	May-12		Sep-11		Dec-11	
2011-2012	Jul-14		Sep-13		Jan-14	
2013-2014	Dec-16		Oct-15	Mar-16	Mar-16	
2015-2016	Jan-19		Sep-17		Jan-19	
2017-2018	Mar-20		Feb-20		Dec-20	Mar-21
2017- Pre 2020	Sep-21		Aug-21		Oct-21	

Again, any and all analyses that EPA is relying on that included NHANES data must use the most accurate datasets supplied by NHANES.

5. Dong et al., 2019, a key study upon which EPA relies, has serious methodological issues that render it unreliable.

EPA repeatedly cites Dong et al. (2019) in estimating Point of Departure (POD), reference dose (RfD), and benchmark dose (BMD) (USEPA 2023b, 2023d). The importance of this paper in EPA's analysis can be seen in particular on:

- Page F-10 of USEPA 2023b states "Although the datasets and models were not exactly the same in all NHANES-based studies, to avoid estimate dependency issues due to overlapping populations in the meta-analysis, EPA also performed a sensitivity analysis including only the data from the study covering the broadest range of NHANES cycles (2003–2014) (Dong et al.,2019)."
- Page K-4 of USEPA 2023b states "The use of single study-based TC effect estimates, rather than EPA meta-analysis-based effect estimates. To this end, EPA used estimates from a large NHANES study (Dong et al., 2019) …"
- Page E-298 of USEPA 2023c states that EPA re-analyzed the data using the regression models from the Dong et al., 2019 study, together with updated NHANES data, applied to a modified hybrid model to develop BMD and BMDL estimates for various time periods and assumptions.

Methodological issues with Dong et al.(2019) that seriously impact the veracity of the statistical associations found and alter the fundamental representational aspects of NHANES data include:

1. Dong et al. (2019) did not analyze the full NHANES dataset but rather excluded certain cholesterol and PFAS values. On page 463 the authors state, "to ensure no influential points heavily impact on the analysis results, the outliers for PFASs and cholesterol (data points more than 1.5 interquartile ranges (IQRs) below the first quartile or above the third quartile) were excluded."
2. Not only did the authors exclude portions of the original data for outliers, they also excluded based on age on page 464. The authors state, "The regression analysis was also conducted for adults [20-80 years] since most correlations observed for adolescents were insignificant." Data should only be excluded when they are known to be incorrect, due to laboratory measurement errors, etc. When data exclusion changes the results of the study or misrepresents the study, exclusion of the data is improper (Resnick 2000). EPA has not justified data exclusions by any of the outside authors, and EPA has not internally rigorously evaluated data treatment nor established good data treatment guidelines that are consistent with DQOs.
3. The final regression models for BMD calculations published by the authors did not adjust for gender nor age despite the fact that these co-variates were found to be significant by their own analyses.
4. As recognized by EPA, Dong et al. (2019) did not explicitly state that the models generated used the appropriate NHANES weighting.
5. Dong et al. (2019) used custom code within a statistical software package (Matlab) to conduct a hybrid BMD calculation rather than using EPA approved BMD modelling software (e.g. BMDS (USEPA 2022))

Given these serious statistical and methodological issues, rating the Dong et al. (2019) study as a medium quality study, as EPA did here, is inconsistent with EPA statements on how it judged the merits of specific studies for the purpose of assigning a quality score. Additionally, given that the exclusion done by the authors removes the national representative nature of the NHANES dataset and introduces strong bias into the analysis, it is inconsistent with sound science and EPA's own guidance to use it as a basis for calculating BMDs.

Despite these significant issues with Dong et al., (2019) EPA retained the slope estimates and used these flawed estimates to calculate BMD and BMDL (see page E-298 of U.S, 2023c "where m is the slope, β, (from the Dong regression model) and b is the intercept."). It is not proper statistical practice to realize that a previous analysis used flawed methodologies and verify that with your own analyses as EPA did here, only to go ahead and use the incorrect values.

EPA has not followed its own QC guidelines when using findings from outside sources. EPA has not questioned many of the selected author's findings or taken steps to replicate them, nor has EPA reviewed the original author's poor data treatment. Given the deviation from sound practice and EPA guidance with respect to EPA's treatment of Dong et al. (2019), it is likely this lack of quality control and poor statistical practice has carried over to other data and statistical modeling activities throughout the technical portion of the Proposed NPDWR.

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6. EPA's approaches to Benchmark Dose (BMD) are insufficient and inconsistent with accepted statistical standards.

EPA's approach to BMD calculations is lacking in appropriate sensitivity testing, choice of equation, and in some cases inappropriate use of information from the original publications. We discuss below the inappropriate information use and practice utilized by EPA for BMD calculations.

(6A) EPA does not properly address statistical significance

In Appendix E, Table E-1 (USEPA 2023c, e) displays BMDs in the Budtz-Jørgensen & Grandjean (2018) paper. In Table E-1, the slope coefficient which is used to calculate the BMD is clearly not significant, nor even close to significant. EPA states that the non-significant parameter can be used to calculate the BMD and BMDL. What is not shown is that the models in Table E-1 are poor representations of the original data (which are not available for review and testing) and fit the data poorly (they have a non-significant t-statistic). Therefore, the resulting non-significant slope is not correlated with the original data, and therefore is inconsistent with the underlying science inferred by the model. We note that the unavailability of the data negates the ability to rerun the model and thereby ensure the published results are reproducible and precise. No practicing statistician would agree that a BMD or a BMDL estimated from a non-significant model including a non-significant model parameter should be used to set a standard. EPA repeats this mistake throughout the BMD calculation process.

(6B) EPA's choices regarding statistical and/or biological properties of analyzed data are inconsistent with accepted practice.

EPA clearly states that selection of the BMR for the purpose of estimating a BMD involves making judgements about the statistical and biological properties of the data set. Yet, EPA provides no analysis of the sensitivity that these choices may have on the final BMD. The choice of BMR and the choice of "extra risk" (the p(0) term in the BMD calculation) simply will not withstand scientific review without a clear association back to clinical effects on the US population. As noted in the EPA QAPP guidelines, it is bad statistical practice to make judgement calls and subsequently calculate costs and benefits, without exploring the ramifications of and sensitivity of the results to these decisions in practice.

In summary (1) EPA has not conducted a sensitivity analysis of these arbitrary BMR and p(0) terms; (2) EPA provides no scientific basis for the choice of model equation; (3) EPA provides no scientific justification for (or against) specific BMR and p(0) choices, other than to state what EPA believes is commonly used; and most importantly,(5) EPA provides no explanation or examples of how the BMD calculations relate to actual human health risk. EPA must scientifically support how these calculations result in reduced mortality on a national scale.

For example, in the below table we demonstrate BMD and BMDL outcomes using two different BMD model equations (the Budtz-Jørgensen & Grandjean (2018) model, and the EPA Hybrid method used in Dong et al.(2019)). Models with three different sets of co-variates are fit (rows of the table) for NHANES total cholesterol data. (Dong et al., 2019). The appropriate NHANES weighting functions are used to generate the model estimates (there is no mention of weights in Dong et al. 2019). The choice of the extra risk term, and the choice of BMR make a significant difference in the resulting BMD and BMDL and could highly influence the final reference dose and ultimately the MCLG. Key co-variates that possibly affect the model parameter estimates

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should be included in all BMD calculations, which many of the papers selected by EPA do not do. These co-variates include the presence of a cholesterol lowering drug, age, ethnicity, gender, and BMI. Note in the analysis below the wide range of BMD and BMDL values found with relatively small changes in the BMR and p(0) terms. Also note that the slope parameter (the parameter multiplied by the total cholesterol concentration) is non-significant in every model. We supply this table only to show the range of BMD and BMDL values that can occur with arbitrary values of BMR and p(0). Good statistical and scientific practice requires EPA to relate the selected BMR and p(0) terms to the endpoints of interest, which according to EPA are severe disease or mortality estimates for the US population on a national basis. We also note that EPA claims the Dong et al. (2019) model included key co-variates like those above; however, this is not noted in the actual paper.

There are many BMD model forms and analytical approaches to choose from (Budtz-Jorgensen, Keiding, & Grandjean, 2001; Crump, 1995; Liu et al., 2016; USEPA 2012, 2022; Wheeler, Cortinas, Aerts, Gift, & Davis, 2022; Wheeler et al., 2023), including regression approaches, maximum likelihood approaches, and Bayesian approaches. How EPA chose from these differing approaches was not explained. Additionally, EPA did not robustly compare results from the various model forms and statistical paradigms. Without these explanations and comparisons, EPA's decision-making and the scientific basis for its Proposed NPDWR are not transparent and prevent meaningful comment and analysis by reviewers.

Table 2 (below) provides an examination of the sensitivity of the BMD and BMDL calculations using two different model equations, and various values of BMR and p(0). Note that for any specific model and set of co-variates, the BMD and BMDL values vary tremendously. This results in a large variance in the resulting RfD. The equations are associated and follow a specific set of progressive calculations. Uncertainty at any specific level of the calculation hierarchy results in a compounded uncertainty in the final reference dose and ultimately the MCLG. EPA has not addressed this compounding of uncertainty in any of the technical documents or appendices. This issue is critical, because the cascading uncertainty sheds light on the lack of scientific integrity of the EPA proposed rule.

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Table 2. Demonstration of range of BMD values with arbitrary choice of BMR and p(0): Total Cholesterol. Dong et al. (2019) reports BMD=10.5 mg/dL, BMDL=5.6 mg/dl.

Co-variates	(Budtz-Jørgensen & Grandjean, 2018) Method				Liu et al., 2016 Method			
	BMR=0.05		BMR=0.1		p(0)=.1 BMR=0.05		p(0)=.20 BMR=0.05	
	BMD	BMDL	BMD	BMDL	BMD	BMDL	BMD	BMDL
None	55.8	30.8	109.0	60.3	152.4	83.9	504.4	204.4
Age (<20, 21-80) Taking cholesterol drug (yes, no)	150.3	60.9	293.6	118.9	387.8	157.1	341.9	150.1
Age (<20, 21-80) Taking cholesterol drug (yes, no) Ethnicity Gender	102.7	45.4	200.6	88.6	262.0	115.2	341.9	150.1
Age (<20, 21-80) Taking cholesterol drug (yes, no) Ethnicity Gender BMI Category (healthy, obese, overweight, underweight)	103.6	45.0	202.5	87.8	262.0	113.7	345.9	150.1

The following comments (6C – 6F) are specific to USEPA 2023c, but likely also apply to USEPA 2023e.

(6C) EPA made repeated statistical mistakes contrary to accepted practice

In Table E-2 (page E-274) EPA repeats the mistake of excluding important co-variates and acknowledges in Table E-2 that no information is available to ascertain model fit. Again, without the ability to replicate the Budtz-Jorgensen results and identify if the model from which the BMDL was derived has statistical validity, these results are invalid.

The fundamental statistical mistakes noted above continue with Table E-3 (E-275).

(6D) Inappropriate calculations to reproduce and/or calculate model parameters

(1) Note that EPA in "Selection of Benchmark Response" (following Table E-3) attempts to calculate a pooled variance using Log base 2 of the 25th and 75th percentiles, and uses these percentiles in an attempt to calculate a pooled variance. This calculation is unsupported. EPA acknowledges it does not have the original data, and therefore, it is not mathematically possible calculate a pooled variance. There are many distributions that could result in the same 25th and 75th percentile, but a pooled estimate based on actual data could be very different than what was calculated by EPA. This attempt to overcome lack of actual data is statistically inappropriate. In addition, EPA has no knowledge of

how the 25th and 75th percentiles were generated, and cannot replicate these values without the original data set. Also, because the authors make no mention of it, EPA presumably does not know how the original authors treated issues with non-detected values, possibly dropped records, or dealt with sampling issues and weights. Again, EPA cannot use mathematical calculations to overcome the non-available data issue where the results cannot be repeated by the general public or other scientists. The outputs in Table E-4 are unsupported. Even EPA admits there is low confidence in the results, yet EPA continues to use the information. For example, in Section E.71 EPA states "[t]he Agency notes that the estimated models are potentially subject to omitted variable bias from other sources, such as income level, but EPA does not have adequate information to evaluate the impacts of this bias…"

(2) On page E-278, EPA seems to not have the original data for Timmermann et al. (2021) and attempts to back out a regression slope in order to calculate the BMD. This practice is mathematically indefensible, and could easily result in a wrong answer. Also, EPA is required under its own guidelines (USEPA 2003, USEPA 2006) to ensure that, consistent with the data, the original authors did not incorrectly treat the data (i.e., removal of outliers, etc.) prior to using the results for standard setting.

(3) The above inappropriate mathematical and statistical comments also apply to Section E.1.1.4, Modeling Results for Decreased Diphtheria Antibody Concentrations (page E-279).

(4) In Section E.1.2.1. EPA again makes unsupported assumptions as to the mean and sigma estimates based on the 25th and 75th percentiles in Chu et al. (2020). EPA needs to obtain the original data, examine the original data using good data practices, and then calculate mean and sigma values. Using the ratio of percentiles reported in a paper is not in line with best statistical practice, and will most likely not represent values obtained using actual data.

(5) See sections E.1.2.2 – E.1.2.7 for continued statistical issues as described above.

(6) In each of the six high confidence studies for which EPA uses to calculate BMD/BMDLs (Sections E.1.2), EPA inappropriately uses the regression coefficients published in the paper, ignoring the fact that the published models incorporate co-variates in their final model. For instance in Chu et al.(2020) the paper published in Table 2 adjusted regression coefficients for "gestational age, maternal age, maternal occupation, maternal education, family income, parity, and infant sex" (see page 4). When these types of adjustments are made, they are part and parcel of the final and the regression coefficient of interest. For example, b in Table 2 is only statistically valid *in the presence of the co-variates* (also known as confounding variables). In this, and other sections of the report, EPA has repeatedly ignored the full model specification and instead only used the regression coefficient of interest, violating standard statistical principles.

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(6E) Single variable regression models can overinflate the relationship to PFAS

Table E-9: EPA states that PFOS is significant in the single-PFAS model. As noted above, when a single variable regression model is applied to a larger data set, the basic tenants of hypothesis testing theory results in significant parameter estimates, simply due to sample size. However, we have showed in our comments that when critical co-variates like gender and age are included in the regression models, the coefficients on PFOA and PFOS are generally non-significant. This is a "signal and noise" problem, with the co-variates easily showing they are much more important to the endpoint (i.e., antibody titer) than PFOS and PFOA blood concentrations.

(6F) EPA's attempts to overcome missing information are inconsistent with accepted scientific practice

EPA's calculation of the "extra risk" in E.1.2.7 is not consistent with sound scientific practice. First, EPA does not know what the true background percentage of PFOS or PFOA is in the US. EPA has not evaluated a national-level exposure of these substances, which would vary tremendously on a national basis. Therefore, EPA's attempts to calculate an "alternative control group" response is not appropriate, and simply represents a statistical calculation that EPA has not defined explicitly. Without an exact understanding of background values (which EPA has not adequately addressed in this rule making), statistical calculations such as those in E.1.2.7 are inconsistent with sound and acceptable practice.

7. Ignoring of the totality of NHANES immune and vaccine data

The Bulka, Avula, & Fry (2021) study used NHANES data to investigate the relationship between PFAS and possible immune effects investigated eight different pathogens (cytomegalovirus (CMV), Epstein Barr virus (EBV), hepatitis virus types C and E (HCV, HEV), human immunodeficiency virus (HIV), herpes simplex virus types 1 and 2 (HSV-1, HSV-2), Toxoplasma gondii (T. gondii), and *Toxocara canis* and *Toxocara cati* (*Toxocara* spp.)). No relationships between PFAS and these pathogens were found, until the authors constructed a composite measure to sum across all these pathogens. However, in 2020 these same authors, using NHANES data proposed lead exposures increased the risk of CMV infection and impair immune control of the virus in young adults. The usage of the same dataset to support radically different pathways for impairment represents p-hacking which is a form of data exploitation to discover patterns which would be presented as statistically significant, when in reality, there is no underlying effect.

8. EPA is overly conservative in the calculation of RfDs.

EPA employs a series of highly conservative uncertainty and safety factors to generate an RfD. These values are not consistent with best practice for selection of such factors. EPA did not use robust statistical uncertainty techniques, as is expected as part of best available science, in order to replace the arbitrary safety and uncertainty factors with data-based measures of uncertainty. Model-based prediction uncertainty (for both statistical and toxicological models) approaches are available and should be used by EPA in place of overly conservative and subjective factors.

Classic safety factors and uncertainty factors are generally not based on models or data, which, as noted above does not meet EPA's own quality assurance guidelines. Any uncertainty used by EPA should be peer-reviewed, and based on actual data (e.g., uncertainty in BMD dependent on choice of model, BMR, p(0), etc.). Safety factors should be based on true data, and in particular,

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reflect the ability of others replicate EPA's results. EPA does not have actual data sets for many of the endpoints addressed in the rulemaking, and EPA did not oversee the work ensuring good quality control of the author's findings.

Without proper uncertainty analysis based on EPA's guidance on good statistical practice, the uncertainty and safety factors employed by EPA do not result in a scientifically defensible RfD value.

9. Comments on Framework of a Bayesian Hierarchical Markov Chain Monte Carlo Occurrence Model (Appendix A, (U.S, 2023b))

(9A) EPA introduced bias in establishing PFOA/PFOS water concentrations

EPA states that small PWSs were selected using a population-weighted stratified random sampling design, in part because the data from these systems have lower detection limits. EPA states that non-detects are less informative than reported values. EPA states that if state data met certain specifications, then the data were comparable to UCMR 3 and could be used to inform the national occurrence model. Further, the state data were limited to those PWS already in the UCMR 3 data set.

The above approach by EPA is inconsistent with standard methods for selecting random samples for establishing an un-biased estimate of PFOA and PFOS water concentrations across the US. Limiting the state data to only those PWS selected by UCMR 3 imposes an artificial geographic restraint on the drinking water exposure distribution. EPA's logic results in only 17 states, which is likely unrepresentative of PFOS and PFOA water concentrations across the US. In fact, Table A-1 indicates that not only are few states selected, the number of systems included for each state are highly inconsistent. For example, only 1 PWS is available for the states of ME, GA, and ND; which effectively gives these states no influence on the final results, even though these states have many small communities representing a large number of populations and geographic factors.

Also, to generate an exposure distribution on a national level, a representative sample must be derived using metrics other than state population totals. The actual concentrations of PFOA or PFOS are a function of many factors, including distance from the PFAS source, topography, number of private drinking water wells in the area or state, climatology, distance to nearest large water and river systems, and other environmental factors. EPA's state data are clearly not representative of the PFAS exposure distribution on a national level. Therefore, any conclusions drawn based on these data do not represent the expected PWS concentrations across the US and cannot be used to support a MCL.

EPA does not explain what it means when it says that "… if the state data met certain specifications, EPA assumed that they were statistically comparable with the UCMR 3 data…" EPA must define what "certain specifications" means. For example, did EPA remove all PFOA or PFOS concentrations that were non-detects?

EPA uses a natural log of the PFAS concentrations. Many state-level data sets, especially those with a large number of non-detects, set the value to zero. Ln(0) is undefined. The results indicate that EPA removed all zero values from the data set because the use of a natural logarithm of zero

does not exist. This approach arbitrarily deletes small values from the data set. According to best scientific practices, EPA should be using Ln(x+1) rather than the Ln(x) so as to not introduce bias into the analysis.

(9B) Conceptual Model Structure

EPA uses something called a "fixed factor shift" for small systems. This approach seems to increase the influence of small system data on the overall population mean. EPA does not explain why this adjustment is necessary (equation A-2). If the data are indeed representative of the US, no adjustment would be necessary. Equation A-2 seems to be an admission by EPA that the state data were not obtained using a pre-specified data collection plan containing DQOs, as required by EPA guidance documents. EPA must explain the degree to which equation A-2 influences the final answers.

EPA's use of small-system specific standard deviations is not clear, and it is not clear how EPA mathematically used these standard deviations. EPA states it uses within-system standard deviations pooled across size categories for PFHxS and PFHpA. Note, a within-system variance component for those systems with small sample sizes (and in particular when the small sample is composed predominately of non-detects) is unreliable at best. EPA must provide insight into the relative influence of this issue on the final results in order to assuage worries of veering from statistical best practices.

A Bayesian model is fully capable of estimating both within- and between- small system variances if the model is constructed correctly. There is no reason, outside of the model, to create covariance matrices or evaluate variance components independent of the full model. The beauty of a correctly constructed Bayesian Hierarchical Model is that the data inform the parameters and associated variance components at each level of the hierarchy. Therefore, EPA's approach as described in this section appears to be invalid.

As noted above, EPA did not include key geographic co-variates when building the Bayesian model (e.g., distance from the source, environmental metrics, climatology, etc.). These values should have been included in the model in an effort to correctly account for geographic variability among the water systems. Without these terms, or an attempt to build a model that explicitly accounts for geographic variance components, the outputs from the model are inaccurate and cannot be used to establish an exposure distribution for the US population.

EPA used "weakly informative prior distributions." EPA must provide the mathematical details of the prior distributions, and how the prior distributions were constructed. If indeed they are fully non-informative, EPA must provide the basis for using non-informative distributions. If the prior distributions do not account for natural geographic variability, then the prior distributions are incorrectly constructed and the resulting marginal predictive distributions are incorrectly constructed. Without this additional information, it is unclear whether EPA followed best available practices in the creation of its model.

EPA must provide the mathematical details of its calculations within the Bayesian model. EPA needs to provide mathematical equations showing the construction of the marginal mean distributions at each level of the hierarchy, the construction of marginal predictive distributions,

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the construction of the joint likelihood and prior distributions, etc. Without an explicit mathematical statement of the model, the model and its components cannot be fully evaluated.

10. Comments on Effects of Reduced Birth Weight on Infant Mortality (Appendix E, (USEPA 2023b))

(10A) Data Sources

EPA describes a data set with only two years of data. Given the discussion about changes over time in infant mortality described by EPA, a data set with only two years of data is insufficient to build the regression models described in Appendix E. Natural changes over time must also be included in the model. Otherwise, any correlation of birth weight and infant mortality will be erroneous and could easily be due to other time-dependent factors not included in the model.

EPA must make the data set described in E.3.1 available to the public under the EPA's quality assurance and good statistical practice guidelines. It has failed to do so in the supporting documents for the Proposed NPDWRs.

(10B) E.7.1 Mortality Regression Models

Figure E-1 indicates that EPA has built a series of models, generating different model coefficients for various factors that influence birth weight and infant mortality including gender and ethnicity. This approach is inconsistent with scientific best practice. The proper approach is to build a single model with key co-variates like gender and ethnicity included in the single model (Harrell 2016). Otherwise, the model error term (which is the basis for hypothesis testing) is biased and not representative of the entire population included in the data set. EPA could use linear contrast or estimate methods to evaluate differences in gender and ethnicity, but the error term must result from a single model fit.

EPA does not show the significance of each of the regression and logistic model parameters. In other parts of the technical appendices supporting the MCLG, EPA has ignored the fact that many co-variates (e.g., gender or ethnicity) are the variables highly associated with the model response variable, and either PFOS and PFOA are not significant or are minor parameters relative to the key phenotype co-variates. EPA must demonstrate a strong relationship, considering the entire data set and scientifically derived and supported co-variates in the statistical models. As the presentation currently stands, the lack of information provided by EPA negates the ability of the public to evaluate the validity of the models.

EPA must show which co-variates are included in the models generating the odds ratios of Table E-4, including their statistical significance. Otherwise, the validity of the models cannot be examined from a scientific perspective.

11. Comments on Figure 6-10 Overview of Analysis of Co-Removal Benefits ((U.S, 2023a))

In a decision tree like that seen in Figure 6-10, each step of the decision analysis is comprised of models with uncertain predictions, decisions based on subjective judgement, value-based judgements, and uncertain cost estimates and cost expectations. This graphic represents the decision process EPA has both implicitly and explicitly used to generate the MCL. At issue is the

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level of uncertainty a multi-branched decision analysis actually represents. In practice, EPA has not identified nor quantified the measurable uncertainty in each step of the decision process used by EPA. EPA must provide the public with an honest estimate of the degree to which the MCGL will result in a benefit to human health, including the actual costs which the public must incur for these indeterminate benefits. A rigorous uncertainty analysis of the Figure 6-10 decision tree will result is such a large uncertainty in the total value of reduced bladder cancer, that any positive benefit will not be quantifiable.

Conclusion

The methods and procedures used by EPA to support the Proposed NPDWR did not follow EPA's own established procedures and guidance, including those for good data practice, good statistical analysis practice, consistency of methods and models, and the ability to replicate analytical results. Therefore, the analytical findings by EPA and outside sources cannot be validated, and EPA's proposed standard lacks scientific and statistical merit. EPA's reliance on non-national data bases, work by external authors, inability to quality control the data, models, and outputs is shown to be a major criticism of the underlying statistical approaches EPA has used to support the MCLG and MCL.

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Wheeler, M. W., Lim, S., House, J., Shockley, K., Bailer, A. J., Fostel, J., . . . Motsinger-Reif, A. A. (2023). ToxicR: A computational platform in R for computational toxicology and dose-response analyses. *Comput Toxicol, 25*. doi: 10.1016/j.comtox.2022.100259

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William Warren-Hicks, Ph.D.

Phone: (919) 628-2064 Email: billwh@ecostat-inc.com

Education:

1990 Ph.D., Environmental Statistics, Duke University
1979 M.S., Environmental Toxicology and Statistics, University of Texas School of Public Health
1976 B.S., Magna cum laude, Biology with Honors, University of Houston

Professional Associations:

American Statistical Association
Society of Environmental Toxicology and Chemistry

Positions:

EcoStat, Inc., Mebane, NC

2004 – ongoing **Chief Executive Officer.** EcoStat Inc. is a small women-owned business specializing in the quantitative environmental and human health sciences. Areas of expertise include environmental risk assessment in air, water and terrestrial environments; statistics and data analysis in both human health and environmental sciences; data base development and management; computer programming; water and air quality permitting; quantitative toxicity test evaluation; terrestrial and water quality modeling and model validation; and chemical exposure modeling and model validation.

Example Clients: 3M, Dow Chemical, Syngenta Crop Science, private clients through attorneys, British Petroleum, US EPA Clean Air Markets Division, US EPA Office of Water, US EPA Office of Groundwater and Drinking Water, Bayer Crop Science, Department of Energy, Water Environment Research Foundation (WERF), Florida Power and Light, California Wind Energy Association (CalWEA), and NextEra Energy.

Social and Scientific Systems, Durham, NC

2015 – 2016 **Director of Biostatistics.** Provide senior leadership in the statistical sciences and related quantitative disciplines applicable to public health research. These areas include (1) public and private clinical trials of new and existing pharmaceutical products, (2) analysis of epidemiological data including –omics studies, (3) statistical analysis of laboratory derived assay data, and (4) oversight of data operations and data management for clinical studies. Manage a group of approximately 40 individuals, in the areas of statistics, modeling, statistical programming, data base management, and analytics.

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Clients: National Institute of Health, Center for Disease Control, Coast Guard, National Institute of Environmental Health Sciences, private biotech firms, and private pharmaceutical companies.

Cardno ENTRIX., Raleigh, NC

2011 – 2015 **Principal/Vice President/Technical Director/Biostatistics Practice Leader.** Responsible for Cardno-wide intellectual leadership and business development in the quantitative sciences. Lead statistician for BP Gulf Oil Spill (Clean Water Act litigation, National Resource Damage Assessment litigation). Incrementally managed over 25 statisticians and scientists in the role of biostatistics practice leader.

Other clients: US Fish and Wildlife Service, Upper Neuse River Basin Association, Mosaic Fertilizer, Inpex Oil (Australia), Sidley Austin (Washington), Arnold and Porter (New York), and Duke Energy.

The Cadmus Group, Chapel Hill, NC

2003 - 2004 **Vice President for Strategic Science Initiatives**: Member of the Cadmus executive committee that provides overall business oversight and direction for the company; responsible for business management and development in human health and environmental sciences, strategic company planning, market forecasting, and intellectual leadership at the corporate level. Technical areas of responsibility include human health and environmental risk assessment, modeling and statistics in the air quality sciences, and exposure and effects assessment in both human and ecological risk sciences.

Example clients: **Government:** EPA Office of Research and Development, EPA Office of Water, EPA Office of Air and Radiation, EPA Clean Air Markets Division, EPA Office of Ground Water and Drinking Water, Department of Energy, Corps of Engineers. **Industry:** 3M, Syngenta Crop Science, Bayer Crop Science, Aventis Crop Science, City of Cary, NC, Weyerhaeuser Pulp and Paper, American Chemistry Council, CEFIC, Water Environment Research Foundation (WERF), American Metropolitan and Sewage Association (AMSA), Utility Water Act Group.

1997 - 2003 **Vice President and Group Manager**: Responsible for business development, business management, and personnel management in the ecological risk sciences, statistics, and engineering; manager of the Cadmus North Carolina office; responsible for offices in Ottawa, Ontario, Canada, Oak Ridge, TN, Laramie, WY, Springfield, MA, and Cincinnati, OH; Managed over 60 scientists, statisticians, and engineers; developed both a government and private client practice; responsible for group-level contracts, budgets, legal issues, and personnel issues. Responsible for

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over 100 projects in the human and environmental risk sciences, and air quality.

1991 - 1997 **Principal Scientist**: responsible for business development and personnel management in the ecological risk sciences, statistics, and engineering; manager of the Cadmus North Carolina office and four other offices in the US and Canada.

Kilkelly Environmental Associates, Raleigh, NC

1988 - 1991 **Senior Scientist**: responsible for data analysis and statistical assessments of environmental exposure and effects data; worked with EPA's Corvallis Laboratory to develop EPA's first risk assessment documents including the development of assessment and measurement endpoint concepts; published well received papers on toxicity test variability; worked with EPA's Acid Rain Division to develop the Acid Rain rules for utility emissions of SO_2, NO_x CO_2, and particulates.

Carolina Power and Light Company, Raleigh, NC

1982 - 1988 **Senior Statistician**: supported over 60 biologists in the assessment of impacts to biota at CP&L's nuclear and coal-fired power plants; generated survey designs, performed statistical analyses, participated in on-site sample collection activities, and generated reports to State and Federal agencies; developed thousands of lines of code in SAS and Fortran for the statistical assessment of environmental data.

TRW Environmental, RTP, NC

1980 - 1982 **Engineer:** supported EPA's Office of Air Quality Policy and Standards (OAQPS) in running air quality models, setting of NAAQS values, and PSD permit development.

Duke University Center for Demographic Studies

1977 - 1985 **Programmer and Statistician**: developed maximum likelihood statistical models of longitudinal cancer trends over various demographic groups and geographical areas of the US; developed program code in Fortran, IBM assembly language, and Basic.

Professional Highlights

- Over 35 years of experience supporting industry, government programs, academic institutions, and research initiatives in water, air, and terrestrial environments. Areas include development of statistical analysis of water, air, biota, and groundwater data; NRDA studies; exposure and effects data analysis, risk assessment methods and procedures development in both human health and environmental sciences, evaluation of toxicity data for both terrestrial and aquatic species, criteria development, development

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and implementation of regulations, overall support of programmatic goals and objectives, formal research activities, analysis of avian survey measurements, development collision risk assessment methods and models for the wind industry.

- Manager of over 400 projects for industry and government resulting in numerous reports, conference proceedings, and peer-reviewed publications in the areas of NRD litigation, wind power, water quality, air quality, environmental statistics, epidemiology studies, human health risk assessment, probabilistic risk analysis, watershed assessment, bioassessment, and Bayesian decision and inference.

- Initiated and developed four individual businesses within existing firms: (1) air quality division The Cadmus Group, (2) risk assessment division The Cadmus Group, (3) statistics group Cardno ENTRIX, (4) Biostatistics Center within Social and Scientific Systems.

- Originated, managed, and maintained EcoStat, Inc., a small business working with both industry and government.

- Science Advisory Board: Restoration of the Missouri River (ongoing).

- EPA Science Advisory Board: Ecological Risk Assessment of PCB Impacts, Kalamazoo River, Michigan.

- Statistician: Evaluation of airborne risk from radioactive nuclides. Hunters Point, CA Superfund Site.

- Statistical support to Dow Chemical: Tittabawassee River Risk Assessment. Evaluation of risk to avian species.

- Fish and Wildlife Service Science Advisory Board: Evaluation of PCB toxicity on the Hudson River, NY: Evaluation of Laboratory Toxicity Tests.

- Fish and Wildlife Service Science Advisory Board: Evaluation of PCB toxicity on the Hudson River, NY: Evaluation of PCB Effects on Mink.

- Fish and Wildlife Service, State of Michigan, EPA- Science Advisory Board: Evaluation of PCB toxicity to avian species on the Hudson River, NY.

- Invited panel member of the National Wind Coordination Committee (NWCC), Risk Assessment Workgroup.

- Invited speaker and associated lead chapter author of six SETAC Pellston Conferences including Sediment Risk Assessment, Multiple Stressors (steering committee member), Probabilistic Risk Assessment of Pesticides, Whole Effluent Toxicity Testing,

Uncertainty Analysis In Ecological Risk Assessment (chair, lead editor, lead conference organizer, and creator), and Pesticide Risk Assessment for Pollinators.

- Instructor and creator of a continuing education course sponsored by the Duke University School of the Environment entitled *New Advances in Quantitative Ecological Risk Assessment*. Invited speaker in the School of the Environment at Duke University in the areas of risk assessment, data analysis, probability, and ecological modeling.

- Invited panel member and reviewer of the EPA Framework Document For Ecological Risk Assessment, The Superfund Risk Assessment Guidance Document, and the Canadian Risk Assessment Guidance Document for New Substances.

- Lead consulting statistician supporting the majority of the EPA Acid Rain Division's (now the Clean Air Markets Division) regulatory development activities under the 1990 Clean Air Act Amendments.

- Project manager for major research initiatives including: ecological risk assessment methods and software (WERF), assessments of whole effluent toxicity test variability (WERF), site-specific nutrient criteria, development of risk assessment methods for DOE sites (DOE EM-6), state-of-the-science in ecological risk assessment uncertainty methods (American Chemical Society), and case studies in ecological risk assessment (CEFIC Long-term Research Initiatives).

- Lead statistician for British Petroleum on the Deepwater Horizon Oil Spill in the Gulf of Mexico.

- Developer of *Using Monte Carlo Analysis In The Probabilistic Risk Assessment of Pesticides*, a course in uncertainty analysis methods that was given multiple times to EPA's Office of Pesticide Programs (OPP), individual chemical companies, and industry coalitions. Created courses in statistics and probability for Environment Canada's Priority Substances Assessment Program. Developer of courses at Duke University and SETAC in decision sciences, statistics, and probabilistic risk assessment.

- Lead statistician to the Federal Insecticide, Fungicide and Rodenticide Act Environmental Model Validation Task Force (FEMVTF) Statistics Committee in conducting an uncertainty analysis of the PRZM3.12 model.

- Lead statistician supporting 316(b) studies for the assessment of fish entrainment at the Brunswick nuclear power plant, Duke Energy.

- Over 50 platform and poster presentations at NWCC, SETAC, and SOT annual meetings. Frequent invited session chair and speaker at conferences, symposium, and ASTM meetings.

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CLASSES TAUGHT

Decision-Making Under Uncertainty – Bayesian Inference. 2016. Seminar Series. Law Seminars International.

New Advances in Ecological Risk Assessment: July 2008. Duke University, School of the Environment, Durham, NC.

Statistical Methods for Water Quality Data Analysis. March 2008. U.S. EPA Region 5. Chicago, Ill.

Bayesian Statistics for Dummies. With Tom Aldenberg. November 2004. Portland, Oregon.

Statistics MTH 112. Fall Semester. 2004. Elon University, Elon, NC.

New Advances in Ecological Risk Assessment: June 2004. Duke University, School of the Environment, Durham, NC.

Methods (Old and New) in Probabilistic Ecological Risk Assessment. April 2004. SETAC Europe Annual Meeting Short Course, Prague, Czech Republic.

Methods (Old and New) in Probabilistic Ecological Risk Assessment. November 2003. SETAC Annual Meeting Short Course, Austin, TX.

Technical Approaches to Setting Site-specific Nutrient Criteria. September 2002. Water Environment Federation, Chicago, IL.

Using Monte Carlo Analysis in the Probabilistic Risk Assessment of Pesticides. June 2002. Syngenta, Jealott's Hill Research Station, Jealott's Hill, England.

Uncertainty Analysis. Duke University School of Engineering. Spring Semester 2001. Durham, NC.

Using Monte Carlo Analysis in the Probabilistic Risk Assessment of Pesticides. November 2001. Syngenta, Greensboro, NC.

Using Monte Carlo Analysis in the Probabilistic Risk Assessment of Pesticides. July 2001. American Crop Protection Association, Baltimore, MD.

Using Monte Carlo Analysis in the Probabilistic Risk Assessment of Pesticides. January 2001. EPA Office of Pesticide Programs, Washington, DC.

Using Monte Carlo Analysis in the Probabilistic Risk Assessment of Pesticides. March 2000. EPA Office of Pesticide Programs, Washington, D.C.

New Advances in Ecological Risk Assessment: April 2002. Duke University, School of the Environment, Durham, NC.

Advanced Topics in Ecological Risk Assessment: March 1999. Duke University, School of the Environment, Durham, NC.

Uncertainty Analysis in Ecological Risk Assessment. 1998. SETAC Annual Meeting, Charlotte, NC

Advanced Topics in Ecological Risk Assessment: March 1998. Duke University, School of the Environment, Durham, NC.

Statistics Course. April,1997. Priority Substances Assessment Program. Environment Canada. Hull, Ontario, Canada.

Advanced Topics in Ecological Risk Assessment: March 1997. Duke University, School of the Environment, Durham, NC.

Uncertainty Analysis in Ecological Risk Assessment. 1996. SETAC Annual Meeting, Washington, DC.

Aquatic Ecological Risk Assessment: Methods for Screening-Level and Probabilistic Risk Assessments. November 1996. Sponsored by the Water Environment Federation. Washington, DC.

Advanced Topics in Ecological Risk Assessment: February 1996. Duke University, School of the Environment, Durham, NC.

Invited Lectures: Overview of Ecological Risk Assessment. Spring 1995. Course title: Environmental Risk Assessment and Decision Making. Duke University, School of the Environment, Durham, NC.

Aquatic Ecological Risk Assessment: April 1995. Duke University, School of the Environment, Durham, NC.

Invited Lectures: Risk Assessment Methods in Water Quality. Spring 1993. Course title: Environmental Risk Assessment and Decision Making. Duke University, School of the Environment, Durham, NC.

Invited Lectures: Risk Assessment Methods in Water Quality. Spring 1992. Course title: Environmental Risk Assessment and Decision Making. Duke University, School of the Environment, Durham, NC.

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Invited Lectures: Risk Assessment Methods in Water Quality. Spring 1992. Short course: Environmental Risk Assessment. Duke University Continuing Education Series, Duke University, Durham, NC.

Invited Lecture: Variability of Biological Endpoints and Effects on Standard Setting. Fall 1991. Course title: Environmental Toxicology. Duke University, School of the Environment, Durham, NC.

Regression Analysis, With Laboratory. Spring Semesters 1986-1988. Duke University, School of Environmental Sciences, Durham, NC.

Graduate Student Committee Assignments

Eric Thirolle, M.S.: Thesis title: Guidance for the selection and use of exposure models in ecological risk assessment. Duke University School of the Environment. 1996.

Tom Stockton, Ph.D. Thesis title: Using Bayesian MARS methods for assessing acid deposition. Duke University School of the Environment. 1998.

Molly Haviland. M.S. Thesis title: Soil carbon and dryland spring wheat yield response to a one-time compost application. Montana State University. Ongoing.

PRESENTATIONS

Warren-Hicks, W. J. Role of Statistics in Litigation. 2019. Law Seminars Institute. Albuquerque, New Mexico.

Warren-Hicks, W. J., Bohrmann, T., Robbins, K., 2013. Geospatial Modeling: Don't Take Your GIS Statistics Software for Granted. SETAC National Conference. Nashville, TN.

Warren-Hicks, W. J. and S. Bartell. 2009. Models Versus Data. Invited Presentation. SETAC Debate Series. SETAC National Conference. New Orleans, LA.

Kravits, M., Eskew, D., Warren-Hicks, W. J. 2008 Application of the Stressor Identification (SI) Methodology to a Contaminated Floodplain and Adjacent Irrigated Meadows – Upper Arkansas River, Colorado Case Study. SETAC Annual Meeting, Tampa, Fl.

Zillioux, E. J., Newman, J. R., Warren-Hicks, W. J. 2008. Ranking Wildlife Risks from Multiple Anthropogenic Stressors. SETAC Annual Meeting, Tampa, Fl.

Giddings, J., and Warren-Hicks, W. J. 2008. Developing a plant-based chronic water quality standard for acetochlor. SETAC Annual Meeting, Tampa, Fl.

Warren-Hicks, W. J. 2006. Chair: The Future of Environmental Statistics and Ecological Modeling. SETAC Annual Meeting, Montreal, Canada.

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Arnold, R.W, and Warren-Hicks, W. J. Site-specific, Regional, or National Metals Criteria? – A Case Study With Cu In San Francisco Bay. 2005. SETAC Annual Meeting, Baltimore, MD.

Warren-Hicks, W. J., Parkhurst, B. R. 2003. Whole Effluent Toxicity Tests: Using Bayesian Methods To Calculate Model-Based Endpoint Variability. SETAC Annual Meeting, Austin, TX.

Parkhurst, B. R., Warren-Hicks, W. J. 2003. Alternatives to EPA's Methods for Calculating Reasonable Potential for WET: Case Studies. SETAC Annual Meeting, Austin, TX.

Giddings, J. M., Gonzalez-Valero, J. F., Warren-Hicks, W. J. 2003. Exposure Duration and Effects of Atrazine on Aquatic Plant Communities in Mesocosms. SETAC Annual Meeting, Austin, TX.

Giddings, J. M., Gonzalez-Valero, J. F., Warren-Hicks, W. J. 2003. Integrating Dose-Response With Species Sensitivity Distributions. SETAC Annual Meeting, Austin, TX.

Warren-Hicks, W. J. 2003. Statistical Methods and Approaches in Risk Assessment: Lessons Learned. Invited Address. SETAC European Congress, Hamburg, Germany.

Warren-Hicks, W. J., Parkhurst, B.P., Beach, S., Butenhoff, J., Giesy, J. 2002. Understanding the Global Distribution and Environmental Effects of PFOS. Society of Toxicology Annual Meeting. Salt Lake City, Utah.

Warren-Hicks, W. J., Qian, S., Dobbs, M. 2002. Species Sensitivity Distributions in Non-Target Plant Risk Assessments. Society of Toxicology Annual Meeting. Salt Lake City, Utah.

Dobbs, M. G., Ramanarayanan, T. S., Warren-Hicks, W. J., Qian, S., Giddings, J. M., Kelly, I.D., Allen, R., Fischer, R.W. 2002. Assessing the risk to non-target crops through irrigation water. Society of Toxicology Annual Meeting. Salt Lake City, Utah.

Parkhurst, B. P., Warren-Hicks, W. J., Bartell, S., Smart, M. 2002. Site-Specific Nutrient Criteria: An Alternative To US EPA Nutrient Criteria. Society of Toxicology Annual Meeting. Salt Lake City, Utah.

Parkhurst, B. P., Warren-Hicks, W. J., Bartell, S., Smart, M. 2002. Site-Specific Nutrient Criteria: An Alternative To US EPA Nutrient Criteria. Water Environment Federation Annual Meeting. Chicago, IL.

Warren-Hicks, W. J., Santoro, M., Bacon, D., Parkhurst, B. P., Moore, D. J. 2001. Ecological Risk Assessment of PFOS. Invited Address. Society of Toxicology and Chemistry World Congress. Baltimore, Maryland.

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Warren-Hicks, W. J., Carbone, J.P., Havens, P. 2001. Using Monte Carlo Techniques to Judge Model Prediction Accuracy: Validation of PRZM 3.1. Society of Toxicology and Chemistry World Congress. Baltimore, MD.

Carbone, J. P., Havens, P., Warren-Hicks, W. J. 2001. Validation of a Complex Fate and Transport Model. Model Accuracy and Regulatory Criteria. Society of Toxicology and Chemistry World Congress. Baltimore.

Salvito, D. T., Allen H. E., Parkhurst, B. R., Warren-Hicks, W. J. 2001. Comparison of Trace Metals in the Intake of Discharge Water of Power Plants Using "Clean" Techniques. Water Environment Research. Vol 73, No. 1, 24-29.

Dobbs, M., R, Ramanarayanan, T., Warren-Hicks, W. J. 2001. The Risk of Balance To Non-Target Plants. Society of Toxicology and Chemistry World Congress. Baltimore, Maryland.

Warren-Hicks, W. J., Santoro, M., Bacon, D. Parkhurst, B.P., Moore. D.J. 2000. Understanding the Global Distribution and Environmental Effects of PFOS. SETAC Annual Meeting. Nashville, TN.

Warren-Hicks, W. J., Wolpert, R. L. 2000. Estimating national distributions of *Giardia* and *Cryptosporidium* in the U.S. with Hierarchical Bayesian models. Third SETAC World Congress. Brighton, United Kingdom.

Warren-Hicks, W. J. 2000. Propagating Uncertainty In Non-Hierarchal Models. SETAC Annual Meeting. Nashville, TN.

Warren-Hicks, W. J., Moore, D. 2000. Uncertainty Analysis In Ecological Risk Assessment: American Chemistry Council and CEFIC Long-Range Research Initiatives. SETAC Annual Meeting. Nashville, TN.

Warren-Hicks, W. J., Biddinger, G. 1999. Debates In Ecological Risk Assessment. Chair. Society of Toxicology and Chemistry World Congress. Philadelphia, PA.

Warren-Hicks, W. J., Moore, D. 1999. Beyond Monte Carlo. Invited Address. Society of Toxicology and Chemistry World Congress. Philadelphia, PA.

Warren-Hicks, W. J., Parkhurst, B. R., Moore. D. R. J. 1999. Whole Effluent Toxicity Test Variability: A Variance Components Analysis. Water Environment Federation Annual Meeting.

Moore, D. R. J., R. S. Teed, W. J. Warren-Hicks, B. R. Parkhurst, R. B. Berger, J. J. Pletl, D. L. Denton, R. B. Baird. 1999. Intra- and Inter-treatment variance in reference toxicant tests. 20th Annual Society of Environmental Toxicology and Chemistry Conference.

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Warren-Hicks, W. J., Parkhurst, B. R., Moore, D., Berger, B., Pletl, J., Denton, D., Baird, R. 1999. Whole Effluent Toxicity Test Variability: A Variance Components Analysis. Society of Toxicology and Chemistry World Congress. Philadelphia, PA.

Parkhurst, B. R., Warren-Hicks, W. J., Moore, D., Berger, B., Pletl, J., Denton, D., Baird, R.1999. WET Test Variability: Demonstration of Effects on Compliance with WET.

Warren-Hicks, W. J., Moore, D. 1999. Uncertainty Analysis: With Examples From the Chemical Industry. Society of Toxicology and Chemistry World Congress. Philadelphia, PA.

Carbone, J. P., Havens, P., Warren-Hicks, W. J. 1999. A Critical Evaluation of PRZM3.12 Estimated Environmental Concentrations Accounting For The Uncertainty Associated With Measured Environmental Fate Data and Model Inputs. Society of Toxicology and Chemistry World Congress. Philadelphia, PA.

Teed, R. S., Qian, S. Warren-Hicks, W. J. 1999. Examination Of The Spatial Relationship and Interaction of Selected Environmental Parameters To Mercury Concentration In Fish Tissue in the Northeastern United States. Society of Toxicology and Chemistry World Congress. Philadelphia, PA.

Warren-Hicks, W. J., Biddinger, G. 1998. Debates In Ecological Risk Assessment. Chair. Society of Toxicology and Chemistry World Congress. Charlotte, NC.

Warren-Hicks, W. J., Solomon, K. R. R., Gentile J. H., Butcher, J., Ratner, B.A. 1998. Linking Stressors and Ecological Responses. Society of Toxicology and Chemistry Annual Meeting. Charlotte, NC.

Warren-Hicks, W. J., B. Parkhurst. 1995. Review of EPA's Framework for Ecological Risk Assessment. Invited Address. Colloquium on Developing an EPA Ecological Assessment Guidelines.

Warren-Hicks, W. J., B. Parkhurst. 1995. The Role of Laboratory Selection in Passing Toxicity Tests and Conducting Toxicity Reduction Evaluations. Presented at the Water Environment Federation's Conference: Toxic Substances in Water Environments. Cincinnati, Ohio. May 14 B 17.

Warren-Hicks, W. J., 1995. Uncertainty in Ecological Risk Assessment: A Review of the 1995 Pellston Conference. Second Society of Toxicology and Chemistry World Congress. Vancouver, British Columbia, Canada. November 6B10.

Warren-Hicks, W. J., 1995. Variability of Chronic Toxicity Tests. Invited Address. Presented at the 75th N.C. American Waste Water Association Conference. Greensboro, North Carolina. November 13.

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Parkhurst, B. P., Warren-Hicks, W. J., 1994. The Role of Laboratory Selection in Passing Toxicity Tests and Conducting Toxicity Reduction Evaluations. Presented at Water Environment Federation 1994. Chicago, Illinois. October 15B19.

Warren-Hicks, W. 1994. The Role of Laboratory Selection in Passing Toxicity Tests and Conducting Toxicity Reduction Evaluations. Presented at the SETAC Ecological Risk: Science, Policy, Law, and Perception Conference. Denver, Colorado. October 30BNovember 3.

Warren-Hicks, W. J. 1992. The Use of Bayesian Inference in Environmental Assessments and Decision-Making: Explanation of Theory and Case Study Examples. Invited Presentation. Atmospheric Environmental Research Laboratory, Research Triangle Park, NC.

Parkhurst, B. R., W. J. Warren-Hicks. 1988. What is the Role of Environmental Toxicology In Assessing the Ecological Impacts of Superfund Sites? Presented at the Ninth Annual Meeting of the Society of Environmental Toxicology and Chemistry. Arlington, VA. November13 B 17.

SELECTED PUBLICATIONS

Kishi T, Warren-Hicks W, Bayat N, Targoff IN, Huber AM, Ward MM, Rider LG; with the Childhood Myositis Heterogeneity Study Group. Corticosteroid discontinuation, complete clinical response and remission in juvenile dermatomyositis. Rheumatology (Oxford). 2021 May 14;60(5):2134-2145. doi: 10.1093/rheumatology/keaa371. PMID: 33067611; PMCID: PMC8121446.

Kishi T, Bayat N, Ward MM, Huber AM, Wu L, Mamyrova G, Targoff IN, Warren-Hicks W.J., Miller FW, Rider LG, for the Childhood Myositis Heterogeneity Study Group. (2018). Medications Received by Patients with Juvenile Dermatomyositis. Seminars Arthritis and Rheumatism. Mar 28. pii: S0049-0172(17)30753-9. doi: 10.1016/j.semarthrit.2018.03.016. [Epub ahead of print]. PMID: 29773230, PMCID PMC6162169.

Kishi T, Warren-Hicks W.J., Ward M, Bayat N, Wu L, Mamyrova G, N. Targoff I, Miller F, Rider LG. (2017). Predictors of Corticosteroid Discontinuation, Complete Clinical Response and Remission in Patients with Juvenile Dermatomyositis]. Arthritis Rheumatol. 2017; 69 (suppl 4). http://acrabstracts.org/abstract/predictors-of-corticosteroid-discontinuation-complete-clinical-response-and-remission-in-patients-with-juvenile-dermatomyositis/.

Kishi T, Wilkerson J, Smith M, Bayat N, Henrickson M, Lang B, Passo M, Miller FW, Ward M, Rider LG. Early Treatment with Intravenous Pulse Methylprednisolone or Methotrexate Is Associated with Decreased Medication Requirements at 12 and 24 Months in Patients with Juvenile Dermatomyositis: A Propensity Score Analysis [abstract]. Arthritis Rheumatol. 2018; 70 (suppl 9). https://acrabstracts.org/abstract/early-treatment-with-intravenous-pulse-methylprednisolone-or-methotrexate-is-associated-with-decreased-medication-requirements-at-12-and-24-months-in-patients-with-juvenile-dermatomyositis-a-propensi/.

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Kishi T, Warren-Hicks W, Ward M, Bayat N, Wu L, Mamyrova G, N. Targoff I, Miller F, Rider LG. Predictors of Corticosteroid Discontinuation, Complete Clinical Response and Remission in Patients with Juvenile Dermatomyositis [abstract]. Arthritis Rheumatol. 2018; 70 (suppl 9). https://acrabstracts.org/abstract/predictors-of-corticosteroid-discontinuation-complete-clinical-response-and-remission-in-patients-with-juvenile-dermatomyositis/.

Schwede, D., Bowker, G., Warren-Hicks, W. J. 2011. Quality Assurance Decisions with Air Models: A Case Study of Imputation of Missing Input Data Using EPA's Multi-Layer Model. Water, Air, and Soil Pollution. Vol. 222, pps. 391-402.

Warren-Hicks, W. J., and Hart, A. eds., 2010. Application of Uncertainty Analysis to Ecological Risks of Pesticides. Taylor & Francis, New York, New York.

Warren-Hicks, W. J., S. Qian, J. Toll, D. L. Fischer, E. Fite, W. G. Landis, M. Hamer, and E. P. Smith. Monte Carlo, Bayesian Monte Carlo, and First-Order Error Analysis. 2010. In Application of Uncertainty Analysis to Ecological Risks of Pesticides. Eds. W. J. Warren-Hicks and A. Hart. Taylor & Francis, New York, New York.

D. R. J. Moore, W. J. Warren-Hicks, S. Qian, A. Fairbrother, T. Aldenberg, T. Barry, R. Luttik, and H. T. Ratte. Uncertainty Analysis Using Classical and Bayesian Hierarchical Models. 2010. In Application of Uncertainty Analysis to Ecological Risks of Pesticides. Eds. W. J. Warren-Hicks and A. Hart. Taylor & Francis, New York, New York.

Giddings, J. M., Barber, I., Warren-Hicks, W. J. 2008. Comparative aquatic toxicity of the pyrethroid insecticide lambda-cyhalothrin and its resolved isomer gamma-cyhalothrin. Ecotoxicology. Published online at: http://www.springerlink.com/content/e85343g234802606.

Arnold, R. W., Warren-Hicks, W. J. 2007. Assessment of Aquatic Ecological Risk and Site-Specific Criteria of Copper in San Francisco Bay, California, USA. Integrated Environmental Assessment and Management. Vol 3, No. 1, pp. 32 - 48.

Arnold, R. W., Warren-Hicks, W. J. 2007. Probability-Based Estimates of Site-Specific Copper Water Quality Criteria for the Chesapeake Bay, USA. Integrated Environmental Assessment and Management. Vol 3, No. 1, pp. 101 - 117.

Warren-Hicks, W. J., Efroymson, R. A., Newman, J., Strickland, D. 2006. Ecological Risk Assessment: A Framework for Wildlife Assessments At Wind Energy Facilities. National Wind Coordinating Committee, Washington, D. C.

Warren-Hicks, W., B. J. Parkhurst, Butcher, J. B. 2002. Methodology for Aquatic Ecological Risk Assessment. In: Species Sensitivity Distributions in Ecotoxicology. Leo Posthuma, Glenn Suter, Theo Trass. eds. Lewis Publishers, New York. 206p.

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Warren-Hicks, W. J., Carbone, J. P., Havens, P. L. 2002. Using Monte Carlo Techniques To Judge Model Prediction Accuracy: Validation Of The Pesticide Root Zone Model 3.12. Environmental Toxicology and Chemistry. Vol. 21, No. 8, pp. 1570 - 1577.

Carbone, J. P., Havens, P. L., Warren-Hicks, W. J., 2002. Uncertainty Analysis in Model Validation. Environmental Toxicology and Chemistry. Vol. 21, No. 8., pp. 1532 - 1548.

Qian, S., Warren-Hicks, W. J., Keating, J. 2001. A Predictive Model of Mercury Fish Tissue Concentrations for the Southeastern United States. Environmental Science & Technology. Vol. 35, No. 5, 941-947.

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DONALD G. CATANZARO, PHD

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Dr. Catanzaro is a Project Scientist and Project Manager that has over 20 years of experience working in statistics, human and ecological health, internet technologies, and Geographic Information Systems (GIS). I have devoted my career to turning large data systems into information and eventually into knowledge. I have developed skills over the long-term using several different GIS, remote sensing, CAD, and GPS software and hardware systems. Dr. Catanzaro's previous employment has been with County Planning Agencies, Federal Agencies, and private firms where his clients have included Federal, State, Tribal, Local, Non-Government organizations as well as private companies. I have a broad Biogeographical and Computer Science background and am well grounded in data analysis including survival, uni/multi-variate, nonparametric, and spatial statistics. My career has been multi-disciplinary in approach, wide in scope, and international in scale.

I have the ability to move seamlessly between large relational databases (multi- million rows) and several computer languages and have analyzed large datasets such as forest inventory data for bioenergy assessments; risk analysis of invasive species to the Great Lakes based on shipping data and habitat niche models; analysis of NO_2 and SO_2 National Ambient Air Quality Standards (NAAQS) for the EPA; analysis of long term monitoring of air quality monitors within California; creating interactive graphical libraries to explore the scientific literature, and conceptual models of nitrogen and phosphorus flows through ecosystems; analyzing pollution attenuation through ground water with spatial statistics; genetic determinates of Extensively Drug-Resistant Tuberculosis (XDR-TB); and; creating population models using multiple US Census Bureau products. I am also currently investigating the effects of air pollution on TB patients (California and Viet Nam), long-term mortality trends in Moldova TB patients, and the use of Artificial Intelligence (Google's TensorFlow) to detect tuberculosis in chest x-rays.

Education

PhD, Biology, University of Arkansas, 1998
BA, Geography, University of California – Los Angeles, 1991

Additional Training

Human Subjects Training (CITI and NIH)
McGill Infectious Diseases and Global Health (2016)
- Course I: Tuberculosis Research Methods
- Course II: Advanced TB Diagnostics Research

Good Clinical Practice (GCP)
Curry International Tuberculosis Center (2015)
- Course I: Focus on LTBI
- Course II: Tuberculosis Clinical Intensive

Specialized Computer Applications

Microsoft Office
Excel (expert), Word, PowerPoint, Access
Business Intelligence
PowerBI
Relational Databases
MS SQL Server/Azure, MySQL, PostgresSQL, Oracle, Informix

Statistics
R, MatLab/Octave, SAS , SAS JMP, SPLUS
Programming
SQL, Python, Visual Basic for Applications, Java, JavaScript, HTML, XML, Flash / Flex, UNIX
GIS/Remote Sensing
ESRI ArcPro/GIS/View/Info, CAD, GRASS 6.4, ERMapper, GeniePro, PCI, ERDAS

Other Technical Skills

Univariate, Multivariate Parametric and Non-Parametric Statistics, Artificial Intelligence/Machine Learning, Regression, Geostatistics, Time Series, Survival Analysis
Database Theory and Management
Integration of data collection hardware and software - mobile computers, depth sounder, GPS
Remote Sensing Application and Theory (aerial photography and digital systems)

Professional Experience

University of Arkansas, Fayetteville, Department of Biological Sciences
Dates Employed: 2014 - Present

Research Assistant Professor: I am the lead Data Analyst & Statistician for a large group researching various aspects tuberculosis diagnostics and treatment. My core responsibilities includes installing & managing REDCap (a browser-based clinical data system), developing and implementing data capture/entry systems (paper, computer, mobile), and creating web-enabled databases which drive project related analysis. As leader of the Data Core, I develop SQL code (and other languages) to support project management by displaying analytics of disparate datasets and creating unique data visualizations. I have used Artificial Intelligence (Google's TensorFlow) to detect tuberculosis in chest x-rays; combined Python & SQL to ingest data from REDCap to MS SQL Server and display information in MS PowerBI, implemented a bioinformatics pipeline to process whole genome sequencing data; developed SQL code which ingests and processes XML data created by a tuberculosis diagnostic device; performed statistical analysis (e.g. trend, regression) for several scientific papers; served as SQL developer to use the common cellphone to provide a simple/easy way to monitor adherence to anti-tuberculosis therapy; performed spatial analysis combining coccidioidomycosis natural history, epidemiology, and global climate change data to predict areas where coccidioidomycosis may increase over time; and used SQL and R to analyze Arkansas All Payer's Claim Database (APCD) investigating age/gender relationships and nontuberculous mycobacterial infection.

Sustainment & Restoration Services (SRS) / Oneida Total Integrated Enterprises (OTIE)
Dates Employed: Jan 2006 - Present

Landscape Ecologist: I have been both a Project Manager (PM) and Project Scientist (PS) for OTIE for the last 16 years. On work assignments where I was PM, I was responsible for developing work plans and budgets, ensuring the overall quality of project work, supervising work performed by other PS and staff members, writing monthly reports and summaries, and preparing final project report(s). On work assignments where I was a PS, I was responsible for assembling data sources, analyzing spatial and temporal patterns, running statistical analysis, reviewing and writing reports.

Projects I have been involved in over the last 16 years include: providing technical support to the EPA National Center for Environmental Assessment (NCEA) and National Exposure Research Laboratory (NERL) who provide guidance to regions, states and tribes on how tools and science to support implementation of the Clear Water Act & Clean Air Act. Both offices in particular are working to develop metrics that define a relationship between specific ecosystem service and one (or more) aspects of community health.

I have worked with Census 2010, 2000, and 1990 as well as American Community Survey (ACS) data and recreational user data (e.g. USFWS National Survey of Fishing, Hunting, and Wildlife-Associated Recreation).

Selected Project Experience

- **Lyme Disease -** Over three Work Assignments served as the statistical analyst and GIS support for determining the generalized applicability of a model to predict Lyme disease incidence across Maryland and Pennsylvania from landscape variables such as population and forest cover. An online interactive viewer was developed tying ArcGIS for Server Javascript API to logistic regression predictive equations and assisted users as they explore models by the usage of interactive sliders to vary disease rate thresholds and risk probabilities and examine the consequences
- **CADStat** – Served as QA/QC Manager for two EPA Work Assignments to develop CADStat, a menu-drive statistical package of several data visualization and statistical methods. CADStat is currently deployed on EPA's server (http://www.epa.gov/caddis) and is a Java Graphical User Interface to R (R is an open source statistical software). Methods in CADStat include: scatter plots, box plots, correlation analysis, linear regression, quantile regression, conditional probability analysis, and tools for predicting environmental conditions from biological observations
- **CCAT** – I developed an HTML5/Javascript application for the EPA called the Community Cumulative Assessment Tool (CCAT)

which combines EPA's Environmental Justice, Risk Assessment, and Community Involvement concepts to address multiple stressors within the EPA's cumulative risk assessment framework.

- **C/T-FERST** – Performed data development, integration and deployment of the EPA's Community/Tribally-Focused Exposure and Risk Screening Tool (C/T-FERST) which supports EPA's integration with other decision-support tools for communities and tribes. C/T-FERST is intended to assist community partners with the challenge of identifying and prioritizing community environmental health risk issues.

EcoStat, Inc
Dates Employed: Feb 2010 - Present

Statistician Provided data quality, processing and statistical analysis for multiple projects including in the development of Data Quality Objectives (DQOs) for the EPA's NO_2 and SO_2 National Ambient Air Quality Standards (NAAQS). NAAQS are designed to provide requisite protection of public health as appropriate under section 109 of the Clean Air Act (CAA). The interacting effects of precision, bias, and completeness were investigated using hourly measurements at over 300 monitoring stations across the country. Other projects include developing an interactive data exploration tool (using MS Excel) for pesticide risk assessment, data processing and analysis of MTBE contamination of private wells, spatial and time series analysis of pollutant inputs into Puget Sound ,exploratory data analysis and model development between Carbon Dioxide emissions and measurements of other power plant variables.

San Diego State University, Bioinformatics & Medical Informatics Department
Dates Employed: May 2012-May 2013

Adjunct Faculty: Data Core leader, lead statistician, and member of the Leadership Team for a NIH sponsored project to test new genetic-based diagnostics tools to detect XDR-TB (U01-AI082229). The project enrolled over 1,110 subjects in three international sites to investigate common mutations which confer drug-resistance. I provided technical oversight of data collection systems (both web and laptop/netbook based), quality assurance, as well as liaison support between the Health Information Technology Group and the clinical staff.

The complexity of project components required several staff members input into how to most efficiently store, manage, query, analyze, and visualize the large quantity of data collected. I played a major role in many of these activities, using expert knowledge to maintain a high level of data collections efficiency and quality. I provided statistical analysis, geographic analysis, and data visualizations to other project staff working with epidemiological and genetic data.

BioEnergy Systems LLC
1726 N Charlee Fayetteville, Arkansas 72703
Dates Engaged: 2007-2012

As a consultant to BioEnergy Systems, I worked on natural resource evaluations, project site assessments (desk studies), renewable energy systems, and data visualizations of complex issues for clients. I compiled the data to support an assessment of agricultural and forest biomass resources in the mid portion of the Mississippi River Alluvial Valley, an area that included 98 counties in Arkansas, Kentucky, Mississippi, Missouri and Tennessee)

Co-developed a high-resolution user-interactive tool for analyzing biomass feedstock supplies (BioFeedStAT® see http://www.biomass2.com/fsa/fsa.html). The tool is used to determine quantities vs. distances (in 0.5-mile increments -- actual road miles, not air miles) and transport costs of any combination of target feedstocks. Source data for BioFeedStAT® is a combination of large databases housing data from the US Forest Service Forest Inventory Data, USDA Cropland Data Layer, and USDA Census of Agriculture.

US Census Bureau / Census Coverage Measurement, Kansas City Regional Census Center
Dates Employed: May 2009- July 2011

Regional Technician (Grade GG-0301-12): As a Regional Technician for 2010 Census, provided technical assistance to the Kansas City Regional Census Center (KC-RCC) for all five Census Coverage Measurement (CCM) operations. CCM operations have three primary objectives: (1) to inform the public about the quality of the census counts; (2) to help identify sources of error to improve census taking, and (3) to provide alternative counts based on information from the coverage measurement program.

As a Regional Technician, I worked under specific direction from the regional office to provide technical and administrative support for all recruitment, personnel, payroll, field data collection, group quarters, office and evaluation operations, automation activities, postal liaison activities, map/geography problems.

Served as a Master Trainer and trained Field Operation Supervisors, Crew Leaders, and Enumerators in all CCM operations in Arkansas, Oklahoma, Missouri, and Minnesota. I trained over 350 employees in small group settings (classes of 10-20). I served as trouble shooter in all five CCM operations and backfilled Field Operation Supervisors, Crew Leaders, and/or Enumerators when field staff quit or not available to work.

Enercon Services, Inc
Dates Employed: Mar 2006 – May 2007
Project Scientist: Provided training to subordinate employees on how to conduct a Severe Accident Mitigation Alternatives (SAMA) for the Nuclear Regulatory Commission (NRC). Oversaw work of subordinate employees, and performed quality checks to ensure high quality work was submitted.

Provided project work, Quality Assurance, and Technical Review for several different nuclear license renewal applications from Entergy Corporation to the NRC. Project works included using GIS to collect, analyze, and support the writing of reports to support the construction of a SAMA for submittal to the NRC. Used US Census Bureau Summary File (SF) 1 and SF3 (for general and environmental justice populations) and Agricultural Census, and local sources of data (e.g. tourism, tax assessment, population growth) to investigate how a severe accident at a nuclear power plant may affect the surrounding communities.

Quality reviews included ensuring all calculations and methodologies follow NRC guidance, performing independent checks on data, reviewing all written materials and sources to ensure accuracy and veracity.

FTN Associates, LTD
Dates Employed: Oct 2002 – Dec 2005
Landscape Ecologist: Provided GIS, biological and statistical expertise for industrial, governmental, and non-governmental clients for a water resources environmental consulting company. Wrote proposals (technical and cost), analyzed data, wrote monthly and final report(s) and recruited and supervised subordinate employees (as necessary).

Created socio-economic and agricultural datasets (data sources were Census 2000 SF1 and SF3 and Census of Agriculture 1997 and 2002) to support Severe Accident Mitigation Alternatives (SAMA) and NEPA analyses for nuclear power industry; providing global climate change research on coral reefs of American Samoa; used GIS to model a new framework for sustainable water resources management; remote sensing and wildlife assessment for Columbian Sharp-Tailed Grouse; organizing and facilitating a 30 person workshop to address multiple stressors to aquatic ecosystems; synthesizing and reviewing the results of the EPA STAR Ecosystem Indicator Program; conducting literature review and analysis on nitrogen phosphorus-algae dynamics; and used GIS to model pollution attenuation through groundwater.

National Park Service, Virgin Islands / South Florida Cluster – Long Term Ecological Monitoring
Dates Employed: Oct 1999 - Oct 2002

Inventory & Monitoring Coordinator (Grade GS-0401-12): Number of Employees: 3

Budget: $350,000Supervised employees, responsible for purchasing major/minor equipment, develop and tracked

budgets for a brand new Inventory & Monitoring Program. Responsible for developing and implementing a statistically defensible program to inventory and monitor six marine natural resources found in the 98,000 acres of natural resources at three National Park Service (NPS) units: Virgin Islands National Park, Buck Island Reef National Monument, and Dry Tortugas National Park. These six resources were: water quality, coral reefs, seagrass, seabirds, fish, and sea turtles. Infused several technological improvements in the monitoring program which reduced field time and data transcription such as: obtaining remote sensing datasets (multispectral and hyperspectral), creating several park-wide fully functional GIS, using SONAR technology to locate monitoring sites for coral reefs and seagrass beds, standardizing underwater digital photography and videography, use of digital field data recorders, and storage of field data in relational databases. During my tenure, I was able to infuse several technological improvements in the monitoring program which reduced field time and data transcription by at least 30%. Developed and maintain a comprehensive GIS and Relational Database Management System (RDMS) for spatial and biological data to link coral reef, seagrass, fish population, seabird, water quality and sea turtle datasets together into one cohesive unit. Created interactive programs to ensure correct data entry into computerized systems, served as primary statistical consultant for data analysis, and presented results of data analysis to NPS management.

National Park Service
Virgin Islands / S Florida Cluster – Long Term Ecological Monitoring
Dates Employed: Apr 1999 – Oct 1999

Ecologist/Data Manager (Grade GS-0401-11): Primary duties were to develop and maintain a comprehensive Relational Database Management System for spatial and biological data associated with the Virgin Islands-LTEM program. I was responsible for the upkeep of computer systems and linking previously collected datasets together into one cohesive unit. As the lead individual for the VI-LTEM program, I provided oversight for the construction of statistically defensible I & M protocols that are consistent with current policies and guidelines. Hired new employees, tracked budgets and projected budgetary needs into the future. I increased the visibility of the Virgin Islands-LTEM program by increasing communication and information flow to the national NPS I&M Program, higher level management in each park, and division managers within each park.

National Park Service
Prairie Cluster-Long Term Ecological Monitoring Program
Wilson's Creek National Battlefield
Dates Employed: Sep 98 – Apr 99

Ecologist/Data Manager (Grade GS-0401-11 (Term Position)): Primary duties were to develop and maintain a comprehensive Relational Database Management System for spatial and biological data associated with the Prairie Cluster LTEM program. As Data Manager, I met with Principal Investigators which were writing monitoring protocols and worked to standardize data collection procedures while ensuring contracted work fulfilled NPS I&M goals. I constructed digital databases using geographically registered data, analyzed and derived new data themes to interpret long-term monitoring data, ensured that documentation of these datasets was maintained and that long-term archiving, integration, and retrieval of data sets produced by the Prairie Cluster LTEM program and supporting cooperators occurred. I was program liaison with GIS providers to ensure appropriate development of spatial layers and integration of Prairie Cluster LTEM datasets into GIS themes. I provided technical support with respect to accuracy, precision and completeness of all resultant datasets of Prairie Cluster LTEM work. Other duties included interpreting aerial photographs, satellite and other types of data using knowledge of geography, physical and biological resources and wrote a scope of work for an adjacent land use study using historic aerial photographs dating to 1936. I installed and integrated GIS and data management software programs and provided training on new software applications.

Message

From: Cordes, Mary [mary.cordes@chemours.com]
Sent: 5/12/2025 5:55:27 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Abboud, Michael [abboud.michael@epa.gov]; Simon, Robert [robert_simon@americanchemistry.com]
Subject: RE:
Attachments: rhee 2023.pdf

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Hi Jess – sharing another study for you to review.

Thanks,
Mary

From: Cordes, Mary
Sent: Friday, May 9, 2025 1:20 PM
To: kramer.jessical@epa.gov
Cc: Abboud, Michael <abboud.michael@epa.gov>
Subject: FW:

Jess – see attached for study that shows PFOA is non-carcinogenic.

Thanks,
Mary
202-394-4893

From: Gannon, Shawn A <shawn.a.gannon@chemours.com>
Sent: Friday, May 9, 2025 1:18 PM
To: Cordes, Mary <mary.cordes@chemours.com>
Cc: Wellman, Amber D <AMBER.D.WELLMAN@chemours.com>
Subject:

Mary,

One example of a PFOA study that shows a lack of kidney cancer or any other mortality cause.

Shawn

Shawn Gannon, Ph.D., DABT

Toxicologist & Manager, Toxicology and Risk Assessment (TRAC),

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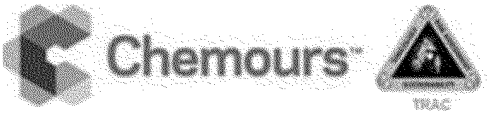

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Full length article

Serum concentrations of per- and polyfluoroalkyl substances and risk of renal cell carcinoma in the Multiethnic Cohort Study

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[b] Department of Epidemiology and Biostatistics, University of California San Francisco, San Francisco, CA, USA
[c] Organic Analytical Toxicology Branch, Division of Laboratory Sciences, National Center for Environmental Health, Centers for Disease Control and Prevention, Atlanta, GA, USA
[d] Heart Disease Phenomics Laboratory, Epidemiology and Community Health Branch, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD, USA
[e] Biostatistics Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institutes of Health, Rockville, MD, USA
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Kidney cancer
Multiethnic cohort

ABSTRACT

Per- and polyfluoroalkyl substances (PFAS) are environmentally persistent organic pollutants detectable in the serum of most U.S. adults. We previously reported a positive association between serum perfluorooctanoate (PFOA) concentrations and risk of renal cell carcinoma (RCC) within the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, comprising predominantly White individuals enrolled in 1993–2001. To extend our investigations to a larger and more racially and ethnically diverse population, we conducted a nested case-control study of serum PFAS concentrations and RCC within the Multiethnic Cohort Study. We measured pre-diagnostic serum concentrations of nine PFAS among 428 RCC cases and 428 individually matched controls. We estimated odds ratios (ORs) and 95 % confidence intervals (CIs) for risk of RCC in relation to each PFAS using conditional logistic regression, adjusting for RCC risk factors and other PFAS. PFOA was not associated with RCC risk overall [doubling in serum concentration, $OR_{continuous} = 0.89$ (95 %CI = 0.67, 1.18)]. However, we observed suggestive positive associations among White participants [2.12 (0.87, 5.18)] and among participants who had blood drawn before 2002 [1.49 (0.77, 2.87)]. Furthermore, higher perfluorononanoate (PFNA) concentration was associated with increased risk of RCC overall [fourth vs. first quartile, OR = 1.84 (0.97, 3.50), $P_{trend} = 0.04$; $OR_{continuous} = 1.29$ (0.97, 1.71)], with the strongest association observed among African American participants [$OR_{continuous} = 3.69$ (1.33, 10.25)], followed by Native Hawaiian [2.24 (0.70, 7.19)] and White [1.98 (0.92, 4.25)] participants. Most other PFAS were not associated with RCC. While PFOA was not associated with RCC risk overall in this racially and ethnically diverse population, the positive associations observed among White participants and those with sera collected before 2002 are consistent with previous PLCO findings. Our study also

Abbreviations: EtFOSAA, 2-N-ethyl-perfluorooctane sulfonamido acetate; MeFOSAA, 2-N-methyl-perfluorooctane sulfonamido acetate; BMI, Body mass index; Cis, Confidence intervals; eGFR, Estimated glomerular filtration rate; IARC, International Agency for Research on Cancer; ICD-O-3, International Classification of Diseases for Oncology Third Revision; LOD, Limit of detection; n-PFOS, Linear perfluorooctane sulfonate; n-PFOA, Linear perfluorooctanoate; MEC, Multiethnic Cohort Study; NCI, National Cancer Institute; NHANES, National Health and Nutrition Examination Survey; NHPI, Native Hawaiians and Pacific Islanders; ORs, Odds ratios; PFAS, Per- and polyfluoroalkyl substances; PFDA, Perfluorodecanoate; PFHxS, Perfluorohexane sulfonate; PFNA, Perfluorononanoate; FOSA, Perfluorooctane sulfonamide; PFOS, Perfluorooctane sulfonate; PFOA, Perfluorooctanoate; PFUnDA, Perfluoroundecanoate; PLCO, Prostate, Lung, Colorectal and Ovarian; QC, Quality control; Sb-PFOA, Sum of branched perfluorooctanoate isomers; Sm-PFOS, Sum of perfluoromethylheptane sulfonic acid isomers.

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provided new evidence of a positive association between PFNA and RCC risk that was strongest in African American participants. These findings highlight the need for additional epidemiologic research investigating PFAS exposures and RCC in large racially and ethnically diverse populations.

1. Introduction

Per- and polyfluoroalkyl substances (PFAS) are a group of synthetic chemicals used since the 1940s in a broad range of industrial and consumer applications, such as nonstick cookware, food packaging, water-resistant fabric, cosmetics, and firefighting foams (Glüge et al., 2020). Despite decreased production of certain PFAS in the United States since the early 2000s, PFAS are highly persistent in the environment and remain ubiquitous contaminants of soil and water around the globe (Buck et al., 2011). Human exposure to PFAS occurs mainly via consumption of contaminated water and food and, to a lesser extent, inhalation of indoor air and dust and dermal contact (Sunderland et al., 2019). Once absorbed, some PFAS can accumulate in the human body over long periods of time, with serum elimination half-lives ranging from 2 to 8 years (Olsen et al., 2007; Li et al., 2018; Li et al., 2022). According to nationally representative data from the National Health and Nutrition Examination Survey (NHANES) between 1999 and 2008, > 95 % of the general U.S. population of 12 years of age or older had detectable concentrations of four major PFAS in their blood, including perfluorooctanoate (PFOA), perfluorooctane sulfonate (PFOS), perfluorohexane sulfonate (PFHxS), and perfluorononanoate (PFNA) (Calafat et al., 2007; Kato et al., 2011). Notably, serum concentrations of several PFAS have been found to differ by race and ethnicity. For example, elevated concentrations of PFOS and PFNA, especially in middle-aged or older populations, have been observed among non-Hispanic Black compared to non-Hispanic White persons in NHANES and other studies (Calafat et al., 2007; Kato et al., 2011; Park et al., 2019; Shearer et al., 2021). Data are more limited for other racial and ethnic groups; however, recent (since 2011) NHANES reports (Centers for Disease Control and Prevention) and a study in midlife women (Park et al., 2019) also reported higher serum PFNA concentrations among Asian American compared to non-Hispanic White individuals.

Given their widespread exposure and high environmental persistence, PFAS have emerged as a major public health concern worldwide, with a growing body of literature linking specific PFAS to adverse health outcomes, including cancer (National Academies of Sciences, Engineering, and Medicine, 2022; Steenland et al., 2020; Steenland and Winquist, 2021). In 2014, the International Agency for Research on Cancer (IARC) classified PFOA—the only PFAS evaluated by IARC to date—as "possibly carcinogenic to humans" (Group 2B) based in part on limited epidemiologic evidence of an association with kidney cancer (Benbrahim-Tallaa et al., 2014; International Agency for Research on Cancer, 2017). This conclusion was mainly drawn from studies that reported higher kidney cancer incidence or mortality among PFOA-exposed workers at a fluoropolymer production plant in West Virginia (Steenland and Woskie, 2012), and those residing in the surrounding communities who were highly exposed to PFOA through contaminated drinking water (Vieira et al., 2013; Barry et al., 2013). More recently, our group conducted the first prospective study to investigate associations between measured pre-diagnostic serum concentrations of PFAS, including PFOA and seven other PFAS, and risk of renal cell carcinoma (RCC; the most common form of kidney cancer) in a cohort with PFAS serum concentrations comparable to those observed in the general U.S. population (Shearer et al., 2021). In that nested case-control study of 324 RCC cases and 324 matched controls (89 % non-Hispanic White) within the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, we observed a statistically significant association between higher serum PFOA concentrations and increased RCC risk, including after adjustment for several other PFAS. We also observed positive associations with RCC risk for PFOS and PFHxS, although those associations were attenuated in mutually adjusted analyses. Importantly, our findings from the PLCO cohort provided evidence in support of PFOA as a renal carcinogen and demonstrated for the first time that general population exposures may contribute to RCC development. The incidence of RCC in the U.S. differs by race and ethnicity, with higher rates of disease in African American and American Indian / Alaskan Native populations than among non-Hispanic White Americans, while Latino and Asian and Pacific Islander populations experience lower rates (National Cancer Institute, 2023). In the current investigation, we sought to replicate our findings from PLCO in a larger and more racially and ethnically diverse population by conducting a nested case-control study to evaluate RCC risk in relation to pre-diagnostic serum concentrations of PFOA, PFOS, PFHxS, and six other PFAS in the Multiethnic Cohort Study (MEC).

2. Methods

2.1. Study population

Details of the MEC study design and data collection procedures have been described previously (Kolonel et al., 2000). Briefly, the MEC is a large racially, ethnically, and socioeconomically diverse prospective cohort of >215,000 men and women aged 45–75 years at baseline (1993–1996) from five different racial and ethnic groups (African Americans, 16 % of participants; Japanese Americans, 26 %; Latinos, 22 %; Native Hawaiians, 6 %; and Whites, 23 %) living in Hawaii and California (primarily Los Angeles County). Each participant completed a self-administered mailed questionnaire that inquired about demographic factors, anthropometric measures, personal behaviors, medical conditions including history of hypertension, diet, and family history of cancer. Assignment of study participants' race and ethnicity was based on their questionnaire responses (Kolonel et al., 2000). Incident cancers were identified through record linkages to the Surveillance, Epidemiology, and End Results Program's Hawaii Tumor Registry and the California State Cancer Registry.

Biospecimen collection in MEC first began in 1994 with cancer case-control studies, where samples were collected from cases after diagnosis and from a representative set of controls. Subsequently, from 2001 to 2006, the prospective MEC biorepository was created by asking surviving cohort members to provide blood and urine specimens (Park et al., 2009). The controls from the earlier studies and participants with sera in the prospective MEC biorepository were eligible for inclusion in the current study. Blood samples were processed within 4 h of collection, and aliquoted into 0.5-mL cryotubes that were stored in the vapor phase of liquid nitrogen (–186 °C). The majority of participants contributing to the biorepository provided fasting blood samples (~90 % for ≥ 10 h). The study was conducted in accordance with the Declaration of Helsinki; participants provided written informed consent for biospecimen collection, and the study protocol was approved by Institutional Review Boards at the University of Southern California and the University of Hawaii. De-identified samples and data were provided to National Cancer Institute (NCI) investigators and designated laboratories under a material transfer agreement between the NCI and the University of Hawaii and the University of Southern California. Analyses conducted by NCI and the designated laboratories did not constitute engagement in human subjects research given the de-identified nature of the transferred data and specimens.

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2.2. Case and control selection

We included all incident cases of RCC with an available pre-diagnostic serum sample that were diagnosed through 2018. Incident RCC cases were defined as the International Classification of Diseases for Oncology, Third Revision (ICD-O-3) code C64.9, with the exclusion of transitional cell carcinomas (ICD-O-3 morphology codes 8120 and 8130). Controls were individually matched to cases with a 1:1 ratio on sex, race and ethnicity, study center (Hawaii, California), age at serum collection (±1 year), date of serum collection (±1 year), time of serum collection (±3 h), and fasting status (0-<6, 6-<8, 8-<10, ≥10 h). Matching criteria were gradually relaxed for a small subset (7 %) of the case-control pairs, with nearly all sets matched within 3 years for both age at serum collection and date of serum collection. Eligible controls were alive and free of RCC as of the age of diagnosis of their matched case. For each case and control, we selected one parent aliquot of serum. In total, 428 RCC cases and 428 controls (n = 856) were included for analysis.

2.3. PFAS and creatinine measurements

We measured serum concentrations of 11 PFAS: perfluorooctane sulfonamide (FOSA), 2-N-methyl-perfluorooctane sulfonamido acetate (MeFOSAA), 2-N-ethyl-perfluorooctane sulfonamido acetate (EtFOSAA), PFHxS, linear PFOS (n-PFOS), sum of perfluoromethylheptane sulfonic acid isomers (Sm-PFOS), linear PFOA (n-PFOA), sum of branched PFOA isomers (Sb-PFOA), PFNA, perfluorodecanoate (PFDA), and perfluoroundecanoate (PFUnDA). The limit of detection (LOD) was 0.1 μg/L for all PFAS; concentrations below the LOD were assigned a value of the LOD/$\sqrt{2}$ (0.071 μg/L). We calculated the concentrations of PFOA and PFOS by summing the concentrations of their respective isomers [i.e., PFOA (n-PFOA and Sb-PFOA) and PFOS (n-PFOS and Sm-PFOS)]. Serum PFAS concentrations were quantified at the Centers for Disease Control and Prevention (CDC, Atlanta, GA) using online solid-phase extraction coupled to high-performance liquid chromatography–isotope dilution-tandem mass spectrometry, as described previously (Kato et al., 2018). Samples from each matched case/control set were placed next to each other within the same batch. To evaluate measurement reproducibility, we included replicate quality control (QC) samples among batches (n = 96; ~11 % of the total number of test samples) from pooled serum from subjects recruited in Hawaii, selected to have similar distributions of race and ethnicity, age, and sex as the cases and controls. The QC samples were coded such that laboratory personnel were blinded to the replicates. All PFAS evaluated in this study had within-batch coefficients of variation ≤ 20 % except PFUnDA (21 %).

To address concerns that kidney function may affect serum PFAS concentrations and could potentially confound or modify the associations with RCC (Shankar et al., 2011; Jain & Ducatman, 2019; Dhingra et al., 2017), we also measured serum creatinine and calculated estimated glomerular filtration rate (eGFR) using the 2021 CKD-EPI creatinine equation (Inker et al., 2021).

2.4. Statistical analysis

As preliminary analyses, we calculated Spearman rank correlations between PFAS concentrations among controls and examined the distributions of participant characteristics by case-control status using chi-squared tests. We also estimated adjusted geometric least-squares mean concentrations of each PFAS across categories of participant characteristics [sex, race and ethnicity, study center, calendar year of blood draw, age at blood draw, fasting status, smoking status at baseline, body mass index (BMI) at or close to time of blood collection, history of hypertension at or close to blood collection, eGFR, and (among female participants) years since menopause] among controls (n = 428) using multivariable linear regression.

For our main analyses, we calculated odds ratios (ORs) and 95 % confidence intervals (CIs) for the risk of RCC in relation to serum concentrations of each PFAS using conditional logistic regression among the matched case-control pairs. PFAS were modeled both as continuous variables (log2-transformed) and across categories defined using quartiles of concentrations among controls as cut-points. For PFAS with ≥ 20 % non-detectable concentrations (EtFOSAA, PFUnDA), we assigned subjects with concentrations below the LOD as the referent group and created categories using control tertiles as cut-points. For FOSA, because 76 % of results were non-detectable, we created a binary variable (non-detectable, detectable) for the analysis. Linear trends across categories of each PFAS (except FOSA) were assessed using a Wald test by modelling within-category median concentrations as a continuous variable. In addition to conditioning on the matched factors, all models were adjusted for established RCC risk factors, including BMI (<18.5, 18.5-<25, 25-<30, ≥30 kg/m^2, missing), eGFR (<60, 60-<90, ≥90 mL/min/1.73 m^2, missing), smoking status (never, former, current, missing), and history of hypertension (yes, no); missing values were assigned as separate categories. To assess independent associations of each PFAS with RCC risk, we performed analyses additionally adjusting for serum concentrations of other PFAS, including those with *a priori* evidence of associations in the PLCO investigation (log2-transformed concentrations of PFOA, PFOS, and PFHxS) (Shearer et al., 2021) and those found to be associated with RCC risk in the current investigation [PFNA (log2-transformed) and FOSA (non-detectable, detectable)].

We also conducted analyses stratified by matching factors [race and ethnicity (African American, Japanese American, Latino, Native Hawaiian, White), sex (male, female), study center (Hawaii, California), calendar year of blood draw (<2002, ≥2002; before and after the phaseout or decreased production of certain PFAS and subsequent declines in concentrations in the general U.S. population (Calafat et al., 2007), age at blood draw (<65, ≥65 years), and fasting status (<10, ≥10 h)], smoking status (never, ever), eGFR (<60, 60-<90, ≥90 mL/min/1.73 m^2), history of hypertension (no, yes), and BMI (<25, 25-<30, ≥30 kg/m^2) and evaluated statistical significance of multiplicative interactions using the Wald test for cross-product model terms. For analyses stratified by non-matching factors (smoking status, eGFR, history of hypertension, and BMI), we broke the matched case-control sets and fit unconditional logistic regression models adjusting for matching factors. We also investigated associations stratified by median years of follow-up (<7, ≥7 years) and restricted to clear cell RCC subtype. As sensitivity analyses, we restricted to RCC cases diagnosed > 2 years after the time of blood draw (376 cases and 376 controls) and participants without any history of cancer prior to blood collection (353 cases and 351 controls). We also repeated analyses restricting to participants with no missing data on BMI, smoking, and/or eGFR (404 cases and 404 controls). Lastly, we conducted analyses restricting to post-menopausal women with > 10 years since menopause at blood collection (127 cases and 133 controls) as menstruation has been related to serum PFAS concentrations. (Rickard et al., 2022) All statistical analyses were performed with SAS software version 9.4 (SAS Institute, Cary, NC) and RStudio Version 1.3.1093 (https://www.rstudio.com/). All statistical tests were two-sided.

3. Results

Selected characteristics of the RCC cases and controls are presented in Table 1. Participants were racially and ethnically diverse (African American 17 %, Japanese American 25 %, Latino 27 %, Native Hawaiian 12 %, White 19 %), with a median age at blood draw of 67 years. The majority of participants were male (63 %), provided serum in 2002 or later (79 %), and had fasted for ≥ 10 h prior to blood collection (85 %). Nearly all female participants (99 %) were post-menopausal at blood collection and 87 % of them became menopausal at least 10 years before blood draw. Cases were more likely to be overweight or obese and have a history of hypertension compared to controls (P = 0.03 and 0.002, respectively). Nearly 30 % of study participants had impaired kidney

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Table 1
Selected characteristics [n (%)] of renal cell carcinoma cases and controls in the Multiethnic Cohort Study.

Characteristic	Controls (n = 428)		Cases (n = 428)		P[a]
Sex					
Male	268	(62.6)	268	(62.6)	—
Female	160	(37.4)	160	(37.4)	
Race and ethnicity					
African American	72	(16.8)	72	(16.8)	—
Japanese American	107	(25.0)	107	(25.0)	
Latino	116	(27.1)	116	(27.1)	
Native Hawaiian	50	(11.7)	50	(11.7)	
White	80	(18.7)	80	(18.7)	
Other[b]	3	(0.7)	3	(0.7)	
Study center					
Hawaii	211	(49.3)	211	(49.3)	—
California	217	(50.7)	217	(50.7)	
Age at blood draw, years					
<60	82	(19.2)	82	(19.2)	—
60 to < 65	92	(21.5)	93	(21.7)	
65 to < 70	91	(21.3)	89	(20.8)	
70 to < 75	86	(20.1)	88	(20.6)	
≥75	77	(18.0)	76	(17.8)	
Calendar year of blood draw					
1994–2001	91	(21.3)	91	(21.3)	—
2002	50	(11.7)	79	(18.5)	
2003	122	(28.5)	112	(26.2)	
2004	106	(24.8)	87	(20.3)	
2005–2006	59	(13.8)	59	(13.8)	
Fasting status, hours					
<10[c]	63	(14.7)	63	(14.7)	—
≥10	365	(85.3)	365	(85.3)	
History of hypertension[d]					
No	229	(53.5)	183	(42.8)	**0.002**
Yes	199	(46.5)	245	(57.2)	
Body mass index[e], kg/m^2					
<18.5	9	(2.1)	2	(0.5)	**0.03**
18.5 to < 25	139	(32.5)	113	(26.4)	
25 to < 30	165	(38.6)	194	(45.3)	
≥30	114	(26.6)	117	(27.3)	
Unknown	1	(0.2)	2	(0.5)	
Cigarette smoking status[e]					
Never	174	(40.7)	188	(43.9)	0.71
Former	181	(42.3)	175	(40.9)	
Current	65	(15.2)	56	(13.1)	
Unknown	8	(1.9)	9	(2.1)	
eGFR, mL/min/1.73 m^2					
<60	116	(27.1)	124	(29.0)	0.85
60-<90	257	(60.0)	244	(57.0)	
≥90	52	(12.1)	57	(13.3)	
Unknown	3	(0.7)	3	(0.7)	

Abbreviations: eGFR, estimated glomerular filtration rate.
Bold indicates statistical significance at P < 0.05.
[a] *P*-value for difference between cases and controls, calculated using chi-squared test for history of hypertension and smoking status and Fisher's exact test for body mass index and eGFR. Not reported for matching factors (sex, race and ethnicity, study center, age at blood draw, calendar year of blood draw, and fasting status).
[b] Includes Chinese, Filipino, Korean and other ethnic groups.
[c] Includes fasting < 10 h or unknown.
[d] Based on information reported at or close to time of blood draw.
[e] Reported at baseline.

function (eGFR < 60 mL/min/1.73 m^2), although no difference between cases and controls was observed.

PFHxS, PFOS, PFOA, and PFNA were detected in ≥ 97 % of participants samples. MeFOSAA, EtFOSAA, PFDA, and PFUnDA had non-detectable concentrations ranging from 15 to 30 %, and the majority of participants had non-detectable FOSA concentrations (76 %). The nine PFAS were moderately correlated with one another in pair-wise comparisons among controls (Supplementary Table S1); some of the strongest correlations were observed between PFNA and PFDA (ρ = 0.84) and PFUnDA (ρ = 0.64), PFOA-PFOS (ρ = 0.61), PFOA-PFNA (ρ = 0.57), and PFOS-PFHxS (ρ = 0.55).

Among controls, we observed that the adjusted geometric least-squares mean concentrations of PFOS, PFNA, PFDA, PFUnDA, and MeFOSAA significantly differed by race and ethnicity (Supplementary Table S2). Compared to White participants, African American and Native Hawaiian participants had higher PFOS, PFNA, PFDA, and MeFOSAA concentrations and Japanese American participants had higher PFNA, PFDA, and PFUnDA concentrations. PFAS concentrations among Latino participants were generally lower than in the other racial and ethnic groups. Concentrations of PFDA and PFUnDA were higher among participants recruited from Hawaii compared to those from California (P = 0.01 and 0.0001, respectively). We observed significant declining patterns of PFOS, MeFOSAA, and EtFOSAA by calendar year of blood draw, while concentrations of PFNA and PFDA increased slightly by calendar year (Supplementary Table S2). We observed higher PFAS concentrations among men in general and particularly for PFHxS (P = 0.003), PFOS (P = 0.02), and MeFOSAA (P = 0.03). In addition, concentrations of most PFAS except PFHxS and EtFOSAA decreased marginally by increasing age at blood draw. PFAS concentrations were similar across categories of eGFR, smoking, BMI, and hypertension.

In this population, PFOA was not associated with RCC risk overall, when serum concentrations were modelled categorically [fourth vs. first quartile, OR_{Q4} = 1.04 (95 % CI = 0.60, 1.81)] or continuously ([doubling in concentration, $OR_{continuous}$ = 0.89 (0.67, 1.18), Table 2]. However, we observed a suggestive positive association among White participants [$OR_{continuous}$ = 2.12 (0.87, 5.18), Table 3; ORs ranging from 2.1 to 3.6 for quartiles 2–4 vs. quartile 1, Supplementary Table S3] and among participants who provided their serum before 2002 [$OR_{continuous}$ = 1.49 (0.77, 2.87)], although differences by race and ethnicity ($P_{interaction}$ = 0.65) and calendar year ($P_{interaction}$ = 0.98) were not statistically significant. We also observed some evidence of heterogeneity across categories of eGFR ($P_{interaction}$ = 0.05), with a suggestive inverse association among those with impaired kidney function ([eGFR < 60, $OR_{continuous}$ = 0.59 (0.34, 1.01)] and non-significant positive associations among those with normal kidney function [e.g., for eGFR ≥ 90, $OR_{continuous}$ = 1.25 (0.39, 4.04); Table 3].

Furthermore, higher PFNA concentrations were associated with increased risk of RCC overall, with a statistically significant exposure–response trend [OR_{Q4} = 1.84 (0.97, 3.50), P_{trend} = 0.04; $OR_{continuous}$ = 1.29 (0.97, 1.71), Table 2], adjusting for RCC risk factors and other PFAS. The strongest association with PFNA was observed among African American participants [$OR_{continuous}$ = 3.69 (1.33, 10.25), Table 3], and we also observed elevated but non-statistically significant risk estimates among Native Hawaiian [$OR_{continuous}$ = 2.24 (0.70, 7.19)] and White [$OR_{continuous}$ = 1.98 (0.92, 4.25)] participants. Positive associations with PFNA were also most apparent among participants with blood drawn in 2002 or later [1.43 (1.01, 2.01); $P_{interaction}$ = 0.25, Table 3], those with blood samples collected < 7 years prior to diagnosis [1.58 (1.04, 2.41); $P_{interaction}$ = 0.86], and those who fasted for ≥ 10 h [1.58 (1.15, 2.17); $P_{interaction}$ = 0.005, Supplementary Table S4]. Patterns of associations with PFNA overall and by race and ethnicity were similar after further adjustment for additional PFAS that were correlated with PFNA concentrations (PFDA and PFUnDA; Supplementary Table S5).

We also observed a positive association for FOSA (detectable vs. non-detectable) overall [OR = 1.78 (1.05, 3.04), Table 2] after adjustment for other PFAS. This association was only evident among women [11.72

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Table 2
Odds ratios (ORs) and 95 % confidence intervals (CIs) evaluating PFAS serum concentrations and risk of renal cell carcinoma in the Multiethnic Cohort Study.

PFAS (μg/L)	N control	N case	OR (95 % CI)[a]	OR (95 % CI)[b]
PFOA[c]				
≤3.27	106	107	1	1
>3.27–4.47	102	99	1.09 (0.73,1.64)	1.26 (0.80,1.97)
>4.47–6.22	113	122	1.05 (0.70,1.56)	1.26 (0.78,2.05)
>6.22	107	100	0.88 (0.58,1.35)	1.04 (0.60,1.81)
P-trend			0.46	0.75
Continuous[d]	428	428	0.87 (0.73,1.05)	0.89 (0.67,1.18)
PFOS[c]				
<16.65	107	118	1	1
16.65-<25.05	107	105	0.90 (0.60,1.35)	1.05 (0.66,1.66)
25.05-<36.40	106	100	0.89 (0.57,1.37)	0.99 (0.58,1.68)
≥36.40	108	105	0.83 (0.53,1.30)	0.93 (0.51,1.72)
P-trend			0.44	0.72
Continuous[d]	428	428	0.92 (0.79,1.07)	0.95 (0.74,1.23)
PFHxS				
<1.6	105	121	1	1
1.6-<2.4	103	116	0.94 (0.64,1.38)	0.97 (0.64,1.49)
2.4-<3.55	113	88	**0.65 (0.44,0.98)**	0.67 (0.43,1.06)
≥3.55	107	103	0.79 (0.52,1.21)	0.84 (0.50,1.41)
P-trend			0.27	0.54
Continuous[d]	428	428	**0.84 (0.74,0.96)**	**0.82 (0.69,0.98)**
PFNA				
≤0.5	121	119	1	1
>0.5–0.8	120	113	0.88 (0.59,1.32)	1.13 (0.70,1.82)
>0.8–1.1	85	78	0.90 (0.57,1.42)	1.24 (0.71,2.16)
>1.1	102	118	1.29 (0.78,2.12)	1.84 (0.97,3.50)
P-trend			0.24	**0.04**
Continuous[d]	428	428	1.03 (0.85,1.24)	1.29 (0.97,1.71)
PFDA				
≤0.1	121	128	1	1
>0.1–0.2	128	101	0.77 (0.52,1.14)	0.91 (0.57,1.46)
>0.2–0.4	106	119	1.15 (0.74,1.79)	1.37 (0.77,2.42)
>0.4	73	80	1.26 (0.75,2.14)	1.42 (0.70,2.89)
P-trend			0.24	0.26
Continuous[d]	428	428	1.05 (0.88,1.24)	1.11 (0.85,1.43)
PFUnDA				
<LOD (non-detectable)	111	130	1	1
0.1–0.2	139	118	0.75 (0.50,1.13)	0.75 (0.48,1.17)
>0.2–0.4	77	66	0.75 (0.43,1.31)	0.79 (0.42,1.48)
>0.4	101	114	1.05 (0.61,1.82)	0.88 (0.45,1.72)
P-trend			0.34	0.80
Continuous[d]	428	428	0.97 (0.84,1.12)	0.90 (0.75,1.08)
MeFOSAA				
≤0.3	117	118	1	1
>0.3–0.6	114	103	0.93 (0.63,1.36)	0.94 (0.64,1.40)
>0.6–1.1	96	104	1.07 (0.71,1.63)	1.13 (0.73,1.74)
>1.1	101	103	1.16 (0.74,1.81)	1.22 (0.76,1.97)
P-trend			0.42	0.34
Continuous[d]	428	428	1.00 (0.88,1.13)	1.00 (0.87,1.14)
EtFOSAA				
<LOD (non-detectable)	100	90	1	1
0.1-<0.3	102	112	1.16 (0.76,1.76)	1.15 (0.75,1.78)
0.3-<0.7	112	104	1.07 (0.66,1.72)	1.12 (0.67,1.86)
≥0.7	114	122	1.35 (0.76,2.37)	1.35 (0.73,2.49)
P-trend			0.34	0.40
Continuous[d]	428	428	1.03 (0.92,1.16)	1.03 (0.90,1.18)

(*continued on next page*)

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Table 2 (*continued*)

PFAS (μg/L)	N control	N case	OR (95 % CI)[a]	OR (95 % CI)[b]
FOSA[c]				
Non-detectable	331	319	1	1
Detectable	95	107	1.58 (0.95,2.60)	**1.78 (1.05,3.04)**

Abbreviations: EtFOSAA, 2-N-ethyl-perfluorooctane sulfonamido acetate; FOSA, perfluorooctane sulfonamide; MeFOSAA, 2-N-methyl-perfluorooctane sulfonamido acetate; PFAS, per- and polyfluoroalkyl substances; PFDA, perfluorodecanoate; PFHxS, perfluorohexane sulfonate; PFNA, perfluorononanoate; PFOA, perfluorooctanoate; PFOS, perfluorooctane sulfonate; PFUnDA, perfluoroundecanoate; eGFR, estimated glomerular filtration rate.
Bold indicates statistical significance at $P < 0.05$.

[a] Analyses were conducted using conditional logistic regression models of matched case-control sets adjusting for smoking status (never, former, current, missing), body mass index (<18.5, 18.5-<25, 25-<30, ≥30 kg/m^2, missing), history of hypertension (yes, no), and eGFR (<60, 60-<90, ≥90 mL/min/1.73 m^2, missing).

[b] Additionally adjusted for serum concentrations of PFOA (log2-transformed), PFOS (log2-transformed), PFHxS (log2-transformed), PFNA (log2-transformed), and FOSA (non-detectable, detectable, missing).

[c] PFOA and PFOS here represent the sum of their corresponding linear and branch isomers.

[d] Continuous odds ratios (95 % confidence intervals) for renal cell carcinoma in relation to a 1-unit increase in serum PFAS concentrations on the log base 2 scale, corresponding to a doubling in analyte concentrations.

[e] FOSA analysis was conducted using 426 cases and 426 controls because of missing FOSA measurements [1 case and 1 control; we additionally excluded their respective matched control (n = 1) and case (n = 1) for conditional logistic regression].

(2.84, 48.38) vs. 1.04 (0.56, 1.94) among men; $P_{interaction} = 0.005$, Table 3]. An inverse association with RCC risk was found for continuous concentrations of PFHxS overall [$OR_{continuous} = 0.82$ (0.69, 0.98), Table 2] and particularly among Latino individuals [0.64 (0.42, 0.99); $P_{interaction} = 0.84$, Table 3] and individuals aged < 65 years at blood draw [0.69 (0.51, 0.94); $P_{interaction} = 0.03$]. Other PFAS were not associated with RCC overall (Table 2), although for PFOS we observed a suggestive positive association in Japanese American participants [$OR_{continuous} = 1.54$ (0.91, 2.62), Table 3] and statistically significant inverse associations among African American [0.40 (0.20, 0.79)] and White [0.36 (0.13, 0.95); $P_{interaction} = 0.18$] participants.

We observed no statistically significant differences in associations by other stratifying factors, including hypertension, smoking status, and BMI (Supplementary Table S4). In addition, we observed similar results in sensitivity analyses restricting to RCC cases diagnosed > 2 years after serum collection, participants without any history of cancer prior to blood collection, participants with no missing data on BMI, smoking, and/or eGFR, and post-menopausal women with > 10 years since menopause at blood collection.

4. Discussion

In this nested case-control study of 428 cases and 428 matched controls from a racially and ethnically diverse population-based cohort from Hawaii and California, we found no association between pre-diagnostic serum PFOA concentrations and RCC risk overall. However, we observed suggestive associations between higher PFOA concentrations and increased RCC risk among White participants and among individuals with pre-diagnostic serum samples collected prior to year 2002; such observations are notable because our previous study within the PLCO cohort consisted of a predominantly non-Hispanic White population enrolled in 1993–2001 (Shearer et al., 2021). In the current study, we also observed a suggestive positive association between serum PFNA concentrations and RCC risk overall, particularly in analyses adjusted for other PFAS. Race and ethnicity-specific analyses for PFNA further revealed a statistically significant positive association with RCC risk among African American participants and positive but non-statistically significant associations among Native Hawaiian and White participants. Furthermore, participants with detectable serum concentrations of FOSA, a precursor of PFOS (Benskin et al., 2009; Xu et al., 2004), had a statistically significantly elevated risk of RCC compared to those with non-detectable FOSA concentrations. In stratified analyses, this association was only apparent in women. Finally, we found an inverse association between continuous serum concentrations of PFHxS and RCC risk overall and no associations overall for PFOS or other PFAS.

Serum concentrations of PFAS among controls in our study, overall and by demographic factors such as sex and age, are generally within the ranges observed in NHANES during a similar time period (Calafat et al., 2007; Kato et al., 2011; Centers for Disease Control and Prevention), suggesting that exposures among MEC participants reflect exposures experienced by the general U.S. population. Consistent with other studies (Calafat et al., 2007; Kato et al., 2011; Park et al., 2019; Shearer et al., 2021; Centers for Disease Control and Prevention), we observed racial and ethnic differences in concentrations of several PFAS, even after accounting for study site and other factors potentially related to PFAS concentrations. Notably, African American and Native Hawaiian participants had the highest concentrations of PFOS, while African American, Japanese American, and Native Hawaiian participants had higher concentrations of PFNA relative to Latino and White participants. Similar to our findings in this older population, elevated concentrations of PFOS and PFNA have also been observed among non-Hispanic Black individuals aged ≥ 55 years compared to non-Hispanic White individuals and Mexican Americans in NHANES (Calafat et al., 2007), and among Black (vs. White) control participants (ages ≥ 55 years) in PLCO (Shearer et al., 2021). Likewise, PFNA concentrations were elevated among Japanese American (vs. White) women in a multiethnic study of middle-aged women across the U.S. (Park et al., 2019) and among Asian Americans (all ethnicities combined) in NHANES (Centers for Disease Control and Prevention). Little is known about PFAS exposure among Native Hawaiian and Pacific Islander (NHPI) populations; the higher concentrations observed among Native Hawaiian participants in our study warrant further investigation in larger samples of this population. Racial and ethnic differences in PFAS concentrations likely reflect differences in sources of exposure, including drinking water supply, dietary consumption (e.g., packaged foods, fish/shellfish), and consumer product use (Park et al., 2019; Boronow et al., 2019; Obeng-Gyasi, 2022; Nelson et al., 2012). Future research investigating race and ethnicity-specific determinants of PFAS concentrations is needed to better understand these disparities and identify potentially modifiable factors for reducing exposure.

The previously observed association between PFOA and RCC risk in the PLCO cohort (Shearer et al., 2021) was not replicated overall in our current investigation within MEC. Differences between these two cohorts, particularly in the racial and ethnic distributions and time periods of blood collection, may have contributed to this discrepancy. While most participants in PLCO were non-Hispanic White (89 %; vs. 6 % Black and 5 % other) (Shearer et al., 2021), the MEC targeted recruitment from five main racial and ethnic groups (African American, Japanese American, Latino, Native Hawaiian, and White) (Kolonel et al., 2000), with Latino and Japanese Americans together comprising ~50 % of all

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participants in this study. Notably, when analyses were restricted to White participants (19 %), we observed a greater than two-fold increase in RCC risk associated with a doubling in serum PFOA concentration; despite a lack of statistical significance, the magnitude of this association is similar, and even slightly stronger, compared to that in PLCO (OR = 1.7) (Shearer et al., 2021). In contrast, we found no evidence of an association among each of the other racial and ethnic groups. Racial and ethnic variations in exposure sources and pathways could have played a role in the RCC association, with higher serum PFOA concentrations noted among non-Hispanic White compared to other groups in several studies (Kato et al., 2011; Park et al., 2019; Boronow et al., 2019); however, our data did not reveal such a difference. To our knowledge, this was the first study to evaluate the PFOA–RCC association by race and ethnicity and among non-White individuals. Additional research in both White and other specific racial and ethnic groups may help clarify whether this association is most relevant among White individuals and whether the results are generalizable to other populations. Furthermore, nearly 80 % of participants in this study had blood drawn in 2002 or

Table 3
Odds ratios (ORs)[a] and 95 % confidence intervals (CIs) evaluating PFAS serum concentrations and risk of renal cell carcinoma stratified by selected characteristics in the Multiethnic Cohort Study.

Characteristic	N controls	N cases	PFOA[b]	PFOS[b]	PFHxS	PFNA	FOSA
All	428	428	0.89 (0.67,1.18)	0.95 (0.74,1.23)	**0.82 (0.69,0.98)**	1.29 (0.97,1.71)	**1.78 (1.05,3.04)**
Race and ethnicity							
African American	72	72	1.01 (0.51,1.98)	**0.40 (0.20,0.79)**	0.70 (0.38,1.31)	**3.69 (1.33,10.25)**	1.05 (0.26,4.19)
Japanese	107	107	1.00 (0.47,2.13)	1.54 (0.91,2.62)	0.69 (0.47,1.01)	0.82 (0.41,1.61)	2.28 (0.56,9.29)
Latino	116	116	1.04 (0.53,2.03)	1.30 (0.68,2.49)	**0.64 (0.42,0.99)**	1.03 (0.56,1.89)	2.05 (0.63,6.66)
Native Hawaiian	50	50	0.57 (0.21,1.55)	0.59 (0.20,1.73)	1.05 (0.59,1.88)	2.24 (0.70,7.19)	6.69 (0.86,51.9)
White	80	80	2.12 (0.87,5.18)	**0.36 (0.13,0.95)**	0.83 (0.56,1.23)	1.98 (0.92,4.25)	1.35 (0.38,4.83)
P-interaction[c]			0.65	0.18	0.84	0.96	0.81
Sex							
Male	268	268	1.05 (0.72,1.53)	0.94 (0.67,1.34)	0.80 (0.64,1.02)	1.22 (0.84,1.76)	1.04 (0.56,1.94)
Female	160	160	0.67 (0.39,1.12)	0.95 (0.60,1.49)	0.80 (0.58,1.09)	1.59 (0.96,2.63)	**11.72 (2.84,48.38)**
P-interaction[c]			0.65	0.89	0.97	0.81	**0.005**
Study center							
Hawaii	211	211	0.96 (0.61,1.49)	0.92 (0.63,1.36)	0.88 (0.70,1.11)	1.31 (0.88,1.95)	1.65 (0.79,3.47)
California	217	217	0.88 (0.60,1.31)	0.94 (0.65,1.35)	**0.75 (0.56,0.99)**	1.31 (0.86,2.00)	1.97 (0.89,4.34)
P-interaction[c]			0.29	0.41	0.17	0.55	0.78
Calendar year of blood draw[d]							
<2002	90	90	1.49 (0.77,2.87)	0.77 (0.40,1.48)	0.67 (0.42,1.06)	0.89 (0.49,1.62)	1.06 (0.36,3.08)
≥2002	336	336	0.80 (0.56,1.13)	0.96 (0.73,1.28)	0.85 (0.70,1.03)	**1.43 (1.01,2.01)**	**2.48 (1.19,5.16)**
P-interaction[c]			0.98	0.52	0.42	0.25	0.17
Age at blood draw[d], years							
<65	170	170	0.84 (0.51,1.41)	0.97 (0.59,1.57)	**0.69 (0.51,0.94)**	1.22 (0.72,2.07)	**2.84 (1.01,8.04)**
≥65	249	249	0.92 (0.63,1.33)	0.94 (0.68,1.29)	0.95 (0.76,1.19)	1.30 (0.91,1.84)	1.51 (0.77,2.96)
P-interaction[c]			0.32	0.30	**0.03**	0.28	0.88
Years of follow-up							
<7	206	206	0.86 (0.57,1.31)	0.74 (0.52,1.05)	0.88 (0.69,1.13)	**1.58 (1.04,2.41)**	**2.73 (1.19,6.30)**
≥7	222	222	0.91 (0.60,1.37)	1.28 (0.84,1.94)	**0.73 (0.56,0.96)**	1.11 (0.75,1.64)	1.26 (0.61,2.61)
P-interaction[c]			0.66	0.23	0.85	0.86	0.41
eFER[e] mL/min/1.73 m^2							
<60	116	124	0.59 (0.34,1.01)	0.97 (0.58,1.64)	0.93 (0.68,1.27)	1.53 (0.90,2.59)	1.73 (0.84,3.57)
60-<90	257	244	1.11 (0.77,1.60)	0.97 (0.68,1.38)	0.82 (0.65,1.03)	**1.43 (1.03,1.97)**	1.19 (0.72,1.96)
≥90	52	57	1.25 (0.39,4.04)	0.51 (0.20,1.35)	0.56 (0.26,1.20)	1.53 (0.53,4.42)	2.02 (0.50,8.26)
P-interaction[c]			0.05	0.13	0.10	0.54	0.88

Abbreviations: eGFR, estimated glomerular filtration rate, FOSA, perfluorooctane sulfonamide; PFAS, per- and polyfluoroalkyl substances; PFHxS, perfluorohexane sulfonate; PFNA, perfluorononanoate; PFOA, perfluorooctanoate; PFOS, perfluorooctane sulfonate.
Bold indicates statistical significance at $P < 0.05$.

[a] Unless otherwise specified, analyses were conducted using conditional logistic regression models of matched case-control sets adjusting for smoking status (never, former, current, missing), body mass index (<18.5, 18.5-<25, 25-<30, ≥30 kg/m^2, missing), history of hypertension (yes, no), eGFR (<60, 60-<90, ≥90 mL/min/1.73 m^2, missing), PFOA (log2-transformed), PFOS (log2-transformed), PFHxS (log2-transformed), PFNA (log2-transformed), FOSA (non-detectable, detectable, missing). Continuous odds ratios (95 % confidence intervals) for renal cell carcinoma in relation to a 1-unit increase in serum PFAS concentrations on the log base 2 scale, corresponding to a doubling in analyte concentrations. For FOSA analysis, ORs for detectable FOSA vs. non-detectable FOSA are presented.

[b] PFOA and PFOS here represent the sum of their corresponding linear and branch isomers.

[c] P-value for multiplicative interaction evaluated using the Wald test for a cross-product term between PFAS and stratifying factor.

[d] For analysis of calendar year of blood draw and age at blood draw, unmatched sets were excluded from the analysis (n = 4 and n = 18, respectively).

[e] Analyses were conducted using unconditional logistic regression models adjusting for matching factors [sex, race and ethnicity (African American, Japanese, Latino, Native Hawaiian, White, other), study center (Hawaii, California), calendar year of blood draw (1994–2001, 2002, 2003, 2004, 2005–2006), age at blood draw (<60, 60-<65, 65-<70, 70-<75, ≥75 years), fasting status (≥10 hours, <10 hours or missing)], smoking status (never, former, current, missing), body mass index (<18.5, 18.5-<25, 25-<30, ≥30 kg/m^2, missing), history of hypertension (yes, no), eGFR (<60, 60-<90, ≥90 mL/min/1.73 m^2, missing), PFOA (log2-transformed), PFOS (log2-transformed), PFHxS (log2-transformed), PFNA (log2-transformed), and FOSA (non-detectable, detectable, missing).

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later (i.e., after the phaseout of certain PFAS), which likely explains the generally lower PFAS concentrations than those observed in PLCO. In fact, although suggestive, our finding for PFOA and RCC risk among those with sera collected before 2002 is consistent with the association observed in PLCO (Shearer et al., 2021). In addition to the generally higher serum PFOA concentrations that were observed in the general U. S. population during this time period (Calafat et al., 2007), it is possible that the measured PFOA concentrations among these participants in our study could also reflect more stable estimates of longer-term PFOA exposure relative to those with later serum collections when PFOA concentrations were declining in the U.S. population overall. Future studies that can evaluate associations between PFOA and RCC in populations with a wider range of serum concentrations and with exposures assessed during different secular time periods may help to clarify these relationships. Another difference between the MEC and PLCO study populations is the higher prevalence of eGFR < 60 in MEC compared with PLCO (28 % vs. 7 %), which may be attributable in part to the older age at blood draw in MEC than PLCO ($\geq$ 65 years: 59 % vs. 36 %, respectively). We note that there was some evidence of heterogeneity in our findings for PFOA by eGFR category, with a suggestive inverse association among participants with eGFR < 60 and non-significant positive associations in those with higher eGFR.

Our investigations within the PLCO (Shearer et al., 2021) and MEC cohorts are, to our knowledge, the only studies to date to assess directly measured serum PFOA (and other PFAS) concentrations in relation to kidney cancer risk in the general population. Other epidemiologic studies, including those cited in IARC's previous evaluation of PFOA, have been conducted in occupational settings or in highly exposed communities (Steenland & Winquist, 2021; International Agency for Research on Cancer, 2017; Bartell & Vieira, 2021). In a study of workers from a PFOA-producing chemical plant in West Virginia, an excess in deaths from kidney cancer was observed among those with high model-estimated cumulative serum PFOA concentrations (Steenland & Woskie, 2012), whereas another occupational cohort study in Minnesota found no evidence of elevated kidney cancer mortality or incidence among workers highly exposed to ammonium perfluorooctanoate (ammonium salt of PFOA), estimated using air monitoring data (Raleigh et al., 2014). Two studies that included partially overlapping populations were conducted among residents of Mid-Ohio Valley communities exposed to PFOA-contaminated drinking water; both studies reported increased kidney cancer risk associated with higher estimated PFOA serum concentrations, which were predicted using historical PFOA emission data, residential history, and drinking water source and consumption patterns (Vieira et al., 2013; Barry et al., 2013). Taken together, several epidemiologic studies of populations that have experienced relatively high exposures to PFOA support an association between PFOA and RCC risk, and the evidence from studies measuring PFAS concentrations comparable to concentrations observed in the general population is limited to PLCO and the current study and warrants additional research. Additionally, as all previous studies were conducted in populations consisting largely of non-Hispanic White individuals, associations in non-White populations need to be further investigated.

Potential mechanisms through which PFOA may contribute to RCC development include induction of oxidative stress, alterations in inflammatory pathways, suppression of immune function, and modulation of receptor-mediated activity (International Agency for Research on Cancer, 2017; Stanifer et al., 2018; Temkin et al., 2020; Liu et al., 2023). In particular, evidence from human cells *in vitro* and animal experiments suggests that PFOA can promote activation of peroxisome proliferator-activated receptor alpha (International Agency for Research on Cancer, 2017; Stanifer et al., 2018), a nuclear receptor protein involved in lipid metabolism and oxidative stress pathways and has been implicated in nephrotoxicity and renal carcinogenesis (Gao & Gu, 2022; Abu Aboud et al., 2013; Abu Aboud et al., 2015). Moreover, PFOA exposure has been shown to induce renal tubular epithelial hypertrophy or hyperplasia and increased kidney weights in rodent models (Stanifer et al., 2018).

Our study provided novel evidence of a positive association between PFNA and RCC risk, which had the largest effect estimates among African American participants, followed by Native Hawaiian and White participants. This study is the first to present results of PFNA-RCC relationships stratified by race and ethnicity, with statistically significant or suggestive associations observed in both White and non-White individuals. Our previous investigation in PLCO found a suggestive positive association for PFNA (doubling in serum concentration, OR = 1.19, 95 % CI = 0.91, 1.55), although the observed association became null after adjusting for other PFAS (Shearer et al., 2021). Compared to results in PLCO, we observed a stronger association with PFNA in White participants (doubling in serum concentration, OR = 1.98, 95 % CI = 0.92, 4.25), even after adjusting for other PFAS. No other previous studies have examined PFNA-RCC relationships using pre-diagnostic serum samples in the general population. In analyses stratified by calendar year of blood draw, we only observed associations among participants with blood drawn in 2002 or later; this is notable because of the observed increase in PFNA concentrations in the general U.S. population during this time period that was also apparent in our study population (Calafat et al., 2007; Nelson et al., 2012). The association with RCC was also more apparent among cases diagnosed within 7 years of follow-up; whether this reflects PFNA exposure during an etiologically relevant time period for RCC development is unclear, and as such confirmation of these findings for PFNA is needed. PFNA is a suspected genotoxic carcinogen that induces DNA damage. *In vitro* studies reported that exposure to PFNA induced high levels of 8-hydroxy-2-deoxyguanosine, a biomarker of oxidative DNA damage, in human lymphoblastoid cells and increased DNA strand breaks in human hepatoma cells (Yahia et al., 2016; Eriksen et al., 2010; Wielsøe et al., 2015). Some experimental studies reported toxicologic effects of PFNA on kidney health. An animal study of rats demonstrated that prenatal exposure to PFNA resulted in lower renal nephron endowment and elevated blood pressure in offspring (Rogers et al., 2014). Another animal study of male rats observed altered blood plasma levels of diacylglycerols, phosphatidylcholines, and cholesterol derivatives (Skov et al., 2015).

We observed a positive association with RCC for FOSA, which was not measured in the earlier PLCO study. However, this association should be interpreted cautiously given the large proportion of non-detectable concentrations (76 %) and the heterogeneity in effect size in sex-stratified analyses. Notably, serum concentrations of FOSA, a precursor to PFOS, are no longer measured in NHANES because of the high proportion of non-detectable results since the 2003–2004 NHANES cycle (Centers for Disease Control and Prevention), suggesting that FOSA is no longer detected in the majority of the general U.S. population.

We observed an unexpected inverse association between serum PFHxS concentrations and RCC risk, overall and with similar patterns across most racial and ethnic groups. Additionally, while PFOS was not associated with RCC risk overall in our study, statistically significant inverse associations were observed among African American and White participants. Secular trends of declining serum concentrations of PFHxS and PFOS have been observed in the general U.S. population since the early 2000s (Calafat et al., 2007), and concentrations of these PFAS were lower among participants in this study compared with those in PLCO and other studies in highly exposed communities (National Academies of Sciences, Engineering, and Medicine, 2022; Agency For Toxic Substances and Disease Registry). There is limited and inconsistent epidemiologic evidence for the associations of PFHxS and PFOS with kidney cancer risk. In the PLCO cohort, positive associations with RCC risk were observed for both PFHxS and PFOS (doubling in serum concentration, ORs = 1.27 and 1.39, respectively); however, they were attenuated and lost statistical significance in analyses adjusted for other PFAS (Shearer et al., 2021). More recently, in a large Swedish cohort study of individuals who lived in Ronneby, a municipality whose drinking water supplies were historically contaminated with PFAS (predominantly

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PFOS and PFHxS) from firefighting foams used at a nearby military airfield, a moderately increased risk of kidney cancer was observed among those who resided in contaminated (vs. uncontaminated) areas (Li et al., 2022). In another study of three Australian communities exposed to PFOS and PFHxS through firefighting foams, elevated incidence of kidney cancer relative to an external comparison population was observed in one but not the other two communities (Law et al., 2023). In light of these findings and mechanistic studies supporting potential roles of PFOS and PFHxS in kidney health and carcinogenesis (e.g., PFOS-induced endothelial permeability through actin filament remodeling) (Stanifer et al., 2018; Temkin et al., 2020; Qian et al., 2010), our findings may be attributable to differences in the magnitude of exposure to these PFAS during etiologically relevant time periods in our study compared with prior studies, or they could also be due to chance.

A strength of this study is that we were able to evaluate the relationship between PFAS and RCC risk in a cohort with greater racial and ethnic diversity than in previous studies, and our investigation included populations that have been understudied with respect to the health effects of PFAS exposures; there is limited epidemiologic evidence related to PFAS and cancer risk in non-White individuals, particularly NHPI and Asian Americans. In addition, NHANES biomonitoring data do not provide PFAS concentrations for NHPI, although information among Asian Americans has been added since the 2011 survey (Centers for Disease Control and Prevention). Other study strengths include our use of pre-diagnostic serum PFAS concentrations, a direct assessment of exposure to specific PFAS, and analyses of individual PFAS, with and without adjustment for other PFAS. We also measured serum creatinine to adjust for kidney function (eGFR) in the analyses. This study also had some limitations. Our analyses stratifying by racial and ethnic groups had limited statistical power. We did not correct for multiple comparisons given *a priori* evidence of associations for some PFAS in previous studies; however, findings due to chance cannot be ruled out, and the associations observed in certain subgroups, particularly those defined by race and ethnicity, require confirmation in future studies. Another limitation is the reliance on PFAS concentrations measured from a single point in time for exposure assessment. In an investigation of intra-individual variability in PFAS concentrations within PLCO (Rhee et al., 2023) using serial samples (baseline, one and five years after baseline), concentrations of most PFAS were consistent (intraclass correlation coefficient > 0.7), suggesting that single-serum measurements are informative surrogates of exposure status across several years. Since nearly all female participants in our study were post-menopausal at blood draw, our findings may not be generalizable to pre-menopausal women whose serum PFAS concentrations are more likely to be affected by menstrual and reproductive factors (Rickard et al., 2022). Lastly, although our analyses adjusted for eGFR as a marker of kidney function, we did not have data on urine or serum albumin levels and were not able to take albuminuria into account. Albuminuria has been associated with lower serum PFAS concentrations, as well as an increased risk of some cancers, possibly including kidney cancer (Jain & Ducatman, 2019; Mok et al., 2020; Jørgensen et al., 2008; Whittemore et al., 1985; Luo et al., 2023). However, it has been reported that the prevalence of albuminuria is higher among individuals with eGFR < 60 compared to those with eGFR ≥ 60 (33 % and 8 %, respectively), and most participants in our study had eGFR ≥ 60 (The United States Renal Data System, 2022). As such, the impact of the lack of adjustment for albuminuria was likely minimal, in particular for those with no evidence of diminished kidney function. We might expect any potential underestimation of true associations between PFAS and RCC to be most apparent among those with low eGFR, as was observed in our stratified analyses of PFOA.

5. Conclusions

In this large nested-case control study of serum PFAS and RCC risk in a racially and ethnically diverse population, PFOA was not associated with RCC risk overall, although we found suggestive positive associations among White participants and those who had blood drawn before 2002, which are consistent with our previous findings in PLCO. We also provided new evidence of a positive association between PFNA and RCC risk, which was strongest in African American participants followed by Native Hawaiian and White participants. Our findings demonstrate the importance for epidemiologic studies to be more inclusive of non-White participants in order to better understand differences in PFAS exposures and their relationships with cancer risk in various racial and ethnic groups.

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Jongeun Rhee: Conceptualization, Methodology, Formal analysis, Writing – original draft. **Vicky C. Chang:** Methodology, Formal analysis, Writing – original draft. **Iona Cheng:** Data curation, Methodology, Writing – review & editing. **Antonia M. Calafat:** Data curation, Methodology, Writing – review & editing. **Julianne Cook Botelho:** Data curation, Methodology, Writing – review & editing. **Joseph J. Shearer:** Writing – review & editing. **Joshua N. Sampson:** Writing – review & editing. **Veronica Wendy Setiawan:** Writing – review & editing. **Lynne R. Wilkens:** Data curation, Methodology, Writing – review & editing. **Debra T. Silverman:** Writing – review & editing. **Mark P. Purdue:** Methodology, Supervision, Writing – review & editing. **Jonathan N. Hofmann:** Conceptualization, Methodology, Supervision, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

Acknowledgement

We acknowledge Laura Bowen and Nathan Appel from Information Management Services (IMS), Inc for their support in data management and programming and Anne Tome from the University of Hawaii Cancer Center for her assistance in sample selection and data curation. We also acknowledge the technical assistance of Kayoko Kato, Kendra Hubbard, Edgardo Lobo, Bianca Smith, and Denise Tevis (CDC, Atlanta, GA) in measuring the serum PFAS concentrations and Venkata Sabbisetti and Todd Valerius (Canary Biosciences LLC, Boston MA) in measuring serum

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creatinine concentrations.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.envint.2023.108197.

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Message

From: Tracy Mehan [tmehan@awwa.org]
Sent: 5/16/2025 5:29:19 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Voyles, Travis [voyles.travis@epa.gov]; David LaFrance [dlafrance@awwa.org]; dobbins@amwa.net; svia@awwa.org; hartnett [hartnett@amwa.net]; Corinne Snow (csnow@velaw.com) [csnow@velaw.com]
Subject: Re: PFAS and LCRI-Request for meetings

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Jess,

First, I think we just wanted to find out where you were going and how you were going to do it.

Some of us were working assumption that somehow the PFAS case would get bifurcated with the contested parts going forward, the HI being remanded/vacated. But that is rank speculation.

Certainly, if there was serious consideration of a global settlement, that would be a conversation, very much worth having. Thanks.

LCRI is another matter. Thanks, again.

Tracy

Sent from my Verizon, Samsung Galaxy smartphone
Get Outlook for Android

From: Kramer, Jessica L. <kramer.jessical@epa.gov>
Sent: Friday, May 16, 2025 1:05:19 PM
To: Tracy Mehan <tmehan@awwa.org>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net <dobbins@amwa.net>; Steve Via <SVia@awwa.org>; hartnett <hartnett@amwa.net>; Corinne Snow (csnow@velaw.com) <csnow@velaw.com>
Subject: RE: PFAS and LCRI-Request for meetings

I have a quick follow-up question related to the meeting request.

Can you please clarify whether any or part of the intent of this meeting would be to discuss potential resolution to any or all of the ongoing litigation related to PFAS or the LCRI?

From: Tracy Mehan <tmehan@awwa.org>
Sent: Friday, May 16, 2025 12:47 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net; svia@awwa.org; hartnett <hartnett@amwa.net>; Corinne Snow (csnow@velaw.com) <csnow@velaw.com>
Subject: Re: PFAS and LCRI-Request for meetings

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Thanks, Jess.

Standing by.

Tracy

Sent from my Verizon, Samsung Galaxy smartphone
Get Outlook for Android

From: Kramer, Jessica L. <kramer.jessical@epa.gov>
Sent: Friday, May 16, 2025 12:40:10 PM
To: Tracy Mehan <tmehan@awwa.org>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net <dobbins@amwa.net>; Steve Via <SVia@awwa.org>; hartnett <hartnett@amwa.net>; Corinne Snow (csnow@velaw.com) <csnow@velaw.com>
Subject: RE: PFAS and LCRI-Request for meetings

Hey Tracy,

Thanks for reaching out. Yes, due to significant outreach from key stakeholders, including almost all of the water associations representing drinking water systems across the country, as well as in response to the significant Congressional interest the Administrator and I have received, we were excited to announce our intent to extend the compliance deadlines for PFOA and PFOS earlier this week.

I've consulted with OGC leadership here and due to the ongoing litigation, I will need to have additional internal conversations about my ability to meet on the specific topics you've raised at this time and, additionally, who would need to be party to those conversations if they occur.

With respect to conversations about the Hazardous Index, the agency looks forward to engaging with all stakeholders as we work through the rulemaking process.

Thanks again for reaching out!

Jess

From: Tracy Mehan <tmehan@awwa.org>
Sent: Friday, May 16, 2025 12:01 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net; svia@awwa.org; hartnett <hartnett@amwa.net>; Corinne Snow (csnow@velaw.com) <csnow@velaw.com>
Subject: PFAS and LCRI-Request for meetings

[redacted] **Caution:** This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Dear Jess,

Thank you for your positive response to my letter requesting the two-year extension on PFAS compliance and the decision on the Hazardous Index. Notwithstanding the remaining issues on PFOA and PFAS, these are very positive developments for which AWWA and AMWA are most grateful.

I realize that your schedule is extremely crowded, but I wanted to enquire if we could get on your calendar for what is probably two different meetings, depending on your preference.

The first would be on the path forward to implement OW's recent decision on the Hazardous Index vis-à-vis the rulemaking and the judicial process. AMWA and AWWA would participate if that is agreeable.

The second meeting would be on the LCRI and the litigation pertaining to it. AWWA would be pleased to include AMWA, if Tom is so inclined, despite the fact they are not a party to that litigation.

I would leave it to you to decide if DOJ should be a part of either or both meetings.

Of course, if you wish to combine the two into one meeting, we are fine with that. Either way, thank you for your consideration.

Sincerely,

Tracy

G. Tracy Mehan, III
Executive Director, Government Affairs
American Water Works Association
703-850-9401 (cell)

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Message

From: Tracy Mehan [tmehan@awwa.org]
Sent: 5/16/2025 4:44:24 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Voyles, Travis [voyles.travis@epa.gov]; David LaFrance [dlafrance@awwa.org]; dobbins@amwa.net; svia@awwa.org; hartnett [hartnett@amwa.net]; Corinne Snow (csnow@velaw.com) [csnow@velaw.com]
Subject: RE: PFAS and LCRI-Request for meetings

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Thanks, Jess.

Standing by.

Tracy

From: Kramer, Jessica L. <kramer.jessical@epa.gov>
Sent: Friday, May 16, 2025 12:40 PM
To: Tracy Mehan <tmehan@awwa.org>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net; Steve Via <SVia@awwa.org>; hartnett <hartnett@amwa.net>; Corinne Snow (csnow@velaw.com) <csnow@velaw.com>
Subject: RE: PFAS and LCRI-Request for meetings

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Thanks again for reaching out!

Jess

From: Tracy Mehan <tmehan@awwa.org>
Sent: Friday, May 16, 2025 12:01 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net; svia@awwa.org; hartnett <hartnett@amwa.net>; Corinne Snow (csnow@velaw.com) <csnow@velaw.com>
Subject: PFAS and LCRI-Request for meetings

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Sincerely,

Tracy

G. Tracy Mehan, III
Executive Director, Government Affairs
American Water Works Association
703-850-9401 (cell)

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Message

From: Brooks, Wes [Brooks.Wes@epa.gov]
Sent: 5/20/2025 2:39:25 AM
To: Risley, David [Risley.David@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Bender, Emily [Bender.Emily@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]
Subject: RE: GRIST MEDIA QUERY - DEADLINE MAY 19: Press request re: PFAS drinking water standards

Ex. 5 Deliberative Process (DP)

Best regards,
Wes

From: Risley, David <Risley.David@epa.gov>
Sent: Monday, May 19, 2025 9:44 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Bender, Emily <Bender.Emily@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Brooks, Wes <Brooks.Wes@epa.gov>
Subject: FW: GRIST MEDIA QUERY - DEADLINE MAY 19: Press request re: PFAS drinking water standards

Jess –
We have a press inquiry from Grist on the PFAS MCL announcement. We have a proposed response, below with an optional addition if we want to be a little more forward leaning (as the Administrator has been). Please let us know what you think, especially if you like the optional addition or not.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

Message

From: Snow, Corinne [csnow@velaw.com]
Sent: 5/19/2025 7:18:43 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: David LaFrance [dlafrance@awwa.org]
Subject: RE: PFAS and LCRI-Request for meetings

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

I'm so sorry I missed you. I tried to back and I'm free the rest of the day.

Corinne Snow
Counsel
Vinson&Elkins
E csnow@velaw.com
W +1.212.237.0157
2200 Pennsylvania Avenue NW
Suite 500 West
Washington, DC 20037
Vcard | Bio | velaw.com

From: Kramer, Jessica L. <kramer.jessical@epa.gov>
Sent: Monday, May 19, 2025 1:36 PM
To: Snow, Corinne <csnow@velaw.com>
Cc: David LaFrance <dlafrance@awwa.org>
Subject: RE: PFAS and LCRI-Request for meetings

[EXTERNAL]

Hey Corinne,

I just left you a voicemail and would appreciate a call back when you have a minute. I just wanted to flag something for you regarding the chain of emails below.

My number is 202-766-4632.

Thanks so much!

Jess

From: Snow, Corinne <csnow@velaw.com>
Sent: Friday, May 16, 2025 2:34 PM
To: Tracy Mehan <tmehan@awwa.org>; Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net; svia@awwa.org; hartnett <hartnett@amwa.net>
Subject: RE: PFAS and LCRI-Request for meetings

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Jess,

Just to add on to Tracy's message, I think we are trying to better understand the nuts and bolts of how EPA plans to implement the announcement so we can decide what that means in terms of the litigation. I know it's never easy to coordinate many schedules, but it might be most efficient to have OGC and DOJ present at the meeting so we don't end up playing a long game of telephone.

Thank you again for making time to look at this issue in your busy schedule.

Corinne Snow
Counsel
Vinson&Elkins
E csnow@velaw.com
W +1.202.639.6622
2200 Pennsylvania Avenue NW
Suite 500 West
Washington, DC 20037
Vcard | Bio | velaw.com

From: Tracy Mehan <tmehan@awwa.org>
Sent: Friday, May 16, 2025 1:52 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net; Steve Via <SVia@awwa.org>; hartnett <hartnett@amwa.net>; Snow, Corinne <csnow@velaw.com>
Subject: RE: PFAS and LCRI-Request for meetings

[EXTERNAL]

A discussion of a global settlement of the LCRI litigation would also be worthwhile. Thanks.

Tracy

From: Tracy Mehan <tmehan@awwa.org>
Sent: Friday, May 16, 2025 1:29 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net; Steve Via <SVia@awwa.org>; hartnett <hartnett@amwa.net>; Corinne Snow (csnow@velaw.com) <csnow@velaw.com>
Subject: Re: PFAS and LCRI-Request for meetings

Jess,

First, I think we just wanted to find out where you were going and how you were going to do it.

Some of us were working assumption that somehow the PFAS case would get bifurcated with the contested parts going forward, the HI being remanded/vacated. But that is rank speculation.

Certainly, if there was serious consideration of a global settlement, that would be a conversation, very much worth having. Thanks.

LCRI is another matter. Thanks, again.

Tracy

Sent from my Verizon, Samsung Galaxy smartphone
Get Outlook for Android

From: Kramer, Jessica L. <kramer.jessical@epa.gov>
Sent: Friday, May 16, 2025 1:05:19 PM
To: Tracy Mehan <tmehan@awwa.org>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net <dobbins@amwa.net>; Steve Via <SVia@awwa.org>; hartnett <hartnett@amwa.net>; Corinne Snow (csnow@velaw.com) <csnow@velaw.com>
Subject: RE: PFAS and LCRI-Request for meetings

I have a quick follow-up question related to the meeting request.

Can you please clarify whether any or part of the intent of this meeting would be to discuss potential resolution to any or all of the ongoing litigation related to PFAS or the LCRI?

From: Tracy Mehan <tmehan@awwa.org>
Sent: Friday, May 16, 2025 12:47 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net; svia@awwa.org; hartnett <hartnett@amwa.net>; Corinne Snow (csnow@velaw.com) <csnow@velaw.com>
Subject: Re: PFAS and LCRI-Request for meetings

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Thanks, Jess.

Standing by.

Tracy

Sent from my Verizon, Samsung Galaxy smartphone
Get Outlook for Android

From: Kramer, Jessica L. <kramer.jessical@epa.gov>
Sent: Friday, May 16, 2025 12:40:10 PM
To: Tracy Mehan <tmehan@awwa.org>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net <dobbins@amwa.net>; Steve Via <SVia@awwa.org>; hartnett <hartnett@amwa.net>; Corinne Snow (csnow@velaw.com) <csnow@velaw.com>
Subject: RE: PFAS and LCRI-Request for meetings

Hey Tracy,

Thanks for reaching out. Yes, due to significant outreach from key stakeholders, including almost all of the water associations representing drinking water systems across the country, as well as in response to the significant Congressional interest the Administrator and I have received, we were excited to announce our intent to extend the compliance deadlines for PFOA and PFOS earlier this week.

I've consulted with OGC leadership here and due to the ongoing litigation, I will need to have additional internal conversations about my ability to meet on the specific topics you've raised at this time and, additionally, who would need to be party to those conversations if they occur.

With respect to conversations about the Hazardous Index, the agency looks forward to engaging with all stakeholders as we work through the rulemaking process.

Thanks again for reaching out!

Jess

From: Tracy Mehan <tmehan@awwa.org>
Sent: Friday, May 16, 2025 12:01 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net; svia@awwa.org; hartnett <hartnett@amwa.net>; Corinne Snow (csnow@velaw.com) <csnow@velaw.com>
Subject: PFAS and LCRI-Request for meetings

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Dear Jess,

Thank you for your positive response to my letter requesting the two-year extension on PFAS compliance and the decision on the Hazardous Index. Notwithstanding the remaining issues on PFOA and PFAS, these are very positive developments for which AWWA and AMWA are most grateful.

I realize that your schedule is extremely crowded, but I wanted to enquire if we could get on your calendar for what is probably two different meetings, depending on your preference.

The first would be on the path forward to implement OW's recent decision on the Hazardous Index vis-à-vis the rulemaking and the judicial process. AMWA and AWWA would participate if that is agreeable.

The second meeting would be on the LCRI and the litigation pertaining to it. AWWA would be pleased to include AMWA, if Tom is so inclined, despite the fact they are not a party to that litigation.

I would leave it to you to decide if DOJ should be a part of either or both meetings.

Of course, if you wish to combine the two into one meeting, we are fine with that. Either way, thank you for your consideration.

Sincerely,

Tracy

G. Tracy Mehan, III
Executive Director, Government Affairs
American Water Works Association
703-850-9401 (cell)

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Thank You.

Message

From: Risley, David [Risley.David@epa.gov]
Sent: 5/22/2025 4:29:49 AM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Haga, Ellie [Haga.Ellie@epa.gov]; Kozikowski, Lauren [Kozikowski.Lauren@epa.gov]
Subject: Talking Points for NAM
Attachments: NAM TPs_Jess 5-20-25.docx

Jess –
Here are talking points for NAM for your consideration. My sincere apologies that I didn't get these to you earlier today.

Best,
David

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

NATIONAL ASSOCIATION OF MANUFACTURERS ROUNDTABLE
MAY 20, 2025, 3 PM
Jess Kramer's Remarks

Who: The National Association of Manufacturers (NAM) members include manufacturers in every industrial sector and in all 50 states. The industry employs 13 million Americans and contributes more than $2.9 trillion to the U.S. economy annually.

What: Participate in an In-Person roundtable briefing for NAM members, off the record.

Location:
Hyatt Regency Washington on Capitol Hill
400 New Jersey Ave NW, Congressional A

Open press: No

Other EPA Speakers: No

Format: Roundtable

Key Topic Requested: "PFAS Regulations"

Run of Show

- Meeting opening by NAM policy committee chair Thermo Fisher
- Chris Phalen, Vice President of Domestic Policy will introduce **YOU**
- **YOU** provide remarks (10 mins)
- Q&A (kicked off and moderated with NAM members by C. Phalen)

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Introduction

- Thank you, Chris.
- Jess' list of caveats (Senior Advisor until confirmed…)
- Start out by talking about how **Administrator Zeldin's leadership aligns with NAM's goals**.
- **Powering the Great American Comeback** – not just a talking point. We are ensuring that everything the Office of Water does aligns with this goal.
    - Pillar 1: Clean Air, Land, and Water for Every American
    - Pillar 2: Restore American Energy Dominance
    - Pillar 3: Permitting Reform, Cooperative Federalism, and Cross-Agency Partnership
    - Pillar 4: Make the United States the Artificial Intelligence Capital of the World
    - Pillar 5: Protecting and Bringing Back American Auto Jobs
- I see **NAM and its members playing key roles** in advancing progress with EPA.
- Together, we can strengthen our communities by **supporting energy, critical mineral, transportation, AI and chip manufacturing**, and everything in between. And we can do this **while ensuring that Americans can rely on clean and safe water**.
- The Office of Water intends to align policy with practicality. We want to make sure our policies:
    - Follow the law (SDWA, CWA, SCOTUS)
    - Consider the state of the science
    - Informed by practical, on the ground implementation

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Policy Meets Practicality

401

- Earlier today, we rolled out a **memo reinforcing the alignment between Clean Water Act Section 401 and the "Powering the Great American Comeback" Initiative**
- This memo emphasizes the agency's position that states and Tribes must **utilize section 401 only for its statutory purpose – to protect water quality** – and not for policy or political goals unattached to real and direct water quality concerns.
- We also announced our **intent to seek input on implementation challenges** by issuing a Federal Register Notice and opening a docket for public comment. I **look forward to your input** through this process.

WOTUS

- We fully recognize that **industry has been particularly affected by WOTUS ping pong** – meaning the back and forth of different Administrations changing definitions. This has been going on for a decade or longer.
- We know that **you need certainty**.
- The **Sackett decision added much-needed clarity**.
- We intend to provide **clear rules of the road that fully implement SCOTUS' direction** in Sackett v. EPA.
- The agencies have already taken action, by issuing a **memo to the field** addressing a confusing and expansive view of which wetlands are waters of the US.

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- The memo clarifies that **wetlands are only considered jurisdictional if they directly abut a WOTUS and have a continuous surface connection**.
- Additionally, we **will undertake a rulemaking process to revise the 2023 definition of WOTUS** to ensure that it fully implements direction from the Supreme Court.
- Currently, we are **hosting listening sessions** to gather real-world perspectives and experiences with WOTUS implementation.
- We have a **public listening session next week in Utah and you can participate, virtually or in-person**.
    - You can register at epa.gov/wotus, then go to "Public Outreach and Stakeholder Engagement Activities"

Steam Electric ELGs

- We have announced our **intent to revise costly wastewater regulations for coal burning power plants** issued in 2024.
- Our goal is ensuring that **all Americans can rely on low-cost electricity while also protecting our nation's water resources**.
- EPA will **reconsider the 2024 standards and consider how to provide immediate relief and flexibility in terms of compliance planning** (e.g., retirement decisions) **and existing requirements**.
- We've heard from a lot of power utilities that the electricity landscape is changing, with AI coming in, and they need more time to plan. We intend to accommodate that.

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Oil and Gas ELGs

- We have announced our **intent to modernize outdated regulations on wastewater discharges for oil and gas extraction facilities to lower energy costs while supporting environmentally sustainable water reuse**.
- The agency's review will evaluate modern technologies and management strategies to provide regulatory flexibility for oil and gas wastewater – also known as produced water – to be **treated for beneficial reuse, including for Artificial Intelligence and data center cooling, rangeland irrigation, fire control, power generation, and ecological needs**.

PFAS, Generally

- Recognize that one of the best ways to **address PFAS is at the source**.
- A few weeks ago (on April 28), **Administrator Zeldin outlined a suite of EPA actions to address PFAS**.
- It called for the designation of an **agency lead for PFAS**.
- It also included the **development of ELGs for certain PFAS and certain industries** – namely PFAS manufacturers and metal finishers.
- We're currently discussing internally and look forward to announcing next steps soon.

PFAS National Primary Drinking Water Regulation

- As you know, the Trump Administration **reviewed the 2024 National Primary Drinking Water Regulation that established standards for six PFAS**.

- This has been a **holistic review—including the science**, the monitoring data, statutory authority, Safe Drinking Water Act process, implementation flexibilities, etc.
- **When it comes to the science, especially when it comes to PFOA and PFOS, the agency's underpinning of the rule is robust and interconnected.**
- We have found that it's **not based on one study or one factor** that if changed, would change the outcome.
- Rather, if you **pull one string, the web of scientific underpinning remains substantial and compelling**.
- With that said, the Administrator's direction will **provide significant relief to drinking water systems, ensure that water systems can stay in business, and protect American families from water rate hikes.**
- I will talk about the Administrator's intent to:
    - **Keep the current regulations for PFOA and PFOS and un-pause litigation** while
    - **Extending compliance deadlines**
    - Establishing a **federal exemption framework**
    - Pursuing **proactive technical assistance to water systems**—especially in rural and small communities
    - Using the tools available to **hold polluters accountable**
- **At the same time, we intend to rescind the regulations with respect to four additional PFAS.**
    - Specifically, the agency intends to **rescind the regulations and reconsider the regulatory determinations** for PFHxS, PFNA, HFPO-DA (commonly known as GenX), and the Hazard Index mixture of these three PFAS plus PFBS.

    - This action will ensure that the determinations and any resulting drinking water regulation **follow the legal process laid out in the Safe Drinking Water Act**.
- In terms of the **compliance deadlines for PFOA and PFOS**, as you are likely aware the 2024 regulation **gave public water systems until 2029** to comply with the maximum contaminant levels, or MCLs.
- Water systems, associations, elected officials, and others have shared with us that **the compliance schedule is one of the biggest challenges for implementation**.
- The Administrator agrees with this, **especially in light of stacking requirements** on PFOA and PFOS and the Lead and Copper Rule.
- To that end, EPA plans to **develop a rulemaking** to provide additional time for compliance, including proposing an **extension of the compliance date to 2031**.
- EPA plans to issue a **proposed rule this fall** and finalize this rule in the Spring of 2026.
- In addition, in light of this extra time, **EPA encourages states seeking primacy for implementing the PFAS drinking water regulation to request additional time** for developing their applications.
- We will also be announcing our **intent to establish a federal exemption framework for PFOA and PFOS**.
- And we are committed to working with communities to meet their needs through our **new PFAS OUT initiative**.
    - PFAS OUT will enhance engagement on addressing PFAS by **proactively connecting with every public water utility**

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known to need capital improvements to address PFAS in their systems.
    - `EPA will **share resources, tools, funding and technical assistance** opportunities to help utilities meet the federal drinking water standards.
    - PFAS OUT will ensure that **no community is left behind** as we work to protect public health and bring utilities into compliance with federal drinking water standards.
- It is critical to underscore that drinking water systems are **passive receivers of PFAS into their source waters, including PFOA and PFOS**.

Close

- Thank you and I look forward to our discussion today and over the coming years.

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Message

From: Diane C Welding [Diane.Welding@amwater.com] on behalf of John Griffith [John.Griffith@amwater.com]
Sent: 5/30/2025 2:44:51 PM
To: Kramer, Jessica L. [kramer.jessical@epa.gov]
CC: Eng, Connie [Eng.Connie@epa.gov]
Subject: American Water Meeting Follow Up

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Dear Ms. Kramer,

I admire your service to our nation and appreciate your time with us on May 20th, along with members of your Office of Water team. As the nation's largest investor-owned-water and wastewater utility, American Water prioritizes being a private-sector solutions provider for our nation's critical infrastructure needs, and we look forward to partnering with the Trump Administration on constructively addressing these challenges. Specifically, we look forward to supporting and aligning with the Administration's objectives of *Powering the Great American Comeback* to foster health and economic growth for families across the country and recognize the key role that reliable water and wastewater service plays. We appreciate Administrator Zeldin's commitment to protecting water and promoting solutions to address our water infrastructure needs nationwide. We closely monitored the PFAS action announcement on April 28th and the compliance deadline extension for drinking water MCLs for PFOA and PFOS. American Water stands ready to be a resource for the EPA in executing the Administration's agenda.

Building on our proven track record of successful and impactful capital deployment, we plan to invest approximately $42 billion across our footprint over the next 10 years to support system needs. The recently released 2025 American Society of Civil Engineers Infrastructure Report Card paints a sobering picture of the nation's water and wastewater infrastructure: aging systems, mounting investment needs, and persistent funding shortfalls. American Water has a great story to tell about its ongoing efforts to modernize water and wastewater infrastructure across the country – delivering safe, clean, reliable, and affordable water to our customers. We want to be part of the national infrastructure conversation and can be a solution for other systems, often rural and/or in distress, who lack the capital and/or expertise to fix their aging infrastructure.

We will continue to seek your guidance on solutions to better leverage federal funding with private capital, specifically SRF funding and other financing programs, and look forward to working together. Our Capitol Hill presence and expertise will amplify support for these
programs as well as additional priorities that impact the industry. Specifically, we have expanded our efforts to inform lawmakers on the potential impacts of insufficient clarity regarding liability protection for passive receivers, such as water systems, when it comes to CERCLA designation of PFAS compounds. This includes continuing our robust advocacy for the Water Systems PFAS Liability Protection Act, which would allow water utilities to prioritize maintaining water quality over defending against polluters' liability disputes while also continuing to address affordability across our company's footprint.

Additionally, we would welcome an opportunity to leverage our private industry expertise and geographic breadth, by being an active participant on the National Drinking Water Advisory Council. There is precedent in

American Water's participation in the past, and we feel we could be a pragmatic, constructive, and realistic voice in the room.

Should you have any questions or wish to discuss these issues in more detail, please do not hesitate to contact me. We plan to provide the necessary follow-up back to your team on some of the issues identified during our recent meeting.

With warm regards,

John Griffith

John Griffith
President and CEO
American Water | 1 Water Street
Camden, NJ 08102 | C: 917-373-3468

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Message

From: Kramer, Jessica L. [kramer.jessical@epa.gov]
Sent: 2/9/2025 9:20:32 PM
To: Voyles, Travis [voyles.travis@epa.gov]; Vaseliou, Molly [Vaseliou.Molly@epa.gov]
Subject: Re: Water Today Press Inquiry on PFAS

No issues here.

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From: Voyles, Travis <voyles.travis@epa.gov>
Sent: Saturday, February 8, 2025 9:42:38 PM
To: Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>
Subject: FW: Water Today Press Inquiry on PFAS

This one slipped through yesterday and I am just seeing it. I think I am generally fine with the responses, but defer to Jess. I have not said anything back to OW.

--

Travis Voyles
C: (202) 787-0595

From: Risley, David <Risley.David@epa.gov>
Sent: Friday, February 7, 2025 1:17 PM
To: Voyles, Travis <voyles.travis@epa.gov>
Cc: Best-Wong, Benita <Best-Wong.Benita@epa.gov>
Subject: Water Today Press Inquiry on PFAS

Hi Travis!
I hope you are having a good day! We have a press inquiry from *Water Today* regarding PFAS in wastewater, biosolids, and drinking water. Please see OW's draft responses below. Following your review, our responses will go to OPA where Molly Vaseliou and Andrea Drinkard will have an opportunity to weigh in.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

Message

From: Kramer, Jessica L. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7015FF5B2F2D4283BF31D29221973420-58AC10B0-AE]
Sent: 4/24/2025 4:34:39 PM
To: Vaseliou, Molly [Vaseliou.Molly@epa.gov]; Amidon, Eric [Amidon.Eric@epa.gov]; Voyles, Travis [voyles.travis@epa.gov]
CC: Mandy, Cora [Mandy.Cora@epa.gov]; Weiner, Ben [Weiner.Ben@epa.gov]; Gall, Daniel [Gall.Daniel@epa.gov]; Skala, Grant [Skala.Grant@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]; Cook, Steven [cook.steven@epa.gov]; Busterud, John [Busterud.John@epa.gov]; Hall, Jeffrey [Hall.Jeffrey.A@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Beck, Nancy [beck.nancy@epa.gov]; Corlett, Thomas [Corlett.Thomas@epa.gov]; Szabo, Aaron [Szabo.Aaron@epa.gov]; Tardif, Abigale (Abbie) [Tardif.Abigale@epa.gov]; Tisa, Nathaniel [Tisa.Nathaniel@epa.gov]; Donahue, Sean [donahue.sean@epa.gov]
Subject: RE: FOR REVIEW: Draft on PFAS Release

A few edits from me in red. Thanks!

From: Vaseliou, Molly <Vaseliou.Molly@epa.gov>
Sent: Thursday, April 24, 2025 12:04 PM
To: Amidon, Eric <Amidon.Eric@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
Subject: RE: FOR REVIEW: Draft on PFAS Release

Added in testing methods below.

From: Amidon, Eric <Amidon.Eric@epa.gov>
Sent: Thursday, April 24, 2025 11:45 AM
To: Vaseliou, Molly <Vaseliou.Molly@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall, Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
Subject: RE: FOR REVIEW: Draft on PFAS Release

Made a suggested **Ex. 5 Deliberative Process (DP)**

Eric Amidon
Chief of Staff
Environmental Protection Agency

From: Vaseliou, Molly <Vaseliou.Molly@epa.gov>
Sent: Thursday, April 24, 2025 9:06 AM
To: Amidon, Eric <Amidon.Eric@epa.gov>; Voyles, Travis <voyles.travis@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Skala, Grant <Skala.Grant@epa.gov>; Kramer, Jessica L. <kramer.jessical@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Cook, Steven <cook.steven@epa.gov>; Busterud, John <Busterud.John@epa.gov>; Hall,

Jeffrey <Hall.Jeffrey.A@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; Corlett, Thomas <Corlett.Thomas@epa.gov>; Szabo, Aaron <Szabo.Aaron@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Tisa, Nathaniel <Tisa.Nathaniel@epa.gov>; Donahue, Sean <donahue.sean@epa.gov>
Subject: FOR REVIEW: Draft on PFAS Release

Hey team,

Please do a review of the draft below and let us know if there's anything missing from your program and provide edits as you see fit. Travis – Ex. 5 Deliberative Process (DP) Thanks!

Ex. 5 Deliberative Process (DP)

DRAFT – INTERNAL – DELIBERATIVE – NOT FOR PUBLIC DISTRIBUTION

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Message

From: Kramer, Jessica L. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7015FF5B2F2D4283BF31D29221973420-58AC10B0-AE]
Sent: 5/8/2025 2:24:06 PM
To: Clark, Jeffrey B..Sr. EOP/OMB Ex. 6 - Personal Privacy (PP)
Subject: Science
Attachments: Topline messages PFAS health assessments Feb 2025.docx

Message

From: Kramer, Jessica L. [kramer.jessical@epa.gov]
Sent: 5/13/2025 3:01:00 PM
To: Risley, David [Risley.David@epa.gov]
Subject: Fw: EPA Announces It Will Keep Maximum Contaminant Levels for PFAS : TEST

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From: Vaseliou, Molly <Vaseliou.Molly@epa.gov>
Sent: Tuesday, May 13, 2025 9:51:03 AM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Subject: Fw: EPA Announces It Will Keep Maximum Contaminant Levels for PFAS : TEST

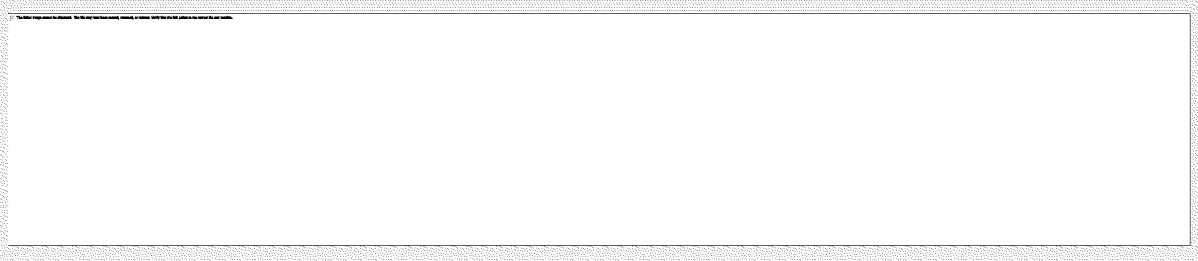
Get Outlook for iOS

From: Skala, Grant <Skala.Grant@epa.gov>
Sent: Wednesday, May 7, 2025 4:59:11 PM
To: Vaseliou, Molly <Vaseliou.Molly@epa.gov>
Cc: Mandy, Cora <Mandy.Cora@epa.gov>; Weiner, Ben <Weiner.Ben@epa.gov>; Gall, Daniel <Gall.Daniel@epa.gov>; Bastasch, Mike <Bastasch.Mike@epa.gov>
Subject: FW: EPA Announces It Will Keep Maximum Contaminant Levels for PFAS : TEST

Preview 2 with updated edits

From: EPA Press <EPAPress@govdelivery.epa.gov>
Sent: Wednesday, May 7, 2025 3:57 PM
To: Skala, Grant <Skala.Grant@epa.gov>
Subject: EPA Announces It Will Keep Maximum Contaminant Levels for PFAS : TEST

View as a webpage / Share



Ex. 5 Deliberative Process (DP)

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Sent: 5/16/2025 4:40:10 PM
To: Tracy Mehan [tmehan@awwa.org]
CC: Voyles, Travis [voyles.travis@epa.gov]; David LaFrance [dlafrance@awwa.org]; dobbins@amwa.net; svia@awwa.org; hartnett [hartnett@amwa.net]; Corinne Snow (csnow@velaw.com) [csnow@velaw.com]
Subject: RE: PFAS and LCRI-Request for meetings

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Thanks again for reaching out!

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To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net; svia@awwa.org; hartnett <hartnett@amwa.net>; Corinne Snow (csnow@velaw.com) <csnow@velaw.com>
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American Water Works Association
703-850-9401 (cell)

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Sent: 5/16/2025 6:34:10 PM
To: Tracy Mehan [tmehan@awwa.org]
CC: Voyles, Travis [voyles.travis@epa.gov]; David LaFrance [dlafrance@awwa.org]; dobbins@amwa.net; svia@awwa.org; hartnett [hartnett@amwa.net]; Corinne Snow (csnow@velaw.com) [csnow@velaw.com]
Subject: Re: PFAS and LCRI-Request for meetings

I will pass this along to our attorneys.

Thanks!

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From: Tracy Mehan <tmehan@awwa.org>
Sent: Friday, May 16, 2025 1:51:31 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net <dobbins@amwa.net>; svia@awwa.org <svia@awwa.org>; hartnett <hartnett@amwa.net>; Corinne Snow (csnow@velaw.com) <csnow@velaw.com>
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Sent: 5/19/2025 5:36:18 PM
To: Snow, Corinne [csnow@velaw.com]
CC: David LaFrance [dlafrance@awwa.org]
Subject: RE: PFAS and LCRI-Request for meetings

Hey Corinne,

I just left you a voicemail and would appreciate a call back when you have a minute. I just wanted to flag something for you regarding the chain of emails below.

My number is 202-766-4632.

Thanks so much!

Jess

From: Snow, Corinne <csnow@velaw.com>
Sent: Friday, May 16, 2025 2:34 PM
To: Tracy Mehan <tmehan@awwa.org>; Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Voyles, Travis <voyles.travis@epa.gov>; David LaFrance <dlafrance@awwa.org>; dobbins@amwa.net; svia@awwa.org; hartnett <hartnett@amwa.net>
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Jess,

Just to add on to Tracy's message, I think we are trying to better understand the nuts and bolts of how EPA plans to implement the announcement so we can decide what that means in terms of the litigation. I know it's never easy to coordinate many schedules, but it might be most efficient to have OGC and DOJ present at the meeting so we don't end up playing a long game of telephone.

Thank you again for making time to look at this issue in your busy schedule.

Corinne Snow
Counsel
Vinson&Elkins
E csnow@velaw.com
W +1.202.639.6622
2200 Pennsylvania Avenue NW
Suite 500 West
Washington, DC 20037
Vcard | Bio | velaw.com

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[EXTERNAL]

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Thank you for your positive response to my letter requesting the two-year extension on PFAS compliance and the decision on the Hazardous Index. Notwithstanding the remaining issues on PFOA and PFAS, these are very positive developments for which AWWA and AMWA are most grateful.

I realize that your schedule is extremely crowded, but I wanted to enquire if we could get on your calendar for what is probably two different meetings, depending on your preference.

The first would be on the path forward to implement OW's recent decision on the Hazardous Index vis-à-vis the rulemaking and the judicial process. AMWA and AWWA would participate if that is agreeable.

The second meeting would be on the LCRI and the litigation pertaining to it. AWWA would be pleased to include AMWA, if Tom is so inclined, despite the fact they are not a party to that litigation.

I would leave it to you to decide if DOJ should be a part of either or both meetings.

Of course, if you wish to combine the two into one meeting, we are fine with that. Either way, thank you for your consideration.

Sincerely,

Tracy

G. Tracy Mehan, III
Executive Director, Government Affairs
American Water Works Association
703-850-9401 (cell)

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Thank You.

Message

From: Kramer, Jessica L. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7015FF5B2F2D4283BF31D29221973420-58AC10B0-AE]
Sent: 5/20/2025 2:44:22 PM
To: Risley, David [Risley.David@epa.gov]
CC: Bender, Emily [Bender.Emily@epa.gov]; Browne, Peggy [Browne.Peggy@epa.gov]; Brooks, Wes [Brooks.Wes@epa.gov]
Subject: RE: GRIST MEDIA QUERY - DEADLINE MAY 19: Press request re: PFAS drinking water standards

Suggested edits from me below. Thanks!

From: Risley, David <Risley.David@epa.gov>
Sent: Tuesday, May 20, 2025 10:21 AM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Bender, Emily <Bender.Emily@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Brooks, Wes <Brooks.Wes@epa.gov>
Subject: RE: GRIST MEDIA QUERY - DEADLINE MAY 19: Press request re: PFAS drinking water standards

Just a friendly bump on this one for Jess.

David Risley
Chief of Staff for the Office of Water
U.S. Environmental Protection Agency
Risley.David@epa.gov
Office: 202-343-9177
Cell: 202-731-3068

From: Risley, David
Sent: Monday, May 19, 2025 9:44 PM
To: Kramer, Jessica L. <kramer.jessical@epa.gov>
Cc: Bender, Emily <Bender.Emily@epa.gov>; Browne, Peggy <Browne.Peggy@epa.gov>; Brooks, Wes <Brooks.Wes@epa.gov>
Subject: FW: GRIST MEDIA QUERY - DEADLINE MAY 19: Press request re: PFAS drinking water standards

Jess –
We have a press inquiry from Grist on the PFAS MCL announcement. We have a proposed response, below with an optional addition if we want to be a little more forward leaning (as the Administrator has been). Please let us know what you think, especially if you like the optional addition or not.

Inquiry (**Ex. 5 Deliberative Process (DP)**

- One of my sources is expressing concern about EPA's intention to launch a "federal exemption framework" for PFAS. They are worried this could open the door to water utilities declining to comply with federal drinking water standards, thereby jeopardizing public health. Can you provide any additional details about the "exemption framework" mentioned in EPA's press release?
- My story also touches on concerns from public health experts and advocacy groups who say that rescinding PFAS limits four some compounds and extending the compliance timeline for the PFOA and PFOS standards prioritizes water utilities' interests at the expense of public health and the environment. Can you comment on the rationale behind EPA's decision to alter the drinking water standards and compliance timeline announced last year, and whether the changes were motivated by lobbying from water utilities?

Responsive Statement

Ex. 5 Deliberative Process (DP)

David Risley
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