RFI Response: Federal Strategic Plan for PFASs, July 2022

Context

On July 13, 2022, the federal Office of Science and Technology Policy issued a *Request for Information; Identifying Critical Data Gaps and Needs To Inform Federal Strategic Plan for PFAS Research and Development* via the *Federal Register* (https://www.govinfo.gov/content/pkg/FR-2022-07-13/pdf/2022-14862.pdf).

My personal response/submission is primarily directed towards "(E) The understanding of the toxicity of PFAS to humans" and secondarily to "(D) The understanding of … pathways to exposure for the public" and "(C) The development and deployment of safer and more environmentally friendly alternative substances." My submission is also directed to the following questions: "1. Should the USG consider identifying priority PFAS when developing a strategic plan for PFAS research and development? If so, what criteria should be used to identify priority PFAS for research and development?"

Summary Statement/Response

Recent programmatic successes regarding the toxicity of PFASs (e.g., release of toxicological assessments for four PFAS acids [ATSDR 2021]) have emphasized ingestion as a pathway of human exposure. Likewise, there has been an emphasis on drinking water as a specific ingestion exposure of interest [see, for example: *Biden-Harris Administration Combatting PFAS Pollution to Safeguard Clean Drinking Water for All Americans;* https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/15/fact-sheet-biden-harris-administration-combatting-pfas-pollution-to-safeguard-clean-drinking-water-for-all-americans/]. Whereas this interest and these initial successes are laudable, human inhalation of PFASs also merits substantial consideration and the PFAS acids are not the only chemical categories of interest. The historic emphasis on ingestion exposures as a subject of scientific scrutiny does not necessarily mean that inhalation exposures will prove to be *de minimus* in the context of human health risk posed by PFASs in consumer and commercial products and as environmental contaminants.

The next section of this submission provides a summary of published information about airborne PFASs. It is offered with the hopes of encouraging pertinent research and development, including toxicity assessment for the inhalation route, that can improve the federal government's collective ability to assess human health risk and make informed risk management decisions in the future regarding PFASs. It is followed by a section that references and supplements specific recommendations about toxicity assessment of PFASs that have been offered by others.

Direct Evidence of Human Exposure to PFASs in Air

During production and usage, PFASs can be and have been released into the atmospheric environment. As a result of long-range atmospheric transport, PFASs have been detected in areas remote from significant industrial activity [Shoeib et al. 2006; Stock et al. 2004; Stock et al.

2007]. These and related findings suggest that human exposure to a wide variety of PFASs in ambient air is globally widespread.

In addition to manufacturing facilities, wastewater treatment plants and landfills have been demonstrated to provide localized sources of emissions of PFASs into the atmosphere. So, for example,

- Ahrens et al. [2011] detected numerous PFASs, including fluorotelomer alcohols (FTOHs), N-Methyl perfluorooctane sulfonamide (MeFOSA), N-Ethyl perfluorooctane sulfonamide (EtFOSA), N-Methyl perfluorooctane sulfonamido ethanol (MeFOSE), N-ethyl perfluorooctane sulfonamido ethanol (EtFOSE), perfluoroalkane sulfonic acids (PFSAs), and perfluoroalkyl carboxylic acids (PFCAs), in air around a wastewater treatment plant (WWTP) and two landfill sites. Regarding the WWTPs, they found "highly elevated" concentrations near the aeration tanks, compared to the other tanks with less wastewater turbulence (i.e., primary and secondary clarifier), which they contended is "likely associated with increased volatilization during aeration that may be further enhanced through aqueous aerosol-mediated transport." Substantially higher total FTOH concentrations (5-36 times) were found on-site at the landfills compared to the upwind samples, whereas total, on-site concentrations of the FOSAs, FOSEs, and PFCAs were less elevated (only 2-3 times higher), relative to upwind samples.
- Tian et al. [2018] detected numerous PFASs [including PFOA, PFOS, perfluorobutane sulfonic acid (PFBS), and more abundant FTOHs] in air overlying two landfills, which was attributed to off-gassing of landfill contents.
- Harrad et al. [2020] detected numerous PFASs (including PFOA, PFOS, PFNA, PFBS, and PFHxS) in air surrounding ten municipal landfill sites in Ireland between November 2018 and January 2019.

There is evidence that concentrations of PFASs in indoor air can be greater than in ambient air. For example: FTOHs, fluorotelomer acrylates (FTACs), MeFOSA, EtFOSA, MeFOSE, EtFOSE, N-methyl perfluorobutane sulfonamido ethanol (MeFBSE), and N-methyl perfluorobutane sulfonamide (MeFBSA) have been detected in indoor air in residential and nonresidential buildings [Langer et al. 2010]; in this case, the airborne PFASs were attributed to suspected indoor sources of vapors, rather than infiltration of ambient air.

Additional research highlighting inhalation of indoor air as a pathway of human exposure to PFASs includes:

- Nilsson et al. [2010] determined concentrations of PFCAs, PFSAs, and FTOHs in air collected in the breathing zone of ski wax technicians during work.

- Fraser et al. [2012] recruited a convenience sample of 31 individuals living and working in the Boston, Massachusetts, area of the United States, sampled indoor air at their respective work-places during the winter of 2009, and had blood samples collected at the end of each participant's week of air sampling. Indoor air samples were analyzed for seven neutral (non-ionized) PFASs (i.e., 6:2-FTOH, 8:2-FTOH, 10:2-FTOH, MeFOSA, EtFOSA, MeFOSE, and EtFOSE). The blood content was analyzed by the Centers for Disease Control for twelve PFASs. The authors found that PFOA concentration in serum

of the office workers was significantly associated with FTOH concentrations in office air. "Dietary factors were evaluated and not found to be significant predictors" of PFASs in serum.

- Fromme et al. [2015] identified and quantified volatile PFASs in indoor air of residences and/or schools in Germany. 6:2 FTOH, 8:2 FTOH, 10:2 FTOH, 8:2 FTAC, 10:2 FTAC, and EtFOSA were detected in eight or more of the 14 samples from schools. 6:2 FTOH, 8:2 FTOH, 10:2 FTOH, 8:2 FTAC, 10:2 FTAC, EtFOSE and MeFOSE were detected in eight or more of the 13 samples from residences.

- Makey et al. [2017] analyzed PFCAs and PFSAs in 50 maternal sera samples collected in 2007−2008 from participants in Vancouver, Canada, while PFCAs, PFSAs, FTOHs, MeFOSA, EtFOSA, MeFOSE, and Et-FOSE (collectively designated as "precursors", or "PreFAAs", along with other PFASs) were measured in matching samples of residential bedroom air. Concentrations of PreFAAs were greater than for PFCAs and PFSAs in air. Positive associations were reported between 10:2 FTOH concentration in air and PFOA and PFNA levels in serum, and between airborne MeFOSE and serum PFOS.

- Winkens et al. [2017] analyzed 57 samples of indoor air from children's bedrooms in Finland for content of 26 PFASs (e.g., FTOHs, PFCAs, PFSAs, FTACs, Me-FOSE, and EtFOSE). Reported findings included: there was a large variability in concentrations between the different homes; among the acids, the PFCAs containing eight to twelve carbons were most frequently detected; among the PFSAs, PFOS was the most frequently detected followed by PFBS; the individual concentrations of FTOHs in air were approximately three orders of magnitude greater than those for the PFAS acids; and 2-perfluorohexyl ethyl methacrylate (6:2 FTMAC) was frequently detected (58%) and displayed some of the highest maximum concentrations.

- Morales-McDevitt et al. [2021] reported the detection of several PFASs in kindergarten classrooms and a commercial storage room in California, and in offices, classrooms and laboratories at a university in southern Rhode Island. 6:2 FTOH and 8:2 FTOH exhibited higher concentrations in indoor air, compared to 10:2 FTOH, 8:2 FTAC, and EtFOSE, which were also detected.

In light of these and other findings, inhalation exposures can be reasonably expected in indoor air in residential and non-residential settings due to PFASs emanating from commercial products, in addition to exposures from ambient air due to emissions from manufacturing facilities, landfills, and wastewater treatment plants.

Recommendations About Toxicity Assessment and Priority PFASs

The peer-reviewed literature offers recommendations from expert toxicologists regarding "studies [that] would yield the most useful information and address the current gaps in understanding PFAS health effects in humans" and the respective challenges posed by "PFAS mixtures and formulations". For example, Cousins et al. [2020]; Fenton et al. [2021]; Goodrum et al. [2021]; Ojo et al. [2021], Patlewicz et al. [2019], and Patlewicz et al. [2018] have offered

recommendations of approaches to address the challenges to determining, efficiently and timely, the toxicity of the large number of PFASs currently in commercial use.

Absent from many published review articles and proposals about toxicity testing is an explicit recognition that the assessment of human health risks posed by PFASs should, for completeness, entail toxicity testing and data collection pertaining to persistent (e.g., chronic) inhalation exposure (i.e., not only for ingestion and dermal contact and for a suitably wide range of effects beyond nasal irritation). So, for example, one proposed scheme for prioritizing chemicals for toxicity testing discounted chemicals with higher volatility (as reflected in the chemical-specific vapor pressure), which could complicate certain types of toxicity testing (e.g., ingestion-dosing studies using animals). To the contrary, the consistent detection of fluorotelomer alcohols (FTOHs), perfluoroalkane sulfonamides (e.g., MeFOSA, EtFOSA), and perfluoroalkane sulfonamide ethanols (e.g., MeFOSE, and Et-FOSE) in indoor air across multiple investigations suggests that these relatively volatile PFASs merit priority consideration for inhalation toxicity assessment.

Why would inhalation toxicity testing be warranted now, when commercial uses of certain PFASs are being re-considered and substitute products are being developed and commercialized? One rationale would be to ensure, via side-by-side testing, that the replacement products exhibit lower potential for toxicity (via inhalation, in addition to ingestion and dermal contact) and ideally to ensure that the new (and previously manufactured) chemicals may not present an unreasonable risk to human health or the environment.

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PFAS Research Needs: E) The understanding of the toxicity of PFAS to humans and animals.

Toxicokinetics in humans:

There are multiple publications on research conducted in humans, animals, and *in vitro* identifying large ranges of possible effects from potential oral PFAS exposure to two primary PFAS (PFOA and PFOS) and data exist for many others; however, there is little understanding how those data relate to specific adverse effects in humans and how safe levels of exposure could be determined. Levels identified in drinking water to be safe for the general population are at or below the limits of detection, yet these substances have been in the environment for decades and many studies have shown concentrations decreasing. New research is needed to precisely understand the mechanisms by which PFAS exert their toxic effects. This information can be used in an evidence integration approach (Lent et al. 2021) to understand whether there is sufficient information for specific adverse effects in humans[1]. Moreover, mechanistic information may also help in identifying descriptors that may be useful in designing quantitative structural activity relationship (QSAR) models that could be used to predict toxicity to other PFAS where toxicity data are lacking.

Some reported adverse effects that require context include the following:

- Liver effects (continuum from single cell hyperplasia to liver enzymes to fatty liver disease).
- Immunological effects (continuum from changes in antibody levels to increased disease incidence and severity)
- Thyroid hormone imbalance (continuum from changes in TSH to T4 to T3)

Additionally, some studies have suggested that the critical effect of PFAS in humans may be non-alcoholic fatty liver disease (NAFLD). The development of non-invasive techniques (no liver biopsy) for assessing NAFLD with some accuracy would be critically important in determining the impact of PFAS on humans, along with an evaluation of possible confounding elements (e.g., alcohol consumption).

Toxicodynamics

Individual PFAS vary in their environmental persistence, bioaccumulation, and excretion rates in humans, animals and between sexes. Some studies suggest a role of the organic ion transporter (OAT) 1 in the kidney. More is needed to better understand the factors in humans responsible for bioaccumulation between PFAS congeners to inform physiologically-based pharmacokinetic (PBPK) models that will aid in improving the precision for extrapolation of dose response toxicity information from controlled laboratory animals to humans.

However, PBPK models are complex, require specific data, and are resource intensive. Where data are lacking, what is the most scientifically defensible method for extrapolating from an animal Point of Departure (POD) to the Human Equivalent Dose (HED)?

[1] To date, no hazard identification has been published on any PFAS where a comprehensive evaluation has been conducted to understand where there is sufficient evidence for specific toxic effects. See Lent EM, Sussan TE, Leach GJ, Johnson MS. 2021. Using Evidence Integration Techniques in the Development of Health-Based Occupational Exposure Levels (OELs). International Journal of Toxicology (on-line ahead of print). 10;109158182097049 https://doi.org/10.1177%2F1091581820970494

- Ratio of clearance levels
- Allometric scaling

EZRATERRA
A PATRICK BRADY COMPANY

August 1, 2022

Agency: Office of Science and Technology Policy
Subject: **RFI Response**: PFAS Strategic Plan

This RFI addresses goals (A), (B), (D) and (E) and Questions 1, 2, 3b, 3c, 5, 6, 7, 8, 9a, and 9b; Document Number 2022-14862 (Document Citation 87 FR 41749). Our response is a public service intended to shed light on a fundamental gap in understanding, a paradigm shift. We have attached a bibliography (not counted in page limit). We achieved non detectable levels in soil total PFAS TOPs/no Thixotropy with an OTM-45 Stack Tested 99.99985% Removal Efficiency (meets Michigan PFAS stack and ambient air standards). Our non-Newtonian Anti-Thixotropic Technology: https://vimeo.com/539308253/2a26a159a7. We encountered phenomena that require your attention. These phenomena are generally not recognized within the environmental industry. Our concepts bridge the understanding gap into existing Regulations/Standard of Care.

A colloidal formulator prospective is necessary to create a scalable PFAS solution. PFAS is released to the environment as a small part of AFFF firefighting foam. AFFF is a "*Colloid*" formulation classified by particle size. Expertise can also be classified by particle size (below).

Particle Dimension Expertise Spectrum

Chemists/Toxicologists
Classic Chemistry
Below 1 nm
(molecules)
Solutions

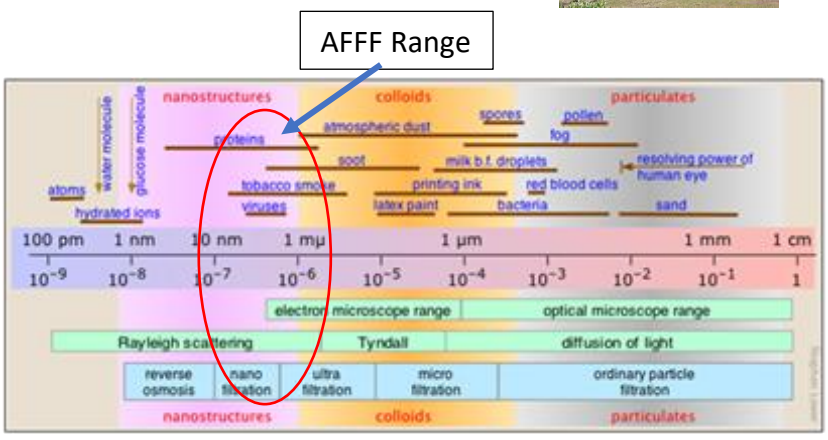
AFFF Formulators

Colloids: In-Between Science
Non-Newtonian Rheology

1 nm to 1,000 nm
Immiscible
Droplets
Dispersed in Fluid

Geologists/Engineers
Newtonian Physics
Above 1,000 nm
(silts/clay)
Suspensions

The PFAS "Knowledge Gap" is actually a PFAS "Colloid Expertise Gap". There are formulation experts that made colloidal AFFF; however, they are largely absent in our industry and have a substantially different technical mindset (a different paradigm).

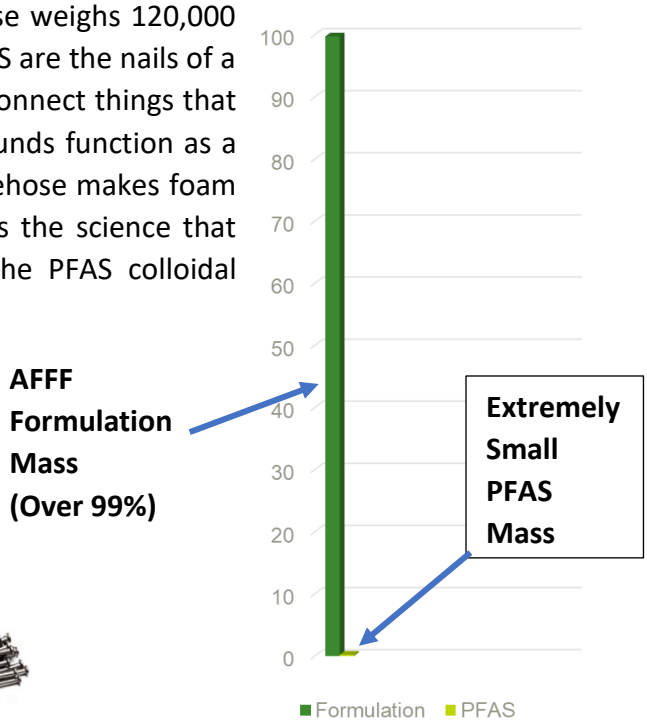


Think of a formulation like a house; a typical house weighs 120,000 pounds held together with 80 pounds of nails. PFAS are the nails of a formulation. PFAS are powerful surfactants that connect things that normally do not connect. PFAS and other compounds function as a colloidal system that when added to a charged firehose makes foam to extinguish liquid hydrocarbon fires. Rheology is the science that generally describes AFFF behavior and bridges the PFAS colloidal expertise gap in our industry.

Typical House weighs 120,000 pounds

House Held Together with 80 pounds of Nails

"PFAS are the nails of AFFF Formulations"



AFFF Formulation Mass (Over 99%)

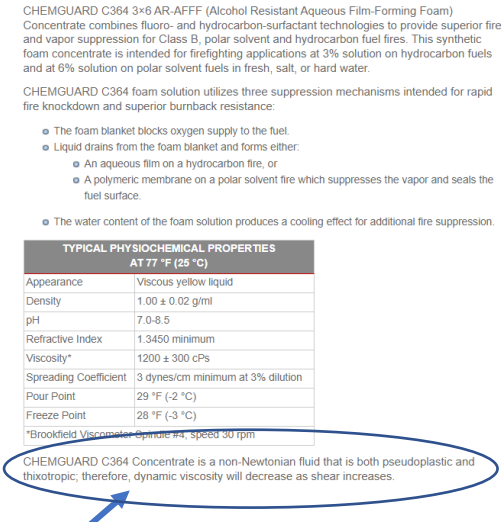
Extremely Small PFAS Mass

PFAS Mass in AFFF per TOPs

The most important sentence in PFAS science is found in all AFFF product specification sheets (notably absent in safety data sheets); it speaks to formulation functionality (a colloidal system):

<u>"AFFF is a Non-Newtonian Fluid with Pseudoplastic and Thixotropic Properties"</u>

Simply put, AFFF concentrate deforms (stretches) when injected into a fire hose to create foam (bubbles) then returns to its original state upon foam decay (bubbles break/water drainage). It's like filling up a water balloon then letting go; the balloon gets big when filled with water (pseudoplasticity) but goes back to its original size when the water drains out (Thixotropy). Thixotropy is the process of spent formulation self-aggregation (<u>increases</u> concentration over time). Thixotropic properties are what causes AFFF foam to form on lakes, rivers, and oceans. AFFF, a chemical colloidal system, sticks together. See Figure/link below.



CHEMGUARD C364 3×6 AR-AFFF (Alcohol Resistant Aqueous Film-Forming Foam) Concentrate combines fluoro- and hydrocarbon-surfactant technologies to provide superior fire and vapor suppression for Class B, polar solvent and hydrocarbon fuel fires. This synthetic foam concentrate is intended for firefighting applications at 3% solution on hydrocarbon fuels and at 6% solution on polar solvent fuels in fresh, salt, or hard water.

CHEMGUARD C364 foam solution utilizes three suppression mechanisms intended for rapid fire knockdown and superior burnback resistance:

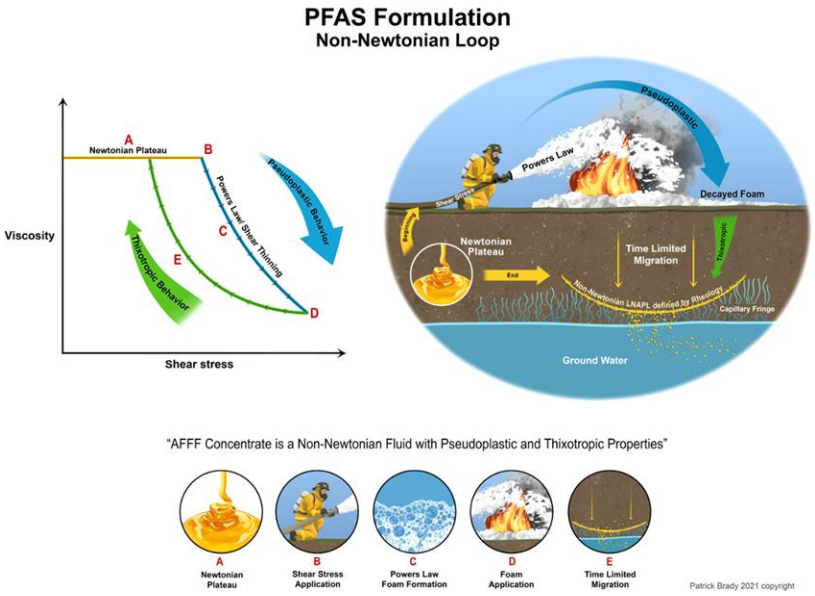
- The foam blanket blocks oxygen supply to the fuel.
- Liquid drains from the foam blanket and forms either:
  - An aqueous film on a hydrocarbon fire, or
  - A polymeric membrane on a polar solvent fire which suppresses the vapor and seals the fuel surface.
- The water content of the foam solution produces a cooling effect for additional fire suppression.

TYPICAL PHYSIOCHEMICAL PROPERTIES AT 77 °F (25 °C)	
Appearance	Viscous yellow liquid
Density	1.00 ± 0.02 g/ml
pH	7.0-8.5
Refractive Index	1.3450 minimum
Viscosity*	1200 ± 300 cPs
Spreading Coefficient	3 dynes/cm minimum at 3% dilution
Pour Point	29 °F (-2 °C)
Freeze Point	28 °F (-3 °C)

*Brookfield Viscometer Spindle #4, speed 30 rpm

CHEMGUARD C364 Concentrate is a non-Newtonian fluid that is both pseudoplastic and thixotropic; therefore, dynamic viscosity will decrease as shear increases.

Critical Information on AFFF Behavior Buried in AFFF Specification Text



<u>Thixotropic Properties</u> Spent AFFF Foam, at rest, increases in Concentration over time

- ***It Self-Aggregates into Non-Newtonian LNAPL just like Petroleum LNAPL***
- ***Requires Rheological Analysis to Define and Fingerprint***
- ***Petroleum LNAPL vs Non-Newtonian LNAPL https://vimeo.com/channels/1653086***

The reason PFAS plumes look like they have distinctive sources is because they do, non-Newtonian LNAPL; Rheology is the missing link in PFAS science.

Relevant Science

The original "Forever Chemical" was lead (used in gasoline, pipes, and other products). Lead was found in most American's blood in the 1970s. Based on our research, between 1922 and 1975 lead toxicity was concealed from the public with diversionary science. It took scientists from outside the lead industry to present lead's true toxicity. Since it appears that PFAS is the second generation "Forever Chemical" we thought it was likely that the same diversionary tactics were used to conceal PFAS toxicity. We performed a "First Principles Analysis" on amphiphilic chemistry, colloidal chemistry, and quantum mechanics to determine the relevant science vs the diversionary science. It appeared to us that PFAS science was clouded with diversionary science.

In today's legal setting, design professionals are bound to a "Standard of Care" requirement due to their specialized knowledge and expertise. The common law "Standard of Care" has been described as what a skilled and reasonably competent professional would do 1) in a similar situation, 2) in a given locale, and 3) in similar conditions. Operating outside "Standard of Care" puts professionals at risk of negligence claims.

The unintended consequences of "Standard of Care" are the scope of solutions are commonly limited to what other professionals are doing or what they have been doing in the past. When new design problems arise that the current "Standard of Care" does not accommodate (like spilled PFAS stabilized colloidal formulations), solutions can be delayed until such time that a new "Standard of Care" evolves; or potentially no solutions are developed at all. "Standard of Care"

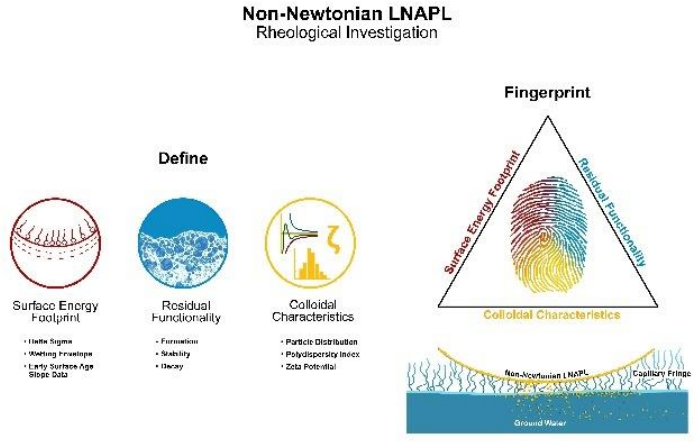
keeps experts in their "lane", which maintains established mindset/paradigm. DOD spent $1.5B on PFAS R&D since 2000. There are now six federal agencies researching PFAS. After reviewing publicly available work plans/research frameworks we found no mention of colloidal matter, viscoelasticity, non-Newtonian behavior, or Rheology. It appears everyone is staying in their lane.

Current PFAS research is taking a chemical specific approach focusing on ***surfactant-water*** interactions, which is generally consistent with existing chemical specific regulatory framework and Standard of Care (staying in lane). Formulations (like AFFF) are ***surfactant-water-oil*** interactions (mixtures/a colloidal system governed by thermodynamics), which is a significant departure from current research/Standard of Care. LNAPL regulations accommodate ***surfactant-water-oil*** interactions. Further, formulations almost always use surfactant blends (numerous surfactants) to achieve their design purpose.

Current laboratory analyses (unoxidized EPA 537.1) and regulatory standards do not consider colloidal matter during analysis, which grossly under reports PFAS concentrations. Total Oxidizable Precursor (TOPs) analysis, which oxidize samples (and colloidal droplets), routinely report 10 to 20 times greater PFAS mass than unoxidized analysis. TOPs was intended to measure PFAS dark matter, fluorine unsaturated PFAS that cannot be detected by commercial laboratory analysis. We believe there is more happening than hydrocarbon cleaving during oxidation. Further, the industry has no analysis assessing formulation functionality like Thixotropic properties (spent formulation time delayed increasing concentration).

Rheological Approach

Most PFAS technologies are adapted traditional technologies designed around a ***surfactant-water*** system. Treatment effectiveness is based on unoxidized analysis, which grossly under reports PFAS mass. Current treatment effectiveness evaluations do not consider all pertinent data. PFAS treatment should be designed for ***surfactant-water-oil*** systems, specifically microemulsions (like AFFF) with particle size ranging from 5 nm to 300 nm. Microemulsions form spontaneously upon mixing (Thixotropic). Rheology describes AFFF behavior. We have patented standardized Rheological methods to detect and fingerprint viscoelastic non-Newtonian formulations in subsurface media/ wastes in real time. We can determine if Thixotropic properties



Rheologic Methods Bridge Expertise Gap, Connects to Existing LNAPL Regulatory Path and Standard of Care

have been destroyed during treatment. Both petroleum LNAPL and non-Newtonian LNAPL fit the definition of LNAPL. The LNAPL regulatory path was specifically designed for formulation mixtures (not isolated specific chemicals).

Recent studies have found that PFAS colloidal formulations are more "surface active" than individual PFAS compounds alone. In other words, the formulations are more toxic than any individual PFAS compound. We created a 3% AR-AFFF concentrate/97% water design mixture for toxicity testing using fish (lethal dose). All fish died immediately at that 3% concentration. We also found that AFFF concentrates have Chemical Oxygen Demand (COD) concentrations up to 200,000 mg/l or 6,000 mg/l COD in the 3% design mixture. Typical POTW discharge standards for COD are 250 mg/l. Thixotropy increases the "at rest" spent formulation concentration over time due to favorable thermodynamics, which increases COD and PFAS concentrations.

AFFF design mixtures have a positive "Spreading Coefficient", which means self-aggregation occurs as PFAS rich films (Langmuir-Blodgett Films). We have monitored a significant PFAS site where it was believed that PFAS was only in the groundwater, not soil. We saw evidence of non-Newtonian LNAPL. Soil was subsequently excavated for an unrelated maintenance issue where 10,000 tons of soil was later found to be contaminated with PFAS. Think of swirl ice cream with a rich fudge layer film in largely vanilla ice cream. When you put the largely vanilla swirl ice cream in a blender you end up with a chocolate shake, not a vanilla shake. Excavation is like a blender.

We also found thermal gradients move AFFF around, they do not remove PFAS. This was proven at Eielson AFB when in-situ thermal technology was operated in an ex-situ pile. Treatment effectiveness cannot be known without considering all PFAS mass and the colloidal functionality of the spilled formulation. Colloidal functionality is driven by thermodynamics and PFAS reaction with water (Hydrophobic Effect). Recommended treatment standards:

- **PFAS TOPs Concentration Standard (Change Laboratory Analysis to TOPs)**
  - Total PFAS Mass (accounts for surfactant blends in formulations)
  - Colloidal Formulation Physics (oxidation liberates PFAS for detection)
- **Chemical Oxygen Demand**
  - Measures footprint of entire colloidal system/has existing discharge standards.
- **Thixotropic Analysis**
  - Rheologic Analysis (treatments should be "Anti-Thixotropic"; destroys thixotropy)

PFAS releases are colloidal formulation releases that require a Rheological based approach. Not including Rheology is like leaving out the roof on a house; it's not complete and doesn't function.

Respectfully,

EZRATERRA, LLC

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August 25, 2022

SRNS-J2200-2022-00177
Tracking Number: 10667

Office of Science and Technology Policy
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500
(Submitted Electronically via JEEP@ostp.eop.gov)

SAVANNAH RIVER NUCLEAR SOLUTIONS, LLC COMMENTS ON REQUEST FOR INFORMATION; IDENTIFYING CRITICAL DATA GAPS AND NEEDS TO INFORM FEDERAL STRATEGIC PLAN FOR PFAS RESEARCH AND DEVELOPMENT

Savannah River Nuclear Solutions, LLC (SRNS) is pleased to submit the attached comments on the Office of Science and Technology Policy's Request for Information on Identifying Critical Data Gaps and Needs To Inform Federal Strategic Plan for PFAS Research and Development, published in the *Federal Register* on July 13, 2022 (Vol. 87 No. 133 *Federal Register* 41749).

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SAVANNAH RIVER NUCLEAR SOLUTIONS, LLC (SRNS) COMMENT ON REQUEST FOR INFORMATION; IDENTIFYING CRITICAL DATA GAPS AND NEEDS TO INFORM FEDERAL STRATEGIC PLAN FOR PFAS RESEARCH AND DEVELOPMENT

August 25, 2022

SRNS GENERAL COMMENTS:

Comment 1

Detection limits for analytical methods are currently not low enough to achieve the <ppt levels: 0.004 parts per trillion (ppt) for PFOA, 0.02 ppt for PFOS, 10 ppt for GenX chemicals, and 2,000 ppt for PFBS that EPA has recommended as safe health-based limits for drinking water. Since EPA will likely use these health-based limits as a basis for establishing Minimum Contaminant Levels for drinking water, SRNS is concerned that owners/providers of drinking water systems will have difficulty demonstrating compliance with established limits with the result that there could be a general erosion of the public's confidence that their drinking water is safe. Further, SRNS has found that the number of certified laboratories capable of performing the analytical method for PFAS or being able to achieve the extremely low detection limits is limited.

Comment 2

EPA and the OSTP must consider the practicality of remediation given the ubiquitous nature of PFAS contaminants, and the lack of current feasible treatment technologies for remediation, particularly at those low levels. Further, final disposal of contaminated media (spent activated carbon, filters, waters – GW/SW, sediments/soils, etc.) appears to be ignored or inadequately addressed. Without an adequate disposal path for treatment residuals, remediation efforts will be stymied and unable to proceed.

SRNS SPECIFIC COMMENTS:

Question 1:

Should the USG consider identifying priority PFAS when developing a strategic plan for PFAS research and development? If so, what criteria should be used to identify priority PFAS for research and development (*e.g.*, tonnage used per year; releases to the environment per year; toxicology or other human or environmental health concerns; national security or critical infrastructure uses)?

SRNS Comment:

SRNS recommends that USG consider identifying priority PFAS when developing a strategic plan for PFAS research and development. It is suggested that the criteria be based on the comparative volume of the type of PFAS that was produced during a specific target period in combination with the toxicity of the PFAS constituent.

Priorities should also be based on highest maximum/mean detectable levels of PFAS-type chemicals found in air and drinking water sources; priorities associated with isomers/analytes should also change over time as more data becomes available. Priority locations should include the number served by public water utilities, groundwater usage, and locations near producers/generators of PFAS chemicals. The 2nd tier priority should be constituents/contaminants with a maximum risk level as these are developed for specific isomers/analytes

Question 3:

Based on the definition of PFAS in this RFI, what are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS and to identify cost-effective:

a. Alternatives to PFAS that are designed to be safer and more environmentally friendly;

SRNS suggests that there may be certain industrial applications in which a specific PFAS constituent is used as a component in products such as lubricants, or gasket material, or may be a critical reaction component that have no technical equivalents. In this case it may be necessary to weigh the benefit of continuing to use the PFAS constituent against the potential environmental/human impact. SRNS has recently raised a similar issue, and provided comment, in response to a recent EPA proposed rule on the regulation of Chrysotile Asbestos under the Toxic Substances Control Act (Federal Register Vol 87, No. 70, 21706-21738). This is especially critical in the nuclear power and defense industries.

Question 7:

What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans (e.g., in vitro, animal toxicological, and epidemiological studies)? Which health effects should be prioritized? What additional impacts beyond health should be prioritized? Social scientific approaches are welcome in addressing this question and any others, as appropriate.

Question 8:

One challenge across all research goals is PFAS mixtures and formulations. Currently, more information is needed to understand the identity, composition, occurrence, source, or effects

on human health and the environment for mixtures of PFAS found in environmental media. Additionally, more information is needed to understand the best way to remediate or destroy media contaminated with multiple PFAS. What should be the research and development priorities for accelerating progress in these areas?

SRNS Comments:

The Key Characteristics of Carcinogens framework recently developed ten characteristics that are commonly exhibited by and shared among carcinogenic agents. Per- and polyfluoroalkyl substances (PFAS) are recognized as carcinogens due to their association with several of the ten characteristics. Health impacts/carcinogenic effects of PFAS, especially the long-chain species like PFOA and PFOS, that have thus far been identified include oxidative stress, immunosuppression, and modulations of receptor-mediated effects. Other health impacts, like chronic inflammation, epigenetic alterations, cellular immortalization, and alterations of DNA repair, have not been fully investigated based on currently available data. So future research is needed to provide evidence on one or more of the key characteristics. For example, can PFAS cause direct genotoxicity (e.g., DNA damage) or lead to genomic instability? Besides PFOA and PFOS, can other PFAS compounds induce epigenetic alterations? Can PFAS alter cell proliferation and death? For human health, can PFAS induce chronic inflammation (e.g., autoimmune disease, osteoarthritis, diabetes, cardiovascular disease)? Given that some assays can be carried out with a high-throughput in vitro approach, we expect future studies can answer the questions mentioned above, especially the ones related to genomic, molecular, and cell toxicities.

In addition, most of these studies linked the toxicological, occupational, community, and/or general population exposure to the long-chain PFAS species. Data gaps remain around the toxic impacts of short-chain PFAS species, certain structural functional groups, and the newly released species. Other limitations of the epidemiology studies are the lack of detailed investigations of different life stages (e.g., newborn, childhood, adolescent, and adulthood) and populations with distinct characteristics (e.g., pregnant women, minority, and/or subpopulations).

Besides the health impacts of PFAS, the toxicological influences on ecological receptors are equally important. Given their propensity to biomagnify, the potential movement of PFAS at environmentally relevant levels is increasingly concerned, especially for ecological receptors occupying high trophic levels, such as birds, predacious fish, and mammals. For example, the bioaccumulation and biomagnification of PFAS in the source-driven and non-source-driven locations, the species of PFAS that are bioaccumulated, and the levels of these PFAS species in the trophic web of federal sites and surrounding environments.

Meanwhile, approaches such as field-tested tools and quantitative methodologies to better inform exposures and risks, integrate toxicities of different PFAS species (and even chemicals other than PFAS) and utilize available toxic data and New Approach Methodology (NAM) are urgently needed. Such approaches will help determine strategies for mitigating contamination-induced disease, establishing remediation plans, facilitating decision-making, and suggesting different management scenarios.

Question 9:

What goals, priorities, and performance metrics would be valuable in measuring the success of National, federally funded PFAS research and development initiatives relating to:

c. Developing safer and more environmentally friendly alternatives to PFAS?

SRNS Comment:

SRNS proposes the following goals, priorities and performance metrics related to developing safer and more environmentally friendly alternatives to PFAS:

- Establish criteria to include or exclude a product from consideration as "PFAS bearing" (in other words, a threshold for application of the term). This could be based either on concentration of PFAS in the product or a risk factor which would be indicative of potential exposure to PFAS as a result of use of the product or a combination of both.
- A goal of collaboratively steering and prioritizing research, and new regulations towards specific products containing PFAS and uses of PFAS chemicals which represent the greatest hazard to human health and the environment based on toxicity and concentration of PFAS.
- A goal of classification of commodities where PFAS declarations are required (similar to the OSHA Hazard Communication or GHS system of product hazard classifications)

Environmental Defense Fund

Comments on OSTP's Request for Information; Identifying Critical Data Gaps and Needs To Inform Federal Strategic Plan for PFAS Research and Development

Document Citation: 87 Fed. Reg. 41749 (July 13, 2022)

Submitted: August 25, 2022

Introduction

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Office of Science and Technology Policy (OSTP) on its Request for Information (RFI) to identify critical data gaps in research and development regarding several aspects of per- and polyfluoroalkyl substances (PFAS).[1]

We believe OSTP's efforts to advance a strategic plan for federal coordination of PFAS research and development are much needed.

In response to most of the questions posed in the RFI, we offer several recommendations that we believe will enable the United States Government (USG) to better understand the potential harms of PFAS and mitigate those harms using a whole-of-government approach, with a focus on the need for:

- Adoption of the Organization for Economic Cooperative Development (OECD) PFAS definition across the USG,
- A better understanding of the bioaccumulative potential[1] and mobility of PFAS in the environment, the current uses of PFAS and available alternatives, and as well as available clean up technologies and costs;
- Additional scientific research on the composition and effects of PFAS mixtures in the environment; and,
- Adoption of cumulative risk assessment for assessing and regulating PFAS.

Environmental Defense Fund (EDF) is a national, non-profit environmental organization dedicated to using science, economics, and law to build a vital Earth – for everyone. EDF's Healthy Communities program strives to make air, water, food, and household products safer through cutting-edge research, wide-ranging partnerships, and a focus on strengthening laws and policies that protect health.

[1] Including traditional bioaccumulation in biota as well as bio-persistence (e.g., elimination half-life in humans).

1. Should the USG consider identifying priority PFAS when developing a strategic plan for PFAS research and development? If so, what criteria should be used…?

Recommendation: In developing a strategic plan for PFAS research and development, the USG should consider all PFAS as a starting point and prioritize subcategories according to clear scientific criteria, including toxicity, environmental fate, and exposure.

Federal agencies should include all PFAS that meet the OECD definition in the scope of any prioritization process. From this starting list of all PFAS, prioritization of PFAS for different regulatory contexts may involve subcategorizing PFAS based on one or more of the following criteria: (1) toxicity, (2) persistence and mobility in the environment, (3) bioaccumulation potential, (4) presence of (or potential for) community-level environmental exposures (e.g., environmental contamination), and (5) presence in everyday consumer products such as food, food contact materials, cosmetics, and stain-resistant carpets. PFAS that meet one or more of these criteria are likely to pose the greatest risk.

3. Based on the definition of PFAS in this RFI, what are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS…?

EDF has identified the following scientific, technological, and human challenges to addressing the environmental and human impact of PFAS, with the recognition that this is not an exhaustive list of challenges.

Scientific challenges: Currently, we have limited information about the bioaccumulation potential of most PFAS, especially newer substances. Bioaccumulation of PFAS in animal, plant, and human can make even short, low-level exposures problematic, which makes traditional toxicity testing a challenge. In addition, we currently have limited information on the environmental fate and transport of PFAS. Finally, PFAS mixtures present a significant scientific challenge that must be addressed, as discussed in more detail in our response to Question 8.

Technological challenges: One substantial technological challenge involves limitations in current PFAS detection methods; specifically, our current inability to measure PFAS at environmentally and risk-relevant levels. For example, EPA's recently published Health Advisories for PFOA and PFOS are below the level of both detection (determining whether or not a substance is present) and quantitation (the ability to reliably determine how much of a substance is present) of current detection methods.[2] Another technological limitation includes the cost of developing and implementing disposal and destruction technologies. The USG should consult a July 2022 report published by the U.S. Government Accountability Office (GAO) for an in-depth analysis aimed at mitigating current technological challenges of PFAS assessment, detection, and treatment.[3]

Human challenges: PFAS pollution presents various "human" or societal challenges. Generally, we do not have a good sense of the total health and economic burden of PFAS pollution, nor the environmental justice implications of PFAS pollution. Nonetheless, recent research on the topic indicates that daily exposure to PFAS costs the U.S. ***billions*** in health costs. In addition to direct health care costs, environmental releases of PFAS (including land application of PFAS-

contaminated biosolids/sludge) have contaminated drinking water[4] and soil[5] throughout this country, further driving up the economic costs of PFAS pollution. While drinking water contamination is most widespread, soil contamination is also occurring, which disproportionately impacts people engaged in farming (industrial or subsistence) and threatens the overall safety of the nation's food and water supply. Finally, many PFAS are highly mobile,[6] which presents a societal challenge because communities can be affected by PFAS even if located far away a source of PFAS pollution (e.g., an industrial facility). The mobile nature of many PFAS necessitates careful consideration of what constitutes a "fenceline" or "frontline" community, and how that may impact environmental justice strategies and implementation plans related to PFAS.

4. Are there specific chemistries and/or intended uses that PFAS provide for which there are no known alternatives at this time?

Recommendation: There is currently limited publicly available information on PFAS uses and available alternatives, which makes addressing this question difficult. To overcome this limitation, the USG should create and maintain a single, shared online repository of PFAS uses (historical, existing, and reasonably foreseen) and existing alternatives. This database should be made widely accessible to government officials and the public.

A centralized federal information system on PFAS uses and available alternatives would help policymakers, regulators, and members of the public identify and evaluate which PFAS uses should be considered "essential uses" (e.g., life-saving medical technologies with no known alternatives at this time) and which are not essential and should be substituted with safer alternatives.

5. What are alternatives to the definition of PFAS provided in this RFI? What are the implications of these alternative definitions on possible remediation strategies?

Recommendation: The USG should adopt the OECD PFAS definition to ensure a clear and consistent definition that accounts for all relevant fluorinated substances in federal initiatives.

EDF recommends that the UGS not use the FY20 NDAA definition of PFAS, as provided in the RFI. Instead, the USG should modify its definition of what constitutes a PFAS and adopt a definition that is consistent with that used by other authoritative bodies in the United States and around the world, such as the OECD.[7] This would allow federal agencies and offices to prioritize individual or groups of PFAS based on different regulatory contexts while maintaining a nationally and internationally shared understanding of what constitutes a PFAS.

We suggest adopting the OECD PFAS definition rather than the definition written into the FY20 NDAA because (1) PFAS is a global environmental health challenge, (2) the U.S. is a member of the OECD, and (3) the application of the proposed FY20 NDAA definition may result in the exclusion of potentially public health relevant PFAS. In terms of remediation, this may have the effect of excluding toxic PFAS from federal remediations efforts.

6. What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of: analytical methods, detection limits, non-targeted detection?

Recommendation: Federal regulatory agencies should require PFAS manufacturers to submit analytical reference standards to ensure the USG's ability to develop analytical methods to test, identify, and measure the vast universe of PFAS in and entering our environment.

Analytical reference standards, or chemical footprints, are crucial to the federal government's efforts to improve its testing methods, identify contaminants, and initiate enforcement actions. As such, it is imperative that the USG require PFAS manufacturers to submit reference standards of their PFAS to regulatory agencies. Once obtained, analytical reference standards should be shared and accessible across the federal government to streamline method development in different environmental media and regulatory contexts, and to reduce industry reporting burdens. This could be facilitated by the National Institute of Standards & Technology, which is currently creating reference materials and data resources to address PFAS measurement needs.

7. What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans…?

Recommendation: Additional studies are needed to determine (1) the bioaccumulative potential of individual PFAS, (2) the health impacts of individual PFAS at low, environmentally relevant doses, and (3) the cumulative risk of PFAS mixtures.

Given the bioaccumulative properties of well-studied PFAS, additional research on the bioaccumulative potential of newer PFAS is needed. Additional research on low dose toxicity is also needed, especially considering EPA's recent Interim Health Advisory updates, in which EPA found that PFOA and PFOS cause human health harms at near-zero levels (e.g., in the parts per trillion).[8] If the USG does not prioritize low dose PFAS research, we risk falling victim to a phenomenon termed "something from nothing"[9] – in which the combination of multiple low-level "safe" doses (i.e., doses below regulatory limits) of different chemicals pose a cumulative health risk.

Regarding the cumulative risk of PFAS, additional toxicological studies on PFAS mixtures are needed to better understand whether PFAS interaction effects are additive, synergistic, or antagonistic, as discussed in more detail in our response to Question 8. Additional epidemiological studies on PFAS mixtures, possibly modeled after the C8 Health Study,[10] are also needed to accelerate our understanding of the health impacts of PFAS mixtures in humans. Finally, additional occupational biomonitoring (to study the half-live of PFAS in humans) and epidemiology (to study at-risk occupations, which, as noted during the NAS Committee on Toxicology 2022 Annual Meeting,[11] is currently a major data gap) would be beneficial to understanding and preventing PFAS risks to workers.

8. One challenge across all research goals is PFAS mixtures and formulations… more information is needed to understand the identity, composition, occurrence, source, or

effects on human health and the environment for mixtures of PFAS… What should be the research and development priorities for accelerating progress in these areas?

Recommendation: Understanding the composition and toxicity of PFAS mixtures in the environment is critical to the advancement of a federal PFAS research strategy. We therefore recommend that the USG (1) adopt a cumulative risk assessment framework for PFAS, (2) develop toxicity information on PFAS mixture effects, and (3) collect data regarding the composition of PFAS mixtures in the environment and products.

Adopt a cumulative risk assessment framework: Thus far, most PFAS risk assessments have been chemical-specific, focusing on one PFAS at a time. However, people are generally not exposed to one PFAS at a time, but rather directly and indirectly exposed to different mixtures of PFAS throughout their lifetime. As a result, a cumulative risk assessment framework that looks at the combined effects of PFAS co-exposures across chemical lifecycles should be applied across the federal government. There are existing tools to understand the potential environmental and human health risks from mixtures of PFAS, such as EPA's draft framework for estimating non-cancer health risks associated with mixtures of PFAS,[12] which could be built on to support other federal efforts to address PFAS mixtures.

Develop toxicity information on PFAS mixture effects: One important consideration for cumulative risk assessment is whether the effects of PFAS mixtures are additive, synergistic, or antagonistic. As introduced in our response to Question 7, mixtures testing plays an important role in identifying the type of mixture effect (additive, synergistic, or antagonistic) to be expected across different combinations of compounds and should therefore be included in the federal strategic plan for PFAS research and development.

It should be noted that EPA's current component-based PFAS mixture modeling approach assumes dose-additivity. While dose-additivity is a reasonable default assumption based on data on a limited number of PFAS, we believe it would be appropriate for EPA to require testing on different mixtures of PFAS to determine if the default assumption of dose-additivity is warranted for all PFAS. This is critical because if the effects of PFAS mixtures are greater-than-additive, or synergistic, a default assumption of dose-additivity would significantly underestimate the toxicity of PFAS mixtures and potentially lead to risk management actions that fail to sufficiently protect public health and the environment. The USG should consider leveraging its authorities under the Toxic Substances Control Act (TSCA) section 4[13] to develop needed toxicity information on PFAS mixtures (beyond well-studied PFAS PFOA and PFOS).

Collect data on PFAS mixtures in the environment and products: The USG should require companies to report releases of PFAS mixtures to the environment (e.g., under EPA's Toxic Release Inventory) and disclose the composition of PFAS mixtures in products (e.g., under the Toxic Substances Control Act) to inform prioritization (or subcategorization) and risk assessment efforts.

* * * * *

Environmental Defense Fund appreciates OSTP's consideration of these comments.

[1] OSTP, Request for Information; Identifying Critical Data Gaps and Needs To Inform Federal Strategic Plan for PFAS Research and Development, 87 Fed. Reg. 41749, July 13, 2022, https://www.federalregister.gov/documents/2022/07/13/2022-14862/request-for-information-identifying-critical-data-gaps-and-needs-to-inform-federal-strategic-plan

[2] EPA, "Questions and Answers: Drinking Water Health Advisories for PFOA, PFOS, GenX Chemicals and PFBS (Question 7)," accessed August 24, 2022, https://www.epa.gov/sdwa/questions-and-answers-drinking-water-health-advisories-pfoa-pfos-genx-chemicals-and-pfbs

[3] GAO, Technology Assessment, Persistent Chemicals: Technologies for PFAS Assessment, Detection, and Treatment (GAO-22-105088), July 28, 2022, https://www.gao.gov/assets/gao-22-105088.pdf

[4] EWG, "Mapping the PFAS contamination crisis: New data show 2,858 sites in 50 states and two territories," June 8, 2022, https://www.ewg.org/interactive-maps/pfas_contamination/

[5] O'Brien, K., "'Forever chemicals' upended a Maine farm – and point to a larger problem," Washington Post, April 11, 2022, https://www.washingtonpost.com/nation/2022/04/11/pfas-forever-chemicals-maine-farm/

[6] Brendel, S., Fetter, É., Staude, C. et al. Short-chain perfluoroalkyl acids: environmental concerns and a regulatory strategy under REACH. *Environ Sci Eur* 30, 9 (2018). https://doi.org/10.1186/s12302-018-0134-4

[7] OECD, Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, 2021, https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO(2021)25&docLanguage=en

[8] EPA, "Drinking Water Health Advisories for PFOA and PFOS," accessed August 24, 2022, https://www.epa.gov/sdwa/drinking-water-health-advisories-pfoa-and-pfos.

[9] Silva E, Rajapakse N, Kortenkamp A. Something from "nothing"--eight weak estrogenic chemicals combined at concentrations below NOECs produce significant mixture effects. Environ Sci Technol. 2002 Apr 15;36(8):1751-6. DOI: 10.1021/es0101227

[10] Frisbee SJ, Brooks AP Jr, Maher A, Flensborg P, Arnold S, Fletcher T, Steenland K, Shankar A, Knox SS, Pollard C, Halverson JA, Vieira VM, Jin C, Leyden KM, Ducatman AM. The C8 health project: design, methods, and participants. *Environ Health Perspect*. 2009 Dec;117(12):1873-82. https://doi.org/10.1289/ehp.0800379

[11] NASEM, Committee on Toxicology | 2022 Annual Meeting, July 21, 2022, ttps://www.nationalacademies.org/event/07-21-2022/committee-on-toxicology-2022-annual-meeting

[12] EPA, EXTERNAL PEER REVIEW DRAFT: Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS), November 2021, https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601

[13] 15 U.S.C. § 2603

To: White House Office of Science and Technology Policy
Re: RFI Response: PFAS Strategic Plan
Date: August 29, 2022

To Whom It May Concern:

The Association of Public Health Laboratories (APHL) appreciates the opportunity to comment on the White House Office of Science and Technology Policy's request for information, "Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development." APHL works to strengthen laboratory systems serving the public's health in the United States and globally. The organization represents state and local governmental health, environmental and agricultural laboratories in the United States. Our members, known as "public health laboratories," monitor, detect and respond to health threats.

APHL is responding to questions 6, 8 and 9 and would like to preface those answers with the following overall statement:

States cannot remediate contaminants they cannot detect and measure. The federal government must invest in building state and local laboratory capability and capacity to test for PFAS in a variety of matrices to work cooperatively and sustainably with their state programs and other federal and local partners. State and local laboratories play a number of analytical roles to meet public health needs, including the niche role of testing for analytes in matrices in locations that do not guarantee a profit.

6. What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of: analytical methods, detection limits, non-targeted detection?

To accelerate progress, improve efficiency, and reduce the cost of analytical methods, detection limits, and non-targeted detection, the following should be considered:

Analytical methods

1. Provide technical assistance, instrumentation, training, personnel, and financial resources to state, local and tribal environmental laboratories to increase analytical capability and capacity nationally for PFAS in environmental media. State and local laboratories have sophisticated testing capabilities and extensive emergency response experience which can be applied to help advance the science related to

PFAS contamination and exposure. To support this, US Environmental Protection Agency (US EPA) should develop a comprehensive network of state and local laboratories dedicated to identifying and measuring emerging chemical contaminants supported by advanced analytical training, technical assistance and direct and sustained funding, similar to sister agencies. Unlike laboratory network programs at the CDC (Laboratory Response Network, or LRN) and at the FDA (Food Emergency Response Network, or FERN), the Environmental Response Laboratory Network (ERLN) at US EPA receives nominal funding and therefore cannot provide funding to state and local laboratories to develop capability and capacity including funding large instrument purchases.

   a. COST ESTIMATE: For all 50 states and some large local laboratories, an initial investment of $1,000,000 per jurisdiction to bring on this testing, and then $300,000-$500,000 annually to sustain the work.

2. CDC should increase support for building capability and capacity for human biomonitoring in the state public health laboratories and for expansion of the National Biomonitoring Network.
   a. COST ESTIMATE: $120 million annually.

3. Harmonize testing methods for environmental and food matrices to streamline workflows and ensure laboratories do not spend extra time developing, validating and switching between methods. PFAS testing in state and local laboratories is burdened by needing to run multiple partly overlapping methods (up to five between US EPA and FDA methods) to detect PFAS for different matrices, where one harmonized method could be developed to cover all uses. For example, the new draft US EPA method 1633 utilizes all 40 known PFAS standards and is applicable across all matrices, except drinking water. This exception is due to administrative versus scientific reasons: the method is being promulgated as a Clean Water Act method and cannot be used for drinking water purposes. States must thus run US EPA drinking water methods 533 and 537.1 that together only quantify 29 of the 40 PFAS in method 1633. Ironically, laboratories part of a US EPA multi-laboratory validation study for method 1633 must demonstrate their competency with the method on drinking water first to qualify. Thus, by definition, the method works with drinking water.
   a. COST ESTIMATE: Theoretically $0 because the science is complete and US EPA would just need to enable method 1633 to be a drinking water method.

4. To broaden the capability to detect an ever-expanding list of PFAS, APHL recommends that US EPA require PFAS-manufacturing companies to register each chemical substance and to provide end products to a central repository to be used as reference material. Having this repository of external standards available to states would fill the gap between the 40 standards that are currently available, and the hundreds of PFAS that are known to be in active and future production and use across industries.

5. Support the development of standard and certified reference materials and robust proficiency testing systems for all environmental and human biomonitoring matrices.

6. Support the development of stable, isotopically-labeled internal standards to improve the quality of testing overall.

7. US EPA should set realistically achievable maximum contaminant levels for all environmental matrices. When laboratories need to detect down to drastically lower levels, this decreases the laboratory's efficiency and ruggedness of the assay. The recent PFAS drinking water health advisory levels have increased interest in environmental monitoring, food and consumer product testing and human biomonitoring to assess PFAS exposure.

8. US EPA and the Department of Defense (DoD) should develop and provide laboratories with instrument-specific interfaces and interoperable software packages to streamline reporting to DoD's level-4 validation standard and other strict US EPA or DoD reporting formats. This will greatly aid in participation in multi-laboratory method validation studies and environmental monitoring reporting.
    a. COST ESTIMATE: Three information technology full-time employees (FTEs).

9. Support the development of a national repository for human biomonitoring data related to PFAS exposure.

<u>Detection limits</u>

1. See #7 in section above.

<u>Non-targeted detection</u>

1. States and locals need US EPA to compile a centralized, high-quality library of PFAS physical properties to support unknown identification. States cannot remediate contaminants they cannot detect: of the thousands of known PFAS, current methods can measure only 40 using available target standards. In contrast, non-targeted analysis has the potential to identify all PFAS but depends entirely on a high-quality reference library of PFAS physical properties to translate unknowns to knowns. Commercial libraries are proprietary, small, and outdated, while academic libraries are not readily available and experimental.
    a. COMBINED COST ESTIMATE for #1 and #2 below: $500,000, based upon:
        i. 1-2 hours per analyte (for the data and confidence score),
        ii. times a target number of 2000 analytes (4000 hours or 2 FTEs),
        iii. plus $100 to buy each analyte from scratch to generate the physicochemical properties ($200,000).

2. This library must also output identification confidence scores such that tentative hits do not rely on highly specialized chemistry experience. Only when such a common-currency library becomes available to states and locals, will it become possible to apply non-targeted analysis across the nation and with comparable interpretation. Currently, non-targeted PFAS work is extremely labor intensive, taking up to 100 times more time than targeted PFAS work. The development of this library would significantly decrease the time required for non-targeted testing and free up valuable analyst time.

8. One challenge across all research goals is PFAS mixtures and formulations. Currently, more information is needed to understand the identity, composition, occurrence, source, or effects on human health and the environment for mixtures of PFAS found in environmental media. Additionally, more information is needed to understand the best way to remediate or destroy media contaminated with multiple PFAS. What should be the research and development priorities for accelerating progress in these areas?

1. Develop technical PFAS standards that accurately represent both branched and linear isomers to ensure all isomers can be detected with confidence.

2. Require all companies that make and sell PFAS to register with US EPA or the National Institute of Standards and Technology and provide external standards for every analyte they create. Also see the #4 analytical methods response for question six above.

9. What goals, priorities, and performance metrics would be valuable in measuring the success of National, federally-funded PFAS research and development initiatives relating to:
a. The removal of PFAS from the environment;
b. Safely destroying or degrading PFAS; and
c. Developing safer and more environmentally-friendly alternatives to PFAS?
d. Mitigating negative human effects of PFAS, whether related to health or additional domains?

<u>The removal of PFAS from the environment:</u>

1. States cannot remediate contaminants they cannot detect and measure. Invest in building state and local laboratory capability and capacity to test for PFAS in a variety of matrices to work cooperatively and sustainably with their state programs and other federal and local partners. State and local laboratories play a number of analytical roles to meet public health needs, including the niche role of testing for analytes in matrices in locations that do not guarantee a profit. This investment would create a network of laboratories that can conduct testing and generate results that can directly support public health decision-making for communities nationwide. This would include investment in:
    a. infrastructure
    b. analytical instrumentation
    c. supplies
    d. technical training
    e. laboratory information management systems
    f. skilled staff
    g. retention of highly-trained laboratory scientists

    On-going training is essential to support the production of reliable data. Due to the high stakes of these tests, some state programs are requiring quality control to have no qualifiers. This ensures confidence in the results, but also requires additional resources to achieve.

87 FR 41749: Request for Information on Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development

August 26, 2022

Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development

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RTI INTERNATIONAL

RTI International is pleased to provide the following response to the Request for Information on Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development. RTI is driven by our own mission to improve the human condition, and we seek to create and apply programmatic and technological solutions that will make a positive difference around the world. With decades of experience in supporting the federal government in advanced research to combat pollution, RTI is uniquely qualified to respond to this RFI. Our response presents relevant examples selected to illustrate important work we have performed, and lessons learned.

1. Should the USG consider identifying priority PFAS when developing a strategic plan for PFAS research and development? If so, what criteria should be used to identify priority PFAS for research and development (*e.g.,* tonnage used per year; releases to the environment per year; toxicology or other human or environmental health concerns; national security or critical infrastructure uses)?

The USG should consider identifying priority PFAS for research based on toxicology and human health concerns. The extensive matrix of health concerns, variety of PFAS chemicals, and deficiency in the database necessary for understanding exposure and effects of each PFAS compound suggest that it would be prudent to identify priority PFAS for extensive evaluation. However, the slow nature of the contaminant-by-contaminant approach for understanding human exposure and characterizing health risks will put many in the population at risk for longer than necessary. Establishing a priority list of PFAS may have the benefit of accelerating the removal from use of these compounds but may lead to replacement with new and untested compounds, as was the case for example with bisphenol A. Consideration must be given to the toxicity and health effects of PFAS both from animal bioassays and epidemiology studies, environmental persistence, bioaccumulation potential, and prolific use in selecting priority PFAS. As new data are generated in *in vitro* test systems, in animal investigations, and in human health investigations, additions to a priority list should be possible.

3. Based on the definition of PFAS in this RFI, what are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS and to identify cost-effective:

    a. Alternatives to PFAS that are designed to be safer and more environmentally friendly.

Traditionally, PFAS molecules have seen wide adoption because the unique chemistry of a fluorocarbon provides performance that is appealing across numerous product categories. From a formulary angle, PFAS provides high performance at very low concentrations, which often yields a price advantage. This has led to PFAS proliferating across multiple product categories and types including outdoor gear and apparel, cookware, textiles, firefighting foam, ski wax, cosmetics, packaging, electronics, and oil and gas. Through our work with industry, we know the PFAS problem is endemic—we have seen PFAS in niche products such as cat litter, dental floss, and markers/writing utensils.

Currently, we are at a unique point in industry regarding replacing chemicals of concern (including PFAS). A critical mass in industry is actively looking for alternative, more environmentally benign, fluorine-free compounds to replace the family of PFAS molecules. Many have been spurred by consumers or by EPA's release of the PFAS Strategic Roadmap. In many cases, these companies are even indicating that they are willing to take a "performance hit" with an alternative (something we have not seen previously). This is a unique time where substantial energy and appetite exists within industry to find better replacements. As with other sustainability challenges, PFAS replacements are a systems challenge that require cooperation and coordination across industry's value chains. Many companies in the United States are struggling as they attempt to find replacements on their own. We know from our work in the space that finding replacements in a vacuum can be cost-prohibitive and slow. Like other systems challenges within sustainability, these companies' efforts could be amplified via collaboration and organization. This is currently being accomplished in other areas of sustainability by establishing consortiums or working groups.

One noteworthy example of a working group for the PFAS space can be found in Sweden where is it managed by the Research Institute of Sweden (RISE), an independent state-owned research institute. RISE has created POPFREE. POPFREE has been working with various industry players across Sweden to identify or develop replacement chemistries for PFAS. This working group has found and co-developed alternatives to PFAS in ski wax, among other projects. In January 2022 they convened a working group for cookware and invited international attendance. Traditionally POPFREE has worked exclusively with Swedish industry. A similar U.S.-based initiative would be beneficial to industry and help to harness the energy that already exists in finding replacement chemistries. It would also help to offset the cost of replacing PFAS.

It is worth noting that earlier in this decade chemical companies that play in the PFAS space developed "PFAS alternatives" that transitioned from longer C8 chain compounds to shorter chain C6 compounds that were marketed as "more environmentally benign" chemistries. In reality there was little testing done to back up their improved properties, and these chemistries turned out to be equally or in some cases more environmentally harmful. Today these C6 replacement chemistries are now included in the PFAS family of chemicals. This trend of replacing one chemistry with other chemistries (such as the incorporation of ether groups within the alkyl chains) that in turn pose similar environmental and health risk is known within the industry as "substitution whack-a-mole." Indeed, the biggest challenge with replacement of chemicals that are identified as harmful with safer alternatives is that the testing of alternatives is frequently inadequate, and we are replacing a harmful substance with a substance with unknown properties. More transparency and greater collaboration with industry and academia is required to ensure that alternatives truly are safe. Maine has an interesting law that will be enacted in 2023, with reporting of products containing detectable levels of PFAS compounds with fluorinated carbon and banning of the sale of carpets rugs and fabrics with intentionally added PFAS.

4. Are there specific chemistries and/or intended uses that PFAS provide for which there are no known alternatives at this time?

Much of the work occurring with identifying/developing alternatives is centered on well-known traditional usages of PFAS. Thus, we are seeing a good deal of work on PFAS alternatives in stain and oil resistance (oleophobicity) and water repellency (hydrophobicity). Some great strides and viable, fluorine-free alternatives have been identified in these spaces. Of the major traditional PFAS uses, nonstick cookware continues to lack viable chemistries. Numerous approaches have been tried and are generally tested within industry using the "egg test." The egg test fries an egg on the surface without using any fat. We are not aware of any technologies that have passed the egg test.

We are most concerned with the replacement chemistries available for the myriad niche applications. These applications tend to "fly under the radar," and most people are not even aware that these products use PFAS. For instance, we have completed work with industry where PFAS was used as a de-dusting agent in a very price-sensitive product. Few off-the-shelve replacements functioned as well. We have also done work to find a replacement where PFAS was used as a wetting and leveling agent for a coating that was particularly difficult to replace. We have worked on several other examples as well that have limited alternatives; for example, marker or pen "windows" that show how much ink is left are coated with PFAS. These applications are not as high profile and tend not to have many viable alternative replacement chemistries.

There have also been some notable successes in a few areas that are worth mentioning. For instance, good replacements have been developed for firefighting foam. Additionally, through the previously mentioned Swedish consortium POPFREE some excellent alternatives have been implemented in ski wax. We also know that PFAS usage has been essentially eliminated in cosmetics.

6. What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of: analytical methods, detection limits, non-targeted detection?

The most significant barrier to progress and cost-effective analysis of PFAS is the limited availability of chemical standards of many PFAS. Many of the thousands of compounds classified as PFAS have only been

described in patent literature. They may be synthesized and used commercially as components in a mixture (such as firefighting foams) or generated as unintended byproducts during industrial or manufacturing processes. Although certified standards for more common legacy PFAS are commercially available, analytical standards of newer replacement and emerging PFAS are needed to support their detection, identification, and quantification.

Certified standards are critical for both targeted quantitative analyses and nontargeted analytical workflows, where they are used to confirm the identification of compounds. Further, in quantitative mass spectrometric analysis, stable isotope-enriched (i.e., mass-labeled) analogs of known compounds serve as internal standards to compensate for changes in instrument operating conditions or in sample composition that can impact measurement accuracy. As such, synthesis of a wider range of isotope-enriched compounds would facilitate detection and quantification of more PFAS in samples. In addition, a government repository of PFAS standards, similar to those maintained by the National Institute on Drug Abuse for controlled substances and by the National Cancer Institute for natural products, could facilitate the generation of and access to PFAS standards for research.

Another priority area of research investment is the elucidation of synthetic methodologies to allow noncommercial researchers to keep pace with the commercial development of novel PFAS compounds. As discussed above, the chemical diversity of PFAS compounds is constantly evolving as manufacturers develop new replacement molecules to adjust to regulatory oversight. Currently, very few independent groups have the capabilities and expertise to synthesize novel PFAS compounds because of the specialized equipment and hazardous reagents needed for existing methods. Investment in the development of safer, easier methods would support the expansion of these capabilities and allow researchers and regulatory agencies to keep abreast of developments in industry.

Adding to the challenge of the chemical diversity of PFAS being produced globally, the ubiquitous use of the compounds and their persistence in the environment results in the need to measure PFAS in a plethora of sample matrices. However, there is no universal analytical method for measuring all forms of PFAS in all environmental media and consumer products. Currently a limited number of standard validated methods exist for PFAS analysis, making interlaboratory variability a concern. These techniques require experienced chemists to prevent contamination of these ubiquitous compounds and skilled data analysts to accurately interpret the complex data generated, particularly by nontargeted analysis. Additionally, current methods require sophisticated, dedicated instrumentation not routinely available in most labs. For example, identification and confirmation of novel PFAS relies on high-resolution mass spectrometry and other specialized laboratory techniques such as multistage solid phase extraction.

The development and validation of additional standard protocols with applicability to more PFAS and a range of sample types can help to mitigate interlaboratory variability and ensure accuracy of results. One approach to supporting this goal would be the establishment of PFAS-focused analytical centers of excellence like the National Institute of Environmental Health Sciences Exposure Resources Human Health Exposure Analysis Resource, and Children's Health Exposure Analysis Resource, with a goal of standardizing PFAS measurements. Likewise, development of a PFAS lab accreditation program, including analyst proficiency training, could also improve laboratory efficiency and consistency.

7. What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans (*e.g., in vitro,* animal toxicological, and epidemiological studies)? Which health effects should be prioritized? What additional impacts beyond health should be prioritized? Social scientific approaches are welcome in addressing this question and any others, as appropriate.

In vitro, animal toxicological, and epidemiological studies are needed to build the weight of scientific evidence needed to understand the health effects of PFAS and to adequately regulate PFAS compounds.

***In vitro* studies**, particularly high-throughput toxicity assays, can rapidly assess large numbers of PFAS compounds. Novel *in vitro* cell models that examine differential effects of gender and race must be developed with a variety of cell types to understand the impact of PFAS exposure on specific target organs to help predict toxicity, provide insight for PFAS groupings, and facilitate prioritizing PFAS for further characterization.

Animal toxicological studies enable scientists to vary exposure conditions (e.g., exposure routes, multiple PFAS compounds, co-exposures with other pollutants) and concentrations. This can not only improve our understanding of the toxicity of PFAS compounds, but also provide insight on the absorption, distribution, metabolism, and elimination of PFAS compounds. Animal studies can also provide toxicity data needed for risk assessment and risk management.

Epidemiology studies can directly investigate and document associations between PFAS exposures and disease outcomes and provide data needed for risk assessment and risk management. These studies can be designed to address the following four areas of need:

A. Understanding the adverse health effects of PFAS exposure

Exposure to specific PFAS compounds has been associated with a variety of health effects (e.g., liver, kidney, and thyroid disease; lipid and insulin dysregulation; adverse reproductive and developmental outcomes; and several types of cancer). To date, most studies have been cross-sectional in nature, have small sample size, or have been conducted in occupational cohorts or in communities known to have had high environmental PFAS exposure. Additional studies are needed to address specific health concerns (e.g., a case-control study to evaluate associations between PFAS exposure and increased risk of specific cancers). Because many epidemiologic studies rely on self-reported exposure, large prospective cohort studies with sufficient follow-up time are needed that include objective exposure assessment, serum PFAS measurements, and health outcome data. Studies are needed to investigate the effect of PFAS exposure in pregnant women, breast-fed infants, and children including studies to understand whether maternal PFAS exposure is associated with epigenetic changes that can negatively impact offspring health. It will also be important to study the health effects of acute or long-term exposure to high levels of PFAS (e.g., in occupations where PFAS are commonly used like firefighting) versus long-term exposure to lower levels of PFAS (e.g., in communities with contaminated drinking water).

B. Understanding populations at risk for adverse health effects of PFAS exposure

Environmental justice and epidemiological research is needed to investigate whether (1) specific sociodemographic groups defined by age, sex, race/ethnicity, and birth cohort are at a higher risk for certain adverse health effects from PFAS exposure; and (2) there are genetic factors that predispose certain individuals to increased risk of adverse health effects. Geographic Information Systems and environmental monitoring data could be used to supplement community surveys in understanding at-risk populations.

C. Understanding levels of exposure

Exposure assessment studies are needed to understand the level of exposure required to adversely affect human health. Serum levels for specific PFAS compounds that may lead to health effects are currently unknown. Systematic assessment of environmental concentration-dose-response relationship, interactions between different PFAS compounds, simultaneous exposure of PFAS and other environmental contaminants, and different sources and routes of exposure are all required to develop an effective public health policy to regulate PFAS compounds and to design *in vitro* and *in vivo* studies for realistic exposure scenarios and toxicities. Furthermore, laboratory methods to quantify PFAS levels in humans and in environmental media in addition to drinking water need to be standardized and validated.

D. Developing guidance for communities and healthcare providers

There is a need to provide better guidance to affected persons and their healthcare providers on ways to monitor the health of persons exposed to high levels of PFAS. This includes effective communication methods for

researchers and the ethical aspects involved. Results of epidemiological studies in occupational cohorts can help develop guidelines to protect the health of workers exposed to high levels of PFAS.

9. What goals, priorities, and performance metrics would be valuable in measuring the success of National, federally funded PFAS research and development initiatives relating to:

    c. Developing safer and more environmentally friendly alternatives to PFAS?

A priority as we look to develop safer and more environmentally benign alternatives to PFAS is to not repeat the mistakes of the past. Specifically, as mentioned earlier, shorter chain C6 alternatives were developed to replace longer chain C8 PFAS compounds only to later learn that these compounds are equally as bad and sometimes worse for human health and the environment. These PFAS compounds that were deemed alternatives were developed and made it into market because at the time a different value system proliferated through industry and because these C6 alternatives were developed by industry, for industry, and without other stakeholder input. The value system that governed industry:

- was focused on meeting consumer demand and preference, which industry believed was increased or improved performance at a price they could afford; and
- had little to no designing for end of life or long-term health effects.

Today, the commercial environment is quite different as consumers are demanding better, safer chemicals in the products they use. We are currently also in a sustainable revolution within industry. Spurred by NGOs such as the Ellen Macarthur Foundation and ESG reporting, companies are making deep commitments to improving their environmental and human health effects of their operations, suppliers, and products. Industry also believes that regulation is coming to the United States related to PFAS and other chemicals of concern. We believe that the government should strike while the iron is hot. The momentum is now and provides an excellent opportunity for the government to capitalize on this. In the short term, we would prioritize the following actions:

1. Alternatives of the past presented health and human safety challenges because they were developed in a vacuum by industry and did not consider the needs and concerns of stakeholders outside of this group. To improve the environmental qualities of alternatives one must consider the perspective of various stakeholders and we suggest the government take a human-centered design approach to developing these. Establish a consortium or working group that includes these perspectives from product development experts, innovation experts trained in technology scouting and able to find viable alternatives used within other industries, toxicologists looking at the long-term fate of the molecules, government regulators who will impact policy, academia who could be working on alternatives, and industry who must implement the chemistry in a complex solution at a specific price. We recommend that this working group be housed in a benign organization such as a research institute or an academic institution that can ensure collaboration between all parties.
2. Require reporting of products that currently contain PFAS compounds. Given the endless applications and products that currently contain PFAS it is prohibitive to find all the niche uses without disclosure from industry.
3. Restrict the use of PFAS in the United States as industry expects. Regulation is a strong motivator for innovation. We are currently seeing that play out. This already may be play with EPA's PFAS Strategic Roadmap.

In the long term it also equally important to better arm the chemists of the future who will venture into industry so that they can make better synthesis and formulary decisions. Chemical education traditionally has not included the fundamentals of green chemistry. However, if we trained our chemists that certain classes of molecules have proven to be problematic and should be avoided, we could prevent many of these decisions being made. Funding and curriculum for university courses could help to address this need.

Request for Information: Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development; Office of Science and Technology Policy (OSTP); Federal Register, Vol 87., No. 133; Wednesday, July 13, 2022.

Montrose Environmental Group, Inc.

Montrose Environmental Group (MEG) is pleased to provide the following in response to the Request for Information (RFI) published in the Federal Register on July 13, 2022 (Vol 87, No. 133) from the Office of Science and Technology Policy's RFI titled *Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development*. Specifically, MEG is responding in part or in total, to questions 3 and 9.

Response to Question 3:

MEG believes there are several scientific, technological and human challenges that must be addressed to understand environmental and human impacts of PFAS and to identify cost effective methods for removal and destruction of PFAS from the environment. The most significant of those challenges are improving the performance of technologies to remove PFAS from water and eliminating the PFAS present in the residual contaminated media that remains post-treatment. **With the recent EPA notice of proposed rulemaking designating perfluorooctanesulfonic acid and perfluorooctanoic acid as CERCLA hazardous substances, the importance of reducing waste volumes during treatment operations is imperative.**

Conventional treatment technologies are semi-effective at removing PFAS from media such as soil, water, and air. However, these technologies ultimately transfer the contaminant from one matrix (soil, water, air) to either an adsorbent (i.e., granular activated carbon or ion exchange resin) or into a concentrated brine reject stream (i.e., reverse osmosis or nanofiltration membrane technologies). When using adsorbents or membranes, further processing of the residuals must occur, resulting in additional time, cost, and potential future liability.

Concurrently, novel technologies are being investigated and developed to move beyond *concentration* of PFAS and instead *destroy* PFAS. Destruction technologies, while reducing potential harm and eliminating future liability concerns, are still in a nascent stage of maturity and are only likely to be viable for treating concentrated PFAS waste. Higher capital and operational costs combined with a limited ability to treat significant flow-rates make immediate full-scale implementation of these destructive technologies impractical. The development of destructive technologies is due, in large part, to the support of the research and development community, and it is the opinion of MEG that this should be continued (e.g., the Strategic Environmental Research and Development Program, Environmental Security Technology Certification Program and the Navy Environmental Sustainable Development to Integration program). In all likelihood, **a combination of technologies, or a treatment train approach, will be the solution going forward for comprehensive PFAS treatment**. Combining a technology concentrating a higher volume of low concentration PFAS into a higher PFAS concentration at a lower volume will make destructive technologies more cost-competitive and quicker to market.

One technology which has been demonstrated at the bench-, pilot- and full-scale is the use of *regenerable* ion exchange resins. **It is the opinion of the authors that regenerable resin technology has not been as thoroughly investigated or optimized and is deserving of additional research, development, and demonstration by the broader scientific community.**

Conceptually, the idea of the regenerable resin capitalizes on the same removal mechanisms as single-use ion exchange resins. **The ability for regeneration and *the subsequent waste reduction* of PFAS-impacted media is what differentiates regenerable resin technology**. The regeneration process involves the use of a solvent and brine solution to remove the PFAS on the resin, followed by a distillation step allowing near 100% of the solvent for reuse in follow-on regeneration cycles. **The volume reduction of the remaining PFAS waste (or still bottoms) is significant; it has been demonstrated at full-scale capacity at a ratio of 1,000,000:1.** The still bottoms are a concentrated matrix well-suited to PFAS destructive technologies as described earlier using a "treatment train" approach. **The ability to achieve such significant waste reduction *today* – and a commensurate reduction in future liability - is the differentiation and the bridge between today's conventional *concentrating* technologies and tomorrow's *destructive* technologies.**

Four areas are highlighted below to further the evaluation of regenerable resin and more generally, the efficiency of managing PFAS issues.

a) <u>Understanding the environmental impacts of PFAS treatment technologies through comparative life cycle assessment.</u>

The cost implications of treatment selected are important, but a more holistic approach considering other, second-order and follow-on effects should be further characterized. This can be accomplished with a comparative life cycle analysis (LCA) of regenerable resin vs conventional technologies. Important metrics to consider when selecting remedial technologies include, but are not limited to: global warming potential, cancer and noncancer toxicity along the value chain of materials used, environmental effects of waste disposal decisions made, as well as acidification, eutrophication, ecotoxicity and fossil fuel depletion. In addition to directly supporting the Biden Administration's goal to protect Americans from PFAS, quantifying these metrics will provide valuable data for environmental justice and climate change initiatives. **Regenerable resins have shown more favorable environmental metrics than granular activated carbon** (Emery, 2018), but verifying and updating the metrics used to reflect current energy mixes and making comparisons to single-use resins should be undertaken.

As an example, optimal deployment of the regenerable resin treatment technology involves properly operating and maintaining a regeneration system. The siting of the regenerable resin facility can be accomplished via two primary pathways: an on-site regeneration facility for larger remediation efforts or a 'hub-and-spoke' approach allowing for multiple, smaller sites to use one collective facility for regeneration. Failure to optimize facility siting results in incomplete or inaccurate analysis of cost and environment impacts. Solvent/brine/water mixing

ratios and energy requirements are other variables that can have a large influence on both financial and environmental implications to the regenerable resin technology. Incorporating more environmentally friendly production methods for solvents used during regeneration (e.g., particular solvent generation steps, steam vs electric turbine drives for compressors, etc.) will alleviate environmental burden. Brine selection and supply chain considerations (e.g., material extraction, energy use for evaporation, abstractions and discharges to the environment during mining and production, etc.) also carry unique environmental impact. Additionally, ensuring a greater mix of renewable energy (i.e., a more accurate 2022 mix) into the analysis for the required electrical and heating requirements will further reduce CO2e emissions.

b) Validation of the Rapid Small-Scale Column Test (RSSCT) for the evaluation of IEX resin performance.

The use of the rapid small-scale column test (RSSCT) allows for qualitative, and sometimes quantitative, predictive breakthrough data of organics from granular activated carbon and has been studied extensively (Crittenden et al. 1989; Kempisty et al. 2021). The use of the RSSCT requires significantly less quantities of water and expedites the time until results are received. Recent work has been accomplished using the RSSCT for IEX applications (Zeng et al. 2020; Schaefer et al. 2021); however, standard methodology has not been published and standard operating procedures are still evolving. Furthermore, fundamental questions remain to confirm the homogeneity of ion exchange resins when ground (compared to full bead size). Isotherm capacity and kinetic work has been accomplished, but a comprehensive understanding of scale-up, gel vs macroporous considerations, constant diffusion vs proportional diffusion designs, bead grinding methodologies, and design considerations for mass transfer zone capture is not complete. **Understanding and publishing more rigorous RSSCT information would go a long way to expedite evaluation of various media in PFAS remediation, saving significant time and costs.**

c) Destructive technologies specifically for still bottoms– i.e., high salt matrices.

As stated previously, extensive research and development has been committed to PFAS destruction technologies. Sonolysis (Kalra et al. 2021), non-thermal plasma (Singh et al. 2020), electron-beam (Lasalle et al. 2021), reductive UV/sulfite-iodide (Liu et al. 2022), electrochemical oxidation (Liang et al. 2018), and sub- and super-critical thermal treatment technologies (Hao et al. 2022, McDonough et al. 2022) have all been researched. It is the opinion of MEG that this should continue. However, **further research involving destruction of regenerable resin still bottoms should be an additional focus for academia, private enterprise and the Federal and State government**. The still bottoms provide the 1,000,000:1 waste reduction, making the regenerable resin so noteworthy that destructive technologies should focus on this particular matrix. With its high salt content and high PFAS concentrations, this matrix may be more challenging for certain destructive technologies (e.g., supercritical water oxidation (McDonough et al. 2022) than others (e.g., reductive UV sulfite treatment (Liu et al., 2022). Novel

technologies could be investigated (e.g., salt separation) to allow for destructive PFAS treatment in high salt waste streams with a pre-treatment step.

d) Materials science focus using catalytic carbon nanofibers, or other novel materials, to develop PFAS sensors.

The lack of real-time PFAS measurement capabilities in the field is a hinderance to efficient operation of PFAS treatment systems. Site characterization work and remedial investigation would both benefit from development of such technology. Preliminary efforts have been carried out using carbon nanotubes for the catalytic destruction of micropollutants (Wang et al. 2021, Vijwani et al, 2018). The same catalytic degradation processes produce an electrical signal which is detectable through the highly conductive carbon nanotubes. The intensity of the signal can be correlated to the concentration of PFAS. To date, nanoparticle technologies have been hampered by loss of nanomaterial to the environment. More recent work has resulted in the development of durable and reusable hybrid adsorbent-catalyst membranes with the same advantageous properties but with durability in the environment. Further **advancing materials science and sensors research would optimize PFAS characterization and treatment, and remediation of other hydrophobic contaminants**.

Response to Question 9:

When developing goals, priorities and performance metrics for research and development efforts, it is important to think through the environmental implications of the technology selected. Similar to our response for question 3, **a comparative LCA will provide quantitative insight into the different environmental impacts of different technologies.** Similarly, it is important to be aware of the additional environmental impacts associated with destructive technologies (e.g., perchlorate formation during electrochemical destruction, destruction technologies not achieving full mineralization and forming shorter-chain PFAS residuals).

Conclusion:

Regenerable resin is capable of treating high flow rates while producing significantly reduced volumes of PFAS waste. The residual waste is highly concentrated and ideal for tomorrow's destructive technologies. Planned **CERCLA Hazardous Substance designation for at least two PFAS, emphasizes the importance of diminishing future liability with waste minimization (regenerable resin) and achieving ultimate PFAS destruction.** Regenerable resin and the destruction of residual still bottoms should be more thoroughly investigated and optimized by an unbiased and independent research community.

Fully understanding environmental benefits and consequences of both regenerable resin and destructive technologies with quantitative LCA work is worth the investment. **It directly supports the Biden Administration's progressive stance on combatting PFAS. It provides a holistic perspective on the environmental impact of remediation efforts that can last for decades. Finally, it facilitates moving the treatment approach from a concentration-based**

approach towards ultimate destruction of these recalcitrant chemicals. Additionally, further development of destructive technologies to handle the unique regenerant matrix is encouraged. Ensuring the fundamentals of using the RSSCT for ion exchange resins and development of real-time sensors with novel materials would also greatly improve PFAS project efficiencies.

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Response of The MITRE Corporation to the OSTP RFI on PFAS Research and Development

August 29, 2022

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About MITRE

MITRE is a not-for-profit company that works in the public interest to tackle difficult problems that challenge the safety, stability, security, and well-being of our nation. We operate multiple federally funded research and development centers (FFRDCs), participate in public-private partnerships across national security and civilian agency missions, and maintain an independent technology research program in areas such as artificial intelligence, intuitive data science, quantum information science, health informatics, policy and economic expertise, trustworthy autonomy, cyber threat sharing, and cyber resilience. MITRE's 9,000-plus employees work in the public interest to solve problems for a safer world, with scientific integrity being fundamental to our existence. We are prohibited from lobbying, do not develop or sell products, have no owners or shareholders, and do not compete with industry. Our multidisciplinary teams (including engineers, scientists, data analysts, organizational change specialists, policy professionals, and more) are thus free to dig into problems from all angles, with no political or commercial pressures to influence our decision-making, technical findings, or policy recommendations.

MITRE supports multiple federal agencies, ranging from defense- to health-focused, as they address challenges emerging from per- and polyfluoroalkyl substances (PFAS) contamination. We help provide a systems-level perspective by bringing together chemists, geospatial analysts, environmental epidemiologists, and water quality experts to collaboratively study issues and develop solutions. MITRE scientists explore ways to apply our capabilities to emerging challenges in key areas, such as the development of novel sensors, indicators and warnings, resilience, and mitigation capabilities, where we already have significant expertise. This includes developing rapid, real-time screening of PFAS in water, geospatial models to prioritize areas of increased PFAS vulnerability for continuous monitoring, and decision support tools to evaluate tradeoffs in remediation technologies. Our experts have also worked with state governments (e.g., Colorado, New Hampshire), industry (e.g., remediation companies, drinking water treatment plant operators) and academic institutions (e.g., University of Alabama, Clarkson University) to identify research gaps and develop capabilities and solutions that would enable more rapid, lower-cost detection and remediation of chemical contaminants across the defense and public sectors. As such, the MITRE team has gained insight into critical research and capability gaps, which informs the response to this RFI.

Questions Posed in the RFI

1. Should the USG consider identifying priority PFAS when developing a strategic plan for PFAS research and development? If so, what criteria should be used to identify priority PFAS for research and development (e.g., tonnage used per year; releases to the environment per year; toxicology or other human or environmental health concerns; national security or critical infrastructure uses)?

Priority PFAS species should be a combination of those species that have the highest tonnage usage per year in addition to high toxicity to human and environmental health. As toxicity profiles do not exist for all known PFAS species, priority should be given to classes with similar structures to known toxicants, like per-fluorinated carboxylic acids (PFCA) and per-fluorinated

sulfonic acids (PFSA). PFCA and PFSA are the most common breakdown products and are frequently found in contaminated water and soil. Additionally, a broad and simple definition for PFAS should be maintained and chemical providers should be required to report the amount of any PFAS chemical. This will keep a pulse on replacement molecules once other PFAS become regulated.

3. Based on the definition of PFAS in this RFI, what are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS and to identify cost-effective:
   a) Alternatives to PFAS that are designed to be safer and more environmentally friendly;
   b) Methods for removal of PFAS from the environment; and
   c) Methods to safely destroy or degrade PFAS?

3B: A vital consequence of any method used to remove PFAS is the generation of additional waste streams that will ultimately need to be destroyed. For example, granular Activated Carbon (GAC) and Ion-Exchange Resin (IX) currently stand as the two most common technologies for removing PFAS from water[1] and are used in wastewater treatment facilities and as part of remediation efforts. Both work by attractively adsorbing PFAS to their structure. As contaminants interact with the sorbents, sites get filled; full sites result in PFAS breakthroughs[2]. This leads to filter replacement or regeneration, both of which produce additional waste streams for PFAS. Current sampling protocols for PFAS are not fast enough to detect breakthrough on a meaningful time scale. A filter could be failing for a week before an operator receives indication.

There are several promising emerging technologies for capturing PFAS. Surface-Activated Foam Fractionation (SAFF™) exploits PFAS' preference for the air-liquid interface to concentrate the chemicals in bubbles. These bubbles can be collected, removing the contaminant, but creating an additional waste stream. Several plant-based solutions are being tested as well. Cattails have been shown to act as water filters and will store PFAS. This acts to purify the water, but again produces an additional PFAS waste stream.[3] When it comes to landfilling PFAS-contaminated waste, this may lead to leachate ending up back in the wastewater stream. Novel sorbents are being developed to bind PFAS more effectively, but all sorbents will eventually experience breakthrough. Rapid, on-site testing is needed to adequately manage PFAS contamination.

3C: There are several promising technologies that still require development and testing, but the field is rapidly expanding. Newly reported research in *Science* suggests a path towards low-temperature mineralization of specific PFAS species that leveraged computational power to identify effective degradation paths for perfluoroalkyl carboxylic acids.[4] Most destructive technologies are not selective towards PFAS, but rather break down all organic substances. This

[1] H. Vo, et al. Poly- and perfluoroalkyl substances in water and wastewater: A comprehensive review from sources to remediation. 2020. Journal of Water Process Engineering

[2] R. Verma, et al. Remediation and mineralization processes for per- and polyfluoroalkyl substances (PFAS) in water: A review. 2021. The Science of the Total Environment

[3] W. Zhang, et al. Destruction of Perfluoroalkyl Acids Accumulated in Typha Latifolia through Hydrothermal Liquefaction. 2020. ACS Sustainable Chemistry & Engineering.

[4] B. Trang, et al. Low-temperature mineralization of perfluorocarboxylic acids. 2022. *Science*, *845*(August), 839–845.

means that the efficiency of PFAS breakdown is impacted by the other substances found with it. A concentration of organic material will require more cycles to see the needed degradation of PFAS. This usually means additional filtering steps before destruction. Additionally, many destructive techniques show incomplete destruction of PFAS. True mineralization will reduce all fluorine to fluoride (F-), but the energy requirements needed to break down PFAS often yield small, usually volatile, PFAS compounds. These techniques are also limited in their throughput. Scaling up these technologies may be challenging. Energy costs should be considered as well.

For any PFAS remediation effort to be successful, it is critical that rapid, on-site detection occur to allow for the remediation conditions to be adjusted as the process is performed. As current laboratory methods are experiencing sometimes months of backlog, this gap poses a significant challenge.

6. What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of: analytical methods, detection limits, nontargeted detection?

Lack of accurate and rapid field-testing methods limits R&D breakthrough and our ability to make informed decisions in regard to contamination. Currently, samples are sent out to an EPA-accredited laboratory to perform LC-MS/MS analysis for a subset of PFAS compounds. This process can take 2-6 weeks, preventing site managers from making decisions in real-time. In the case of water treatment facilities, a breakthrough of PFAS could go unnoticed for a week and effect countless end users. It also limits understanding on how PFAS moves as a function of weather, natural disasters, or emergency action (like use of AFFF). The most significant analytical improvement would be developing a tool for on-site analysis of PFAS. This tool does not need to replace LC-MS/MS analysis or even compete with its accuracy. It needs to serve as a screening tool to provide rapid decision support. This would reduce the number of samples sent for testing and reduce the overall time requirement moving forward.

In the interim, focus should be on accelerating or optimizing current methods (e.g., increased preconcentration or sample preparation methods), focusing on sampling for not only bodies of water, but other media that contain PFAS (e.g., soil, air, biomass), and improving non-target methods. Non-target methods, like total organic fluorine (TOF), provide valuable information when assessing the scope of contamination, but heavily rely on thermal degradation of the sample which can be difficult to reproduce.

7. What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans (e.g., in vitro, animal toxicological, and epidemiological studies)? Which health effects should be prioritized? What additional impacts beyond health should be prioritized? Social scientific approaches are welcome in addressing this question and any others, as appropriate.

To address the current gaps in understanding PFAS health effects in humans, additional health studies are needed to gather PFAS blood serum data for “low exposure” populations across a range of PFAS analytes. As part of the National Health and Nutrition Examination Survey (NHANES), data on PFAS blood serum levels for “low exposure” populations has been collected

for ~20,000 individuals, but additional cross-sectional and cohort studies are needed from diverse communities and geographies. PFAS exposure assessment via biomonitoring of blood and urine concentrations is critical to surveillance efforts, ideally, as part of a system integrating health outcome data from disease registries (cancer, birth defects, etc.). Adequate time series data of PFAS serum levels are also lacking. Consistent time series data (for example: weekly/daily data of PFAS blood serum levels versus weekly/daily data of individuals' blood glucose levels), would enable causal modeling and analysis (Bayesian networking, Granger, etc.) to examine health effects across different PFAS species beyond the correlational level.

The most studied health categories for their relationship with PFAS are developmental, bodyweight, and hepatic health categories. Based on the toxicological profile from the Agency for Toxic Substances and Disease Registry (ATSDR), there are a few health categories specifically that have conflicting studies on the health effects of PFAS:

- Immunological: Conflicting studies on associations between PFAS serum levels and asthma
- Hepatic: Conflicting studies on associations between PFAS serum levels and LDL cholesterol levels
- Cardiovascular: Potential, yet inconsistent associations between several PFAS serum levels and risk of pregnancy induced hypertension
- Reproductive: Inconsistent and few studies on associations between several PFAS serum levels and reproductive hormone levels
- Cancer: Inconsistent studies on associations between PFDA + FOSA serum levels and breast cancer risk

There are also little to no epidemiological health studies that have been conducted for the relationship between ocular and dermal health endpoints and PFAS, although some animal and mechanistic studies exist. These gaps and specific health effects could be prioritized for further research and health studies.

9. What goals, priorities, and performance metrics would be valuable in measuring the success of National, federally funded PFAS research and development initiatives relating to:
   a. The removal of PFAS from the environment;
   b. Safely destroying or degrading PFAS; and
   c. Developing safer and more environmentally-friendly alternatives to PFAS?
   d. Mitigating negative human effects of PFAS, whether related to health or additional domains?

9A: Many promising technologies to remove and destroy PFAS from the environment are still in the development phase and are undergoing testing and pilot studies. Their scalability also remains unknown. While there are some technologies that are effective in destroying PFAS, there are many unknowns and still room for improvement. Specific metrics that would be helpful in assessing each technology's best use may include the durability of PFAS storage (How long will the technology sequester the PFAS before it begins leeching back into the environment? Under what conditions is it more likely to leech?), the amount of removal per unit of material (such as specific surface area or mass) and selectivity towards PFAS. Several materials interact with PFAS, but to increase durability and effectiveness, materials specifically designed to preferentially attract PFAS will be ideal.

Additionally, one goal should be ensuring that the concentration and removal of PFAS from drinking water through filtration processes occurring at water treatment plants does not end up back in the environment. For example, water treatment plants may install reverse osmosis (RO) systems to concentrate PFAS and other contaminants, but then release the concentrated waste downstream, which will negatively impact downstream communities. While removing all PFAS from all environments is not feasible, prioritizing those points in the system where human consumption is greater, such as at drinking water treatment plants, will have a greater impact in reducing exposure. Establishing a goal of removing PFAS *permanently* from the environment is therefore recommended. In addition, destruction technologies that can scale to large water treatment plants will assist in removing PFAS from the environment and prevent the reintroduction of contaminated waste back into the environment.

9B: As technologies become commercialized, it is important to continuously evaluate their effectiveness under different contaminated site considerations and conditions:

- *Destruction Percentage* – Essentially, its effectiveness. This would benefit from non-targeted measurement since several PFAS are uncharacterized.
- *By-Product Analysis* – What happens to the PFAS? Are other fluorinated compounds produced? What about volatiles?
- *Treatable Volume* – How much volume can be handled at a given time
- *Energy Cost* – How much energy is required to treat a given volume of contaminant?

9D: There are significant gaps in guidance on how to mitigate PFAS exposure as it related to health and other domains. For example, current blood testing solutions for PFAS are expensive and support limited analytes. Advances in affordable blood testing will help enable affected populations determine whether various PFAS are in their blood and at what levels.

Recent National Academies recommendations[5] include clinicians encouraging "PFAS exposure reduction if a source of exposure is identified, especially for pregnant persons" for patients with serum PFAS concentration of 2 nanograms per milliliter (2 ng/mL) or higher." Yet sources and levels of exposure are still not well understood (e.g., contaminated drinking water, consumption of contaminated fish or vegetables, etc.). As such, additional research and development is needed to rapidly assess possible sources for exposure. For example, low-cost, real-time detection capabilities to test for PFAS in water, blood and soil could advance efforts to rapidly detect PFAS and thus identify possible sources of exposure. Without these screening capabilities, it will be difficult for patients to follow clinician guidance on limiting PFAS exposure.

[5] Guidance on PFAS Exposure, Testing, and Clinical Follow-Up. 2022. National Academies, https://nap.nationalacademies.org/catalog/26156/guidance-on-pfas-exposure-testing-and-clinical-follow-up. Last accessed August 25, 2022.

THE CITY OF
COLUMBUS
ANDREW J. GINTHER, MAYOR

DEPARTMENT OF
PUBLIC UTILITIES

August 29, 2022

SENT VIA EMAIL
Office of Science and Technology Policy
Executive Office of the President
1650 Pennsylvania Ave., NW Washington,
DC 20504
JEEP@ostp.eop.gov

RE: RFI Response: PFAS Strategic Plan

Office of Science and Technology Policy:

The City of Columbus, Department of Public Utilities ("CDPU") appreciates the opportunity to comment on the OSTP's Request for Information regarding data gaps in PFAS research and the strategic plan for federal coordination of PFAS research. The City of Columbus, Department of Public Utilities operates drinking water and wastewater treatment plants. We also divert 100% of the biosolids from our plants for beneficial use. Our interest in PFAS stretches from the source water that feeds our drinking water plants to the effluent being released from our wastewater plants, and everywhere in between.

As discussed in greater detail below in response to the questions presented in the RFI, CDPU is concerned with balancing the risks, costs, and benefits attributable to controlling the PFAS present in the water leaving its plants versus the water coming from industrial or commercial sources into our City's water system. Additionally, CDPU is interested in data gaps regarding sources of human exposure, background levels, and transformation of PFAS in biological and treatment processes. This information will help utilities like CDPU decide what steps to take to address PFAS in our public water systems to protect human health and the environment.

3. Based on the definition of PFAS in this RFI, what are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS and to identify cost-effective:

a. Alternatives to PFAS that are designed to be safer and more environmentally friendly;
b. Methods for removal of PFAS from the environment; and
c. Methods to safely destroy or degrade PFAS?

Research should be directed to the efforts of, and the resultant impacts of, controlling PFAS at the source (i.e., industrial users) and therefore keeping it out of the water cycle. State-level research exists for this and should be incorporated into the federal research.

5. What are alternatives to the definition of PFAS provided in this RFI? What are the implications of these alternative definitions on possible remediation strategies?

The expansive, inclusive definition used in the RFI is the type of definition that should be used to stave off the reconfiguring of chemicals to avoid regulation as has been the pattern with PFAS, as noted above.

7. What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans (e.g., in vitro, animal toxicological, and epidemiological studies)? Which health effects should be prioritized? What additional impacts beyond health should be prioritized? Social scientific approaches are welcome in addressing this question and any others, as appropriate.

We are specifically interested in the comparative risks of exposure coming from different types of sources such as environmental background, toiletry items, furniture, clothes, food, and drinking water. This broad and multifaceted research into determining background levels of PFAS in the environment, in humans, in households, in consumer products, etc, is necessary in order to set reasonable limits for drinking water, wastewater, industrial discharges, and biosolids based on what exposure paths and background levels that already exist.

8. One challenge across all research goals is PFAS mixtures and formulations. Currently, more information is needed to understand the identity, composition, occurrence, source, or effects on human health and the environment for mixtures of PFAS found in environmental media. Additionally, more information is needed to understand the best way to remediate or destroy media contaminated with multiple PFAS. What should be the research and development priorities for accelerating progress in these areas?

As a water utility, we see water through its life cycle. The water that is treated through our plants comes from manufacturers, industrial facilities, residences, rivers, and landfills. We are unable to control the input of PFAS into these waters but it is likely we will be tasked with removing it. Thus, it is vital for water utilities across the country to fill data gaps to help us decide what to do next.

As a water utility, we are specifically interested in studies that focus on:

- Benefits of controlling PFAS at the source
- Transformation of PFAS in the environment
- Transformation of PFAS through stages of treatment at wastewater plants

Water Treatment Residuals and Biosolids are the focus of the most highly-regarded sustainable processes at drinking water and wastewater plants, respectively. Water utilities often divert this would-be-waste from going to the landfill and beneficially use it in land application, land reclamation, or as compost. The City of Columbus generated—and beneficially used—145,000 wet tons of biosolids in 2021. The amount of beneficially used material is anticipated to grow by over 65,000 dry tons when a water treatment residuals program is implemented in the next couple of years.

As a water utility, we are specifically interested in studies that focus on:

- Effects on land where biosolids are used for composting, land application, or reclamation
- Uptake of PFAS by different types of plants and crops

9. What goals, priorities, and performance metrics would be valuable in measuring the success of National, federally funded PFAS research and development initiatives relating to:
   a. The removal of PFAS from the environment;
   b. Safely destroying or degrading PFAS; and
   c. Developing safer and more environmentally-friendly alternatives to PFAS?
   d. Mitigating negative human effects of PFAS, whether related to health or additional domains?

It is essential that the US develops a data map of background levels of PFAS concentrations in urban, industrial, residential, agricultural, and rural environments and different biomes across the country. In regard to establishing background levels, we are specifically interested in studies that focus on:

- Percentage each type of source contributes to background levels of PFAS, i.e. air deposition, land application, etc.
- Background levels of PFAS in household air pollution

Further, PFAS regulation must be reconciled with climate change regulations and initiatives. When studying levels and effects of PFAS in our environment and bodies, consideration must be given to the overall contribution the studied activity has to climate change, most particularly related to disposal and treatment practices.

The City of Columbus, Department of Public Utilities appreciates your consideration of these comments. Thank you again for your attention to and consideration of these comments.

Harvard John A. Paulson
School of Engineering
and Applied Sciences

August 29, 2022

Re: Request for Information; Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development

The Office of Science and Technology Policy,

We are trainees in the Sources, Transport, Exposure and Effects of PFAS (STEEP) Superfund Research Program at Harvard University. Our research investigates the environmental and *in vivo* behavior of per- and polyfluoroalkyl substances (PFAS). We write to provide information pertaining to questions 6, 7 and 8. For question 6, future work should prioritize the development of standard analytical and statistical methods capable of qualitatively and quantitatively assessing exposures to total PFAS, with a particular focus on short-chain PFAS and precursor compounds. For question 7, better screening tools to predict *in vivo* effects and toxicokinetics of PFAS are needed to link the physicochemical properties of PFAS to their interactions with target biomolecules and associated potential health impacts. For question 8, machine learning methods can be used together with site characterization data to identify common environmental PFAS mixtures associated with sources that should be prioritized in experimental effects studies. Please see below for additional details and relevant literature.

Sincerely,

STEEP Trainees in the Sunderland laboratory

Question 6. What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of: analytical methods, detection limits, non-targeted detection?

Accessible, reliable, accurate, and cost-effective analytical instrumentation and methods are needed for accelerating progress and improving efficiency in PFAS detection. Targeted analysis is the most common analytical technique used to measure PFAS. Currently, there are two standard Environmental Protection Agency (EPA) methods for targeted analysis of PFAS in drinking water (EPA methods 533 and 537.1) and one method for non-potable water (EPA method 8327), which together measure a total of 29 PFAS. For other environmental media, there is currently only one draft, single laboratory validated EPA method (EPA draft method 1633) for targeted analysis of up to 40 PFAS. Most PFAS on these panels of analytes are legacy compounds that are no longer manufactured or used in consumer products in the United States. Future research should prioritize the development of interlaboratory validated methods for analysis of a larger suite of PFAS with available analytical standards in various types of environmental media including non-potable waters, soil/sediments, biosolids, biotic tissues, food/plant materials and consumer products.

Industry has replaced legacy compounds with short chain PFAS, precursor PFAS that degrade/biotransform to perfluoroalkyl acids (PFAA), and PFAS with ether linkages and chlorine substitutions (Wang et al. 2017; Washington et al. 2020). While a handful of these compounds are included in EPA methods, a large body of research has demonstrated that targeted analysis fails to capture the vast majority of PFAS used in modern consumer products (Robel et al. 2017; Shultes et al. 2018; Tokranov et al. 2019; Ruyle et al. 2021a,b) and emitted from point sources (McCord and Strynar, 2019, Washington et al. 2020, Jacob et al. 2021). Coincidental to the shifts in PFAS manufacturing, limited evidence from tap water in New England (Hu et al. 2019) and sera concentrations from European populations (Yeung and Mabury 2016; Miaz et al. 2020) suggests that humans are exposed to increasing amounts of unidentified PFAS that are not captured by current EPA methods. Historically, the inclusion of new PFAS into standard methods and the determination of hazardous exposure levels has lagged behind the pace of industry production by decades (Grandjean, 2018). Efforts to rapidly incorporate current-use PFAS into these methods have been further blocked by industry (Hogue and Battenhousen, 2021). Therefore, targeted analysis alone is unlikely to be sufficient in the near future for assessing exposure to emerging PFAS.

Alternative approaches to targeted analysis have the ability to qualitatively describe and quantitatively measure current-use PFAS and other emerging PFAS without analytical standards. These methods include the total oxidizable precursor (TOP) assay, extractable organofluorine (EOF) and adsorbable organofluorine (AOF), and high-resolution mass spectrometry. Limited applications of these methods to environmental media have been reported in the scientific literature (Sun et al. 2016, Gebbink et al. 2017; McCord, 2020; Spaan et al., 2020; Baygi et al. 2021; McDonough et al. 2021; Zhou et al. 2021; Munoz et al. 2022), and together they suggest that high concentrations of current-use and emerging PFAS, including perfluoroether carboxylates and short chain polyfluoroalkyl substances, are present in the global environment.

Future research should prioritize further method development and additional applications of these methods to a wider range of contamination sources and finished products. Methodologies that employ combinations of some or all of these supplementary approaches (Koch et al. 2020, 2021; Ruyle et al. 2021a,b) have shown particular promise in capturing and

describing profiles of PFAS overlooked by targeted analysis and should be encouraged moving forward. Additionally, the application of these methods outside of highly contaminated environments such as those impacted by aqueous film-forming foam (AFFF) use and fluorochemical manufacturing is necessary to better understand exposure profiles in the general population. Finally, facilitation of collaborations among environmental chemists, risk assessors and toxicologists should be prioritized to rapidly assess the risks of newly identified PFAS in the environment.

7. What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans (e.g., in vitro, animal toxicological, and epidemiological studies)? Which health effects should be prioritized? What additional impacts beyond health should be prioritized? Social scientific approaches are welcome in addressing this question and any others, as appropriate.

With the growing number of PFAS that are in commercial use and being detected globally in samples ranging from the environment to aquatic life to humans, there are many challenges in obtaining information for assessing human health effects for this large group of fluorinated compounds. Sufficient information on human health risks is only available for an extremely limited number of PFAS, predominantly PFOS and PFOA. The broad diversity of chemical structures, concentrations, exposure durations and routes of exposure enable PFAS to enact a wide spectrum of health effects. To inform public health exposure limits, additional studies investigating the cellular mechanisms of PFAS toxicity, PFAS toxicokinetics and dose-response relationships in human and animal models are needed across a wider range of PFAS compounds.

Additional *in vitro* and *in vivo* studies are needed to measure binding of PFAS to biomolecules that are 1) abundant in human tissues and/or 2) relevant for the mechanism of toxic action (e.g., dysregulation of lipid and fatty acid metabolism). There currently remains limited understanding of how the chemical properties of diverse PFAS drive tissue distribution and specific molecular interactions that trigger toxic effects. Quantitative data on 1) PFAS binding strengths at low and high affinity protein binding sites, 2) concentration-dependency/non-linear binding, and 3) hydrogen bonding, electrostatic interactions, and other relevant molecular interactions are scarce. Experimental data are partially limited by the lack of commonly available standards for key biomolecules, such as organic anion transporter proteins that are known to be critical to PFAS toxicokinetic behavior, or breast milk proteins that are associated with sensitive toxicological endpoints (i.e. fetal exposure). In these cases, cell models may be useful alternatives for measuring PFAS binding behaviors (Weaver et al. 2010). Mouse knockout lines can also be used to identify and characterize the relative importance of principal molecular targets that are involved in absorption, distribution, and elimination. Together, such studies can help uncover crucial cellular mechanisms that contribute to PFAS tissue distribution and elimination *in vivo*, and that can potentially be extrapolated to human models.

Existing experimental PFAS-protein binding and membrane permeability studies have focused primarily on a small number of legacy PFAA (i.e. PFCA and PFSA), but it is unknown whether patterns in their bioaccumulation behavior can be extrapolated to novel PFAS compounds with diverse PFAS structures. Recent experimental protein binding and phospholipid membrane permeability studies for perfluoroalkyl ether acids, for example, revealed deviations

in expected behavior based on computational modeling (Ebert et al. 2020). Experimental measurements across a wide cross section of emerging PFAS structures should be prioritized and used to inform *in silico* machine learning or quantitative structure-activity relationship (QSAR) approaches to predict behavior across PFAS classes.

In contrast to classic persistent organic pollutants, the mechanisms underlying uptake, distribution, and accumulation of PFAS in humans are more complex and not depicted well by conventional partitioning-based toxicokinetic (TK) and bioaccumulation models (Arnot and Gobas, 2004). Further development of *in silico* TK models that incorporate physiological parameters and mechanisms driving PFAS accumulation in target organs, including permeation of physiological barriers (e.g., blood-brain-barrier, placental transfer, interstitial fluids), binding to essential biomolecules (e.g., blood proteins, membrane lipids), and translocation and recirculation by membrane transporters (e.g., fatty-acid transporters), should be prioritized.

Furthermore, transformation of precursors to terminal PFAS inside organisms is assumed to contribute considerably to overall PFAS exposure. However, uptake, transformation, and toxicological activation of precursors are poorly understood. Future *in vitro* studies could apply complex long-term 3D cell models in which the multifaceted physiological and biomolecular mechanisms that drive PFAS bioaccumulation and toxicity are represented more accurately. In 3D cell models, transformation of precursors could be better understood by tracing concentrations of precursors and transformation products as well as monitoring toxicological endpoints (e.g., binding to receptors).

8. One challenge across all research goals is PFAS mixtures and formulations. Currently, more information is needed to understand the identity, composition, occurrence, source, or effects on human health and the environment for mixtures of PFAS found in environmental media. Additionally, more information is needed to understand the best way to remediate or destroy media contaminated with multiple PFAS. What should be the research and development priorities for accelerating progress in these areas?

The human population is exposed to different combinations of PFAS and there are limited studies that have done the risk assessment of PFAS mixtures (Carr et al. 2013; Hoover et al. 2019; Ojo et al. 2021). Identification of common environmental PFAS mixtures and their association with sources is a critical first step to identifying mixtures to prioritize in experimental effects studies. Site characterization across diverse environmental media and industrial sources is growing but has historically been focused primarily on large fluoropolymer manufacturing facilities and transport in surface and groundwater media. Inventories of potential PFAS sources at the state level have identified hundreds of potential businesses associated with PFAS production and use, including metal plating, paper, plastics, rubber, electronics, and textile manufacturing facilities (Andrews et al. 2020). These may be associated with different mixture profiles and should be further investigated. Additional measurement and modeling of point source atmospheric emissions is also needed to characterize transport and deposition patterns and inform understanding of PFAS mixtures in the human exposure media of remote regions.

Following methods commonly used for inorganic contaminants, both supervised and unsupervised machine learning approaches have been used to leverage PFAS source and occurrence data, together with hydrological factors that affect fate and transport, to characterize and predict regional-scale PFAS occurrence, concentrations and/or composition in human

exposure media (Zhang et al. 2016, Hu et al. 2021, Ruyle et al. 2021a, McMahon et al. 2022). Current prediction models have focused primarily on PFAS in drinking water, but these approaches can be expanded to other exposure media, such as public water supplies or aquatic biota in surface water bodies commonly used for human consumption. Further development of these models for PFAS mixtures will rely on the development of large, centralized databases of PFAS measurements and source data (including PFAS concentrations and occurrence in surrounding environmental media, and relative magnitudes of emissions) that can be used for model training and prediction.

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NJDEP Response to OSTP Request for Information:
Identifying Critical Data Gaps and Needs To Inform Federal Strategic Plan for PFAS Research and Development

August 29, 2022

The New Jersey Department of Environmental Protection (NJDEP) appreciates the opportunity to comment on the Office of Science and Technology Policy (OSTP) request for information (RFI) to identify data gaps for per- and polyfluoroalkyl substances (PFAS) to support the development of a strategic plan for Federal coordination of PFAS research and development.

Please see NJDEP's responses to each of the questions included in the RFI below. These responses are based on input from multiple NJDEP programs with responsibility for evaluating and addressing PFAS in New Jersey's environment.

1. *Should the US Government (USG) consider identifying priority PFAS when developing a strategic plan for PFAS research and development? If so, what criteria should be used to identify priority PFAS for research and development (e.g., tonnage used per year; releases to the environment per year; toxicology or other human or environmental health concerns; national security or critical infrastructure uses)?*

NJDEP agrees that the USG should consider identifying priority PFAS when developing a strategic plan for PFAS research and development.

In general, research on refining potential approaches for rapid toxicity assessment of PFAS is needed for prioritization of the many PFAS lacking health effects data. Additionally, development of approaches for determining and/or predicting chemical properties related to PFAS fate and transport (i.e., soil-water partitioning coefficient, Henry's law constant, solubility) would greatly aid in the identification of priority PFAS. NJDEP notes that there are many orders of magnitude of variability in the reported values for these properties for some PFAS.

Some criteria for prioritizing PFAS that could be considered are listed below. (Note: these items are not listed in order of importance.)

- Amount used and/or released to the environment per year.
- Potential for human exposure occurrence at levels of concern.
- Frequency of occurrence and concentrations in drinking water, waste stream effluents, fish tissue, consumer products, and other media.
- Potential for bioaccumulation in humans and aquatic species/wildlife.
- Potential for toxicological effects, including toxicological potency and nature of toxicological effects.
- Persistence and mobility of chemical once released into the environment

For prioritization of PFAS that form transformation/degradation products, criteria mentioned above such as environmental persistence/mobility, bioaccumulative potential, and toxicological effects should be considered for both the products and the original PFAS.

2. Are there criteria which could be applied across the five research goals identified above, or should specific criteria be developed for each individual research goal?

In general, human exposure and potential health impacts should be considered across all five research goals. Some of the criteria listed in the NJDEP response to Question 1 (above) may be

more relevant to some of the five research goals than others. The relevance of each criterion should be considered when applying the criteria to the five research goals.

3. Based on the definition of PFAS in this RFI, what are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS and to identify cost-effective:
a. Alternatives to PFAS that are designed to be safer and more environmentally friendly;
b. Methods for removal of PFAS from the environment; and
c. Methods to safely destroy or degrade PFAS?

Note that the response below is relevant to part b of this question.

There is a need for research on how PFAS change in the environment, and in particular, how PFAS change through the wastewater treatment process. There is a need to understand behavior of PFAS in the residual management processes including understanding how expanded certified laboratory methods could contribute to a more holistic quantification of PFAS present (see Question 6).

Socially, an educational component is needed to communicate the threats and impacts of PFAS to various interest groups including the public, drinking water and wastewater facility managers, and local government to minimize misinformation and increase the efficiency of removal of PFAS through various media and use cycles.

The Interim USEPA Drinking Water Health Advisories for PFOA of 0.004 ng/L and PFOS of 0.02 ng/L are far below the current USEPA Reporting Levels of 4 ng/L. Although USEPA has stated that these health-based drinking water levels will change when finalized, they have also stated that it is likely that they will remain below the Reporting Levels of 4 ng/L. Therefore, there is a need for drinking water treatment options that can remove PFAS to levels lower than are currently achievable.

There is need for development of models and analytical techniques to better understand past/present/future air concentrations and wet and dry deposition of PFAS and the widespread soil/surface water/ground water impacts caused by air emissions. This information will be relevant to the need to establish *de minimis* PFAS emission levels at which air pollution controls (thermal oxidizer/wet scrubber or activated carbon adsorption) would have to be installed.

4. Are there specific chemistries and/or intended uses that PFAS provide for which there are no known alternatives at this time?

NJDEP is not providing a response to this question.

5. *What are alternatives to the definition of PFAS provided in this RFI? What are the implications of these alternative definitions on possible remediation strategies?*

In general, NJDEP encourages the development of a common definition of PFAS for use throughout the federal government.

The definition of PFAS used in the RFI is "*manmade chemicals of which all of the carbon atoms are fully fluorinated carbon atoms; and man-made chemicals containing a mix of fully fluorinated carbon atoms, partially fluorinated carbon atoms, and nonfluorinated carbon atoms.*" This definition, which comes from the FY21 National Defense Authorization Act, appears to be highly inclusive and to encompass some compounds not included in definitions of

PFAS from other authoritative bodies. NJDEP recommends that this definition be further evaluated to determine if includes some compounds that should not be classified as PFAS.

NJDEP also notes that the definition in the RFI differs from the one currently used by USEPA - "*per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R''. Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R'') can be hydrogen.*" NJDEP notes that the current USEPA definition may not be sufficiently inclusive, and that it does not include all compounds included in definitions of PFAS from other authoritative bodies such as Organisation for Economic Cooperation and the United Nations Environment Programme (UNEP) (Wang et al., 2021).

6. What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of: analytical methods, detection limits, non-targeted detection?

As above, the Interim USEPA Drinking Water Health Advisories for PFOA of 0.004 ng/L and PFOS of 0.02 ng/L are far below the current USEPA Reporting Levels of 4 ng/L. Although USEPA has stated that these health-based drinking water levels will change when finalized, they have also stated that it is likely that they will remain below the Reporting Levels of 4 ng/L. As such, there is a need for development of analytical methods that can achieve significantly lower reporting levels that are closer to the health-based levels.

There is a need for standardized analytical methods to quantify PFAS in soils, sediments, biological tissues (fish tissue), sanitary discharges and residuals, as well as leachate, and air emissions, including landfill gas. These methods are needed for multiple purposes including determination of compliance with regulatory standards and permit requirements and evaluation of efforts to reduce PFAS entering the environment. In addition to establishing certified methods for multiple media, it is also necessary to understand and establish consistent Practical Quantitation Levels (PQLs) or Reporting Limits for each PFAS included in the methods.

There is a need for greater access to non-target analysis. As additional PFAS (e.g., alternative, replacement, novel, or newly identified PFAS) are detected using non-target analysis, states need a process to obtain third party verified analytical standards that can be used by commercial laboratories to quantify these compounds.

There is a need to improve the analytical methods for total PFAS or total PFAS precursors such as Total Organic Fluorine (TOF) and Total Oxidizable Precursors (TOP) methods so that they can be used more reliably in for routine monitoring and/or regulatory purposes.

7. What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans (e.g., in vitro, animal toxicological, and epidemiological studies)? Which health effects should be prioritized? What additional impacts beyond health should be prioritized? Social scientific approaches are welcome in addressing this question and any others, as appropriate.

NJDEP recognizes the importance of developing high throughput approaches such as *in vitro* assays that can accurately predict human health effects. Such approaches are needed for screening/prioritization of the large number of PFAS of potential concern. However, it is crucial to continue to obtain rodent toxicology data for PFAS that are commonly detected in water and other environmental media. There are virtually no animal toxicology data for several PFAS that are commonly detected in water and other media including perfluoropentanoic acid and perfluoroheptanoic acid. Such *in vivo* data are needed because results of high throughput

toxicology tests cannot be used as the basis for human health criteria under current USEPA risk assessment guidance. Therefore, *in vivo* data, human health standards and guidelines needed to protect of public health cannot be developed. Even a limited set of repeated dose and/or developmental toxicology studies in rats and/or mice would provide valuable information.

While previous focus has been on oral exposure, there is current awareness of the need to evaluate inhalation exposure and to develop of inhalation toxicity factors for PFAS. Inhalation toxicology data for PFAS are very limited, and information supporting the validity of route-to-route extrapolation from oral data is currently available for only a few PFAS. Research to determine whether such extrapolation is valid for other PFAS and/or inhalation studies of additional PFAS are needed for the development of inhalation toxicity factors.

It is well established that breast milk is an important exposure route for PFAS and that exposures (i.e., serum PFAS levels) in breastfed infants are higher than in their mothers (e.g., Fromme et al., 2010; Goeden et al., 2019). This exposure is important because infancy is a sensitive time period for adverse effects of PFAS (e.g., Abraham et al., 2020). As highlighted in recent publications (Lakind et al., 2022; Post, 2022), there are relatively little data on levels of PFAS in breastmilk in the U.S. general population. However, available breast milk monitoring data and prediction of breast milk levels from maternal serum levels indicate concern about exposures to breastfed infants, especially since current exposure levels of concern are much lower than were previously accepted (USEPA, 2021a, b; USEPA, 2022a, b). Research to obtain additional data on PFAS in breast milk in the U.S. general population and in communities with elevated exposures (e.g., through drinking water) should be made a priority.

Factors affecting bioaccumulation for PFAS are different than for many other bioaccumulative compounds which, unlike PFAS, accumulate in fat. There is a need for research to obtain bioaccumulation factors (BAFs) for food chain modeling and to predict uptake to fish tissue for PFAS. These BAFs are important for human health assessment, as related to exposure through fish consumption, and also for modeling of movement of PFAS through the food chain as relevant to ecological effects.

In addition to the need for research on human health effects, additional data on toxicity in ecological receptors (acute and chronic) are needed. There is a need for ecological screening criteria for soils in environmentally sensitive natural resources and for freshwater and estuarine/marine surface water and sediment. In addition, there is also a lack of fish and/or invertebrate tissue residue effect levels.

Guidance on appropriate risk communication will be necessary to support field experiments of treatment technologies. The public will need to understand how monitoring and establishing levels of occurrence is essential to mitigating entrance of these compounds into the environment. For instance, if an air stream from an incinerator is to be evaluated, the public must understand that this is a protective, important first step to reduce emission.

8. One challenge across all research goals is PFAS mixtures and formulations. Currently, more information is needed to understand the identity, composition, occurrence, source, or effects on human health and the environment for mixtures of PFAS found in environmental media. Additionally, more information is needed to understand the best way to remediate or destroy media contaminated with multiple PFAS. What should be the research and development priorities for accelerating progress in these areas?

Somewhat surprisingly, only a few mammalian studies of toxicity of PFAS mixtures have been reported in the scientific literature (USEPA, 2021c; ITRC, 2022). Additional mammalian toxicology studies that are designed to provide information relevant to mixtures of PFAS commonly found in the environment and/or mixtures of PFAS that are representative of important PFAS classes should be conducted to determine whether the current USEPA (2021c) draft recommendation of the assumption of dose additivity for assessment of risks PFAS mixtures is sufficiently protective and supportable.

Mixtures of PFAS found in the environment may include PFAS identified with non-target analysis for which no analytical standard is publicly available. There is a need for a repository of all PFAS chemicals with SDS sheets and third-party verified analytical standards for comparison and tracking, similar to the pesticide catalog/repository. USEPA should be informed whenever a new PFAS compound is created or brought into use in the U.S., and it should be provided with a third-party verified standard that is also made available commercially. It is unacceptable for only the chemical manufacturer to hold the knowledge of what is in the chemical and be the only company able to perform testing of samples to identify that compound.

The lack of standardized lab methods has restricted the ability to collect quality data to share and compare across the wastewater permitted universe for understanding the PFAS universe. Standardized laboratory methods are needed to better evaluate the PFAS mixtures prevalent in wastewater media streams (including residuals), and changes in such mixtures over time, in order to better understand the need for remediation and destruction technologies. It is also important to better understand the domestic contribution to the mixtures of PFAS present wastewater systems.

9. What goals, priorities, and performance metrics would be valuable in measuring the success of National, federally funded PFAS research and development initiatives relating to:

a. The removal of PFAS from the environment;

Identification and prioritization of contributing sources of PFAS to be removed from production and use cycles, including PFAS entering the wastewater stream. This would require standardized lab methods and procedures for comparing across medias, geographically different systems, and treatment technologies.

b. Safely destroying or degrading PFAS;

Technological advances that effectively reduce PFAS from wastewater discharges.

c. Developing safer and more environmentally-friendly alternatives to PFAS?

Regulatory agencies should have the necessary information to apply boundaries for the creation and application of any alternatives when there is potential for human or ecological exposure. Industry will develop alternative to achieve their business objectives, and the regulatory authorities need to establish appropriate rules and guidance to ensure chemicals that are persistent, toxic, and bioaccumulative do not enter the environment.

d. Mitigating negative human effects of PFAS, whether related to health or additional domains?

Nothing to add to this time.

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August 29, 2022

Sent via email to: *JEEP@ostp.eop.gov*

RE: RFI Response: PFAS Strategic Plan

To Whom It May Concern:

Public Employees for Environmental Responsibility (PEER) is pleased to provide comments on the Office of Science and Technology Policy's (OSTP) Request for Information (RFI) on its per- and polyfluoroalkyl substances (PFAS) Strategic Plan. PEER is concerned about the definition of PFAS proposed by OSTP, and about OSTP's focus on the understanding of sources of environmental PFAS contamination and pathways to exposure for the public since these are largely known. Our specific comments are set forth in this letter.

Background. OSTP has been tasked under the National Defense Authorization Act for Fiscal Year 2021 (FY21 NDAA) with developing a strategic plan for PFAS research and development. According to the FY21 NDAA, this strategic plan is supposed to identify: alternatives to PFAS; methods for removal of PFAS from the environment; and methods to safely destroy or degrade PFAS. The RFI states five specific goals:

1) The removal of PFAS from the environment;

2) The safe destruction or degradation of PFAS;

3) The development and deployment of safer and more environmentally-friendly alternative substances;

4) The understanding of sources of environmental PFAS contamination and pathways to exposure for the public; and/or,

5) The understanding of the toxicity of PFAS to humans and animals.

The RFI then requests that submitters specifically address a number of questions. PEER offers comments on some of these questions below.

The goal of understanding sources of environmental PFAS contamination and pathways to exposure for the public is too broad given our current knowledge. Academic and NGO scientists are contributing the vast majority of research into PFAS toxicity, sources, and remediation. PEER does not believe that OSTP should waste too much time on "understanding the sources of PFAS contamination," as these are largely known (although additional work needs to be done on issues such as airborne transmission of PFAS). We know where much of the PFAS contamination is coming from: if it is not from a PFAS manufacturer (e.g., Chemours in North Carolina or St. Gobain in New York), PFAS pollution is from Department of Defense sites, landfills, firefighter training facilities, airports, biosolids, paper sludge, pesticides, and even artificial turf fields. PFAS are ubiquitous due to the fact that they are in so many consumer products. Rather than waste time articulating all of these uses and sources, PEER believes OSTP should focus on *eliminating* all non-essential uses of PFAS.

That being said, PEER believes that OSTP should: support immediate access to all PFAS studies using federal funds; end the use of confidential business information (CBI) for all PFAS, particularly information pertaining to where PFAS are used and how they are used; and urge complete reporting on all PFAS uses since even parts per quadrillion can be hazardous. This will provide important data that will contribute to the understanding of sources of PFAS contamination and pathways to exposure.

What are alternatives to the definition of PFAS provided in this RFI? The OSTP is using the definition set forth in the FY21 NDAA, which is "(A) man-made chemicals of which all of the carbon atoms are fully fluorinated carbon atoms; and (B) man-made chemicals containing a mix of fully fluorinated carbon atoms, partially fluorinated carbon atoms, and nonfluorinated carbon atoms." PEER finds this definition confusing, as it is unclear whether a chemical with just one fully fluorinated carbon would be considered a PFAS. More importantly, however, PEER is concerned that federal agencies are not using one consistent definition of PFAS. In fact, even different divisions within the U.S. Environmental Protection Agency (EPA) such as the Office of Pesticide Programs (OPP) and the Office of Pollution Prevention and Toxics (OPPT) use different definitions. States that are starting to regulate PFAS in the absence of strong federal action are using "any molecule with one fully fluorinated carbon." While we understand that PFAS chemistry is complicated, and that the one fully fluorinated carbon definition may capture some chemicals that are not quite as toxic as some of the more well-studied PFAS, we believe that a consistent and broad definition is appropriate given the persistence and toxicity of so many of these PFAS. Given that the FY21 NDAA has statutorily defined PFAS for OSTP, there is no choice but to move forward with this definition. However, we urge OSTP to consider how these differing PFAS definitions make it more difficult to regulate and therefore mitigate the effects of PFAS on human health and the environment. PEER believes that one consistent definition that encompasses as many PFAS as possible is appropriate, and urges use of the Organisation for Economic Co-operation and Development (OECD) definition.

Are there specific chemistries and/or intended uses that PFAS provide for which there are no known alternatives at this time? PEER does not believe that this is the best question to be posing; rather, OSTP's focus should be more on which PFAS are essential for the functioning of society (PFAS in medical devices or medicine, for example). The vast majority of PFAS are used as a convenience, not a necessity (e.g., waterproof mascara, dental floss, non-stick cookware, carpet and upholstery coatings, etc.) and these uses should be banned as soon as possible. By focusing on PFAS for which "there are no known alternative at this time," OSTP is implying that all uses of PFAS are valid and necessary. PEER urges OSTP to take a step back, and first determine which PFAS uses are necessary before you investigate alternative uses.

Should the USG consider identifying priority PFAS when developing a strategic plan for PFAS research and development, and if so, what criteria should be used to identify priority PFAS? Depending on which definition of PFAS is used, there are anywhere from roughly 6,000 PFAS to millions. Even if we assume there are only 6,000 PFAS, regulating this class chemical by chemical will take thousands of years to gather toxicity information, usage, and necessity. Therefore, it is imperative that the OSTP and other federal agencies define PFAS broadly and regulate them as a class. In June of 2022, EPA announced that there is virtually no safe level of two PFAS, perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA).[1] Moreover, a 2022 study found that the global spread of just four PFAS in the atmosphere has led to the planetary boundary for chemical pollution being exceeded.[2] Given the scarcity of toxicity information on the vast majority of PFAS in commerce, together with the fact that CBI cloaks information regarding the majority of PFAS on the Toxics Substances Control Act (TSCA) Inventory, it is impossible to identify which PFAS should be a priority. Therefore, PEER believes that if OSTP and other federal agencies define PFAS broadly, regulate them as a class, and ban all non-essential uses of PFAS, there will be no need to prioritize a class of chemicals about which we know very little.

Conclusion. PEER agrees that it is imperative for OSTP to take a leadership role in PFAS research. However, we believe that the process identified in this RFI is flawed. Instead of attempting the Herculean task of identifying which PFAS should be treated as a priority, and attempting to find "safe" alternatives to PFAS that are used indiscriminately as a convenience, OSTP should define PFAS broadly, "turn off the tap" of non-essential PFAS use, and regulate remaining PFAS as one large class.

Thank you for your consideration of these comments.

[1] https://www.epa.gov/sdwa/drinking-water-health-advisories-pfoa-and-pfos#:~:text=On%20June%2015%2C%202022%2C%20EPA,and%20polyfluoroalkyl%20substances%20(PFAS).
[2] https://pubs.acs.org/doi/10.1021/acs.est.2c02765

Submitted by: Safespill Systems, LLC. (Houston, TX, USA)
Addressed Questions:
3. Based on the definition of PFAS in this RFI, what are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS and to identify cost-effective:

a. Alternatives to PFAS that are designed to be safer and more environmentally friendly

9. What goals, priorities, and performance metrics would be valuable in measuring the success of National, federally funded PFAS research and development initiatives relating to:
c. Developing safer and more environmentally friendly alternatives to PFAS?
d. Mitigating negative human effects of PFAS, whether related to health or additional domains?

System Explanation and Objective: PFAS-Free, Environmentally Safe Fire Protection

Ignitable Liquid Drainage Floor Assemblies (ILDFAs) are a class of technology used for fire protection in aircraft hangars and make the use of PFAS-containing Aqueous Film Forming Foam (AFFF) systems or potentially fatal High Expansion (Hi-Ex) systems obsolete. The system consists of hollow aluminum decking with a perforated top surface, that utilizes the existing slope of a hangar floor to drain spilled ignitable liquids to trenches, where the liquid is removed from the hazardous area and contained in a safe storage location outside of the hangar.

Through extensive fire testing, ILDFA has been proven as an equivalent method of fire protection to foam-based fire protection systems. The difference is that ILDFA doesn't use any chemicals; it simply removes the fuel, which is a drastically different approach compared to a foam system. ILDFA uses water, gravity, and marine-grade aluminum flooring to mitigate fires. ILDFA is now used by all MILDEPs for their aircraft hangars, avoiding the inherent challenges from inadvertent foam discharges that lead to chemical contamination, damaged aircraft, and potential fatalities.

Maintenance, Repair, and Overhaul (MRO) facilities frequently experience small fuel leaks from aircraft, even if not reported, that pose a fire risk. Since most significant maintenance to aircraft is performed in the hangar, spills are a fact of hangar life. Foam systems are reactive and when activated, risk damaging equipment, harming personnel, and discharging chemicals and/or PFAS into surrounding areas. ILDFA is proactive, instantly removing any spill away from the source, and when activated poses no risk of damage to equipment or personnel or contamination of surrounding areas. Feedback from maintainers using ILDFAs cite only positive results, including an ease on day-to-day operations for spill clean-ups, minimized downtime, and no fear of loss of life or assets due to a foam system discharge.

Video comparison of an ILDFA vs. Hi-Ex System: safespill.com/spill-and-fire-tests/?video=foam-system-v-safespill-floor

Approvals and Vetting Process:

Fire protection systems must work 100% of the time – to mitigate fire risk and protect life, the building, and multi-million-dollar assets. However, testing of fire protection systems is costly and time consuming. Despite this, ILDFA has been thoroughly vetted using DoD testing standards and by the world's largest property insurance carrier and leading authority in fire protection, Factory Mutual (FM) Global.

A timeline of ILDFA testing and approvals is shown below:

May 2017:	Received FM Approval under FM Standard 6090
Aug-Sept 2020:	Independent testing conducted by US AFCEC at Tyndall Air Force Base, (Wells et al.)
Sept-Nov 2020:	Several military contracts awarded
Sept 2021:	NFPA 409, 2022 Edition – ILDFA adopted as an equivalent to existing fire protection (previously Hi-Ex or AFFF was required in all hangars)
Nov 2021:	Per the Air Force Sundown Policy, ILDFA is the primary fire protection option for new Tier 1 hangars
April 2022:	AFCEC releases its report with maintainer feedback (Wells et al.)
May 2022:	Per the Navy ITG Policy, ILDFA is the primary option for the Marine Corps and Navy's existing hangars
August 2022:	ILDFA adopted in FM data sheet 7-93 for hangars housing fueled aircraft

Factory Mutual:

ILDFA was tested at the FM Global Research Campus and a new Approval Standard was written to define this technology, beginning an era of adoption of an environmentally safe fire protection system. Ultimately, ILDFA was adopted as the preferred method of fire protection for "Hangars with Fueled Aircraft" according to FM Data Sheet 7-93, "Aircraft Hangars, Aircraft Manufacturing and Assembly Facilities." This data sheet is frequently referenced by defense contractors for designing military aircraft hangars.

NFPA 409:

National Fire Protection Association (NFPA) 409 is a fire protection standard for commercial aircraft hangars, referenced by the International Building Code (IBC), and is referred in UFC documents. The code is revised every 5 years and the 2022 edition of the code adopted ILDFA by a nearly unanimous vote by the country's leading fire protection professionals.

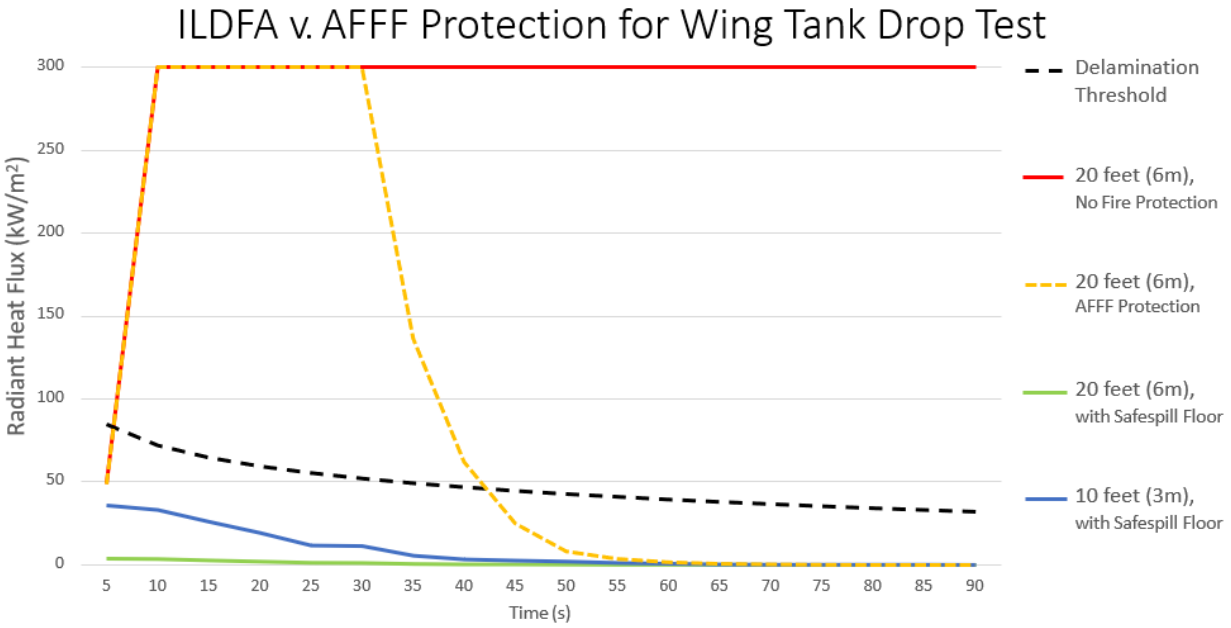
This decision was made based on evidence, supported by full scale fire testing, that demonstrated that ILDFA was equivalent to, or outperformed, AFFF and Hi-Ex systems as a fire protection system for aircraft hangars (NFPA 409, Ballot). In 2018, the NFPA 409 Technical Committee advised ILDFA manufacturers to demonstrate equivalency by conducting a fire test known as the "Wing Tank Drop Test," a test devised by the Air Force in 1989 to evaluate Halon fire extinguishing systems (Zallen et al.). In this test, 165 gallons of ignited jet fuel is instantaneously spilled onto the floor of a protected aircraft hangar.

An extensive testing program was conducted and testing data, independently validated by US AFCEC (Wells et al.), was submitted to the NFPA 409 technical committee (Giubbini). Results demonstrated that ILDFA greatly reduced the overall fire size in this scenario and reliably extinguished the fire within 90 seconds. No publicly available data exists for this scenario using

AFFF or Hi-Ex foam systems. However, the consensus within the fire protection industry is that AFFF would extinguish this fire quite quickly. There is no consensus regarding the performance of Hi-Ex.

ILDFA Testing Report Submitted to NFPA 409: https://safespill.com/wp-content/uploads/2021/02/NFPA_409-Test-Report_Safespill_Web.pdf

The graph below shows an estimation of the performance of an AFFF system compared to ILDFA in the "Wing Tank Drop Test."



The "delamination threshold" line represents the level at which radiant "heat flux would certainly cause delamination, and possibly ignition, of composite aircraft components." (Bocchieri et al.).

This graph demonstrates that AFFF is an extremely effective extinguishing agent, however, the reactive nature of this methodology allows significant damage to nearby assets. In comparison, ILDFA is proactive and mitigates fires before they can grow large enough to damage assets.

UFC and other DoD Directives:

Unified Facilities Criteria (UFC) provides requirements for aircraft maintenance hangars for the various MILDEPs, specifically UFC 4-211-01, where it has been indicated that ILDFA may be included in the draft language of these MILDEP submissions. To date, the Navy released an Interim Technical Guidance (ITG) policy in May 2022 authorized the use of ILDFA in all retrofit hangar projects. Additionally, the Air Force released the Sundown Policy (revised in May 2022) for ILDFA to protect the Air Force's highest valued assets in Tier 1 hangars.

System Installations and Feedback:

Naval Air Station Point Mugu, VX-30, Ventura County, CA

- In use since March 2022 16,900 sqft ILDFA for C-130 and P-3
- Feedback (below)

"Good morning,
I hope this email finds you doing well. *Safespill floor is awesome!* We have had *C130 on the floor regularly and currently have a P-3 and an E-2* in the Hangar.
Additionally, we had a retirement ceremony in the hangar last week, so it was a chance to see how people faired in dress shoes and high heels….no one fell or slipped so that is good :)

V/R

Dated: Wednesday, April 13, 2022

Naval Air Weapons Station China Lake, VX-31, Ridgecrest, CA

- In use since May 2021 (below), (2) 8,000 sqft ILDFAs for F/A-18s

- Feedback (below)

"Our experience to date has been excellent… both with the floors and with your company.
As you know, we have floors installed in two tension fabric hangars (TFS), each capable and weight tested to hold two of our heaviest aircraft (EA-18G) and support equipment simultaneously. They are rated to jack aircraft, which we have done on many occasions, and seen no issues from the floor shifting or buckling or in any way giving any indications of stress. We've not experienced any issues either with the floor or adjacent plumbing, pumps or tanks.

Dated: Monday, April 11, 2022

Edwards Air Force Base, VX-31, Ridgecrest, CA

- In use since August 2021, 4,800 sqft ILDFA for a T-38 Talon and C-130 nose gear
- AFCEC's Test Floor for Maintainer Feedback, *See Fuel Spill Fire Testing of an Ignitable Liquid Drainage Floor Assembly (ILDFA) for Chemical-Free Fire Control/Suppression, April 14, 2022*

Guam Army National Guard, Helicopter Hangar, Barrigada, Guam

- In use since July 2022, 1,800 sqft ILDFA for UH-72 Lakotas

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August 29, 2022

Office of Science and Technology Policy
RFI Response: PFAS Strategic Plan

Submitted via email

The Coalition for Responsible Waste Incineration (CRWI) appreciates the opportunity to submit a response to the *Request for Information; Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development*; Notice of Request for Information. 87 FR 41,749 (July 13, 2022). CRWI is a trade association comprised of 26 members representing companies that own and operate hazardous waste combustors and companies that provide equipment and services to the combustion industry.

General comments

CRWI supports the development of a government-wide strategic plan to address the issues associated with PFAS contamination and cleanup. This is a problem that transcends all government agencies and a consistent plan should be developed. CRWI's expertise is in the destruction of organic chemicals through the use of high-temperature combustion. Our members have been successfully destroying organic chemicals since the 1980's. CRWI members have been destroyed fluorinated organic compounds (ozone depleting substances) for decades under the Montreal Protocol and are required to demonstrate effective destruction for those compounds. While ozone depleting compounds are not considered to be PFAS under the current definitions, both sets of compounds have carbon-fluorine bonds. The destruction of organic chemicals in our industry are regulate under 40 CFR Part 63, Subpart EEE. All of our members must comply with these regulations or cease operations. We will focus our comments on the destruction methods and how that destruction is measured.

There is currently only one commercially available method for destroying PFAS compounds – high temperature incineration. There are other methods that have shown promise but to date, these methods do not achieve the same destruction efficiency as incineration or they are still in pilot or demonstration scale. All destruction technologies have the same issues with measurement methods and products of incomplete destruction.

In the request for information, the Office of Science and Technology Policy asked for specific responses to nine questions. Below are our responses to all or parts of three questions that are associated with destruction and the ability to measure emissions. We have used the question numbers from the *Federal Register* notice to make it easier to know where each comment is directed.

Background

Before we actually respond to the questions, some background information on how the hazardous waste combustion industry already performs their requirements will make the responses easier to understand.

Hazardous waste combustors have been using performance testing and continuous monitoring to show compliance with RCRA and Clean Air Act requirements since the 1980's. This process was developed under RCRA and refined under the Clean Air Act Amendments of 1990. A performance test includes a method to demonstrate destruction of the original organic compounds. This method is a destruction and removal efficiency (DRE) test as required in 40 CFR 63.1219(c). To make this demonstration, the facility must conduct a test proving they can destroy at least 99.99% of an organic compound that is more difficult to destroy than the compounds they would normally combust. In the process of conducting that test, operating parameter limits are established so the facility can demonstrate continuous compliance. This concept was developed early in the regulation of hazardous waste incinerators under Subpart O of RCRA. In the guidance document for hazardous waste incinerators,[1] EPA discusses the concepts for demonstrating DRE for organic hazardous waste. In the opening paragraphs of this guidance document, EPA explains this concept.

> "The Subpart O regulations require that POHC's (Principal Organic Hazardous Constituents) be designated for each waste feed. The required DRE must then be demonstrated for the POHC's during the trial burn. Since the POHC's must be representative of the waste feed, they are chosen on factors such as difficulty to incinerate and concentration in the waste feed. The operator is then limited in the permit to burning only waste containing hazardous constituents no more difficult to incinerate than the POHC's for which compliance was demonstrated during the trial burn."

This guidance gives detailed instructions on selecting POHCs and the entire process of demonstrating DRE. Hazardous waste combustion facilities have used this guidance since 1989 to demonstrate the ability to meet these criteria. Appendix VIII of the guidance contains a list of organic compounds ranked on how difficult they are to destroy (incinerability index). This approach was initially developed by researchers at the University of Dayton.[2] Class 1 chemicals on this list are the most difficult to destroy.

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[1] *Guidance on Setting Permit Conditions and Reporting Trial Burn Results*. Volume II of the Hazardous Waste Incineration Guidance Series, January 1989, EPA/625/6-89/019

[2] Dellinger, B. and D. L. Hall. 1986. *The Viability of Using Surrogate Compounds for Monitoring the Effectiveness of Incineration Systems*. Journal of the Air Pollution Control Association, 36:179-183

For example, chlorobenzene is a Class 1 chemical. When a facility demonstrates a minimum DRE of 99.99% for chlorobenzene, it is inferred that the facility can destroy a similar or greater percentage of any organic chemical ranked lower in Class 1 or any chemical in Classes 2 through 7.

Thus, the method for demonstrating the destruction of organic compounds is to conduct a test where the facility selects one or more POHCs that is at least as difficult to destroy as the constituents in waste feed and prove at least 99.99% destruction and removal efficiency of those POHCs. In the process of conducting a successful DRE test, the facility sets the operating limits that are used to demonstrate continuous compliance with the DRE requirement. Facilities are only allowed to operate when they meet the operating limits as defined by their latest test results. Once the facility has successfully completed these tests, they not only show more than 99.99% destruction and removal but set the operating parameters to show they can accomplish this on a continuous basis.

Response to specific questions

3. What are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS and to identify cost-effective methods to safely destroy or degrade PFAS?

   CRWI believes that high temperature combustion has already been shown to be able to destroy a subset of the most common PFAS compounds. This has been demonstrated at a large-scale facility by test results from Chemours, Clean Harbors, and a Department of Defense sponsored project at TD*X (additional information available upon request). In addition, there have been published studies under laboratory settings showing 99.99+% destruction from both industry and EPA (discussed below). There are three main data gaps that need to be addressed in developing a strategic plan for thermal destruction of PFAS compounds. These are:

   - Determining where PFAS compounds fit into the incinerabiity index;
   - Development of standardized methods to measure PFAS emissions during testing; and
   - Development of standardized methods to identify and measure products of incomplete destruction.

   Incinerability index. At this point in time, there are no PFAS compounds listed in the incinerability index. There are fluorinated organic compounds (mostly ozone depleting compounds) in the index but none fit the current definition of PFAS. There have been a limited number of studies that indicate where certain PFAS wastes fit within this index. In 2001, 3M commissioned a series of tests on the thermal degradation of perfluorooctanesulfonic acid (PFOS) and two C8 perfluorosulfonamides (FC-1395 and FC-807A). The report was issued in 2003 and

submitted to EPA's docket.[3] In the report, University of Dayton researchers demonstrated approximately 99.95% destruction of PFOS and the two C8 perfluorosulfonamides at 900 °C with a 2 second residence time. Two studies were commissioned by DuPont. In the first,[4] DuPont wanted to know if paper and textiles treated with fluorotelemer-based acrylic polymers would release perfluorooctanoic acid (PFOA) when combusted under conditions found in a typical municipal incinerator. In this study, University of Dayton researchers determined that the temperature at which 99.9% of the polymers were destroyed was 1000 °C (with a 2 second residence time). For the paper and fabric coated with the polymers, 99.9% of the PFAS compounds were destroyed at 750 °C (with a 2 second residence time). In the second DuPont study,[5] University of Dayton researchers confirmed and extended the findings of the 2005 study. It should be noted that the purpose of the studies mentioned above was to show relative destruction under defined process conditions for the purpose of ranking these compounds in the incinerability index. These numbers should not be confused with a 99.99% DRE requirement under Subpart EEE.

The Department of Defense and EPA have recently funded a study at the University of Dayton to at least partially confirm where PFAS compounds fit within the incinerability index. These two Federal Agencies should be encouraged to complete these studies and release the results. This additional information is necessary to determine where the PFAS compounds being studied fit into the existing incinerability ranking.

Stack gas measurement methods. EPA has released one method for measuring certain PFAS compounds in stack gases (OTM-45). It was released as an Other Test Method (OTM). In the opening paragraph, the Agency states that posting this method is "neither an endorsement by EPA regarding the validity of the test method nor a regulatory approval of the test method." OTM-45 is designed to measure emissions of 50 semi-volatile compounds. It is our understanding that EPA will release another OTM for volatile compounds in late 2022. An OTM is not a standard method. Without a standard test method to measure PFAS emissions from stack gases, facilities cannot demonstrate during a test that they are achieving a given level of destruction or would meet potential regulatory requirements. One of the highest priorities for the government should be to develop standardized methods for measuring PFAS compounds in stack gases.

Products of incomplete destruction. The same measurement problems exist when attempting to quantify PFAS products of incomplete destruction. This issue applies equally to all existing and proposed destruction methods. Until a standard method

[3] EPA-HQ-OPPT-2003-0012-0151
[4] Yamada, T., P. Taylor, R. Buck, M. Kaiser, and R. Giraud. 2005. *Thermal degradation of fluorotelemer treated articles and related materials*. Chemosphere. 61:974-984.
[5] Taylor, P., T. Yamada, R. Striebich, J. Graham, and R. Giraud. 2014. *Investigation of waste incineration of fluorotelomer-based polymers as a potential source of PFOA in the environment*. Chemosphere 110:17-22.

for measuring all PFAS compounds of interest is available, it is not possible to demonstrate that air emissions from these destruction methods are below levels of concern.

6. What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of analytical methods, detection limits, non-targeted detection?

   CRWI believes that the primary research and development priorities should be to determine the following information:

   - What specific POHCs should be used to demonstrate that a facility can destroy PFAS containing wastes;
   - Where selected PFAS compounds fit into the incinerability index; and
   - What methods should be used to measure the PFAS compounds and fluorinated products of incomplete destruction of interest.

   With this information, all treatment facilities will be able to use the DRE process to demonstrate destruction of the PFAS compounds in question as well as accurately determining whether there are any fluorinated products of incomplete destruction.

9. What goals, priorities, and performance metrics would be valuable in measuring the success of national, federally funded PFAS research and development initiatives relating to safely destroying or degrading PFAS.

   The performance metrics for the destruction of fluorinated organic compounds should be the same for all destruction methods regardless of the technology deployed. This should include a quantification of four items:

   - The destruction of the original compound;
   - The emissions to the air;
   - The amount of PFAS remaining in the residuals from the treatment process; and
   - The products of incomplete destruction.

   All destruction methods must be judged by the same performance metrics. It is important to note that different treatment methods will likely be needed for different circumstances. For example, the destruction technologies for a very high volume wastes at very low PFAS concentration, as would be the case for wastewaters, will be very different from the technology needed for destroying concentrated aqueous film-forming foam. However, all destruction methods should have the same performance metrics and the chosen technology should be based on a combination of destruction efficiency and minimizing the releases to the environment.

No one treatment method is the “best” under all circumstances. The government should continue to research and develop other methods, especially for those circumstances where high temperature combustion is not optimal.

29 August 2022

To the Science and Technology Policy Office:

We are writing to provide information and guidance on key data gaps in PFAS research and development as requested in document 87 FR 41749. We are a group of academic researchers who study the social, scientific, and political factors related to PFAS. We work to produce accessible research and information about PFAS contamination and work in collaboration with impacted communities to educate populations about this crisis.[1] This response is informed by our work with PFAS toxicology and exposure science, regulatory analysis, and community-based participatory research. We write specifically in response to questions 5, 7, and 9.

5. PFAS must be defined broadly to protect public health. Recently, many U.S. states and federal agencies have used the definition of human-made chemicals with at least one fully fluorinated carbon atom. The PFAS definition presented in the RFI is incongruent with a precautionary approach to PFAS management. The EPA currently recognizes over 12,000 unique PFAS substances.[2] This large number of PFAS substances presents a monumental challenge for case-by-case regulation and research.. This issue has been addressed by international scholars,[3,4] including members of our research team,[5] who call for a class-based regulatory approach in service of a public health, environment, and resource-protective system of PFAS management. Precautionary chemical regulation requires a broad chemical definition to adequately address known uses and subsequent contamination. The ongoing system of "regrettable substitutions" for long-chain PFAS exemplifies the need for a comprehensive PFAS definition.[3] Short chain PFAS, developed to replace PFOA, PFOS, and other long-chain species, are shown to be more easily distributed in surface waters, similarly environmentally persistent, and as detrimental to human health as their predecessors.[6–8] Reflecting growing concern about replacement PFAS, the EPA adopted Health Advisory Level (HAL) guidelines for GenX and PFBS when updating their PFAS regulatory guidelines in 2022.[9] Regulating PFAS chemical-by-chemical is resource and time-intensive and allows for continued release of other PFAS chemicals, as demonstrated by the case of PFOA, PFOS, and replacement PFAS.[5,10] In such cases, the burden of exposure is inappropriately placed on the public and our ecosystems.[3,11–13]

Class-based regulation has been successfully employed against notable environmental contaminants including polychlorinated biphenyls, organophosphate pesticides, halogenated flame retardants, and chlorofluorocarbons.[4,5] Such an approach is feasible in the case of PFAS and has already been used successfully at the state level. For example, Maine and California regulate PFAS in consumer products as a broad class.[14–16] In their 2022 report, the Massachusetts PFAS Interagency Task Force strongly supports adopting such regulation in the state and defines PFAS as "fluorinated organic chemicals containing at least one fully-fluorinated carbon atom."[17] The European Commission and EU REACH program also advocate for class-based approaches and broad chemical definitions.[3,18] Federally, the FDA adopted a smaller-scale class-based approach to certain PFAS in food packaging, demonstrating that class-based regulation is indeed possible at the federal level using existing mechanisms.[5]

7. Community-based research is necessary to inform PFAS action. Community-informed biomonitoring studies like the C8 study[19] and the California Biomonitoring Program[20] have produced critical information on the human health impacts of PFAS exposure and spark social

discovery of emerging contaminants.[21–23] Such studies are integral to the future of PFAS research and our understanding of the multifaceted impacts of contamination. Researchers should prioritize these biomonitoring studies not only to gain understanding of the human health and social effects of PFAS exposure, but to engage with and provide transparency to those living with everyday exposure.[24–26] The National Academies of Science, Engineering, and Medicine (NASEM) recently published an assessment of human health data and established clinical guidance for PFAS exposure, which was developed in collaboration with members of impacted communities.[27] The NASEM report included a systematic review that identified PFAS-related health effects and emphasized the value of medical monitoring for impacted individuals.[27] Medical guidance is of central concern for members of contaminated communities, who often relay that their medical providers are unaware of the health impacts of PFAS. Through our work in community-based participatory research, we have observed particular interest in PFAS carcinogenicity. At the 2022 National PFAS Conference, community members called for research into connections between cancer outcomes and PFAS exposure. Further, the 2022 NASEM panel reported emerging links between PFAS exposure and breast cancer.[19,27] Community-informed biomedical research provides the opportunity for individual and collective report-back of monitoring data, and continuing dialogue with impacted individuals and community stakeholders.[26,28]

It is essential to investigate the interactions of PFAS contamination and climate change. PFAS have been identified as threats to Earth's safe operating boundaries in the planetary boundary model, a systems framework for understanding the planet's climate stability.[29] PFOS contamination was identified as a threat to the chemical pollution boundary (now termed "novel entities") in 2014 due to its global scale and the irreversibility of its disruptive effects.[30,31] PFAS, including short-chain replacement PFAS, were recently found to contaminate rainwater across the globe, demonstrating the scale at which PFAS are currently distributing through the global environment and the challenges of conventional methods of removal and treatment.[31,32] The authors of the rainwater analysis argue that the PFAS has exceeded the safe planetary boundary and endangered planetary health.[31] This threat to climate health further endangers public health and exacerbates the environmental injustices of climate change. Thus, researchers must elucidate the impacts of PFAS contamination on the climate at multiple scales and through multiple disciplines to address and mitigate harm. One such area of study is the climate warming activity of PFAS chemicals.[30,33] Some PFAS may themselves be highly persistent greenhouse gasses, such as perfluorotributylamine (PFTBA).[34] As the PFAS class is so broad, it is pertinent to assess their potential greenhouse activity with the goal of preventing further exacerbation of climate change. According to a 2021 report by Toxic Free Future, in 2019 alone one US PFAS manufacturing plant emitted over 200,000 pounds of HCFC-22 (chlorodifluoromethane),[35] a hydrofluorocarbon greenhouse gas that is at least 1,800 times more potent than carbon dioxide[36] and has been banned worldwide for its ozone depletion potential.[37] Other greenhouse gasses, including HFC-23 (trifluoromethane), are also released during fluoropolymer production.[4,36,38]

9c. Stop the cycle of "regrettable substitutions." As discussed above, the current system of selective PFAS management is unsustainable and allows for environmental accumulation of highly persistent contaminants.[3] PFAS phase-outs must be designed in collaboration with strong legislation to prevent "regrettable substitutions," which require extensive retroactive action and result in continued environmental contamination and exposure.[39] The burden of proof should not

lie with workers, communities, and ecosystems to show that replacement PFAS have deleterious impacts. The first goal for the development of PFAS alternatives must be to eliminate the use of PFAS and other hazardous chemicals wherever possible. PFAS and alternatives to PFAS should be considered under the "essential use" framework described by Cousins and colleagues.[40] This approach, adapted from the Montreal Protocol for CFC elimination, defines three categories of chemical use. *Non-essential* use is "not necessary for the betterment of society in terms of safety, health, or function." *Substitutable* use "fulfills important functions but [is] assessed to be non-essential because substitutions are available that provide the necessary technical function." *Essential* use is "considered necessary with no current established alternatives that provide necessary function" with the caveat that essentiality is not a static designation.[40] In the case of hazardous chemicals like PFAS, research and development of suitable substitutions must be prioritized. In keeping with a precautionary and health-protective approach to PFAS management, non-essential and substitutional PFAS should be removed from consumer products. PFAS manufacturing must be limited except for the few cases of essential use. The criteria for essential use must be assessed regularly and the overarching goal of regulation and research should be the eventual end of PFAS manufacturing and environmental release. Substitutions to PFAS must be assessed for health and environmental impacts before approval and throughout use. Negligence in PFAS substitution assessment thus far has resulted in cost- and resource-intensive retroactive regulation and remediation.[5,8,40] Examples of substitution of essential-use PFAS in the US are the use of silk surgical products, replacing Teflon-coated materials and blood plasma replacing synthetic blood substitutes.[41–45]

9d. Engage impacted communities in research and share results. As with nearly all environmental exposure and health issues, community involvement is central to identifying the problem and steering the solutions. Community activism around PFAS has been one of the most prominent forms of toxics activism in recent history, and has been successful at local, state, and national levels in terms of public information, research, regulation, and remediation. Funds need to be made available through EPA headquarters and regional offices to provide funding for community groups to do water and blood testing, engage with water utilities and WWTPs on monitoring. In addition, a multi-agency task force could be established to provide new and creative forms of assistance to community activists and groups. Many Native American Tribal lands are proximate to known and suspected PFAS contamination sites, and they have been under sampled for PFAS in UCMR3 and we estimate that will continue in UCMR5,[46] and they are over-exposed to other water contaminants and other toxic sources.[47,48] Additional support for individual Tribes and for groups like the Tribal PFAS Working Group could come from EPA, NIH's Tribal Office, and BIA (DOI), to engage in water and blood monitoring, public education, medical guidance activities, and capital funds for water systems and remediation. The NASEM PFAS Medical Guidance committee experience shows how important the voices of affected community residents were, in terms of educating NASEM committee members and helping the committee reach its valuable recommendations.[27] Similar mechanisms should be implemented throughout state and federal agencies, task forces, and committees. NIEHS and EPA both have a history of funding community-driven research and education projects, and more support for those efforts around PFAS is needed. Support is also needed for larger environmental groups to work with producers and retailers on reducing the production and sale of PFAS-contaminated products. Lay action has been central to such work to date.[23,49,50]

Improve the environmental literacy and engagement with PFAS among medical professionals. PFAS education and resources for physicians is sparse, due to the recency of PFAS research[11,51] and the minimal level of environmental health training currently provided to medical professionals.[26,52] Environmental health education is not a key component of current medical curricula.[53] While the Agency for Toxic Substances and Disease Registry (ATSDR) provides free continuing medical education (CME) material on a variety of environmental health topics,[53,54] information on PFAS is only available through guidance documents and fact sheets. Although the Centers for Disease Control and Prevention (CDC) once hosted a PFAS CME, the program expired in 2020 and is no longer available.[55] This exemplifies the need for updated and accessible PFAS information for medical professionals. The recency of the NASEM report and guidelines on blood testing presents an opportunity for physician engagement.[27] The education of medical professionals should be a goal of PFAS research, since communities are becoming aware of PFAS contamination and often seek advice from their doctors on the health implications of exposure.[11,27,28] Forms of medical education and outreach can include CME development in collaboration with communities and medical groups,[52] medical monitoring with report-backs to both community members and their physicians (see above), and open-access information.[56]

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August 29, 2022

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RE: Request for Information (RFI); Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development, FR Doc. 2022-14862

The Natural Resources Defense Council (NRDC) appreciates the opportunity to respond to the Office of Science and Technology Policy's (OSTP) request for information on PFAS research and development. Our responses are lettered and numbered to match the corresponding goals and questions indicated in the RFI.

As a threshold matter, OSTP, the United States EPA (US EPA), and the rest of the federal government should be using a scientifically credible definition of the PFAS class, based on the hazard characteristic of persistence and consistent with states, Congress and international organizations.[*] The United States Government (USG) must also adopt a class-based approach for each of these priority areas.

Response to request for information on the five goals listed:

(A) PFAS are persistent and mobile in the environment. Therefore, the goal should be complete removal and destruction of PFAS in all environmental media. Currently available removal and remediation efforts are highly inefficient in that they collect and/or concentrate PFAS before

[*]"Organic chemicals containing at least one fully fluorinated carbon atom" is the most widely used definition across the United States, with at least 18 states having adopted this definition into law, including AR, AZ, CA, CO, CT, KY, HI, IL, LA, MD, ME, MN, NH, NV, NY, RI, VT, and WA. This definition has also been adopted into federal law as part of the 2019 National Defense Authorization Act (NDAA) (US Congress 2019).

Alternatively, a very similar definition was developed by the Organisation for Economic Co-operation and Development (OECD) and will be used by the EU in their pending regulation of PFAS (OECD 2021). "PFASs are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e., with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–) is a PFAS."

reintroduction back into the environment. This is the case for traditional remediation efforts (e.g., water filtration) and disposal methods (e.g., landfilling, deep well injection, and incineration). To date there has been very little to no oversight or monitoring of disposal sites in order to understand how PFAS are concentrated, potentially transformed and then further dispersed into the environment. Although it is infeasible to store all PFAS contaminated media, highly contaminated media, such as spent water filters and unused aqueous film forming foam (AFFF), should be stored until a safe destruction technology is available.

(B) To our knowledge, there are currently no large-scale methods that result in the complete destruction and degradation of PFAS. However, research in this area is progressing rapidly and funding and government support is needed to evaluate proposed methods. Funding and support are also essential in moving promising technologies from the lab-scale to field deployment. In all situations, a class-based approach is needed to ensure that destruction and degradation techniques do not result in the creation of as-of-yet unknown or unquantifiable PFAS degradation products or ultrashort chain PFAS like trifluoroacetic acid (TFA). For example, broad spectrum assays, such as the total organofluorine, total oxidizable precursor, or non-targeted testing should be used to estimate the change in PFAS mass balance in remediated environmental media. Until safe destruction or degradation methods are available and validated, OSTP and related agencies should use their authority (or seek authority as needed) to require storage of unused AFFF and other highly contaminated PFAS media.

(C) This question is premised on the erroneous assumption that drop-in replacements to PFAS are needed in order to move away from PFAS use. This is not the case for many uses of PFAS, which do not require a functionally similar drop-in replacement. Some uses are not necessary for product function and should be immediately phased out. For other uses, safer alternatives are already available and in use, therefore PFAS use should also be immediately phased out. In the few cases where no safer alternatives exist and PFAS use is serving an essential function for the product and for the health, safety, and function of society, funding would be useful to help with the development of safer alternatives. Experts in the field are recommending this approach, the essential use framework, to efficiently phase out chemicals of concern such as PFAS (Cousins et al. 2019).

Any substances put forward as PFAS alternatives should be subject to stringent review and evaluated for common hazards associated with PFAS, including their persistence, mobility and toxicity. Existing tools such as GreenScreen Certified ("GreenScreen CertifiedTM" n.d.), are already being used to identify safer alternatives across product sectors.

(D) Understanding the sources of environmental PFAS contamination and pathways to exposure will not be adequately addressed without: a) adopting a reporting rule based on a comprehensive and scientifically defensible definition of PFAS; b) requiring companies to provide reference standards (including storage directions) and analytical methods to find PFAS in the environment.

The US EPA maintains a National Pesticide Standard Repository to which pesticide manufacturers are required to provide samples (and regular updates) as well as environmental chemistry and analytical methods for detection as a condition of pesticide registration (US EPA 2014). Federal agencies, states, and tribes can request standards to aid in product testing and environmental monitoring. A similar program is needed for PFAS in which PFAS manufacturers

are required to submit standards as well as analytical methods to test for PFAS in various environmental matrices (e.g., ground, surface, and drinking water, soil).

The burden of understanding PFAS environmental contamination and human exposure has been on scientists who identify PFAS sources after the fact. However, required reporting directly from PFAS manufacturers and users is much more efficient. To this end, the Toxics Release Inventory should be expanded to include all PFAS and the "*de minimis* exemption" of the reporting rule should be abandoned for all PFAS, not just specific PFAS that are given the label of "chemicals of special concern" (Lerner 2022).

(E) Current efforts to understand the toxicity of PFAS to humans and animals have focused on individual PFAS exposures, despite real-world exposures to complex mixtures of PFAS. Additional research to understand the cumulative effect of lifetime exposure to the PFAS most frequently detected in human biomonitoring studies and common exposure media is needed. Current PFAS hazard assessments and scoping activities prioritize rodent toxicity data over all other available types of data, potentially missing important health and ecotoxicological effects (Carlson et al. 2022; Pelch and Kwiatkowski 2022; Pelch et al. 2022; US EPA 2021). Reliable information on chemical specific absorption, distribution, metabolism and excretion (ADME) and toxicokinetics (both human and animal) has been a limiting factor in several PFAS hazard assessments, yet it is a critical component of translating exposures in rodent toxicological studies to potential human exposures.

Response to specific questions listed in RFI:

(1) A class-based approach for PFAS is required in all strategic planning. Research and development activities should aim for comprehensive PFAS coverage.

In situations when prioritization is necessary, agencies should make use of all the information available to them to make informed decisions, including the consideration of toxicity, usage, Toxics Release Inventory release data, and exposure and environmental monitoring data. However, the information currently available is highly limited by the US EPA's use of a non-scientifically based definition of PFAS, lack of reference standards and analytical methods to detect PFAS, and poor reporting requirements of uses and releases of PFAS by industry.

In addition to the criteria suggested above, USG should consider equity issues as there are communities exposed to exceedingly high levels of PFAS from legacy exposures such as being sited near manufacturing locations, landfills, AFFF training or deployment sites, etc.

(2) A class-based approach should be applied across the five research goals identified above in order to most effectively address the PFAS crisis. The class-based approach is necessary to avoid lengthy delays in health protections and wasted resources so that scientists and governments are not stuck on the toxic treadmill of identifying, detecting, monitoring, regulating and cleaning up individual chemicals one at a time, an approach that will fail to meaningfully address the crisis or protect the public.

(3) In order to identify alternatives to PFAS and methods for removal and destruction of PFAS, the USG must use a scientifically-supported definition of the PFAS class and adopt a class-based approach for each of these priority areas.

Evidence suggests that all PFAS are of concern and their use should be phased out wherever possible, and no new PFAS or new uses of existing PFAS permitted under the Toxic Substances Control Act (TSCA). There needs to be a mindset change to assume all PFAS are persistent, harmful, and non-essential until proven otherwise. Adoption of a class-based approach premised on an inclusive, scientific definition of PFAS will open opportunities for safer non-PFAS alternatives to be developed and taken up. It will also avoid the creation of new PFAS that remain unaccounted for and unregulated to enter the market as "alternatives" for existing PFAS.

A challenge to effective monitoring and treatment of PFAS from the environment is that there is a focus on a small subset of individually quantifiable PFAS. Methods that more comprehensively measure PFAS in a variety of environmental matrices exist but are not validated in a way that allows for their use in a regulatory setting. Such methodologies and validation are urgently needed to better ensure complete and comprehensive removal of PFAS.

Current methods to remove PFAS from the environment create new waste streams of concentrated PFAS, with no way to safely destroy and degrade these wastes. Some bench-scale solutions look promising, the challenge lies in scaling these technologies up, while still ensuring safe and complete destruction of PFAS. These developing technologies require government evaluation to help states, municipalities, and companies understand whether they are truly destroying PFAS in a safe manner. Ideally destruction methods would be used in-line with techniques that remove PFAS from environmental media, which will avoid the necessity of transporting concentrated PFAS waste long distances. This will help the USG ensure that PFAS burdens are not spread among additional communities as a result of end-of life activities.

(4) PFAS uses should be evaluated through the essential use framework. Alternatives are not required for non-essential uses. Essential uses should only be given a time-limited exception for use in order to develop safer alternatives.

(5) As stated in **(3)**, the USG should use a scientifically supported definition of the PFAS. The use of the narrow definition is highly problematic and will result in wasted resources and extended exposure to at-risk populations.

(6) Please refer to our response in **(D)**. USG should use its existing authority to require manufacturers to provide reference standards (including storage instructions and regular updates) and analytical methods for all PFAS, as defined above in **(3)**, produced in the last ten years. USG should also require comprehensive reporting (without *de minimus* exceptions) of all uses and releases of all PFAS.

(7) USG currently does not make full use of currently available data including observational animal studies, experimental animal studies in non-mammalian species, and *in vitro* studies despite that these data streams may be informative for understanding human health effects. Importantly, although *in vitro* studies and other new approach methods (NAMs) can provide a lot of potentially helpful data, they are not advanced enough to determine a PFAS is nontoxic on their own. Health assessments for PFAS highlight the need for additional reproductive and developmental toxicity studies as well as ADME and toxicokinetic studies across species.

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(8) Understanding the health impacts of chemical mixtures, even beyond PFAS, is an important and underfunded area of research. There should be more funding programs and opportunities designed to specifically – and adequately account for these exposures (Kato et al. 2011).

(9) USG must commit to publishing public timelines and providing timely updates on the progress of all goals identified in the strategic plan. USG's priority should be the advancement of class-based approaches to addressing the goals outlined in its strategic plan. Specific priorities include: a departure from the PFAS toxic treadmill including the halt of new PFAS approvals and the adoption of a scientifically supported definition; the implementation of the essential use framework where possible; the development and validation of sensitive broad-spectrum tests for PFAS in different environmental media; and the advancement and evaluation of complete destruction technologies that do not create additional hazardous waste streams.

In summary, it is critical that the USG adopt a class-based approach to managing PFAS, including the use of a scientifically-supported definition of the PFAS class based on the hazard characteristic of persistence – as used by multiple states and Congress, or alternatively as has been developed by OECD.

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August 29, 2022

Dr. Alondra Nelson, Director
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Re: RFI Response: PFAS Strategic Plan

NSF International (NSF) appreciates the opportunity to provide comments to the Office of Science and Technology Policy on the request for information *Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development*.

NSF is an independent, not-for-profit organization founded in 1944 in Ann Arbor, MI that develops consensus national standards, provides product inspection, testing and certification, auditing, education, and related services in public health and safety. For more than 75 years, our mission has been to protect public health and safety.

Per- and polyfluoroalkyl substances have properties such as persistence, resistance to degradation, and ability to repel both oil and water making these compounds highly desirable for a variety of manufacturing processes leading to their use in carpeting, upholstery, food containers, and cosmetics as well as aqueous film forming foam used in fighting petroleum fires (EPA, 2022). As these substances have been studied, concern has been raised over human health effects which led to the discontinuance of use of PFOA and PFOS in the United States and 25 states setting specific PFAS levels in one or more environmental media (Longsworth, 2022).

In consideration of key data gaps and proposed areas of research for the PFAS class of compounds, NSF recommends the following:

- While there has been considerable concern about PFAS, only a handful of the thousands of PFAS in commerce have been studied for their toxicity (Fenton, et al., 2020). Additional research is needed on the effects of exposure to these different PFAS and their fate and transport in the environment. Although significant efforts have been made in defining and categorizing PFAS (OECD, 2021), we would highlight the need to better characterize environmental degradants (e.g. perfluoroalkyl acids (PFAA)) of precursor PFAS, in particular fluoropolymers and PFAS-functionalized polymers, and the potential use of PFAAs and similar compounds in the manufacture of PFAS and other polymeric materials (e.g. as surfactant in emulsion polymerization) that may be present as unexpected residuals (Zhou, Jin, Shen, & Zhou, 2021) (SEMI “PFOA Compliance” Working Group, 2017).

- Existing research on Point-of Use drinking water treatment devices show the potential for technologies such as granulated activated carbon, ion exchange and membrane filtration to

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reduce PFAS concentrations in drinking water (Mulhern, et al., 2021) (Zhou G. , 2022). NSF/ANSI 53 and 58, American National Standards for *Drinking Water Treatment Units – Health Effects* and *Reverse Osmosis Drinking Water Treatment Systems* respectively, were updated in 2019 to include criteria to test for the reduction of PFOA and PFOS to below the 70ppt health advisory level set by the EPA in 2016. These NSF standards are currently being revised to lower the maximum levels of PFOA and PFOS in drinking water to 20 ppt and to include reduction claims for PFHpA, PFHxS, PFNA, and total PFAS (based on a mixture of the prior mentioned specific PFAS as well as PFBS and PFDA). The EPA's 2022 interim updated PFOA and PFOS health advisory levels of 0.004 ppt and 0.02 ppt respectively place both compounds beyond current detection limits highlighting the need for more research on detection methodologies.

- We would also encourage additional research on the disposal of these point of use treatment device cartridges. As the EPA and state drinking water agencies and utilities suggest the use of certified point of use treatment, greater understanding is needed regarding the fate of the PFAS substances captured by these devices (e.g. in landfill) and whether consideration needs to be given for their disposal (EPA, 2020). Recently, South China Normal University Environmental Research Institute conducted a study in Guangzhou, finding that PFAS leachate from landfill (from all sources using a targeted and non-targeted analysis) was a major source of PFAS in local groundwater (Liu, et al., 2022).

NSF appreciates the opportunity to make comment on this request for information.

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August 29, 2022

Stacy Murphy
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RE: RFI Response: PFAS Strategic Plan

Dear Stacy Murphy,

On behalf of the Water Quality Association (WQA), we would like to express our support to the department for further coordinating a federal response to per- and polyfluoroalkyl substances (PFAS) in drinking water and the environment. Recognizing gaps in research and development to address these chemicals will be vital in identifying and treating PFAS to ensure the health and safety of the American people.

WQA and the broader scientific community, the Environmental Protection Agency (EPA), and the agency's Science Advisory Board (SAB) have raised concerns over the long-term health and environmental impact PFAS has on drinking water and the public. Considering EPA actions and the agency's PFAS Strategic Roadmap and updated interim Health Advisory (HA) for these chemicals, it is worthy to note the feasibility of treatment and detection technology.

Many factors influence the ability to identify and treat PFAS in drinking water. As PFAS are a large family of man-made chemicals used in various household, commercial, and industrial applications, the contaminant's characteristics largely depend on the chemical composition of these substances. The basic structure of PFAS consists of a carbon chain bonded to fluorine attached to other elements and functional groups (such as alcohols, carboxylic acids, sulfonic acids, etc.). The chemical bond between carbon and fluorine is one of the strongest in organic chemistry making them resistant to degradation and persistent, meaning these "forever chemicals" accumulate in the environment and your body over time. Branched isomers also play a role in the type of PFAS present, these are often separated into two categories – long-chain PFAS typically consisting of a carbon chain of seven or more, and short-chain PFAS holding less than six. Other factors including the spatial arrangement of these groups can influence the strength and energy associated with PFAS, referred to as Steric Hindrance. These aspects of PFAS and other environmental factors greatly impact the ability to identify and remove drinking water contaminants.

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Due to the variations of PFAS chemical structures, there is considerable research needed to investigate factors that impact the efficacy of water treatment systems and development of laboratory methodologies for detection at the health advisory levels. In response to question 3 of the RFI, the association recommends scientific research to examine the efficacy of removal technologies in relation to the chemical structure of PFAS, including the impact of steric hindrance, natural organic matter, and pH.

We encourage OSTP to engage with NSF International Joint Committee on Drinking Water Treatment Units (DWTU) Task Group on PFAS to understand the industry's current capabilities. This is where consensus-based standards are developed through the American National Standards Institute (ANSI) process to which these technologies are tested and certified for PFAS reduction, along with many other drinking water contaminants.

Increasing research and development in these areas will position the government, public, and water treatment industry to properly address PFAS in drinking water. Funding scientific research and investing in public-private partnerships are pillars of advancing the betterment of society. The Water Quality Research Foundation (WQRF) is a universally recognized independent organization that conducts and funds scientific research on subjects relating to the water quality improvement industry. Since 2016, WQRF has funded over $1.5 million in research aimed at advancing knowledge and the science of high-quality, sustainable water and plans to fund more than $3 million in data collection and research projects through academia and environmental consultants. WQRF has already made progress in understanding the broader scope of drinking water contaminants and would welcome the opportunity to work alongside the EPA and the federal government to support the research and the development of water treatment products that already play a vital role for many individuals, households, and businesses to improve their drinking water quality.

In response to this challenge, it is crucial that federal activities and research support scientific and technological capabilities for remediation. Thank you for your consideration of these recommendations and we hope to continue serving as a valuable resource to OSTP and the broader scientific community moving forward.

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About WQA

WQA is a not-for-profit trade association representing the residential, commercial, and industrial water treatment industry with over 2,500 members worldwide. Since its creation in 1974, WQA has worked tirelessly to improve water quality through sustainable technologies and services. Our members are manufacturers, dealers, and distributors who specialize in point-of-use (POU) and point-of-entry (POE) water filtration systems, which treat water at the tap or entry point of a home or building. WQA also operates an American National Standards Institute (ANSI) accredited testing and certification laboratory that certifies water filtration products to nationally accepted industry standards for contaminant removal.

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ENDOCRINE SOCIETY
Hormone Science to Health

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August 29, 2022

Dear Dr. Nelson

The Endocrine Society appreciates the opportunity to provide comments on a strategic plan for Federal coordination of PFAS research and development. Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization of scientists and healthcare professionals dedicated to research on hormones and the clinical treatment of patients with endocrine diseases. Our membership includes 18,000 clinicians and scientists from over 120 countries, including many researchers engaged in the study of the adverse effects of per- and polyfluoroalkyl substances (PFAS) on endocrine systems. While we appreciate that the Office of Science and Technology Policy (OSTP) is interested in research gaps and opportunities, we note there already is ample evidence of harm to a variety of endocrine organs and systems due to PFAS exposure. We therefore encourage OSTP to focus research and development priorities towards knowledge gaps and solutions that will reduce further harm to individuals and communities. Below we identify several pressing challenges that should be addressed by the plan and propose solutions that would help overcome these issues.

Volume and Diversity of PFAS In Use: An overarching challenge in addressing PFAS is that this is an extensive group comprising at least 9,000 compounds with detailed information on only a few chemicals. Considering this, it is unrealistic to expect that we can ever achieve comprehensive toxicity data on all members of this growing class of chemicals. While we certainly know enough about certain PFAS to act now, we believe OSTP should work with academic researchers and across federal agencies to develop a common definition of PFAS with the goal of enabling researchers and regulatory agencies to assess and restrict these chemicals as a class. PFAS classes should be determined based not just on exposure data and chemicals that are co-located or utilized together, but also on other parameters such as structure and activity. Known hazards in well-studied compounds should be assumed for similar structures that have little or no data available until the data gaps are filled and in the public domain. These classes should be defined and acted upon with urgency, given current known and presumed levels of contamination.

Widespread PFAS Contamination: Removal of PFAS from the environment is an urgent goal that will require research on effective strategies that communities can deploy to minimize their exposure. We stress that the goal of removal should be destruction of PFAS, and not simply

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displacing contamination to another site. In addition to environmental remediation, interventions to reduce an individual's PFAS body burden are urgently needed given updated clinical guidance on PFAS screening and health monitoring[1]. Research to advance the destruction of PFAS should be applied for the purpose of removing existing PFAS from the environment, not as a justification to continue use and production of this hazardous group of chemicals. Therefore, research and development should focus on removing existing PFAS to reduce current human and ecological exposures.

At least 97% of Americans have detectable levels of PFAS in their blood, and individuals with any level of exposure but in particular disproportionately impacted populations such as fluorochemical workers, want to reduce their personal PFAS levels and they may use blood levels as an indicator of exposure. However, because PFAS may reside in other tissues, blood levels may give an incomplete picture of total body burden; the risk-benefit of interventions like phlebotomy that may reduce PFAS concentrations in blood require urgent further investigation. We recommend that research dedicated to understanding how best to achieve reduction of PFAS in human blood and tissue be conducted, and messaging on this issue be communicated to medical providers to enable them to effectively help their patients lower their body burdens through safe and tested approaches.

Lack of Analytical Standards for Newer or Replacement PFAS: Our members note that the lack of analytical standards for many PFAS is a challenge both for research and public health. Biomonitoring and epidemiological studies lack the necessary analytical standards to capture data on the level of many PFAS in the environment and in human bodies. Agencies should seek to help communities better understand the outcomes of PFAS exposure so that they can make better informed healthcare decisions; however, this will require standards and research-based educational resources for patients and providers. We strongly recommend that analytical standards be produced as a required part of any development strategies for replacement products.

Unregulated Discharges and Complex Mixture Effects: A history of unregulated use and discharge of PFAS into the environment has created an immense variety of exposure scenarios, including in medical devices and other commonly used consumer products, that complicate epidemiological studies. Additionally, mixture effects further render a chemical-by-chemical approach to PFAS assessment and remediation ineffective. Research resources should be dedicated to understanding common PFAS mixtures in concentrations and proportions relevant to consumer and environmental exposures. OSTP should work with agencies to ensure that there is no longer any unregulated discharge for PFAS or replacement chemicals. Furthermore, understanding mixture composition and impacts is impossible when compounds utilized by companies are frequently replaced with new unknown chemicals. Research lead by the Federal government could

[1] https://www.epa.gov/sdwa/drinking-water-health-advisories-pfoa-and-pfos

require and access confidential information on chemicals utilized in different sectors to conduct an impact analysis on predicted health and cleanup costs to society, to help identify compounds that are truly essential.

Unclear Definition of Essential Uses: We are concerned that OSTP implies that infrastructure or other uses of PFAS are essential or require chemical alternatives to PFAS. OSTP should prioritize the development of nonchemical and safe and sustainable by design approaches to replacements for current uses of PFAS. In parallel to this research objective, OSTP should establish definitions for essential uses that apply across agencies, taking into account the health effects and consequent economic damages suffered by society due to exposure including health costs as well as cleanup costs that are borne in large part by utility rate payers. Research programs should also seek to understand and develop mitigation strategies for communities that may be disproportionately impacted through 'essential use' exposures.

In conclusion, we strongly urge OSTP to develop a strategic plan with the necessary goal of reducing exposures such that human and ecological impact is minimized. We acknowledge that minimizing impacts of these chemicals, where there may be no safe level of exposure, may require aggressive action by multiple federal agencies. However, such actions may be necessary in the short- and long-term to protect human and environmental health. The strategic plan should encourage agencies to adopt policies that place prevention and remediation costs on polluters themselves, for example by requiring that companies develop analytical standards for replacement chemicals and requiring that companies develop effective remediation approaches for prior releases into the environment. Thank you for considering the Endocrine Society's comments; we welcome the opportunity to meet with your office to discuss these and other science and technology priorities.

August 29, 2022

Re: Waste Management Comments on Request for Information; Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development

Waste Management (WM) appreciates the opportunity to provide comments on the Office of Science and Technology Policy's (OSTP's) Request for Information (RFI) on Identifying Critical Data Gaps and Needs to Inform a Federal Strategic Plan for Research and Development on Per- and Polyfluoroalkyl Substances (PFAS). WM is the leading provider of environmental services in North America, with nearly 50,000 employees operating 263 solid waste landfills, 348 transfer stations, 103 materials recovery facilities, 44 organics processing facilities, 5 hazardous waste facilities, and a fleet of over 20,000 collection vehicles throughout the United States and Canada.

WM is pleased that OSTP seeks to collaborate with industry stakeholders to identify cost-effective methods for removing PFAS from the environment. Furthermore, as OSTP has acknowledged the difficulty of comprehensively evaluating the environmental and human impacts of PFAS exposure, we believe it is critical to address both foundational analytical data needs and key data gaps before certain regulatory standards are promulgated. WM thus encourages OSTP to support private research efforts around PFAS disposal and treatment, as discussed below.

I. The Role of Landfills in End-of-Life Management of Materials Containing PFAS

WM is actively engaging with states to provide recommendations on minimizing the potential environmental risks associated with landfill acceptance of PFAS wastes. Landfills do not manufacture or use PFAS and, as such, are mainly passive receivers of PFAS that are commonly found in the stream of commerce. Our customers nevertheless are seeking solutions for waste streams with high concentrations of PFAS, including media from cleanup and remediation projects, chemical manufacturing wastes and byproducts, and product demonstration and training wastes and residuals. Given the increasing focus on end-of-life management of materials containing PFAS, WM has developed a draft waste acceptance framework aimed at directing these waste streams to the most suitable disposal facilities—effectively removing PFAS-containing wastes from the environment and breaking the cycle of redistributing PFAS across various media.

We have been refining our draft framework as scientific information on PFAS continues to evolve. The framework currently includes a qualitative site evaluation method that considers both the unique properties of PFAS and specific landfill attributes that provide high levels of environmental protection. We are open to discussing concepts of this framework with OSTP to ensure the agency appreciates certain environmental safeguards fundamental to our sector and recognizes areas where additional research would be beneficial.

II. Addressing Priority Data Gaps Around the Removal of PFAS from the Environment

The RFI acknowledges the challenges associated with identifying cost-effective methods for removing PFAS from the environment. WM agrees that there are many data gaps and scientific uncertainties related to the end-of-life management and remediation of PFAS wastes. As such, we encourage OSTP to support private research efforts in the following priority areas:

- **PFAS Concentrations in Solid Waste Streams.** In evaluating end-of-life solutions for materials containing PFAS, it is important to examine trends and determine the concentrations of PFAS in specific waste streams (e.g., municipal solid waste, industrial waste, biosolids, etc.). Data gathered over many years from a subset of landfills indicate downward concentration trends for perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) potentially related to the production phase-out of these compounds in the United States. Understanding PFAS trends in specific waste streams may allow for better management of these wastes when disposed at landfills.

- **Sequestration of PFAS in Landfills.** Recent research suggests that landfills may preferentially sequester certain PFAS relative to the mass of PFAS in inbound waste streams. More work is needed to better understand the fate, transport, and transformation of PFAS in landfills to allow our sector to make more informed decisions on the acceptance of certain waste streams.

- **Stabilization of PFAS in Landfills.** Performing leach tests on PFAS wastes that have been amended with different binding agents is a key research opportunity that would provide further information on methods to reduce PFAS concentrations/mass in leachate. Further research on stabilization technology is needed as our industry continues to evaluate options for the disposal of PFAS wastes.

- **Field Screening for PFAS.** Effective remediation of PFAS in the field necessitates proven analytical screening methods that meet requisite data quality objectives (DQOs) and are timely and cost effective. At present, no methods exist to perform field screening of solid or semi-solid materials that potentially contain PFAS. Current analytical testing requires shipping samples offsite, with typically a minimum fifteen-day turnaround. This challenge significantly limits the ability to pilot, let alone perform, field treatment or safe and secure disposal of potential PFAS-containing matrices. Development of technologies and associated analytical methods to enable rapid screening-level assessments of samples at sufficient precision and accuracy is foundational to enabling compliant and cost-effective disposal options for PFAS-containing materials that meet standards for the protection of human health and the environment.

- **Risk Evaluation (Analytical Testing and Data Quality Objectives).** Commensurate with identifying cost-effective methods for removing PFAS from the environment, it is critical to establish attainable

DQOs utilizing data that meet analytical precision and accuracy requirements. Regulation of PFAS in the states highlights a widening gulf between analytical capabilities (i.e., reporting limits) and DQOs that require very low and sometimes unattainable reporting limits. Regulatory standards and advisories are in some cases multiple orders of magnitude below analytical detection and quantification capabilities. This inconsistency between DQOs and available analytical technology is foundational and needs to be resolved. We therefore recommend that OSTP prioritize the development of EPA-approved analytical methods for different media such that the data generated provide an accurate foundation for establishing and meeting specific DQOs.

- **Risk Communication.** EPA's recent update to its drinking water health advisory levels for certain PFAS compounds—and the announcement of certain levels that are below analytical capabilities—has brought a renewed focus on the increasing challenge of communicating with the public, elected officials, and media about the health effects of PFAS. The waste sector finds that relevant stakeholders often have divergent information about the potential impacts associated with PFAS exposure. We therefore recommend that OSTP consider directing resources for risk communication that are consistent with the current state of knowledge and technical capability while supporting the Administration's efforts around end-of-life solutions for materials containing PFAS.

WM appreciates the opportunity to comment on this RFI, and we look forward to working constructively with OSTP in the months ahead.

Together, improving life

August 29, 2022
VIA ELECTRONIC FILING

RE: Docket ID NO. 2022-14862
RFI Response: Strategic Plan for PFAS Research and Development

EMAIL: JEEP@ostp.eop.gov

To whom it may concern:

W. L. Gore & Associates, Inc. ("Gore") respectfully submits these comments to the Office of Science and Technology Policy, in their development of a strategic plan for PFAS research and development, and specifically to help identify data gaps, as outlined in FR 2022-14862 RFI; "Identifying Critical Data Gaps and Needs To Inform Federal Strategic Plan for PFAS Research and Development."

Gore is a U.S.-based global materials science company dedicated to transforming industries and improving lives. Since 1958, Gore has solved complex technical challenges in demanding environments — from outer space to the world's highest peaks to the inner workings of the human body. With more than 12,000 Associates, including more than 7,000 in the United States, and a strong, team-oriented culture, Gore generates global annual revenues of $4.5 billion.

Gore is mainly a user of fluoropolymers, which are a sub-category of PFAS with distinct characteristics. We have over six decades of expertise using the unique properties of PTFE (polytetrafluoroethylene) and other fluoromaterials to invent valuable products, including implantable medical devices such as vascular grafts and stents; technical applications such as components for aircraft, automobiles, mobile phones and computers; protective apparel for firefighters and first responders; high performance outerwear; and filters, seals and vents that reduce emissions from power generation, industrial processes and packaging. We invite you to visit our web page and learn more about our highly valued products. www.gore.com

Gore supports the Administration's efforts to develop a strategic plan for PFAS research and development and appreciates the opportunity to provide these responses to the OSTP to help prioritize R&D activities that will most likely address the environmental and human health impacts associated with certain PFAS.

QUESTION 1. *Should the USG consider identifying priority PFAS when developing a strategic plan for PFAS research and development?*

Yes. OSTP states as an initial matter that "Research has shown that PFAS are highly stable chemicals that accumulate in people, animals, and the environment over time, and in several cases, have been shown to cause adverse health effects." Given the broad definition of PFAS being used for this RFI, it is clear that this statement does not apply to all PFAS. The PFAS group as commonly understood includes thousands of substances with different properties, e.g.: polymers and non-polymers; solids, liquids, and gases; persistent and non-persistent substances; highly reactive and inert substances; mobile and insoluble substances; and toxic and nontoxic chemicals. Recognizing that PFAS are not all the same, it is critical to prioritize and assess the hazards/risks of PFAS based on their potential to impact human health or the environment. This would minimize the total effort and provide the highest value to address regulation of PFAS in a proportionate risk-based manner.

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Priority should be given to those PFAS substances that exhibit properties such as: water solubility (mobility), bioavailability, the potential for a substance to bioaccumulate, toxicity and the propensity for a substance to degrade into other substances of concern. These properties are most often associated with the non-polymeric category of PFAS (e.g., perfluoroalkyl acids (PFAA) such as PFOA).

PFAS which meet the criteria for a Polymer of Low Concern (PLC) should not be identified as a priority category. "Polymers of Low Concern are those deemed to have insignificant environmental and human health impacts" [OECD2009][11]. Fluoropolymers are a distinct class within the broad PFAS group and meet the OECD-PLC criteria. High molecular weight fluoropolymers like PTFE are highly stable, too large to be bioavailable, and do not have the potential to become widespread in the environment**.** While these fluoropolymers do contain one or more fully fluorinated carbon atoms, data show that their properties present low health and environmental hazards. [Henry[7] and Korzeniowski[8]] The scientific community considers these materials to be inert. " Most experts agree that "all PFAS" should not be grouped together for risk assessment purposes." [Anderson][2]

PTFE and other high molecular weight fluoropolymers are different from the PFAS that have been detected in water resources. The difference is evident from objective data on their properties, the biologically sensitive applications where they have been extensively used and studied for decades (e.g., medical devices and pharmaceutical processing), and their absence from environmental media. Because PTFE and other fluoropolymers serve important functions that benefit human health, safety and environmental stewardship, support critical infrastructure and meet the OECD-PLC criteria, fluoropolymers like PTFE should not be prioritized in your strategic plan for PFAS R&D. For a more in-depth discussion of the toxicological properties of PTFE, please see Response to ECHA[4] and Attachment 1

Criteria that should be used to identify priority PFAS for R&D development. Recognizing that by definition a substance that is not bioavailable cannot be toxic (cause an adverse health effect) because it cannot enter the cell or trigger cellular activity via surface receptors regardless of its concentration or mobility. Criteria to be considered should focus on Bioavailability/Bioaccumulation/Toxicity. Using recognized protocols for criteria that will, for example, assess the ability of the PFAS chemical to enter the cell or signal changes within the cell and cause harm. Mobility criteria: properties that can be identified and evaluated using recognized protocols that will assess the ability of the PFAS chemical to be available in the environment via transport through different environmental media (e.g., air, water, soil).

QUESTION 2. *Are there criteria which could be applied across the five identified research goals, or should specific criteria be developed for each individual research goal?*

Due to the unique characteristics and behaviors of different PFAS, Gore believes that some criteria could be applied across all of the research goals, however there will also be a need for some goal-specific criteria. Common criteria should include the OECD PLC criteria [OECD2009][11], to exclude PFAS that are not bioavailable or mobile in the environment. In addition, for each goal, PFAS with the highest potential for human health effects should be prioritized (see response to Question 7 for further discussion of a prioritization process).

Goal-specific criteria should include recognition of available and proven technology; for example, incineration has been shown to be effective for the destruction of PFAS [Aleksandrov][1]. PFAS alternatives should consider broad lifecycle aspects as well as cost and performance characteristics. The understanding of sources and exposure pathways should consider the PFASs ability to be bioavailable, bioaccumulative and mobile.

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QUESTION 3. *What are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS and to identify cost-effective alternatives to PFAS?*

As discussed more fully in response to Question 1, Gore believes that the initial scientific and technical challenge is to first identify those individual or sub-class(es) of PFAS substances that should be prioritized for evaluation and determination of mechanisms to reduce any potential environmental or human impacts.

Evaluation of potential alternatives to determine what is "designed to be safer and more environmentally friendly" should use the same criteria used to evaluate potential relative risk of PFAS substances (e.g., bioavailability, bioaccumulation, toxicity, mobility), as well as establishment of objective criteria to define what it means to be "environmentally friendly." Many PFAS, such as fluoropolymers, are used in applications of high societal value and moves to restrict the use of these substances prior to identification of alternatives could have a significant negative socioeconomic impact; socioeconomic implications should also be taken into consideration when evaluating potential alternatives.

Challenges in selection of alternatives include data availability for new materials, understanding and evaluation of application/use performance characteristics and criteria, and alternatives which are readily available (i.e., technologically and economically feasible) in uses where fluorinated materials, like fluoropolymers, provide unique and necessary properties, such as chemical inertness, mechanical strength, friction resistance, stability and flexibility.

Regarding removal of PFAS from the environment, PTFE does not degrade or transform in the environment, nor is it otherwise a source of substances of potential concern. Gore commissioned a study [ECHA[4] and Attachment #1] to provide consistent and reproduceable evidence that any persistence of PTFE does not indicate potential for future toxicity, bioaccumulation, degradation, release or transformation into non-polymeric substances.

Regarding challenges to identify cost-effective methods of destruction, Aleksandrov[1] concluded that, when operating under permit conditions, municipal incineration of PTFE is an effective way to dispose of the fluoropolymer.

QUESTION 4. *Are there specific chemistries and/or intended uses that PFAS provide for which there are no known alternatives at this time?*

Yes. Gore produces products for a wide variety of markets and utilizes primarily fluoropolymers, such as PTFE. Gore also utilizes other specific PFAS materials in combination with fluoropolymers to provide unique and highly valued products for which there are no known alternatives in many applications. The strength of the C-F bond in the PTFE molecules provides one of the least chemically reactive materials available known to this day. This bond imparts a unique combination of many important properties, including but not limited to low adhesion forces, mechanical strength, dimensional stability, chemical stability, electrically nonconductivity, temperature resistance and hydro- and oleophobicity. For example:

- Permanently implantable cardiovascular **medical device**s need to be made from biocompatible materials and perform for long periods of time without surgical replacement or chemical degradation.
- Cables used in **aerospace/defense aircraft** need to withstand large temperature and pressure variations, maintain reliable chemical resistance and mechanical and electrical performance, and have low smoke generation and flame propagation.

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- **Pharmaceutical and life science applications** value resistance to harsh and highly reactive chemicals, and low friction allowing for tighter seal fits without damage to mechanical components.
- **Semiconductor production** needs small, flexible, reliable and ultra clean cables to operate within clean room environments including extreme temperatures, continuous rapid flexing, and harsh chemicals.
- **Chemical manufacturing and industrial gaskets** require chemical compatibility/stability over a range of operating conditions, extreme cleanliness to limit oxidation risk or interference from contaminants, low friction for tighter seal fits, and temperature resistance.
- **Industrial filters** need to have high strength for durability/long filter life, chemical compatibility/stability over a range of operating conditions, and temperature and water resistance, to enable capture of fine dust, dioxins, heavy metals and other toxic or carcinogenic pollutants, while providing low resistance to gas flow.

QUESTION 7. *What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans?*

Given the health endpoints potentially associated with perfluoroalkyl acids, such as PFOA, PFOS, PFHxS, etc., the toxicity tests to address each, prioritization, screening and staging of testing is prudent from an animal use, time and cost perspective. (Attachment #2, TABLE 1, Testing Rationale and Test Methods). Prioritization and triage are necessary considering that performing all of this work would require the use of approximately 7,400 laboratory animals and well over $1,500,000 per individual PFAS evaluation. *In vitro* work with human cell lines could clarify the human relevance of effects seen in animal species. Testing at environmentally relevant doses rather than maximum tolerated doses would also inform human health risk assessments. As more fully described in our response to Question 1, these health endpoints are not common to members of all classes of PFAS (such as fluoropolymers). [All Table references in Question 7 can be found in Attachment #2.]

Acknowledging that some PFAS have adverse health effects reported in the peer-reviewed scientific literature, high priority should be given to screening PFAS to identify those which are: *bioavailable, bioaccumulative and mobile.*

- Bioavailability considerations: For polymeric refer to: Nabholz[9], OECD2009[11], DeToni[3], and for non-polymeric, refer to Guelfo[6], Figure S2, "Biological, chemical and physical property questions for PFAS grouping" Screen these bioavailable PFAS for bioaccumulation using OCSPP 850.1730 or OECD 305.
- Mobility: those PFAS which are bioavailable and bioaccumulative should be screened for physical and chemical properties associated with mobility (e.g., water solubility, see Table 2.).
- *In vivo* half-life testing for stability and biodegradation (see Table 3) to identify chemical entities to which humans may be exposed (e.g., parent, degradant). This would identify and prioritize substances (that are not stable and transform to other PFAS) for potential health hazard assessments.
- Toxicity testing: refer to section 4 of OECD2019[11] and OCSPP[10] and Table 3.
- Carcinogenicity testing. Please note, careful consideration of the weight of evidence of the genotoxicity testing and 90-day sub chronic study should be conducted. If the genotoxicity is negative and histopathology from the sub chronic testing does not indicate potential carcinogenicity (e.g., hyperplasia, pre-cancerous lesion, etc.) a waiver for the carcinogenicity testing may be appropriate.
- Immunotoxicity testing for humoral immunity. Please note, it is essential to obtain national baseline/background antibody titers against which PFAS-exposed population titers would be compared, or evidence of increased clinical disease causally associated with reduced Ab titers to identify toxicologically significant effects and to differentiate adverse from adaptive responses.

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QUESTION 8. *What should be the research and development priorities for accelerating progress in the area of PFAS mixtures and formulations found in environmental media?*

If the approach to prioritizing human health assessments in response to Question 7 were employed, the PFAS with the highest potential for human health effects and their transformation/ degradation products would be individually identified, and subject to further testing to determine those with the highest potential for human health effects. The remediation or destruction of PFAS (with highest potential for health effects) detected in environmental media should be given the highest priority for further research and development. See Guelfo[6] which addressed occurrence and source and Gluge[5] which includes extensive use information in supplementary files.

QUESTION 9. *What goals, priorities or performance metrics would be valuable in measuring the success of PFAS research and development initiatives?*

Focus should be on the mitigation of substances that have both been detected in environmental media and that have been identified as having the potential to impact human health, as more fully described in our response to Questions 1 and 7.

- Goals should include development of robust test methods which are able to provide detection limits to levels which are meaningful to result in action that will meet the goal of reducing the environmental and human impact of PFAS in a proportionate and risk-based manner.
- Develop appropriate key performance indicators, that takes into account analytical capability, technical feasibility, and economic feasibility (for example, avoid removal targets at “zero” or “non-detect”).
- Goals & priorities related to “safe destruction”. Evaluation of destruction of PFAS should include further studies of all PFAS and incineration. R&D for control technologies should also be explored to reduce impact at the source. Innovation and exploration of robust air emissions control technologies to accompany selected destruction methods to reduce impact at the source should be continued and expanded.

In closing, we respectfully request when developing the strategic plan for PFAS research and development, that OSTP provide a mechanism for prioritizing the most appropriate individual or sub-class(es) of PFAS based on their chemical, physical and toxicological properties, along with other criteria as described herein.

Sincerely,

W. L. Gore & Associates, Inc.

Attachments:

- Bibliography: as follows
- Attachment #1: “ECHA”, July 2022, is included as a separate document to this response.
- Attachment #2: as follows

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Attachment #2, Test Methods Recommendations & References > Question 7

Table 1 Testing Rationale and Test Methods

Category	Test	Test Method	Test Method	Rationale/Potential PFAS Effect
Metabolism	Absorption, Distribution, Metabolism, Excretion	OECD 417	EPA 870.7485	Long *in vivo* half-life
Immunotoxicity	Sensitisation, Skin (cell-mediated immunotoxicity)	OECD 406	EPA 870.2600	Disruption of immune system
	Immunotoxicity (humoral immunotoxicity)		EPA 870.7800	
Genotoxicity	Mutagenicity, bacterial and mammalian	OECD 471	EPA 870.5100	Genotoxicity/ carcinogenicity
	Chromosome aberration	OECD 473	EPA 870.5375	
	In vivo mouse micronucleus test	OECD 474	EPA 870.5395	
Subchronic Toxicity	Repeated Dose 90-Day Oral Toxicity Study in Rodents (with enhanced lipid profiling and neurotoxicity group	OECD 408	EPA 870.3150	Disruption of lipid metabolism, liver tox, neurobehavioral effects
Chronic Toxicity/ Carcinogenicity	Combined chronic/carcinogenicity	OECD 453	EPA 870.4300	Chronic toxicity/ carcinogenicity
Reproductive Toxicity	Extended 1-Generation Reproduction Study (with immunotoxicity, neurotoxicity, and 2nd generation included)	OECD 443	EPA 870.3650?	Neonatal toxicity/ death, neurotoxicity
Developmental Toxicity	Prenatal Developmental Toxicity Study (2 species)	OECD 414	EPA 870.3700	Developmental effects
Endocrine Disruption	Uterotrophic Bioassay in rodents: a short- term screening assay for oestrogenic properties	OECD 440	EPA 890.1600	Disruption of endocrine system
	Hershberger Bioassay in rats: a short-term screening assay for (anti)androgenic properties	OECD 441	EPA 890.1400	
	Aromatase		EPA 890.1200	
	Amphibian Metamorphosis Assay	OECD 231	EPA 890.1100	
	Fish short-Term Reproduction Assay	OECD 229	EPA 890.1350 (ToxCast ER and AR binding HTS)	
	H295R Steroidogenesis assay	OECD 456	EPA 890.1550 (ToxCast STR)	
	Pubertal Development and Thyroid Function Assay in Peripubertal Male Rats (Male PP Assay)		EPA 890.1500 (ToxCast AR binding and THY HTS)	

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	Pubertal Development and Thyroid Function Assay in Peripubertal Female Rats (Female PP Assay)		EPA 890.1450 (ToxCast ER and THY HTS)	
	Rat estrogen receptor binding assay	OECD 493	EPA 890.1250	
	Estrogen Receptor Transcriptional Activation		EPA 890.1300	
	Rat androgen receptor binding assay		EPA 890.1150	
Acute Toxicity	Acute Oral LD50	OECD 423	EPA 870.1100	Worker Safety
	Acute Dermal LD50	OECD 402	EPA 870.1200	
	Acute Inhalation LC50	OECD 403	EPA 870.1300	
	Skin Irritation	OECD 404	EPA 870.2500	
	Acute Eye Irritation	OECD 405	EPA 870.2400	

Table 2 Test Methods, Recommendations & References

Category	Test Methods
Water Solubility	OCSPPA 830.7840 OCSPPEPA 830.7860 OECD 105
Lipophilicity: Octanol water partition coefficient	OCSPP 830.7560 OCSPP 830.7570 OECD 107 OECD 117
Molecular Weight	OECD 118
Electrical Charge	Chemistry knowledge-based decision
Bioaccumulation or Bioconcentration Factor	OCSPP 850.1730 OECD 305

Table 3 Test Methods, Stability and Biodegradation

Category	Test Method
Hydrolysis	OCSPP 835.2120 OCSPPEPA 835.2130 OECD 111
Photolysis	OCSPPEPA 835.2210 OCSPPEPA 835.2240 OECD 316
Thermal Stability	OECD 113
Biodegradation: Ready	OCSPPPA 835.3110 OCSPPEPA 832.3140 OECD 301
Biodegradation: Inherent	OCSPPEPA 835.3215 OECD 302
Biodegradation: Aerobic	OCSPPA 835.3100 OECD303
Biodegradation: Anerobic	OCSPPEPA 835.3420 OECD 307 OECD 308

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August 29, 2022 *via* electronic transmission

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Subject: RFI Response: PFAS Strategic Plan

The Household & Commercial Products Association[1] (HCPA) appreciates the opportunity to offer comments to the White House Office of Science and Technology Policy (OSTP) on the Request for Information[2] (RFI) to identify data gaps in research and development regarding several aspects of per- and polyfluoroalkyl substances (PFAS). HCPA believes that there should be a robust science-based effort at the federal level to show leadership on PFAS.

HCPA is a voluntary, non-profit U.S. trade association representing approximately 240 companies engaged in the manufacture, formulation, distribution, and sale of products for the household, institutional, commercial, and industrial use. Some products which HCPA members manufacture and/or market may contain substances which could be considered PFAS, depending on its definition.

There are a wide range of substances which could be considered PFAS and there is not a clear understanding of which ones may pose a potential human health or environmental risk. While there is a patchwork of definitions to describe PFAS as a class,[3] the substances that fit within these various definitions have different chemical, physical and toxicological properties. Fundamentally, it is inappropriate to assume that all substances that could be considered PFAS have the same toxicity and potency. As such, HCPA does not believe that all PFAS compounds should be treated the same, but rather should be assessed within subgroups based on various

[1] The Household & Commercial Products Association (HCPA) is the premier trade association representing companies that manufacture and sell $180 billion annually of trusted and familiar products used for cleaning, protecting, maintaining, and disinfecting homes and commercial environments. HCPA member companies employ 200,000 people in the U.S. whose work helps consumers and workers to create cleaner, healthier and more productive lives.

[2] https://www.federalregister.gov/documents/2022/07/13/2022-14862/request-for-information-identifying-critical-data-gaps-and-needs-to-inform-federal-strategic-plan

[3] Williams AJ, Gaines LGT, Grulke CM, Lowe CN, Sinclair GFB, Samano V, Thillainadarajah I, Meyer B, Patlewicz G, Richard AM. Assembly and Curation of Lists of Per- and Polyfluoroalkyl Substances (PFAS) to Support Environmental Science Research. Front Environ Sci. 2022 Apr 5;10:1-13. doi: 10.3389/fenvs.2022.850019. PMID: 35936994; PMCID: PMC9350880.

criteria, such as bioaccumulation, toxicity, toxicokinetics, etc. Research also should explore ways to identify PFAS of "low priority" on the basis of health and environmental effects to enable greater focus by the Environmental Protection Agency (EPA) and others on substances of highest concern.

Developing a strategic plan for a subgroup of substances that have similar properties can be effective when properly defined. However, a broad definition that encompasses several types of chemistries that have different properties becomes a daunting challenge and can be overwhelming. While a definition for PFAS can be more than "man-made chemicals of which all the carbon atoms are fully fluorinated carbon atoms" and include carbon atoms that are partially fluorinated and nonfluorinated, if the property of most concern is bioaccumulation, then the definition needs to not include compounds that break down naturally in the environment. If other properties of the class of substances are identified as being of most concern, or at the very least something to be addressed, then the definition should be structured to encompass those compounds and exclude ones that don't have those properties. To this end, HCPA recommends certain substances be excluded from being "priorities" for federal research efforts on finding alternatives and methods for removal and treatment. Such exclusions should be risk-based, for example fluoropolymers, fluorocarbon gases such as hydrofluorolefins (HFOs), and PFAS that are active pharmaceutical ingredients (APIs) that have been approved by FDA could be excluded on that basis. This would enable agencies and stakeholders to focus resources efficiently.

Fluorinated compounds are used because of their unique properties, which vary based on the substance. After consensus is reached on the definition, it is important to realize that a single policy approach is not reflective of the current marketplace. An understanding of the current applications and whether or not alternative or replacement chemistry exists for the subgroup or subgroups of PFAS that pose the most risk to human health or the environment based on the criteria previously selected should be the starting point. However, removal of these substances without technologically and commercially feasible substitutes would result in sweeping changes for society, especially for consumers and workers unaware of the contributions these substances make to improving their lives. When alternatives are identified, the risk of switching to the alternative chemistry against the benefit each could provide must be weighed. For instance, if the alternative chemistry reduces potential risk to human health or the environment in one aspect but does not provide a similar benefit to other issues, for example such as climate change or life saving pharmaceuticals, then stakeholders need to weigh the costs and benefits to each type of chemistry. In cases where alternatives do not exist, research should be undertaken to understand what will be needed to identify and develop alternatives. Recognizing the wide gap between a successful R&D initiative and a commercially successful product, HCPA encourages OSTP to include Federal investment in infrastructure and commercialization resources to support the scale-up and deployment of PFAS alternatives as well as investment in basic scientific research. After assessing the subgroup or subgroups of most concern, evaluations should continue for subgroups that have risk based on the criteria of

properties selected in a similar fashion. Subgroups that do not pose a risk based on the criteria selected do not need to be assessed as they do not pose a risk.
An expert panel[4] was recently convened to provide insight and guidance on PFAS grouping for the purposes of protecting human health from drinking water exposures, and how risks to PFAS mixtures should be assessed. Here are some highlights of their key findings:

- Most of the expert panelists agreed that the EPA Toxic Substances Control Act (TSCA) definition and approach for grouping PFAS is pragmatic and generally a good starting place for human health risk assessment
- Physicochemical properties may be used to help approximate the potential for human exposure and/or to screen or prioritize PFAS of potential concern, but these properties are not sufficient in and of themselves for informing either exposure or potential hazardous effects and additional knowledge on toxicological effects and dose-response is necessary for risk assessment.
- It was acknowledged that toxicity, bioaccumulation, toxicokinetic, and exposure profiles would vary among PFAS and therefore, those characteristics should be considered when assessing human health risk.
- Grouping all PFAS together as "persistent" was not supported as practical nor appropriate for assessing human health. This is also known as the "P-Sufficient approach" and one that some of the state DTSCs look upon favorably.
- Most panelists agreed that it is inappropriate to assume equal toxicity/potency across the diverse class of PFAS for human health risk assessment and that robust assessment of potential human health risk to a representative mixture of PFAS is not feasible.

OSTP's efforts should be informed by these findings and take into consideration that most PFAS risk assessments will need to employ substantial assumptions and defaults and these applied assumptions are more likely to overestimate risk than to underestimate risk. Some panelists expressed concerns that these assumptions are often multiplicative and can lead to overestimates of both potency and exposure, and therefore, over-regulation.

Lastly, HCPA believes that more research is necessary into the analytical methods of detecting PFAS, which should have detection limits that are reasonably protective of human health and the environment. HCPA has concerns with the use of Total Organic Fluorine (TOF) analysis for the detection of PFAS. TOF analysis measures all fluorine materials associated with organic fluorine, and while that makes it a good initial exploratory tool, it does not identify an individual substance, nor would anyone be able to conclude whether or not the fluorine comes from any substances that pose risk. Further, EPA has noted[5] that TOF testing can often contain inorganic

[4] Anderson, J.K. & Brecher, R.W. & Cousins, Ian & DeWitt, J. & Fiedler, Heidelore & Kannan, K. & Kirman, Christopher & Lipscomb, J. & Priestly, B. & Schoeny, R. & Seed, J. & Verner, M. & Hays, S.M.. (2022). Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts. Regulatory Toxicology and Pharmacology. 134. 105226. 10.1016/j.yrtph.2022.105226.
[5] https://www.epa.gov/system/files/documents/2022-04/draft-method-1621-for-screening-aof-in-aqueous-matrices-by-cic_0.pdf

fluorine. While there are more specified methods currently under development, such as the EPA Draft Method 1621: Screening Method for the Determination of Adsorbable Organic Fluorine (AOF) in Aqueous Matrices by Combustion Ion Chromatography (CIC) released in April of this year and the Total Oxidizable Precursor (TOP) assay, they too have their limitations, especially in reflecting a product's life cycle. Further, small changes in laboratory protocol may result in substantial differences in measured PFAS. As developing analytical methods across a broad and diverse range of substances is challenging, HCPA recommends developing a targeted approach, focusing on the detection and quantification of the subgroup or subgroups of most concern. HCPA also encourages OSTP to work with industry and intergovernmental agencies to ensure that there are analytical methodologies which are robust and accurate.

HCPA thanks OSTP for considering these comments. Overall, HCPA believes that the broad category of PFAS should be broken down into multiple subgroups based on various chemical, chemical, physical and toxicological properties so that resources can be effectively and efficiently targeted towards the subgroups of most concern. HCPA looks forward to working with OSTP and other stakeholders to ensure consumers and workers continue to have access to the products that improve their daily lives. Please do not hesitate to contact HCPA if OSTP would like to discuss our comments.

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29th August 2022
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To

Office of Science and Technology Policy
The White House
1600 Pennsylvania Ave NW
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Submitted electronically to JEEP@ostp.eop.gov

Subject: RFI Response: Critical Data Gaps and PFAS Strategic Plan

Gujarat Fluorochemicals Limited writes in response to the Office of Science and Technology Policy's Request for Information Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development. Specifically, Gujarat Fluorochemicals provides information in response to question 4, "Are there specific chemistries and/or intended uses that PFAS provide for which there are no known alternatives at this time?"

Background

Gujarat Fluorochemicals Limited (GFL) is an Indian company with over 30 years of expertise in fluorine chemistry. The company is an established worldwide player on Fluoropolymers (FPs), and it is active in all relevant markets for these products. Fluoropolymers are one of the most integral building blocks of the modern world, with applications ranging from automobiles to telecommunications, and their unique properties power inventions that lead industries towards efficiency and better performance. From chemical resistance to harsh outdoor exposure, Fluoropolymers withstand a broad scope of environmental aggression, while ensuring heat stability and good electrical properties. They are widely used in automobiles, semiconductors, electronics and common household appliances because of their unique non-adhesive and low friction properties as well as their superior heat, chemical and weather resistance and superior electrical properties compared to the other polymers.

PFAS is a large family of chemicals that covers thousands of highly fluorinated synthetic substances. Based on their chemical and structural properties, PFAS can be grouped into non-polymer and polymer substances. Certain chemicals within the non-polymer PFAS group, such as short and long-chain per- and polyfluoroalkyl carboxylic acids (PFOA) and sulfonic acids (PFOS) have been recently highlighted by regulators and relevant stakeholders globally, due to concerns related to their toxicity for human health and for the environment, in combination with their potential to bioaccumulate, to be persistent, and/or mobile in the environment.

The Safety of Fluoropolymers

Fluoropolymers belong to the PFAS polymer group, but differ from the classes of PFAS of concern due to their chemical structure. Fluoropolymers are high molecular weight polymers with a chemical structure consisting of fluorine atoms directly attached to their carbon backbone. Their physicochemical properties are unique and completely different from the non-polymer substances, and meet the Polymer of Low Concern (PLC) criteria of OECD. A number of studies have been conducted on a selection of representative fluoropolymer substances, including Polytetra-fluoroethylene (PTFE). The results of those studies show the absence of acute or sub-chronic systemic toxicity, irritation, sensitization, local toxicity, in vitro and in vivo genotoxicity, among other properties. More importantly, fluoropolymers do not degrade to long-chain Perfluoroalkyl carboxylic acids (PFCAs), and these polymers are not included in the OECD list of possible precursors.

The only true concern of fluoropolymers is the use and emission of fluorinated polymerization aids (PFAS) during their manufacture. Gujarat Fluorochemicals developed technologies to combat these concerns and reduce PFAS emissions to the environment. They are i) introducing abatement technologies to significantly reduce low molecular weight fluorinated surfactant emissions to air, water and soil and ii) developing non-fluorinated polymerization aid (NFPA) technology substituting fluorinated polymerization aids in the manufacture of fluoropolymers. Gujarat Fluorochemicals has stopped using fluorinated polymerization aids for the manufacture of PTFE aqueous dispersions and FKM (Fluoroelastomers). Gujarat Fluorochemicals is the first fluoropolymer manufacturer to develop NFPA technology for PTFE aqueous dispersions. We attach two public announcements providing further information.

GFLs' Response to Request for Information 4

Gujarat Fluorochemicals would welcome the opportunity to discuss further with OSTP the above and why fluoropolymers are distinct from, and should be treated differently from the PFAS at the root of OSTP's request from a regulatory perspective. In the interim, to the extent useful, Gujarat Fluorochemicals provides in response to the Request for Information the attached ChemService report on the absence of alternatives to fluoropolymers, and the potential impacts of their prohibition. ChemService prepared the report in response to the upcoming PFAS restriction under REACH, but its conclusions hold true here.

In brief, ChemService demonstrates that fluoropolymers are currently irreplaceable for many critical applications, including many at the heart of current energy initiatives. They are viewed as irreplaceable components in lithium batteries and green hydrogen production, ubiquitous in data processing systems, and optimal for safety in sectors such as transport, chemicals, power, semiconductors, medical devices, or renewable energy. The report highlights examples from the chemicals industry, cars, airplanes, processing of water and food, and the production of vaccines and

medicines. The report goes on to delineate the lack of viable, reliable alternatives that do not compromise the safety of workers, the general population, or the environment, since we cannot yet replace their low flammability, neutral electric charge, and high resistance to degradation, in addition to outstanding thermal, chemical, photochemical, hydrolytic, oxidative and biological stability. They are practicably insoluble in water and are resistant to virtually any chemical. These properties render fluoropolymers as highly valuable products, particularly in situations that are extremely demanding in terms of purity (e.g., manufacture of semiconductors or use of medical devices) or protection against chemical attack (e.g., transport or chemical industries).

Please do not hesitate to contact us with further questions or comments. We will reach out to schedule a convenient time to discuss the distinctions between fluoropolymers and other PFAS.

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August 29, 2022

U.S. Environmental Protection Agency
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Sent via Electronic Mail

SUBJECT: 'RFI Response: PFAS Strategic Plan'

RE: *Request for Information; Identifying Critical Data Gaps and Needs To Inform Federal Strategic Plan for PFAS Research and Development*

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to submit comments with respect to the Office of Science and Technology Policy (OSTP) request on identified data gaps that will help inform a strategic plan for Federal coordination of per- and polyfluoroalkyl substance (PFAS) research and development.

NACWA believes that PFAS should be kept out of our nation's water supplies, and that PFAS polluters should be held responsible. The fundamental mission of water and wastewater utilities is to protect public health and the environment, and in doing so they must also be mindful of affordability and the financial burden borne by their customers and the communities they serve. Utilities are tremendously concerned about what PFAS is doing in their communities and, as they have done with all previous public health and environmental challenges, are committed partners in finding a solution to this problem.

Unfortunately, much is still unknown about PFAS and its impact on the environment and public health, including at what thresholds it presents an actual risk to human health. Before public wastewater utilities potentially invest millions of dollars to treat for PFAS – with all the money coming from local communities via higher sewer bills – it is critical that scientific research identify exactly what public clean water utilities should be treating for. This is especially true when public wastewater utilities – and their local ratepayers – are not responsible for creating PFAS in the first place.

Our understanding of the relationship between PFAS exposure and human health is incomplete due to limitations in study sample size, over-reliance on mortality data, scarcity of data for less-studied PFAS compounds, and inconsistent use of research methodology. Addressing these questions will require targeted research and new analytical methods that are means tested and standardized by EPA. It also will require significant federal inter-agency coordination and cross-sector partnerships to advance our understanding and ability to mitigate the human health effects of PFAS exposure.

Analytical monitoring techniques have advanced over the years, allowing PFAS compounds to be detected at extremely small concentrations in controlled laboratory settings. However, the mere presence of these chemicals in very small amounts does not necessarily mean they present environmental and public health risks.

Public clean water utilities are faced with complex, heterogenous wastewater that include domestic, industrial, and commercial sources of PFAS. The sensitivity and specificity of existing PFAS analytical methods has not proven robust enough to be reliable and regulatorily binding for public clean water utilities. These utilities were not traditionally designed or intended with PFAS treatment capabilities in mind. Today, there are no cost-effective techniques available to treat or remove or destroy PFAS from the sheer volume of wastewater, municipal stormwater, or tons of biosolids managed daily by clean water utilities.

Closing scientific gaps in risk assessment is imperative to gain a better understanding of the concentrations of these chemicals, individually or aggregated, that pose an actual risk to public health and the environment, as well as the fate and transport pathways by which these chemicals move in the environment. A greater focus on understanding exposure routes from various media (consumer goods; food; water; air etc.) will also help guide appropriate responses to reducing PFAS risks and understanding the best opportunities for source control and reducing unnecessary exposures.

Beyond our scientific methodology concerns, EPA's actions to designate PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) provides a mechanism for leveraging federal action to address existing contamination. With a CERCLA hazardous substance designation, there could be unintended consequences that hold public utilities potentially liable for cleanup costs, particularly where biosolids from the treatment process containing low levels of PFAS have been beneficially land applied for their fertilizer value.

Removing these chemicals from wastewater influent/effluent would require advanced treatment techniques such as granular activated carbon (GAC), ion exchange (IX) or reverse osmosis (RO). These treatment methods are prohibitively expensive for the volume that needs to be treated, and it remains unanswered how and where to dispose of the PFAS contaminated concentrated generated from these processes.

The federal strategic road map must focus on identifying and addressing sources of PFAS at the point of generation and introduction into the environment, and must also ensure that liable parties – not passive receivers of PFAS like wastewater treatment plants - are held responsible. Federal guidance must also prioritize identification of the highest-priority PFAS discharges to municipal wastewater facilities and provide utilities with any additional authorities necessary to prevent the pass-through of these constituents and interference with the treatment processes.

NACWA urges OSTP to consider these concerns so that federal response guidance appropriately reflects the risks posed by PFAS, closes the unresolved scientific gaps—including fate, transport, and toxicity of PFAS using a science-based approach—and evaluates the appropriate regulatory response to target the sources of PFAS and the responsible disposal of contaminated concentrate.

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August 29, 2022

Re: Request for Information on Identifying Critical Data Gaps and Needs To Inform Federal Strategy Plan for PFAS Research and Development, White House Office of Science & Technology Policy (OSTP); Document Number 2022-14862, 87 FR 41749

The Chemours Company (Chemours)is a global leader in Titanium Technologies, Thermal & Specialized Solutions, and Advanced Performance Materials providing its customers with solutions in a wide range of industries with market-defining products, application expertise and chemistry-based innovations. We deliver customized solutions with a wide range of industrial and specialty chemicals products for markets, including coatings, plastics, refrigeration and air conditioning, transportation, semiconductor and consumer electronics, general industrial, and oil and gas. The company has approximately 6,400 employees and 29 manufacturing sites serving approximately 3,200 customers in approximately 120 countries. Chemours is headquartered in Wilmington, Delaware.

Comments on Question 7

"What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans (e.g., in vitro, animal toxicological, and epidemiological studies)? Which health effects should be prioritized? What additional impacts beyond health should be prioritized? Social scientific approaches are welcome in addressing this question and any others, as appropriate. (https://www.federalregister.gov/d/2022-14862/p-38)"

In vitro studies with transcriptomic analyses

Transcriptomic analyses of *in vitro* experiments using primary human cells provides human-relevant mechanistic data that can be used to 1) screen and prioritize PFAS for *in vivo* testing, 2) fill in important data gaps related to mechanisms and mode of action (MOA), and 3) compare to transcriptomic responses in rodents and humans to better understand similarities and differences in response to PFAS. Each of these points are described in further detail below.

1. *Screen and prioritize PFAS for in vivo testing.*
   PFAS can be tested *in vitro* using primary human cells to screen for potential toxicity. Transcriptomic responses and potency across individual PFAS compounds using benchmark concentration (BMC) analysis can be compared to identify and

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prioritize compounds for further *in vivo* testing, as appropriate. For example, Rowan-Carroll et al. (2021) compared four well-studied PFAS across several concentrations and timepoints in human primary liver cell spheroids. BMC analysis showed 3 out of the 4 PFAS tested had similar potencies, however, only two out of the three equipotent PFAS shared highly similar transcriptional profiles.

If a few or several individual compounds share similar transcriptomic signatures and potencies in human cells, a representative compound might be selected to carry out initial *in vivo* studies.

2. *Fill in data gaps related to mechanisms and mode of action.*
   Transcriptomic analyses, high-throughput phenotypic profiling, and other types of cell-based assays can be used to evaluate the mechanisms of toxicity for individual PFAS *in vitro* (Nyffeler et al., 2020; Harrill et al., 2021). Some MOAs for PFAS might be prioritized over others, such as those with the most human relevance, thereby focusing *in vivo* studies on those deemed the most important.

   Differential gene expression signatures were found to be highly reproducible in human-derived MCF7 cells across an array of environmental chemicals (Harrill et al., 2021). In addition, results from transcription profiling of various hepatotoxicants *in vitro* demonstrated that changes in gene expression were specific to their known MOA *in vivo* (De Abrew et al., 2015).

3. *Compare to transcriptomic responses in rodents and humans to better understand similarities and differences in response to PFAS.*
   In order to determine human health effects of PFAS, it is important to be aware of potential species differences in responses to PFAS exposure, as toxicity values for PFAS are often based on *in vivo* rodent models. Comparing the *in vitro* transcriptomic signatures of humans to mice and rats can provide useful information as to how biological responses differ between species following PFAS exposure (McMullen et al., 2020). This knowledge can then be applied in risk assessment when selecting candidate endpoints to derive toxicity values.

Subacute *in vivo* studies with transcriptomic analyses

Gwinn et al. (2020) have proposed the use of 5-day *in vivo* liver and kidney studies in rats with dose-response modeling of transcriptomic responses to estimate benchmark dose (BMD) values for apical endpoints and prioritizing chemicals for further testing. Therein, Gwinn and colleagues propose to use the S1500+ platform for so-called high-throughput transcriptomics (HTT); however, whole genome transcriptomics would be preferred for PFAS to inform the molecular initiating events (e.g., PPAR-alpha activation) leading to tissue changes. Such analyses could potentially distinguish between PFAS that cause effects that are relevant for humans versus those that act through mechanisms that are not relevant to humans.

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Overall, data generated using these methods will provide baseline levels of toxicity for data-sparse PFAS that can be compared to other more well-studied PFAS to establish whether additional *in vivo* testing is needed.

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Comments of the
Semiconductor Industry Association (SIA)
To the
Office of Science and Technology Policy (OSTP)
On the
Request for Information
on
Identifying Critical Data Gaps and Needs To Inform Federal Strategic Plan
for PFAS Research and Development

87 Fed. Reg. 41,749 (July 13, 2022)

Submitted August 29, 2022

The Semiconductor Industry Association (SIA)[1] submits these comments to the Office of Science and Technology Policy (OSTP) in response to the Request for Information (RFI) on "Identifying Critical Data Gaps and Needs To Inform Federal Strategic Plan for PFAS Research and Development." 87 Fed. Reg. 41,749 (July 13, 2022).

The semiconductor industry and its key suppliers are currently working to collect the information and data needed to address these issues. The industry and its key suppliers have formed a Semiconductor PFAS Consortium to collect the technical data needed to better inform public policy and legislation, including:

- Identification of critical uses,
- Application of the pollution prevention hierarchy to, where possible: reduce PFAS consumption or eliminate use, identify alternatives, and minimize and control emissions,
- Identification of research needs, and
- Development of socioeconomic impact assessments.

The consortium membership includes semiconductor manufacturers and members of the supply chain including chemical, material and equipment suppliers.

SIA offers the following responses to several of the questions posed in the RFI:

> OSTP Question 1 – *"Should the USG consider identifying priority PFAS when developing a strategic plan for PFAS research and development? If so, what criteria should be used to identify priority PFAS for research and development (e.g., tonnage used per year; releases to the environment per year; toxicology or other human or environmental health concerns; national security or critical infrastructure uses)?"*

[1] The Semiconductor Industry Association (SIA) is the voice of the semiconductor industry, one of America's top export industries and a key driver of America's economic strength, national security, and global competitiveness. Learn more at www.semiconductors.org.

As part of its strategic plan for PFAS research and development, the USG should prioritize PFAS used in the semiconductor industry, along with other essential uses of PFAS that are critical to the economy and national security and where there are no known substitutes for these chemicals.

PFAS are essential to the continued ability of the semiconductor industry to innovate and achieve new advancement in semiconductor technology. The unique properties of PFAS enable continued innovation in process technology necessary to fabricate increasingly complex devices at smaller feature sizes and employing complex designs and novel materials.

U.S. leadership in semiconductor manufacturing and design is a national priority and essential to the U.S. economy, national security, and technology leadership.[2] To maintain U.S. leadership in semiconductor technology while also addressing emerging environmental and health concerns and sustainability requirements, the federal research agenda on PFAS must prioritize the research needs of the U.S. semiconductor industry.

> *OSTP Question 3 – "What are the scientific and technological challenges that must be addressed?"*

SIA believes research is needed to ensure the semiconductor industry can continue to use PFAS for the foreseeable future, while at the same time identifying substitutes that may be suitable for future use. In particular, we believe PFAS-related research is needed on (A) treatment methods, (B) measurement technologies, (C) alternatives to specific PFAS that are identified as presenting potential concerns, (D) predictive models for physicochemical properties, environmental fate parameters, and toxicity endpoints of PFAS, and (E) methods for the identification of high priority PFAS.

A. Treatment methods

To ensure ongoing uses of PFAS can continue during the near term in a manner that protects the environment, research is needed on technologies to detect, treat, control, and minimize or eliminate environmental releases of PFAS.

Use of PFAS chemistries within the manufacturing process has the potential to result in the production of PFAS-containing waste streams that require further characterization and the development of controls aimed at the permanent destruction of the very strong carbon-to-fluorine bonds that PFAS contain. Many promising new PFAS destruction techniques are being researched that will require further innovations, development,

[2] Congress recently passed legislation, the CHIPS and Science of 2022 (P.L 117-167), to incentivize increased semiconductor manufacturing in the U.S. This legislation also includes substantial investments in semiconductor research, and SIA believes some of this funding should be directed at PFAS-related research applicable to the semiconductor industry.

demonstration and integration to treat complex semiconductor wastewaters. However, at present, demonstrated technologies do not exist for identifying and treating all of the substances of concern. Additional treatment techniques will need to be developed and will require time-consuming and costly evaluations.

We believe priority research efforts should encompass the following:

- Gaseous emission controls – on-site
- Liquid effluent controls – on-site for high volume, low concentration wastestreams within complex matrices (i.e., those containing high organic and dissolved solid content)
- Solid and hazardous waste disposal – off-site

In order to be cost effective and useful in large scale manufacturing, these treatment technologies need to use low energy and achieve the destruction of PFAS at low concentrations in complex vapor and liquid phase mixtures.

B. Measurement technologies

The semiconductor industry currently uses carefully selected PFAS for many of which no proven analytical techniques exist, particularly PFAS that could be present at the very low concentrations (<1 ppb) that might be found in semiconductor wastestreams. The semiconductor industry believes that validated analytical methods will be required to show the ability to meet the intent and the letter of emerging regulations.

We believe near-term research efforts are needed particularly on the following:

- Air and wastewater techniques for low concentration wastestreams, including both consumed PFAS and all its PFAS-based byproducts.
- Quick portable identification methods of PFAS in solids
- Methods useful for development of treatment systems, like the ability to measure the extent of PFAS destruction via measurement of mineralization

C. Alternatives to PFAS

To assist in the exploration of alternatives to PFAS, fundamental research is needed to identify environmentally preferable alternatives to PFAS that also meet the stringent functional needs and performance characteristics of substances used in the semiconductor industry.

To date, no suitable alternatives have been found that successfully replace the remaining PFAS in use within the semiconductor industry. If suitable non-PFAS alternatives can be identified, larger studies will need to follow which must identify and resolve all aspects related to the integration of these new materials into the highly complex and inter-dependent semiconductor manufacturing process. A typical

semiconductor process technology change timeline is approximately 10-15 years to fully prove and integrate such solutions.

In order to be deployed at commercial fabs, such alternatives need to be highly purified and achieve the same (or improved) performance as existing PFAS analogues.

D. Predictive models for physicochemical properties, environmental fate parameters, and toxicity endpoints of PFAS

PFAS encompasses a large and diverse group of chemicals of potential concern to human health and the environment. To date, only limited toxicity studies have been conducted across this large set of compounds with much work being focused primarily on perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA), two compounds which are no longer used by the semiconductor industry. Data suitable for assessing the potential risks for the majority of PFAS are lacking. Given the size and diversity of PFAS as a chemical category, the lack of environmental fate and transport data as well as biological effects data cannot be readily addressed through conventional toxicity testing. Therefore, there is a need to identify methods to efficiently measure or predict the toxicity, bioaccumulation and biomagnification potential of PFAS.
This type of modeling can help enable evaluations of PFAS currently being used by industry as well as avoid the identification of substitutes that fail to offer an improved environmental profile as compared with currently used PFAS.

E. Identification of high-priority PFAS

Rather than focusing on PFAS as a broad category, research efforts should focus on identifying higher-priority PFAS on the basis of the substances' potential effects on human health and/or the environment. This will better enable a systematic quest for seeking substitutes and a focused approach for informing regulatory efforts intended to phase down uses of specific substances of greatest concern. Broad categorical approaches on PFAS using categorical definitions will diffuse research efforts at a time when resources (in terms of funding and laboratory expertise and capabilities) may be limited. Broad categorical approaches will also diffuse implementation efforts of identified replacements for PFAS of greatest concern.

> *OSPT Question 4 – "Are there specific chemistries and/or intended uses that PFAS provide for which there are no known alternatives at this time?"*

The semiconductor industry uses a number of highly specialized PFAS in chemical formulations in the fabrication process. Certain PFAS also can be found within components of manufacturing process tools, and within features of facilities' infrastructure. Given the specific chemical and physical attributes of PFAS, in many of these applications PFAS provide unique performance and functional capabilities in the semiconductor fabrication process, for which there are no known viable alternatives. As documented in one recent article, for example, many of the uses of PFAS in the photolithography process are essential and there are currently no known alternatives for

these uses.[3] The article states: "The use of fluorochemicals in lithography and semiconductor patterning plays a critical role in the success of semiconductor technology." The article continues:

> The addition of small quantities of fluorinated materials enables patterning capabilities that are otherwise not possible to achieve and this leads to superior device performance. The compact size of the fluorine atom and its strong electron withdrawing characteristics make it stand out in the periodic table and gives fluorocarbon materials unique properties, unmatched by other chemical compounds.

OSTP Question 6 – "What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of: analytical methods, detection limits, non-targeted detection?"

SIA believes OSTP should prioritize, among other things, research on analytical methods and detection limits. PFAS may be present in wastewater discharges from semiconductor fabs and extremely small concentrations, and improved analytical methods and detection limits are needed – along with effective treatment technologies – to minimize environmental releases of PFAS.

OSTP Question 9 – What goals, priorities, and performance metrics would be valuable in measuring the success of National, federally funded PFAS research and development initiatives relating to:

a. The removal of PFAS from the environment;
b. Safely destroying or degrading PFAS; and
c. Developing safer and more environmentally-friendly alternatives to PFAS?
d. Mitigating negative human effects of PFAS, whether related to health or additional domains

As stated above in our response to Question 3, SIA's priorities for PFAS research efforts are focused on treatment methods to minimize or eliminate releases of PFAS to the environment and the identification and qualification of safer and more environmentally-friendly alternatives to PFAS that meet the functional and performance requirements of the semiconductor industry.

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SIA appreciates the opportunity to provide input to OSTP on the federal strategic plan for PFAS research and development.

[3] Christopher K. Ober, Florian Käfer, Jingyuan Deng, "The essential use of fluorochemicals in lithographic patterning and semiconductor processing," J. Micro/Nanopattern. Mater. Metrol. 21(1), 010901 (2022), doi: 10.1117/1.JMM.21.1.010901, available at http://dx.doi.org/10.1117/1.JMM.21.1.010901.

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August 29, 2022

Ms. Melanie Buser
Assistant Director of Environmental Health
Office of Science and Technology Policy
1650 Pennsylvania Avenue, NW
Washington, DC 20501

SENT VIA EMAIL

RE: Request for Information; Identifying Critical Data Gaps and Needs To Inform Federal Strategic Plan for PFAS Research and Development

Dear Ms. Buser,

The American Water Works Association (AWWA) appreciates the opportunity to provide comments on the Office of Science and Technology Policy's (OSTP) efforts in developing a strategic plan for Federal coordination of per- and polyfluoroalkyl substances (PFAS) research and development and a subsequent implementation plan. PFAS represent a large class of chemicals that have been widely used and released into the environment for nearly 80 years.

AWWA's 50,000 members represent the full spectrum of water utilities – small and large, rural and urban, municipal and investor-owned. Our membership includes 4,500 utilities that supply 80 percent of the nation's drinking water. While water utilities are not users of PFAS, they are on the forefront of protecting public health from PFAS as suppliers of drinking water. AWWA has been actively engaged on this and other emerging contaminant issues for several decades. AWWA offers the following set of recommendations from the perspective of our members on the frontlines of this issue.

Should the USG consider identifying priority PFAS when developing a strategic plan for PFAS research and development? PFAS represent a large class of thousands of chemicals, which are largely unstudied. A strategic plan for PFAS research and development must be able to prioritize PFAS of highest concern or risk. Research to support risk management decision making processes is time consuming and expensive. Prioritizing PFAS research to focus on chemicals of greatest concern will ensure that limited resources can be leveraged effectively in support of future risk management decisions. Many agencies are already applying prioritization processes for PFAS, including the EPA, National Toxicology Program (NTP), and the Agency for Toxic Substances and Disease Registry.

If so, what criteria should be used to identify priority PFAS for research and development (e.g., tonnage used per year; releases to the environment per year; toxicology or other human or environmental health concerns; national security or critical infrastructure uses)? In developing a process to prioritize PFAS for research and development, a combination of criteria should be considered. For the strategic plan to advance research that can adequately prioritize PFAS of greatest concern, the prioritization of PFAS should consider several key criteria relating to their use, release, likely routes of exposure, and toxicity. They are listed in the table below along with their rationale for inclusion. They are listed in the following table along with the relevant goal the criteria will help to accomplish and the rationale for their inclusion.

Prioritization Criteria	Relevant Goals*	Rationale for Inclusion
Annual releases to the environment	A, B, C, D	Will help Federal agencies recognize magnitude of potential risk that the currently used PFAS may pose on an ongoing basis.
Cumulative releases to the environment	A, B, C, D	Will help Federal agencies recognize cumulative magnitude of potential risk that the PFAS may pose due to historic discharges. The inclusion of cumulative releases, will strengthen the research program's ability to accomplish the goal of removing PFAS from the environment.
Proximity of releases to drinking water supplies (public and private)	A, D	Will help Federal agencies prioritize PFAS that have a higher potential for posing a public health risk due to contamination of drinking water.
Use in household applications	A, C, D	Will help Federal agencies prioritize PFAS that may be released to the environment as household waste and may be PFAS that the general public may have high exposure levels to and to identify PFAS that warrant development of safer alternatives.
Use commercial applications, like food preparation	A, C, D	Will help Federal agencies prioritize PFAS released to environment by these facilities and which may be present in food leading to ingestion exposure, meriting need for safer alternatives.
Likelihood of occupational exposures	C, D, E	Will help Federal agencies identify PFAS for which occupational exposures might be problematic and may serve as guidepost for studies on human health effects.
Phase partitioning characteristics (e.g., likelihood to be partition into	A, B, D	Will help Federal agencies prioritize PFAS that have a higher potential for contaminating drinking water or environmental media that may be a significant exposure route for human or animal health effects.

water, air, and/or soil)		
Human Health Toxicity	E	Will improve Federal agencies understanding of human health toxicity.
Persistence in the environment	A, B, D, E	Will improve Federal agencies recognize PFAS that do not readily break down or degrade in the environment under natural conditions. This will help agencies identify PFAS that require removal or remediation in the environment and may, without remediation, pose a risk to human and environmental health.
Bioaccumulative characteristics	A, D, E	Will help Federal agencies recognize PFAS that pose a greater risk to human and animal health through ingestion or consumption of contaminated food sources.

*Relevant Goals: (A) The removal of PFAS from the environment. (B) The safe destruction or degradation of PFAS. (C) The development and deployment of safer and more environmentally friendly alternative substances that are functionally similar to those made with PFAS. (D) The understanding of sources of environmental PFAS contamination and pathways to exposure for the public. (E) The understanding of the toxicity of PFAS to humans and animals.

Are there criteria which could be applied across the five research goals identified above, or should specific criteria be developed for each individual research goal? Please refer to the table above.

Based on the definition of PFAS in this RFI, what are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS and to identify cost-effective […] Methods to safely destroy or degrade PFAS? PFAS present a challenge for both drinking water and wastewater treatment due to the chemical properties that they are favored for. Available cost-effective technologies (e.g., granular activated carbon, ion exchange resin, and high-pressure membrane treatment) separate PFAS from water but do not destroy it. Current destructive technologies (e.g., incineration, pyrolysis, supercritical water oxidation, etc.) are not generally appropriate for water treatment applications because they are not effective for treating high volume, low PFAS concentration streams. The strategic plan should work to identify cost-effective water treatment methods that destroy PFAS at scales appropriate to both private wells and community water and wastewater treatment systems.

What are alternatives to the definition of PFAS provided in this RFI? What are the implications of these alternative definitions on possible remediation strategies? PFAS definitions vary by the organization but there is widespread agreement within the scientific community that PFAS may be defined by the presence of at least one fully fluorinated

carbon.[1,2] The definition of PFAS is a critical step in addressing PFAS, as it will define the scope of the work. In advancing PFAS research, it is important that the research planning process start from a broad definition of PFAS and then narrow to more focused groups of PFAS relevant to specific research questions. For example, research into PFAS destruction should first focus on the subset of PFAS that are anticipated to pose the greatest health risk and widely occur. Similarly, research on health effects could begin now to target groups of PFAS chemistries to which manufacturers are moving production so that we know that product substitutions do not have undesirable health consequences.

What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of: analytical methods, detection limits, non-targeted detection? Analytical capability for PFAS is advancing rapidly. Unfortunately, method development for more challenging environmental media, e.g. soils, air, industrial wastewaters, etc. has lagged behind method development for water. Research should be prioritized on accelerating progress towards methods for these more complex media to facilitate remediation programs, regulations limiting releases to the environment, and supporting research on the safe destruction of PFAS.

What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans (e.g., in vitro, animal toxicological, and epidemiological studies)? Which health effects should be prioritized? What additional impacts beyond health should be prioritized? Social scientific approaches are welcome in addressing this question and any others, as appropriate. Since PFAS constitute such a large group of chemicals, it is necessary that Federal agencies use a tiered approach in understanding human health effects of PFAS. The Joint EPA's National Toxicology Program (NTP) Responsive Evaluation and Assessment of Chemical Toxicity (REACT) program offers a useful example for such prioritization.

PFAS human health effects research to-date has not been sufficient to form a scientific consensus on the adverse health effects caused by PFAS exposure or importantly the underlying mode of action. The utility of available epidemiological studies is particularly weak as work to-date is: (i) prone to bias and confounding factors, (ii) inconsistent associations between PFAS and health outcomes, and (iii) lack of clear connection to the underlying biology (e.g., mode of action).

Research to discern the linkage between PFAS and adverse human health effects will not help characterize the potential risk to public unless a parallel effort is undertaken to quantitate in a comparable way exposure levels from all routes of exposure (e.g., inhalation, ingestion of food and water, etc).

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[1] Buck et al., 2011. Perfluoroalkyl and Polyfluoroalkyl Substances in the Environment: Terminology, Classification, and Origins. Integrated Environmental Assessment and Management. DOI: 10.1002/ieam.258.

[2] Organization for Economic Co-Operation and Development, 2018. Toward a New Comprehensive Global Database of Per and Polyfluoroalkyl Substances (PFASs): Summary Report on Updating the OECD 2007 List of Per- and Polyfluoroalkyl Substances (PFASs).

What goals, priorities, and performance metrics would be valuable in measuring the success of National, federally funded PFAS research and development initiatives relating to: (a) the removal of PFAS from the environment, (b) safely destroying or degrading PFAS, (c) developing safer and more environmentally friendly alternatives to PFAS, and (d) mitigating negative human effects of PFAS, whether related to health or additional domains? A key goal for this federally funded PFAS research is the protection of human health. This can be accomplished through a variety of approaches, but as the EPA has noted previously, a holistic approach is needed. Research prioritize should focus on the entire PFAS lifespan, from formulation to discharge to the environment. Research that supports the Federal agencies' ability to recognize PFAS that pose a risk to public health from prevent them from entering the environment and drinking water supplies will have the greatest impact on public health.

Best regards,

THE AMERICAN WATER WORKS ASSOCIATION

Who is AWWA

The American Water Works Association (AWWA) is an international, nonprofit, scientific and educational society dedicated to providing total water solutions assuring the effective management of water. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our membership includes more than 4,500 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation's wastewater. Our 50,000-plus total membership represents the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water, our most important resource. AWWA unites the diverse water community to advance public health, safety, the economy, and the environment.

Response of the American Chemistry Council
to the Office of Science and Technology Policy
Request for Information – Identifying Critical Gaps and Needs
to Inform Federal Strategic Plan for PFAS R&D
July 13, 2022 (87 *Federal Register* 41749)

1. Should the US Government consider identifying priority PFAS when developing a strategic plan for PFAS research and development? If so, what criteria should be used to identify priority PFAS for research and development?

Development of a systematic, science-based prioritization methodology is the single most important step the US government can take to ensure that finite research and remediation resources are directed at substances and scenarios that present the most significant risks. Any prioritization scheme should identify categories of PFAS compounds that present the greatest potential for human health and environmental risk using the following key criteria:

- Persistence, solubility, and mobility;
- Potential for human and environmental effects, including an assessment of likely mode of action;
- Potential for environmental release; and
- Bioavailability, biopersistence, and bioaccumulation

Similar to the approach taken in EPA's PFAS Testing Strategy, representatives of the priority classes and subclasses can be identified for testing, using a tiered approach, where existing data are not currently available. Priority should be given to commercially available products and any potential breakdown products to focus on those substances that the population is more likely to come in direct contact with. Where data are available for members of a class or subclass, approaches to extrapolate to other members of the class can be applied, where appropriate.

2. Are there criteria which could be applied across the five research goals identified above, or should specific criteria be developed for each individual research goal?

While the criteria described in question 1 are generally applicable to the five research goals for PFAS, they are of particular importance to considerations of removal from the environment, pathways of exposure, and potential toxicity. Research related to destruction and degradation of PFAS will focus more on the conditions required for the destruction of the strong chemical bonds that are part of all PFAS and on methods to enhance the destruction of those bonds and manage destruction byproducts.

Research into PFAS alternatives will require not only issues related to toxicity, exposure potential, and removal, but also whether the alternative provides the same level of performance (i.e., durability, surfactancy, chemical/water resistance) as the PFAS it is intended to replace and if the alternatives present additional environmental, toxicity, or safety concerns.

3. What are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS and to identify cost-effective alternatives to PFAS and removal and destruction methods?

Of critical importance to the reduction of the potential impact of PFAS is the identification of those technologies and conditions required for the effective destruction of PFAS. Available information indicates that current waste incineration technologies can effectively destroy PFAS if operated under the appropriate conditions of temperature and residence time.[1] The current uncertainty about the effectiveness of existing destruction techniques has led to calls to ban or severely limit thermal destruction of PFAS and prevented further large-scale testing of exiting systems. Such limits can bring removal and remediation efforts to a standstill if there is no viable method for disposal of the waste PFAS.

Disposal and destruction methods must be feasible and broadly applicable and should avoid the generation of undesirable byproducts. This will require the development of validated analytical methods for airborne emissions. The federal strategy should, to the maximum extent possible, coordinate, support and leverage ongoing research efforts in academia and industry. In addition, the development of scientifically sound and practicable clean-up levels for priority PFAS is a prerequisite for identifying, developing and deploying suitable removal technologies.

Alternatives analysis should only be considered or required when a particular, existing use of a PFAS substance is found to present an unreasonable risk, when other measures to limit risk are not possible.[2] When an alternatives assessment is warranted, consideration should be given to whether the alternative (i) is necessary to prevent unreasonable risk; (ii) provides an equivalent level of performance; (iii) is practicable to implement; (iv) presents significantly lower risk; and (v) does not create new environmental, toxicity, or safety concerns.

4. Are there specific chemistries and/or intended uses that PFAS provide for which there are no known alternatives at this time?

The unique physical and chemical properties of PFAS serve to enhance the effectiveness and durability of a wide variety of products throughout society. A few examples include:

Paint and Coatings - Fluoropolymer-based coatings provide unique and imitable characteristics when it comes to durability and longevity.[3] These coatings are used on critical infrastructure to extend the useful life of many products and reduce their environmental footprint. There is no

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1 USEPA. Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances. Interim Guidance for Public Comment (December 18, 2020).

2 For example, fluoropolymer manufacturers have developed alternative processes that eliminate the use of fluorosurfactant processing aides.

3 Organization of Economic Co-operation and Development (OECD). Per- and Polyfluoroalkyl Substances and Alternatives in Coatings, Paints and Varnishers (CPVs): Report on the Commercial Availability and Current Uses. Series on Risk Management No. 70 (2022). http://t4.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/per-and-polyfluoroalkyl-substances-alternatives-in-coatings-paints-varnishes.pdf

functionally equivalent alternative that does not adversely impact the necessary performance required for applications that require uniquely long lifespans.

Semiconductors - The use of fluorochemicals in lithography and patterning plays a critical role in the success of semiconductor technology. The addition of small quantities of fluorinated materials enables patterning capabilities that are otherwise not possible to achieve which allows for superior device performance. The compact size of the fluorine atom and its strong electron withdrawing characteristics give fluorocarbon materials unique properties, unmatched by other compounds.

Fuel Cells and Electrolyzers [4] - The polymer electrolyte membranes used in fuel cell systems is based on ionomers of perfluorosulfonic acid (PFSA) that allow for transport of protons and act as an electrical insulator and barrier to oxygen and hydrogen. The production of PFSA membranes uses solution casting technology, where a PFSA polymer dispersion is applied to a base film.

Polymer Processing – Fluoropolymers used in polymer processing or extrusion aids offer significant advantages compared to the alternatives. They are high molecular-weight polymers with low levels of residual monomers or oligomers, exhibit low water solubility, and are non-reactive and thermally stable.

Refrigeration, Foam Blowing, Aerosol - Substances considered PFAS under some of the broadest definitions (*e.g.*, hydrofluoroolefins, low-GWP hydrofluorocarbons) provide high performance, low toxicity, and in most cases non-flammable attributes to refrigeration and air conditioning fluids, foam blowing agents, aerosol propellants, and many other applications. Many of the fluorinated substances used in these applications are critical technologies for meeting national and global climate change policy goals.

5. What are alternatives to the definition of PFAS provided in this RFI? What are the implications of these alternative definitions on possible remediation strategies?

The definition used in the RFI is overly broad and includes many substances that should not be part of the federal R&D effort, including fluoropolymers, refrigerant gases, blowing agents, and pharmaceuticals. Using such a broad definition will hinder the overall federal research effort by including products of low concern or subject to evaluation under other federal programs.

Although a broad definition may be a useful starting place, the definition needs to be refined for specific risk assessment goals. The refined definition should include the ability to group PFAS into more defined lists based on the problem formulation and regulatory context. Although there is general agreement that persistence alone is not sufficient for grouping PFAS,

[4] US Department of Energy (DOE). Water Electrolyzer and Fuels Cells – Supply Chain Deep Dive Assessment. Response to Executive Order 14017, :America Supply Chains (February 24, 20922).

no single grouping strategy has been identified that would be sufficient for all regulatory or public health risk assessment purposes. [5]

For the purposes of the federal R&D effort, PFAS should be defined as those substances containing at least two fully fluorinated carbon atoms - excluding fluoropolymers, gases, and volatile liquids. This will allow the effort to focus on those substances for which the potential for human exposure is greatest and for which data may not be available otherwise. It will also assist the development of remediation strategies by allowing agencies to focus on the relevant physical and chemical properties of this smaller universe of substances.

Notwithstanding the definition, it is essential to recognize that all substances so defined are not the same and must not be evaluated as one single group. As part of a prioritization scheme, it will be important to identify compounds and/or groups of compounds, and applications, that present substantial human health and environmental risk concerns and, equally important, to de-prioritize compounds and applications that do not present substantial risk concerns.

6. What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of: analytical methods, detection limits, non-targeted detection?

Identification of the conditions and practices for effective disposal and destruction of PFAS, along with the development of clear guidance on these conditions and practices, should be the highest priority. Without clear guidance on disposal and destruction, public uncertainty and mistrust will severely hamper remediation efforts. The current uncertainty may limit the options for dealing with PFAS wastes and lead to calls for restrictions on all uses of PFAS, including those for which their use is critical to the function of the end product or process.

The development of validated analytical methods also should be a priority. As the R&D effort allows for the prioritization of individual PFAS or groups of PFAS, the development of validated analytical methods will be important to assessing the effectiveness of the federal program. In particular, validated analytical methods for PFAS emissions from thermal destruction are essential to the development and adoption of suitable disposal and destruction techniques.

Although further development of non-target detection techniques may facilitate more effective screening of PFAS, existing methods are not sufficiently selective to be of much value. It will be important to communicate that non-targeted assays do not identify what compounds are present; they only indicate the presence of a fluorinated species.

7. What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans (e.g., priority effects, other impacts)?

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[5] Anderson JK *et al.* Grouping of PFAS for human health risk assessment: findings from an independent panel of experts. *Reg Toxicol Pharma* 134:105226 (2022). https://www.sciencedirect.com/science/article/pii/S0273230022001131

Much of the concern about the potential health effects of PFOA, PFOS, and other long-chain PFAS is related to their relatively long biological half-lives. The short-chain PFAS currently available on the market do not exhibit significant biopersistence. Research on the factors that result in longer biological half-life and on the mechanisms of potential toxicity that result from such biopersistence are important to identifying characteristics that can be used to prioritize. Tiered toxicological testing approaches, , including the use of transcriptomics analysis, should be employed with the focus on developing information to create grouping approaches for similar PFAS chemicals. In addition, any consideration of impacts beyond human health must fully account for the socioeconomic benefits provided by PFAS technologies.

8. One challenge across all research goals is PFAS mixtures and formulations. What should be the research and development priorities for accelerating progress in these areas?

Many PFAS treatment and destruction/degradation techniques have been established and shown to be effective for most substances under consideration. However, depending on the chemistries of various PFAS compounds, certain destruction and treatment technologies may be more effective than others. Considering the fact that most materials contain a mixture of various PFAS compounds, the evaluation of treatment technologies on mixtures is a gap that should be explored further.

Addressing PFAS mixtures is a complex subject that will require time to resolve. In the interim, the US government should utilize the prioritization scheme discussed under Question 1 to direct research efforts. One possible outcome of targeted federal research on health and environmental effects is a better understanding of the relative potencies of the individual PFAS or groups of PFAS. Although it is not clear that relative potencies can be derived for PFAS, greater understanding of the mechanisms of potential toxicity could allow for screening assessments of potential effects of exposure to various mixtures of PFAS.

9. What goals, priorities, and performance metrics would be valuable in measuring the success of national, federally funded PFAS research and development initiatives?

A key measure of performance should be whether the activity advances our understanding of those substances and scenarios that present a substantial health and environmental risk. The development of criteria for assessing the health and environmental effects of PFAS and proposed alternatives that is based on sound science should also be a goal of the federal program. At present, the plethora of approaches to evaluating health and environmental toxicity that have been developed has led to conflicting conclusions about the potential toxicity of these substance and considerable confusion about their safety.

Another important goal of a national PFAS R&D effort should be to identify effective disposal and destruction/degradation approaches that can be broadly communicated and, if appropriate, incorporated into the relevant regulatory requirements. This will help to facilitate remediation efforts to remove PFAS from the environment, instill greater confidence in the ability of these approaches to provide for safe and effective disposal, and provide more clarity for those entities wishing to use PFAS for critical uses.

August 29, 2022

Via Electronic Submission

Subject: RFI Response: PFAS Strategic Plan

The Solid Waste Association of North America (SWANA) submits the following comments in response to the Office of Science and Technology Policy's (OSTP) Request for Information (RFI) to identify data gaps in research and development regarding several aspects of per- and polyfluoroalkyl substances (PFAS) [87 FR 41749].

SWANA is an organization of more than 10,000 public and private sector professionals committed to advancing from solid waste management to resource management through their shared emphasis on education, advocacy, and research. For more than 60 years, SWANA has been the leading association in the solid waste management field. SWANA serves industry professionals through technical conferences, certifications, publications, and a large offering of technical training courses.

(D) Understanding the sources of environmental PFAS contamination and pathways for exposure to the public

SWANA has identified the following research gaps that would help to better understand the impact of PFAS deposited in landfills and handled through other solid waste management practices across the country.

PFAS as a hazardous material under CERCLA

Given that PFAS constituents have been disposed in landfills for decades, and that these landfills continue to accept PFAS containing wastes and to generate leachate which contains PFAS, there are many potential unintended consequences of this classification. These include:

- Closure of all Subtitle-D landfills
    - There is a lack of alternate waste disposal technologies to swiftly replace landfills for waste disposal, which would create a waste disposal problem immediately upon promulgation of this designation.
- Classification of landfill leachate as a hazardous waste
    - Leachate is generated for decades after landfill closure. This will create a long-term burden on municipalities to manage these newly designated hazardous wastes.
- There will be limited options for management of residual wastes from remediation systems that are used to remove PFAS from the environment based on currently available technology.
- The possibility exists that all phases of waste management could be impacted by such a classification. By accepting or even transporting materials for processing at a MRF or transfer station, facilities may acquire liability associated with those materials

SOLID WASTE ASSOCIATION OF NORTH AMERICA

PFAS in Waste

- Studies are needed to close the gap in the mass flow of PFAS into and out of landfills. Research is needed to better understand the bulk of post-consumer PFAS products entering the landfill, interactions and degradations occurring within the landfill, and the predominant PFAS constituents released from landfills.
- Additional information is needed regarding PFAS in common consumer products in order to understand the major sources of PFAS coming into the landfill and other solid waste management facilities.
    - This includes understanding how the PFAS make-up changes throughout the waste management process -- from curb to transfer station to landfill.
    - Research is also needed to understand how processes and mechanisms may release PFAS from materials and then become mobile within the landfill environment.
- An inventory should be developed of residual PFAS in carpeting and textiles that will be discarded until PFAS-free products displace older products.
    - Development is needed of 'kinetic' models that can be employed to estimate the release of PFAS into the landfill environment.
    - Research should be done on landfilling practices that can retard the release of PFAS from landfills, such as landfill environmental conditions, use of targeted adsorbents, or isolating wastes known to disproportionally release PFAS.

Everyday Exposure to PFAS

- More information is needed to understand human exposure pathways (carpets, furniture, make-up, food wrappers, etc.) so that closing these exposure pathways can be prioritized. Various reports and references have documented that individual PFAS have different exposure scenarios based on times of manufacture, product uses, environmental presence, and concentration. Current research has focused on legacy compounds and not on the replacements.
- Research and data indicate that ingestion is the major pathway for human exposure. Treatment of potable water is believed to have the greatest and readily deployable approach to protect large segments of the population.

Recycling

- Additional research is needed to understand the PFAS loading in recyclable materials and what the fate of PFAS is during separation and processing.
- Research should compare the PFAS-containing materials in single stream versus source-separated recycling.

Compost

- Compost with and without food waste contains PFAS. Research is needed to identify the prevalence and types of PFAS in compost and a better understanding of its sources.
- Occurrence of PFAS compounds and transfer from biosolids and food waste into end- and waste-products vary by composition, size, age, and other characteristics of operation. Consideration should be given to end users – ornamental versus vegetable/fruit growth, and potential exposure pathways. Also, what are the risks of PFAS uptake to edible food stocks from areas where compost has been applied?

- Research is needed related to and impacts of the PFAS compounds when an anaerobic digestion process is incorporated into the management of organics prior to compost production.

Landfills

- Liners –Are synthetic landfills causing false positives for PFAS detection in groundwater at landfill?
- Landfill Gas – Research is needed to identify which PFAS constituents are most prevalent in municipal solid waste landfill gas. This research should also identify the mechanisms and mass transfer of airborne PFAS (e.g., volatilized, aerosolized, associated with particulate matter) and whether destruction with a flare reduces PFAS emissions.
- Leachate from C&D – Research is needed to identify which PFAS are most prevalent in construction and demolition (C&D) debris wastes.
- Stormwater – Research is needed to identify whether transfer of PFAS from waste and cover materials, including beneficially reused soils and cover materials, into run-off and offsite transportation is occurring. This study should evaluate the contribution as compared to concentrations seen in rainwater.
- Leachate treatment - Does leachate recirculation increase or reduce leachate PFAS content through adsorption to solid waste and cover materials?
    - Study of leachate recirculation is needed to determine if the process of recirculation results in further concentrating or reducing the concentration of PFAS compounds in the remaining leachate and if this process might result in changes to the specific compounds in the leachate.
    - Various treatment scenarios are in different stages of development form lab scale to pilot test, to full implementation. Further documentation is needed. Summaries of reference documents should be added to the inventory of treatment systems experience.

Thermal Destruction

- Research into the efficacy of existing, conventional MSW mass burn facilities to reduce PFAS is needed.
- Studies are needed to close the gap in the mass flow of PFAS into and out of thermal processing facilities to better understand the interactions and degradations occurring within the facility, and the ability of activated carbon injection and other reagents to capture any residual PFAS that is not destroyed.

In regard to information pertaining to PFAS Replacement Studies and Research Prioritization, the following comments are offered.

PFAS Replacement Studies

Given the worldwide impact of PFAS constituents that were designed (and approved) to replace PFOA and PFOS, significant precautionary research must be taken to prevent future PFAS replacements from causing the same global catastrophe in future decades. Ideally, this should include epidemiological research, remediation research, and identification of exposure pathways.

Prioritization of Research for Remediation of PFAS to Limit Risk

Remediation technologies should be evaluated on their ability to scale to practical application, on their speed of deployment, and on their cost. Perfection should not be the enemy of the good.

Thank you for considering the solid waste and resource management industry's perspective to identify data gaps in research and development regarding several aspects of PFAS.

AN INTERNATIONAL ORGANIZATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

PETA

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August 29, 2022

Melanie Buser, Assistant Director for Environmental Health
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
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Via e-mail: JEEP@ostp.eop.gov

Re: 'Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development' (87 FR 41749)

Dear Dr. Buser:

On behalf of People for the Ethical Treatment of Animals (PETA), we would like to thank the White House Office of Science and Technology Policy (OSTP) for the opportunity to provide input on testing of per- and polyfluoroalkyl substances (PFAS). Below, we have provided comments on question 7 from the OSTP request for information "Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development" published in the Federal Register on July 13, 2022 (87 FR 41749).

> **7. What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans (*e.g., in vitro,* animal toxicological, and epidemiological studies)? Which health effects should be prioritized?** What additional impacts beyond health should be prioritized? Social scientific approaches are welcome in addressing this question and any others, as appropriate.

Reliable and Human-Relevant, Non-Animal Testing Approaches
PFAS should be evaluated using human-relevant data, prioritizing epidemiological studies and non-animal testing approaches (e.g., *in silico* models, *in chemico* tests, and *in vitro* tests using human cells). Testing on animals cannot reliably or accurately predict effects seen in humans. Studies demonstrate that experiments using animals have poor reproducibility, and significant physiological differences between humans and other species raise concerns about the human-relevance of data derived from animal tests.[1]

In 2018, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), a permanent committee of the National Institute of Environmental Health Sciences composed of representatives from 17 U.S. federal regulatory and research agencies, published the *Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and*

Entities:
- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Switzerland
- PETA Netherlands
- PETA Foundation (U.K.)

[1]van der Zalm AJ, Barroso J, Browne P, et al. A framework for establishing scientific confidence in new approach methodologies. *Arch Toxicol*. 2022. doi.org/10.1007/s00204-022-03365-4

Medical Products in the United States, which stated, "Many currently accepted methods for assessing potential hazards use laboratory animals. However, animal-based testing has a number of recognized limitations: it can be expensive and time consuming, it raises moral and ethical issues, and it does not always identify toxic effects relevant to humans…. Left unaddressed, the growing disparity between the capabilities offered by 21st century science and continued reliance on animal data for safety evaluations could impede our ability to capitalize on the remarkable progress made [by non-animal testing approaches]."[2]

The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and the U.S. Environmental Protection Agency (EPA) maintain lists of non-animal test methods across different human health endpoints.[3,4] These methods—from computational models to chemical-, cell-, and tissue-based tests—can be used in integrated or defined approaches to provide substantial insights into human-relevant toxicity, including for PFAS. For example, the following studies illustrate how non-animal methods can be used for testing these substances:

- Two *in vitro* models—a lung surfactant function assay and a cell model with human bronchial epithelial cells—can be combined to assess inhalation and respiratory toxicity from PFAS.[5]
- High-throughput screening methods using human cell–based models can be used to test for a variety of toxicity endpoints in short-chain PFAS.[6]
- Human primary liver cell spheroids can identify gene expression changes, human biological responses, and benchmark concentrations for four specific PFAS chemicals.[7]
- A comparison of PPARα networks, which are known to be activated by PFAS, in rat and human liver hepatocytes showed that toxicity effects can be seen in isolated liver cells, instead of testing on live animals. The study also found that rodent endpoints "may be essentially irrelevant for human risk assessment" and "responses may be qualitatively different … in humans versus rats."[8]

Adverse outcome pathways (AOPs) also offer a pathway for gaining useful information to address current gaps in understanding PFAS health effects. AOPs offer a way to arrange mechanistic information related to a pathological outcome into key events (KEs) spanning all organizational levels of a biological system or systems. Test methods anchored to AOPs can help design testing

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[2]ICCVAM. A strategic roadmap for establishing new approaches to evaluate the safety of chemicals and medical products in the United States. 2018. doi.org/10.22427/NTP-ICCVAM-ROADMAP2018

[3]U.S. EPA. List of alternative test methods and strategies (or new approach methodologies [NAMs]) https://www.epa.gov/sites/default/files/2021-02/documents/nams_list_second_update_2-4-21_final.pdf. Accessed August 26, 2022.

[4]NICEATM. Alternative methods accepted by US agencies. https://ntp.niehs.nih.gov/whatwestudy/niceatm/accept-methods/index.html?utm_source=direct&utm_medium=prod&utm_campaign=ntpgolinks&utm_term=regaccept. Accessed August 26, 2022.

[5]Sørli JB, Låg M, Ekeren L, et al. Per- and polyfluoroalkyl substances (PFASs) modify lung surfactant function and pro-inflammatory responses in human bronchial epithelial cells. *Toxicol In Vitro*. 2020;62:104656. doi.org/10.1016/J.TIV.2019.104656

[6]Solan ME, Lavado R. The use of in vitro methods in assessing human health risks associated with short-chain perfluoroalkyl and polyfluoroalkyl substances (PFAS). *J Appl Toxicol*. 2022;42(8):1298-1309. doi.org/10.1002/jat.4270

[7]Rowan-Carroll A, Reardon A, Leingartner K, et al. High-throughput transcriptomic analysis of human primary hepatocyte spheroids exposed to per- and polyfluoroalkyl substances as a platform for relative potency characterization. *Toxicol Sci*. 2021;181(2):199-214. doi.org/10.1093/toxsci/kfab039

[8]McMullen PD, Bhattacharya S, Woods CG, et al. Identifying qualitative differences in PPARα signaling networks in human and rat hepatocytes and their significance for next generation chemical risk assessment methods. *Toxicol In Vitro*. 2020;64. doi.org/10.1016/J.TIV.2019.02.017

strategies using *in vitro* methods that can measure or predict KEs relevant to the biological effect of interest.[9,10]

Existing Data

We urge agencies to coordinate with each other and to consider all existing PFAS test data, including both ongoing and previously conducted studies under the European Chemicals Agency (ECHA) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. The review and use of existing data can be crucial to filling data needs. Agencies should request full studies from industry whenever they exist to avoid duplicative testing on animals.

Test order deadlines should be flexible to accommodate the time needed to search properly for existing data relevant to human health needs. When there are existing data, it may take time to procure full data reports.

Additionally, we support the EPA's use of route-to-route extrapolation to gather data on PFAS health effects. During an EPA webinar hosted on August 17, 2022, it was stated that the EPA's Office of Research and Development is pursuing approaches to extrapolate inhalation data from existing oral exposure studies on animals.[11,12]

Transparency

Data reviews by agencies should be transparent and publicly available. Information on what data were reviewed to determine testing requirements and how the required test data will be used by agencies in risk assessments is necessary to ensure that statutes such as the Lautenberg Amendment to the Toxic Substances Control Act are met. For example, there is currently confusion around the EPA's test orders for 6:2 fluorotelomer sulfonamide betaine (FTSB),[13] including the scientific justification for the test orders and how the EPA will use the data generated by the tests in making risk assessment decisions for PFAS. A more transparent process would result in a more scientific approach for assessing PFAS chemicals.

In addition to transparency regarding specific testing requirements, to increase scientific rigor, agencies should be transparent about testing programs and processes. For example, the EPA has chosen 24 representative PFAS chemical strategies for its National PFAS Testing Strategy. However, neither a list of chemicals in each category nor information on chemical assessment strategies has been released—therefore, it is unclear whether existing data for a different chemical in that class would be considered. Transparency through a clearly defined process and opportunities for public comment—such as through the promulgation of rules rather than the issuance of test orders—would also provide agencies with the opportunity to receive valuable input from stakeholders and potentially identify additional existing data.

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[9]Jarabek AM, Stedeford T, Ladics GS, et al. Poorly soluble, low toxicity (PSLT) polymer category: an integrated approach to testing and assessment (IATA) including new approach methods (NAMs) under the Toxic Substances Control Act (TSCA). Poster presented at: Society of Toxicology 60th Annual Meeting; 2021. https://www.thepsci.eu/wp-content/uploads/2021/03/SOT21_PSLT-Polymer-Category-Poster-02-March-2021.pdf

[10]Henry TR, Salazar KD, Hayes MP, et al. Surfactants category: an integrated approach to testing and assessment (IATA) including new approach methods (NAMs) for assessing inhalation risks under the Toxic Substances Control Act (TSCA). Poster presented at: Society of Toxicology 60th Annual Meeting; 2021. https://www.thepsci.eu/wp-content/uploads/2021/03/SOT21_General-Surfactants-Category-Poster-02-March-2021.pdf

[11]EPA Tools and Resources Webinar. PFAS strategic roadmap: research tools and resources. PowerPoint. https://www.lawbc.com/uploads/docs/PFAS_Tools_Webinar_081722_%28final%29.pdf. Accessed August 26, 2022.

[12]EPA Webinar Series. https://www.epa.gov/research-states/epa-tools-and-resources-webinar-series. Accessed August 26, 2022.

[13]Order Under Section 4(a)(2) of the Toxic Substances Control Act for 6:2 Fluorotelomer sulfonamide betaine. https://www.epa.gov/system/files/documents/2022-06/9829-01_testorder-6_2_Fluorotelomer_sulfonamide_betaine.pdf. Accessed August 26, 2022.

Reduction of Animal Testing
If agencies require testing on animals for the assessment of PFAS, measures such as those listed below should be mandatory to reduce the use of animals to the greatest extent possible:

- Companies should be required to join consortia before conducting testing on animals to ensure that testing is not duplicated, similar to the substance information exchange fora (SIEFs) under REACH.[14] Deadlines should be sufficient to allow the needed time for industry to form consortia.
- Only one species should be used in testing when animal use is required. The EPA's test order for 6:2 FTSB requires testing in two species, both mice and rats, for Tier 2 toxicokinetics (OECD TG 417) and acute inhalation toxicity (OECD TG 403) tests, even though existing studies indicate that rodents are not good models of human health effects.[1,6,8]
- Tests on animals should be integrated or shorter-term tests should be used whenever possible.[15,16]

Prioritization
When assessing PFAS chemicals, OSTP and federal agencies should take into account exposure assessments, specific exposure routes, and the context of use. Since there is a need to develop data efficiently, the scope of human health risk assessments for PFAS should focus on real-life exposure potential (e.g., through workplace exposure measurements) rather than the hazard of a substance alone.

Fifteen years ago, the National Research Council's report *Toxicity Testing in the 21st Century: A Vision and a Strategy* set the stage for using modern, animal-free methods that are more predictive of human health outcomes. PFAS testing programs offer the opportunity to fulfill this vision by moving away from a reliance on decades-old tests on animals and toward the use of more reliable and relevant 21st century non-animal testing approaches.

Thank you for considering these comments, and please contact us if you have any questions.

[14]ECHA Factsheet: SIEF dating sharing and joint submission. https://echa.europa.eu/documents/10162/17223/data_sharing_fact_sheet_en.pdf/f84f1135-e0d4-42a9-be8f-81e9fc726aa0. Accessed August 26, 2022.
[15]Groff K, Evans SJ, Doak SH, et al. In vitro and integrated in vivo strategies to reduce animal use in genotoxicity testing. *Mutagenesis*. 2021;36(6):389-400. doi.org/10.1093/mutage/geab035
[16]Marty MS, Andrus AK, Groff K. Animal metrics: tracking contributions of new approach methods to reduced animal use. *ALTEX*. 2022;39(1):95-112. doi.org/10.14573/altex.2107211

SUSTAINABLE PFAS ACTION NETWORK

Electronically Submitted

Comments of the Sustainable PFAS Action Network (SPAN)
Responding to the Office of Science and Technology Policy (OSTP)
Request for Information on Identifying Critical Data Gaps and Needs To Inform
Federal Strategic Plan for PFAS Research and Development
87 Fed. Reg. 41,749 (July 13, 2022)

Submitted August 29, 2022

The Sustainable PFAS Action Network (SPAN) submits these comments to the Office of Science and Technology Policy (OSTP) in response to the July 13, 2022 Request for Information (RFI) on "Identifying Critical Data Gaps and Needs To Inform Federal Strategic Plan for PFAS Research and Development." 87 Fed. Reg. 41,749 (July 13, 2022).

SPAN is a coalition of PFAS users and producers that are committed to sustainable, risk-based PFAS management. Our members work to advocate for responsible policies that provide assurance of long-term environmental protection and also recognize the important contribution that certain PFAS have made to economic growth and competitiveness in global markets.

SPAN supports OSTP's efforts to develop a government-wide strategic plan for PFAS research and development. Our members support the development of a better understanding of the potential health and environmental effects of those PFAS to enable a more uniform federal policy approach to PFAS regulatory policies that are risk-based and permit practical consideration to be given to sustainable methods to preserve essential uses of critical PFAS for which there are currently no technically feasible alternative substances.

In response to the RFI, SPAN is addressing below certain specific areas of interest to our members which are among the topics and questions OSTP has asked commenters to address.

RFI Question One: Should the US government consider identifying priority PFAS when developing a strategic plan for PFAS research and development? If so, what criteria should be used to identify priority PFAS for research and development?

SPAN Members believe it is critical that when undertaking research efforts in the federal sector, there should be priority PFAS identified. Key criteria should be employed for assessing potential for risk such as:

- Toxicology, Toxicokinetic and Exposure Profiles
- Environmental fate (E-fate) (including mobility, solubility, persistence)
- Bioaccumulation, Bioavailability and Biopersistence potential
- End of Life

Research also should explore ways to identify PFAS of "low priority" on the basis of health and environmental effects to enable greater focus on substances of highest concern.

Further, research should focus on priority PFAS which are identified on the basis of the subject of the research efforts. For example, when undertaking research concerning methods for treating PFAS and/or removing PFAS from the environment, priority should be given to those PFAS determined to be of greater concern based on the substances' health and environmental effects and which have been demonstrated to have the greatest presence in the environment. In contrast, when seeking to identify alternatives to PFAS, focus should be given to those PFAS of greatest health or environmental concern and for which their current levels of use are the most predominant in the US.

RFI Question Two: Are there criteria which could be applied across the five research goals identified in the RFI, or should specific criteria be developed for each individual research goal?

As discussed above, SPAN Members believe it is constructive and necessary to align federal priorities with the greatest potential societal values to be derived from a research effort. Thus, investigations into potential alternative PFAS should focus on those of greatest concern and with the most wide-spread (and highest volume) active uses. When investigating methods for the safe destruction of PFAS, efforts should concentrate on the most significant areas where contamination exists and the most likely sources of environmental contamination attributed to PFAS, and concentrate research efforts in those areas. Research into PFAS alternatives should also take into consideration whether the alternatives present additional environmental, human health, or safety concerns as well as whether the alternative can meet or exceed current performance criteria and characteristics.

RFI Question Three: Based on the definition of PFAS in this RFI, what are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS and to identify cost-effective alternatives to PFAS, methods for removal of PFAS, and methods to safely destroy PFAS.

SPAN Members consider the PFAS definition in the RFI to be extremely broad, and attention in federal research efforts need to be focused on those PFAS which are shown to be the greatest concern due to their potential health and environmental effects. To this end, SPAN recommends certain substances be excluded from being "priorities" for federal research efforts on finding alternatives and methods for removal and treatment. Such exclusions should be risk-based. For example, fluoropolymers, fluorocarbon gases such as hydrofluorolefins (HFOs), and PFAS that are active pharmaceutical ingredients (APIs) that have been approved by FDA could be excluded on that basis.

RFI Question Four: Are there specific chemistries and/or intended uses that PFAS provide for which there are no known alternatives at this time?

SPAN Members are aware that there are no technologically available alternatives for certain applications that require PFAS application in several areas critical to the US economy, national defense, and other priorities to the US government. These should include:

- semiconductor manufacturing, refrigeration, pharmaceutical/medical device applications, renewable energy and certain applications in the construction industry. It is noteworthy that fluoropolymers which meet the OECD criteria as "Polymers of Low Concern" are used extensively in these industries, where Ultra-purity, UV and Weather resistance, radiation resistance, fire resistance, broad chemical resistance, unique barrier properties, electrical properties that support 5G and other high frequency communications, as well as unique arc-tracking resistance are needed.

- Hydrofloroolefins (HFOs) are a class of materials with ultra-low global warming potential that provide high performance, low toxicity, safe, and in most cases non-flammable attributes to refrigeration and air conditioning fluids, foam blowing agents, aerosol propellants, and many other applications. Although there are functional equivalents that may provide one or two of these individual attributes, there is no functional equivalent that provides the entire spectrum of attributes that are provided by HFOs.

To assist in the exploration and identification of alternatives to such PFAS, fundamental research is needed to identify environmentally preferable alternatives to PFAS that also meet the stringent functional needs and performance characteristics of substances used in certain critical industries. Federally-funded research in this regard should encourage partnerships with such critical industries where collaborations between federal researchers and commercial enterprises can occur to identify essential PFAS for which alternatives might be needed, while preserving commercially sensitive, confidential business information. Any inquiry into potential PFAS alternatives should be predicated on: an initial determination that a particular PFAS and application presents an unreasonable risk that cannot be adequately mitigated, making the pursuit of alternatives a priority; and in such circumstances, the alternatives in question should be assessed based in whether they could create new environmental, toxicity or safety concerns and lead to "regrettable substitutions".

RFI Question Five: What are alternatives to the definition of PFAS provided in this RFI? What are the implications of these alternative definitions on possible remediation strategies?

SPAN is aware of several other definitions of PFAS that have been enacted for use in state statutes and which are being considered by EPA for use in certain regulatory matters pursuant to the Toxic Substances Control Act. While the term PFAS was first coined in 2011 by Buck et.al, several other agencies have taken different approaches to defining PFAS since then.

For example, the state of Delaware has enacted legislation in which the statute defines "PFAS" to mean "non-polymeric perfluoroalkyl and polyfluoroalkyl substances that are a group of man-made chemicals that contain at least two fully fluorinated carbon atoms, excluding gases and volatile liquids. "PFAS" includes PFOA and PFOS."

The US EPA has proposed a working definition for a TSCA Section 8(a) Reporting Rule (which is required by the NDAA for FY '21). The Agency's proposal would define PFAS "structurally" to mean "any chemical substance or mixture that structurally contains the unit R-(CF2)-C(F)(R')R". Both the CF2 and CF moieties are saturated carbons. None of the R groups (R, R' or R") can be hydrogen."

Certain states have enacted legislation which define PFAS far more broadly. For example, in July 2021, the legislature in Maine enacted Public Law c. 477 (LD 1503, 130th Legislature) which defines PFAS as "substances that include any member of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom."

SPAN supports the use of PFAS definitions which are more carefully crafted to enable regulators to focus their attention and limited resources on substances of greatest concern on the basis of risk factors, specifically their effects on human health and the environment.

RFI Question Six: What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of: analytical methods, detection limits, non-targeted detection?

SPAN Members recommend federally-funded research efforts should focus on developing practical and affordable analytical methods for the identification and detection of PFAS in waste streams, soil, air, and water. Priority consideration should be given to identifying specific waste streams for priority controls, factors such as volume, mobility, toxicity, and bioaccumulation, and with emphasis on developing emission control methods to improve sustainability and to preserve, where possible, existing critical applications.

RFI Question Seven: What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans? Which impacts beyond human health should be prioritized?

An expert panel[1] was recently convened to provide insight and guidance on PFAS grouping for the purposes of protecting human health from drinking water exposures, and how risks to PFAS mixtures should be assessed. Here are some highlights of their key findings:

- Most of the expert panelists agreed that the USEPA TSCA definition and approach for grouping PFAS is pragmatic and generally a good starting place for human health risk assessment
- Physicochemical properties may be used to help approximate the potential for human exposure and/or to screen or prioritize PFAS of potential concern, but these properties are not sufficient in and of themselves for informing either exposure or potential hazardous effects and additional knowledge on toxicological effects and dose-response is necessary for risk assessment.
- It was acknowledged that toxicity, bioaccumulation, toxicokinetic, and exposure profiles would vary among PFAS and therefore, those characteristics should be considered when assessing human health risk.
- Grouping all PFAS together as "persistent" was not supported as practical nor appropriate for assessing human health. This is also known as the "P-Sufficient approach" and one that some of the state DTSCs look upon favorably.
- Most panelists agreed that it is inappropriate to assume equal toxicity/potency across the diverse class of PFAS for human health risk assessment and that robust assessment of potential human health risk to a representative mixture of PFAS is not feasible.

OSTP's efforts should be informed by these findings and take into consideration that most PFAS risk assessments will need to employ substantial assumptions and defaults; and these applied assumptions are more likely to overestimate risk than to underestimate risk. Some panelists expressed concerns that these assumptions are often multiplicative and can lead to overestimates of both potency and exposure, and therefore, over-regulation.

RFI Question 8: What should be the research and development priorities for accelerating progress in PFAS mixtures and formulations?

The US government should utilize the prioritization scheme discussed under Question 1 to direct research efforts. In addition, advanced analytical methods should also be developed to address the identity and composition of mixtures. Consideration of impacts from the discontinued use of PFAS technologies on

[1] Anderson, J.K. & Brecher, R.W. & Cousins, Ian & DeWitt, J. & Fiedler, Heidelore & Kannan, K. & Kirman, Christopher & Lipscomb, J. & Priestly, B. & Schoeny, R. & Seed, J. & Verner, M. & Hays, S.M.. (2022). Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts. Regulatory Toxicology and Pharmacology. 134. 105226. 10.1016/j.yrtph.2022.105226.

significant health issues such as climate change, clean water, disease prevention and control (through pharmaceuticals, medicals devices and equipment, etc.) must also be studied as a priority.

RFI Question 9: What goals, priorities, and performance metrics would be valuable in measuring the success of national, federally funded PFAS research and development initiatives in these areas?

As noted in our response to RFI Question Six, SPAN Members recommend federally-funded research efforts should focus on developing practical and affordable analytical methods for the identification and detection of PFAS in waste streams, soil, air, and water. Measurements of success should include the prompt timing of deliverable results, the affordability of methods, and the availability of laboratories that are equipped and capable of reliably performing such methods and obtain repeatable, consistent results. Developing an approach to provide training to laboratory personnel in conducting such analyses using commonly-available laboratory equipment should be a component of such federally-funded efforts.

SPAN Members also recommend that an area for priority research should be on methods for reducing and mitigating PFAS emissions in various emissions streams, with an emphasis on gaseous emission controls from facilities where PFAS may be used in manufacturing processes; effluent controls where manufacturing processes involving PFAS might result in detectable concentrations of PFAS in effluent waste streams; and solid and hazardous waste disposal techniques that eliminate or mitigate PFAS that might be present in solid wastes. Metrics to measure success should similarly be the prompt timing of deliverable results, the affordability of treatment methods, and the availability of equipment needed to achieve consistent results.

* * *

SPAN appreciates the opportunity to provide input to OSTP on the federal strategic plan for PFAS research and development.

August 29, 2022

VIA Email to JEEP@ostp.eop.gov

Subject: RFI Response: PFAS Strategic Plan

Re: Request for Information; Identifying Critical Data Gaps and Needs To Inform Federal Strategic Plan for PFAS Research and Development

To whom it may concern:

CropLife America[1] (CLA) and RISE (Responsible Industry for a Sound Environment)® are pleased to submit these comments in response to the Notice of Request for Information (RFI) issued by the Office of Science and Technology Policy (OSTP).[2]

Through the RFI, OSTP seeks "input from all interested parties to identify data gaps in research and development regarding several aspects of per-and polyfluoroalkyl substances (PFAS)."[3] In particular, OSTP is interested in stakeholder responses to nine questions. Based in part on responses to these questions, OSTP will develop a strategic plan as a "precursor to an R&D implementation plan for Federal agencies."[4] CLA and RISE respond only to question one, regarding whether priority PFAS should be identified when developing the strategic plan for PFAS research and development (R&D), and if so, what criteria should be used to identify priority PFAS for R&D? For the reasons set forth below, any pesticide chemistry that may fall under the definition of PFAS do not need to be prioritized for R&D.

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[1] Established in 1933, CropLife America (CLA) represents the developers, manufacturers, formulators, and distributors of pesticides and plant science solutions for agriculture and pest management in the United States. CLA represents the interests of its registrant member companies by, among other things, monitoring legislation, federal agency regulations and actions, and litigation that impact the crop protection and pest control industries and participating in such actions when appropriate. CLA's member companies produce, sell, and distribute virtually all the crop protection and biotechnology products used by American farmers. RISE (Responsible Industry for a Sound Environment)® is the national trade association representing manufacturers, formulators, distributors and other industry leaders engaged with the specialty pesticides and fertilizers used by consumers and professionals.

[2] 87 Fed. Reg. 41749, July 13, 2022.

[3] *Id.*

[4] *Id.*

The United States Environmental Protection Agency (EPA) recently issued a PFAS Strategic Roadmap (Roadmap)[5], which delineates a number of PFAS related actions to be implemented, in part, by EPA's Office of Chemical Safety and Pollution Prevention (OCSPP), in which both the Office of Pesticide Programs (OPP) and the Office of Pollution Prevention and Toxics (OPPT) are situated. No PFAS related activities in the Roadmap fall within OPP. This is not because EPA's PFAS Council, which developed the Roadmap, lacked OPP representation or expertise.

Instead, we believe OPP's lack of Roadmap responsibilities represents an implicit acknowledgment of the robust scientific review apparatus that OPP has had in place for decades – long before PFAS became a priority for EPA - to fully assess the potential risks, both human and ecological, from pesticides, regardless of their chemical structures or composition.

All pesticides distributed or sold in the United States must be registered (licensed) by OPP. Pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), under which pesticides are regulated, OPP independently evaluates chemical-specific data to ensure that pesticides can be used safely and there is reasonable certainty of no harm to consumers from dietary exposure nor are there unreasonable adverse effects to the environment[6] when label directions are followed. Importantly, OPP is also required to review each registered pesticide at least every 15 years to ensure that each pesticide continues to meet FIFRA requirements. As part of this registration review, OPP often seeks additional scientific information from registrants to ensure that OPP has the necessary scientific information to conduct its review, based on the best available science.

To be clear, the Roadmap is risk-based and seeks to actively manage those PFAS only after they can be shown to "adversely impact human health and the environment."[7] But as noted, OPP already ensures that pesticides can be used safely and without unreasonable adverse effects to the environment when label directions are followed.

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[5] OSTP references the Roadmap in the RFI. *Id.*

[6] FIFRA§2(bb) defines the term "unreasonable adverse effects on the environment" to mean: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act."

[7] PFAS Strategic Roadmap: EA's Commitments to Action 2021 – 2024 (October 18, 2021), available at https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.

EPA also recently issued a National PFAS Testing Strategy "to deepen understanding of the impacts of PFAS, including potential hazards to human health and the environment."[8] As with the Roadmap, however, the Testing Strategy does not include any role for OPP and no testing or data collection efforts under FIFRA are envisioned within the Testing Strategy.

In sum, pesticides that may contain PFAS under a broad definition do not need to be prioritized for R&D. CropLife and RISE would be pleased to provide OSTP with further information upon request. Thank you for the opportunity to respond to the RFI.

[8] National PFAS Testing Strategy, available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/national-pfas-testing-strategy.

ASSOCIATION OF METROPOLITAN WATER AGENCIES

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August 29, 2022

Stacy Murphy
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Executive Office of the President

Via email

Dear Stacy Murphy,

The Association of Metropolitan Water Agencies (AMWA) is pleased to have the opportunity to provide comments on identifying critical data gaps and needs for informing federal strategic plans for PFAS research and development. AMWA is an organization of the largest publicly owned drinking water systems in the United States. Members serve over 100,000 customers and collectively provide clean drinking water to over 160 million people. The association believes continuing federally sponsored, health-based research is necessary to address PFAS contamination. Specifically, AMWA emphasizes the need for a robust PFAS research plan that addresses the highest priority human health concerns.

PFAS chemicals have drawn extensive scrutiny due to their persistent nature and potential health concerns, and it is imperative that federal agencies be prepared to address the growing concerns they bring, particularly to drinking water utilities. Any PFAS action plan should include research into understanding the health risks and developing risk assessments; developing improved analytical techniques to measure the level of PFAS chemicals more accurately in drinking water; protecting drinking water supplies from PFAS contamination; and identifying the most reliable and efficient methods for removing PFAS from drinking water. All research should be performed by qualified, reputable research organizations and should, to the extent possible, be oriented to provide information of direct benefit to water supply utilities and regulators. AMWA also supports OSTP's recent guidance making the results of all taxpayer-supported research immediately available to the public at no additional cost.

1. Should the USG consider identifying priority PFAS when developing a strategic plan for PFAS research and development? If so, what criteria should be used to identify priority PFAS for research and development (e.g., tonnage used per year; releases to the environment per year; toxicology or other human or environmental health concerns; national security or critical infrastructure uses)?

PFAS are a group of thousands of chemicals that include many compounds we know little to nothing about. Some may not pose an immediate threat, but others are capable of severely affecting environmental and human health. When considering what criteria should be evaluated to identify priority PFAS for research and development, agencies should not confine themselves to one criterion. Relying simply on tonnage per year or releases to environment per year will not always identify PFAS doing significant harm. Agencies should approach this issue holistically, considering quantity, but also toxicity to wildlife and humans, the extent it is a national problem vs. a state or regional issue, proximity to public water systems, and intended use.

3. Based on the definition of PFAS in this RFI, what are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS and to identify cost-effective:

a. Alternatives to PFAS that are designed to be safer and more environmentally friendly;

b. Methods for removal of PFAS from the environment; and

c. Methods to safely destroy or degrade PFAS?

PFAS pose many challenges for public water systems who are tasked with providing safe, clean drinking water to the public. Any costs associated with treatment of PFAS in drinking water is typically passed down to consumers, resulting in higher cost of water for individuals who had no hand in the PFAS pollution. Federal agencies should be working toward more cost-effective treatment techniques that work for all sizes of water utilities. This ensures all members of the public are receiving similar quality water, further addressing environmental justice issues while protecting public health.

Current methods for destroying or degrading PFAS (incineration, pyrolysis, etc.) are not very feasible for public water systems due to high costs and energy use. Utilities need a reliable and cost-effective way of disposing and eliminating PFAS. AMWA strongly encourages federal agencies to work towards improved destructive technologies that can be utilized by a wide variety of PFAS users and handlers.

5. What are alternatives to the definition of PFAS provided in this RFI? What are the implications of these alternative definitions on possible remediation strategies?

The definition of PFAS varies even among federal agencies, but for research purposes it's important that the definition cover a wider array of compounds rather than be narrowly focused. This ensures research can capture a larger amount of potentially dangerous chemicals and their byproducts. Currently, there is not a consistent definition of PFAS within the federal government, leading to confusion when it comes to risk management and remediation decisions.

6. What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of: analytical methods, detection limits, non-targeted detection?

Detection capabilities have outpaced our knowledge on how to treat and/or remove PFAS from drinking water sources, as well as our knowledge for what exposure to these chemicals means for public health. The ability to detect to near zero concentrations is impractical if the technology to reduce concentrations to those levels is not easily available. This has created a difficult scenario where public health agencies and utilities may have to inform the public that these chemicals exist in their water but will have little information on what that means for their customers' health.

AMWA strongly supports research into new analytical methods to detect PFAS in drinking water and other media. As EPA works towards proposing National Primary Drinking Water Regulations for PFOA, PFOS, and potentially other PFAS, there must be adequate and cost-effective methodology for detection. Having a choice in analytical methods assists in reducing monitoring burdens and costs while preserving the protection of public health.

7. What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans (e.g., in vitro, animal toxicological, and epidemiological studies)? Which health effects should be prioritized? What additional impacts beyond health should be prioritized? Social scientific approaches are welcome in addressing this question and any others, as appropriate.

The health effects of PFAS have been widely debated and are constantly evolving based on new research. Federal agencies must continue to use a variety of reputable methods to work towards a more robust and complete picture of how PFAS mobilizes from source to the human body. This includes research into sources of PFAS, mobility of PFAS in the environment, and human exposures beyond ingestion from drinking water. PFAS are used in a wide variety of everyday products, so to address PFAS exposures, research must be done to create a targeted approach beyond drinking water regulation.

Research should prioritize characterizing the serious health effects of PFAS chemicals. Specifically, research priorities should focus on carcinogenetic properties and developmental effects of ingestion of a variety of PFAS. Studies are needed that reflect the diverse population if the US to gather an accurate representation of the population. While epidemiological studies can be challenging, they offer up important data and information useful for understanding hazard identification in a population.

Specifically, more research is needed to characterize the role of PFAS in the air on human exposure and its environmental effects. In addition to inhalation of PFAS, research into how drinking water treatment of PFAS will affect greenhouse gas (GHG) emissions, how those GHG emissions will impact localized and regional human health, and how facilities such as public water systems can best focus their resources towards reducing these GHG emissions, and therefore, public health risks.

9. What goals, priorities, and performance metrics would be valuable in measuring the success of National, federally funded PFAS research and development initiatives relating to:
a. The removal of PFAS from the environment;
b. Safely destroying or degrading PFAS; and
c. Developing safer and more environmentally-friendly alternatives to PFAS?
d. Mitigating negative human effects of PFAS, whether related to health or additional domains?

The major priority when it comes to PFAS contamination should be implementing measures to prevent it from happening in the first place. In the unfortunate event where this is not possible, more research is needed into the sources and pathways of PFAS contamination. Knowing where these chemicals originate helps defer costs away from the public and hold those who are creating, using, and benefitting from PFAS financially accountable for environmental discharges.

Conclusion

Thank you for the opportunity to comment on potential gaps in PFAS research to help federal agencies create and implement PFAS action plans. The association looks forward to working across the federal government to address PFAS issues and protect public health.

3M Company

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August 29, 2022

3M Response to the Office of Science and Technology Policy's Request for Information; Identifying Critical Data Gaps and Needs to Inform Federal Strategic Plan for PFAS Research and Development

Submitted Electronically to: JEEP@ostp.eop.gov

3M Company ("3M") appreciates the opportunity to respond to the Office of Science and Technology Policy's ("OSTP") request for information ("RFI"). 3M believes the effort to streamline and coordinate a strategic plan for PFAS across the federal family is critical. Currently, the regulated community and the public lack clear guidance, due in large part to inconsistent actions and priorities related to PFAS within and between various parts of the federal government. Research and development on PFAS presents one of the most complex issues in the public domain today. It is not possible to provide a thorough or complete response to the numerous questions regarding this highly complicated issue within the page limit OSTP has imposed, and 3M will not attempt to do so here. Oversimplifying complex issues can create and reinforce an incorrect understanding of the issues, resulting in wasted resources and ineffective regulation. 3M requests and encourages OSTP to offer a more robust process that includes a comprehensive discussion and evaluation of the issues presented. 3M would be pleased to participate in such a process.

1. Should USG identify priority PFAS for R&D? If so, what criteria should be used to do so?

Yes. The primary criteria for identifying priority PFAS should be risk-based, with "risk" defined as some combination of hazards to human health and environment coupled with relevant exposure to both compartments. Using this framework, data and established risk assessments used in chemical inventory registrations and any geographical use evaluations can to be used to rapidly develop preliminary systems of grouping that include properties informing impact on the environment and human health. Inclusion of these environmental properties in risk assessments when determining which substances to study is essential. In addition, a chemical's ability to enter the environment through environmental partitioning should be considered early on in evaluation and be used to frame prioritization of risk assessments and pathways for exposure to the public. The potential for human exposure will largely depend on the environmental compartment to which the chemical is emitted and partitions. The final determination of a threshold risk level will provide the guideposts for developing removal levels and technologies, destruction techniques, and the need for alternatives. Using risk-based criteria is an efficient way to prioritize limited resources and take action that is protective of human health and the environment, while minimizing the allocation of time and resources to substances that pose low risk.

3. Scientific, technological and human challenges to reducing the environmental and human impacts and to identify cost-effective, safer, more environmentally friendly alternatives' methods of removal from the environment, and methods to safely destroy/degrade PFAS?

Sound regulation is based on sound science. Too often, science has become politicized, and particular studies or perspectives that fit a particular narrative are given improper weight to achieve desired policy goals. This is both a scientific and human challenge. Experts interpreting scientific research related to PFAS should be closely vetted for conflicts of interest. Anyone affiliated with plaintiff or defense expert work related to PFAS should be excluded from scientific review panels. This is in contrast to the studies and data independent experts should consider in scientific review. The focus of an expert analysis should be on the quality of the science, not the source, and agencies should ensure literature reviews are comprehensive and up to date. This is essential for PFAS, where there is often not a single conclusive critical study. If regulatory decisions are being made based on the weight of the evidence, an unbiased, comprehensive literature review is necessary to guide further research efforts and to arrive at valid interpretations of the data. Scientifically sound studies should not be excluded from consideration because they are funded by any particular source.

One of the challenges in using scientific research to set regulatory standards is that not all high quality and valid research is appropriate for setting standards. Experts must be knowledgeable in selecting data appropriate for the use to which it is being put.

A key technological challenge is that existing technology is not in line with PFAS-related goals. Whether the extremely low health advisories recently issued by the Environmental Protection Agency, or the ability to measure a broad range of PFAS in multiple media, existing technology is unable to support regulatory goals. If regulatory levels are below the technical capability to detect a substance, it is impossible for the regulated community to demonstrate compliance.

4. Are there chemistries and/or uses that PFAS provide for which there are no known alternatives?

Identifying essential uses does not and should not replace a proper risk assessment. Rather than focusing on chemistries for which there are no known alternatives, 3M suggests using risk-based criteria to make regulatory determinations. *See response to question 1.* That said, there are certain chemistries for which there are no known alternatives. For example, "[f]luoropolymers possess unique combinations of properties and unmatched functional performance critical to the products and manufacturing processes they enable and are irreplaceable in many uses."[1] Fluoropolymers include Fluoroplastics, Fluoroelastomers and Specialty Polymers. Additional Fluoroplastics and their critical applications are described in https://setac.onlinelibrary.wiley.com/doi/10.1002/ieam.4035.

One application of fluoropolymers without commercially available alternatives is critical to the production of lightweight, flexible plastic packaging.[2] Fluoropolymers used as components in

[1] https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4646. Table 1 of this paper lists different industry end uses and table 2 the functional properties of different fluoropolymers.

[2] There are many more examples of chemistries or uses for which there are no known alternatives, but due to OSTP's space limitation, 3M is prevented from expanding further here. *See* https://pubs.rsc.org/en/content/chapterhtml/2022/9781839167591-00001?isbn=978-1-83916-568-9 ; *see also* Ober, C., Review of Essential Use of Fluorochemicals in Lithographic Patterning and Semiconductor Processing, available at https://www.spiedigitallibrary.org/journals/journal-of-micro-nanopatterning-materials-and-metrology/volume-

polymer processing additives (PPAs) or extrusion aids are high molecular weight polymers, have low levels of residual monomers or oligomers, exhibit very low water solubility, and are non-reactive and thermally stable. As an indication for the low risk, they meet simplified regulatory criteria – like OECD criteria of polymer of low concern. They are present in certain plastic packaging components in only very small amounts.[3] There are no commercially available alternatives to these fluoropolymers, so banning their presence in packaging would necessitate reverting to outdated and inefficient packaging technologies that would not meet modern environmental standards.

5. What are the alternative definitions (from the one used here) and implications of alternative definitions on remediation strategies?

As an initial matter, the PFAS definition used in the FY21 NDAA and OSTP RFI is does not make sense. Part A is a subset of Part B, but the definition indicates *both* A and B must be met, which renders Part B either meaningless or inconsistent with Part A.

Many PFAS definitions – including those used in this RFI – are overly broad, inappropriately encompassing a large and diverse range of fluorinated substances that have vastly different physical, chemical, biological, and toxicological properties. As discussed above, material properties inform risk, not chemical structure. Overly broad PFAS definitions which are used to singularly define the scope of rules and regulations will not accomplish what they may set out to achieve which, most often, is simplicity in approach.

Grouping all fluoroalkyl compounds together as PFAS and developing regulations around the extremes of adverse effects would be analogous to grouping all aromatic compounds together and then banning them all due to issues with tetrachlorodibenzo-p-dioxin. While some PFAS compounds may share similar properties, clearly all members of that class do not. Compounds containing CF2 or CF3 moieties can cover a wide range of physical, environmental, and toxicological properties making grouping into one class scientifically inappropriate.

Small distinctions in definitions and regulatory scope of this complex range of chemistries can affect important industries and applications. These differences, while subtle, can have important real-world consequences across industries and applications that support our modern society. These include critical pharmaceutical drugs such as Prozac, Lipitor and Paxlovid, electronics like cell phones, tablets and laptops, semiconductor chips to power our electronics, automotive components which prevent gasoline vapor emissions to the atmosphere, implantable medical devices including heart patches and vascular grafts, refrigeration, agricultural chemicals, and many others.

3M supports establishing precise PFAS definitions to avoid including materials that do not present unacceptable risk to human health or the environment. 3M also supports defining PFAS consistently to avoid confusion and provide certainty to the regulated community. OSTP should identify key PFAS compounds/functionalities – based on risk characterization - and define them using a classification methodology, which involves the combined use of 1) clear and pointed

21/issue-01/010901/Review-of-essential-use-of-fluorochemicals-in-lithographic-patterning-and/10.1117/1.JMM.21.1.010901.full?SSO=1. Additional references are included in the bibliography.

[3] https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4646.

regulation-based definitions that do not rely exclusively on chemical structure and 2) classification schemes, including the following illustrative but not all-inclusive concepts: chemical structure, toxicology, mobility, environmental partitioning, exposure potential, application, etc. This will provide the means to selectively identify compounds that align with risk and target control factors using established data and scientific principles.

These classification schemes and regulation-based definitions should seek to define or categorize substances relative to the established environmental and exposure risks posed by the substance. Chemical moieties that can be uniquely and consistently defined and correlated to no or very low environmental and toxicity profiles should be excluded from any resulting PFAS regulation. This may be accomplished through conditional exclusion of certain substance categories or through grouping and decision tree matrixes that consider holistic assessment of the substance across human health, environmental, and usage scenarios.

6. What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of: analytical methods, detection limits, non-targeted detection?

- Developing testing methods that allow accurate characterization of risk. *See response to question 7.*
- Prioritize development of methods and analytics for PFAS with high exposure potential and exclude substances with low exposure potential or those listed as chemicals of low concern.
- Such assessments must not only be based on the best available science, but also specific ways in which these substances may or may not impact human health. Data and analysis used to make these assessments also needs to be made available to the public for input from relevant stakeholders and the scientific community.
- Prioritize developing analytical methods for PFAS substances in media with high exposure potential.

7. What type of studies yield the most useful information to address current gaps in understanding PFAS health effects in humans? (e.g. toxicological, epidemiological, in vitro)

The most useful studies are those that accurately characterize risk by evaluating a substance in the appropriate media under real world conditions. For example, the potential for human exposure will largely depend on the environmental compartment to which the chemical is emitted and to which it partitions. The relative proportions of the substance that will reside within these phases is determined by the physical/chemical properties of the compound. Thus, compounds with low vapor pressure, high aqueous solubility, and low Koc will markedly partition to the water and to a lessor extent, the atmosphere and terrestrial compartments. Conversely, volatile compounds with low water solubility and low Kocwill extensively partition to the atmosphere. Substances from this latter category are mischaracterized if their environmental fate is assessed through biodegradation studies, which are conduct in aqueous media. Sparingly little, if any, of the parent substance would be found in that compartment in the natural environment. However, examination of the atmospheric degradation products is relevant in the aqueous and terrestrial compartments. Partitioning of chemical species must be considered with evaluating fate and effects.

To summarize, fate and effects analysis needs to focus on relevant exposure pathways of a parent chemistry as well as any degradation product knowing that the exposure pathways can be very different between the two.

It is believed that many PFAS chemistries bioconcentrate due to protein binding rather than due to partitioning to fat. Therefore, an increased understanding of the binding (primarily to albumin as this protein appears to distribute the PFAS throughout the organism). An appropriate understanding of protein binding and the relevance to adverse effects is needed. High quality measurements of physiochemical properties of individual PFAS chemistries or relevant equivalent information of PFAS-based polymers including information on identity and quantity of impurities/unreacted monomers is necessary to understand fate and effects of PFAS chemistries.

8. R&D priorities be for understanding PFAS mixtures and formulations and their effects?

3M submitted extensive comments to the SAB on EPA's proposed Mixtures Framework in February 2022.[4] Among other points, 3M noted that EPA's Mixtures Framework proposed approaches that are at odds with the 1986 and 2000 EPA guidance on mixtures.

The use of an additive toxicity methodology when evaluating mixtures is only appropriate when the mechanisms for toxicity of each substance is the same. The mechanism for toxicity should not be assumed to be the same. Where there are widely varying toxicity guidance levels, they may suffer from inconsistency and a high degree of variability in quality, peer review, use of judgmental uncertainty choices, and completeness of study consideration. That means that in a component mixture assessment, not only could outcomes be inconsistent, but a poorly supported, atypically low, outlier reference value could dominate the final health risk assessment outcome. A lack of data on any particular substance should not lead the risk assessor to provide what could be inappropriate substitutes and unfounded outcomes.

The European Chemical Strategy for Sustainability dedicated a Staff Working Document to mixtures identified mixtures as a high priority workstream. However, the hypothesis and even some of the conclusions have sparked a scientific debate which indicates the need for additional scientific work and critical reviews in this area. Remediation and destruction of PFAS are also topics of intense scientific developments and deserve further attention – some of which counter some of the foundational political labels of "forever chemicals." Destruction of PFAS is also integral step to chemical recycling strategies for fluoropolymers.[5]

[4] 3M's comments may be found at https://sab.epa.gov/ords/sab/f?p=100:19:5942599046586:::RP,19:P19_ID:963.
[5] Documents related to each of these points are included in the bibliography.

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[6] This selected bibliography is not a substitute for a complete literature review in accordance with accepted best practice.

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August 29, 2022

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RE: RFI Response – PFAS Strategic Plan

Dear Ms. Buser:

The Physicians Committee for Responsible Medicine (PCRM) thanks the Office of Science and Technology Policy (OSTP) for the opportunity to comment on its *Federal Strategic Plan for PFAS [per- and polyfluoroalkyl substances] Research and Development*. PCRM is a nationwide nonprofit organization comprised of over 175,000 supporters advocating for efficient, effective, and ethical medical practice, nutrition, and research.

Because PFAS are a large and diverse class of chemicals, PCRM is concerned by the potential for extensive animal use across Federal agencies evaluating their toxicity. As OSTP notes, the U.S. Geological Survey (USGS) and the Environmental Protection Agency (EPA) have existing plans that include PFAS research and development. Both evaluate PFAS toxicity in vertebrate animals, and EPA's implementation of its *National PFAS Testing Strategy* could use over 34,000 animals, based on the test guidelines cited and on the first PFAS test order issued under the Toxic Substances Control Act (TSCA).[1,2] **TSCA establishes an historic mandate to reduce and replace the use of vertebrate animals in the testing of chemicals; PCRM calls upon OSTP to affirm this goal in the testing of PFAS across Federal agencies and to ensure that such testing is never duplicated.**

Relevant to OSTP's request for information, EPA's application of this mandate includes using a category approach to select PFAS for testing and using a tiered approach to select subsequent tests. While EPA's plan focuses on human health and USGS's on the environment, they are interrelated and

[1] U.S. Environmental Protection Agency. October, 2021, Washington, D.C. National PFAS Testing Strategy: Identification of Candidate Per- and Poly-fluoroalkyl Substances (PFAS) for Testing, accessed August 28, 2022. https://www.epa.gov/system/files/documents/2021-10/pfas-natl-test-strategy.pdf.
[2] U.S. Environmental Protection Agency. June 16, 2022, Washington, D.C. Order Under Section 4(a)(2) of the Toxic Substances Control Act, accessed August 28, 2022. https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0897-0002/content.pdf.

are guided by the best available science, as recently reviewed by authors from both agencies.[3] This suggests opportunities for OSTP to facilitate partnerships that leverage expertise and resources across Federal agencies. In addition, EPA's first PFAS test order and early implementation of its testing strategy illustrate practical challenges and suggest additional opportunities for New Approach Methods (NAMs) development. Finally, the test guidelines cited in these documents include specific recommendations for minimizing animal use which should be followed by all Federal agencies conducting PFAS research.

1. Should the USG consider identifying priority PFAS when developing a strategic plan for PFAS research and development? If so, what criteria should be used to identify priority PFAS for research and development (e.g., tonnage used per year; releases to the environment per year; toxicology or other human or environmental health concerns; national security or critical infrastructure uses)?

Given the very large number of PFAS of possible concern, prioritization for testing is critically important, both to optimize the use of limited resources and to minimize the use of animals. PCRM supports prioritizations based on considerations including production volume, conditions of use, environmental fate, and biological activity, along with structural classification.[4] EPA's *National PFAS Testing Strategy* is an example of such an approach, in which PFAS were prioritized for testing based on structural features, defining 70 categories from a starting list of 6,504 chemicals and determining the "most representative" chemical structure in each. For each starting chemical, EPA mapped publicly available and confidential toxicity data onto these categories, ultimately selecting 24 PFAS for testing from categories lacking such data, a reduction of more than 99%. This approach allows for data collected on representative chemicals to be "read across" to others in the same structural category, while minimizing the animals, time, and resources expended. Information can be gathered and acted upon more quickly, rather than spending vastly more time and money conducting tests on thousands of chemicals.

For data-poor chemicals, including many PFAS, computational and bioinformatic approaches can efficiently estimate potential for persistence and bioaccumulation as well as predict biological activity, further targeting testing.[5] In its *Strategic Science Vision*, USGS recommends developing PFAS-specific models based on EPA platforms that predict species relevance and extrapolate mechanisms across chemicals.[6],[7] **OSTP can support critical, ongoing prioritization efforts by expanding, updating, and coordinating PFAS data repositories as well as computational and bioinformatics methods and resources across Federal agencies.**

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[3] Ankley GT, Cureton P, Hoke RA, Houde M, Kumar A, Kurias J, Lanno R, McCarthy C, Newsted J, Salice CJ, Sample BE, Sepúlveda MS, Steevens J, Valsecchi S. Assessing the Ecological Risks of Per- and Polyfluoroalkyl Substances: Current State-of-the Science and a Proposed Path Forward. *Environ Toxicol Chem*. 2021 Mar;40(3):564-605. doi: 10.1002/etc.4869.

[4] Ibid.

[5] Andrea K. Tokranov, Paul M. Bradley, Michael J. Focazio, Dougals B. Kent, Denis R. LeBlanc, Jeff W. McCoy, Kelly L. Smalling, Jeffery A. Steevens, and Patricia L. Toccalino. Integrated Science for the Study of Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) in the Environment, A Strategic Science Vision for the U.S. Geological Survey. U.S. Geological Survey, Reston, Virginia, 2021. https://pubs.usgs.gov/circ/1490/cir1490.pdf.

[6] U.S. Environmental Protection Agency. Sequence alignment to predict across species susceptibility (SeqAPASS): U.S. Environmental Protection Agency web page, accessed August 28, 2022. https://seqapass.epa.gov/seqapass/info.xhtml.

[7] U.S. Environmental Protection Agency. Interspecies correlation estimation: U.S. Environmental Protection Agency web page, accessed August 28, 2022. https://www3.epa.gov/webice/.

7. What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans (e.g., in vitro, animal toxicological, and epidemiological studies)? Which health effects should be prioritized?

In its *Strategic Science Vision*, USGS cites the need for molecular, biochemical, and cell-based tools and techniques to efficiently predict the biological activities of PFAS and their mixtures, as well as to provide mechanistic insights that support extrapolating limited toxicity data across species and exposure routes. Such NAMs can inform both the selection of PFAS and the selection of subsequent tests. In its testing strategy, EPA considers *in vitro* nuclear receptor activation, protein binding, and metabolism studies to be potential first-tier tests and *in vivo* toxicokinetic studies to be second-tier tests. Considering the dramatic differences in elimination half-lives observed among species, as well as effects known to occur by species-specific mechanisms, toxicokinetics and species relevance are of particular importance in assessing both the human health and the environmental effects of PFAS.[8]

The Adverse Outcome Pathway framework provides a framework upon which to understand toxicological effects across a variety of study types, species, and levels of biological organization. The concept has clear utility for a number of PFAS research and decision-making needs in both human and ecological health and has the potential to transform existing data into actionable knowledge, identify data gaps, and formalize testing strategies to fill the most urgent gaps. For example, by placing *in vitro* and epidemiological data in context, biomarkers of effect can be identified, validated, or used to design new test models or surveillance strategies, improving our ability to understand the impacts of PFAS chemicals on human populations and strengthening the utility of toxicological and epidemiological studies together. We recommend coordinated efforts to develop AOPs relevant to PFAS endpoints of concern.

EPA references an ongoing partnership with the National Toxicology Program (NTP) to test 142 representative PFAS in high-throughput, tiered toxicity assays evaluating hepatotoxicity, immunotoxicity, developmental toxicity, mitochondrial toxicity, and developmental neurotoxicity as well as estimating *in vivo* toxicokinetics. Recently, the partnership reported that transactivation assays targeting key transcription factors confirmed known PFAS biological activities, matched structural relationships to target activities, and found novel activities.[9] Ultimately, their goal is to combine these NAMs data with human exposure information to derive biological exposure ratios to inform subsequent testing and human health risk assessment. **By facilitating such partnerships, OSTP can accelerate the development and implementation of such NAMs-based approaches that reduce and replace vertebrate animal testing while providing more species-relevant information.**

Additional Comments

EPA's early implementation of its testing strategy and its first PFAS test order under TSCA for 6:2 fluorotelomer sulfonamide betaine illustrate practical challenges in PFAS research and suggest additional opportunities for NAMs development. Systematic evidence maps for the same set of

[8] Ankley, et al., 2021.

[9] Houck KA, Patlewicz G, Richard AM, Williams AJ, Shobair MA, Smeltz M, Clifton MS, Wetmore B, Medvedev A, Makarov S. Bioactivity profiling of per- and polyfluoroalkyl substances (PFAS) identifies potential toxicity pathways related to molecular structure. *Toxicology*. 2021 Jun 15;457:152789. doi: 10.1016/j.tox.2021.152789.

representative PFAS tested in the NTP partnership confirmed that many PFAS are data poor with human studies found for only 11 of these PFAS and animal studies for 35.[10] Because very few inhalation toxicity studies are available, and EPA cites concerns over respiratory effects, the Office of Research and Development (ORD) is developing approaches for extrapolating data from oral studies. In its first test order, EPA's specific health concerns are based on the chemical's physical-chemical properties indicating potential for portal-of-entry effects from inhalation exposures; while reports of oral toxicity studies are available for this chemical, EPA found they were not relevant to these concerns. Extrapolation approaches could address similar concerns in future test orders, potentially avoiding new animal testing, entirely.

In the second tier of testing, EPA ordered *in vivo* toxicokinetics, acute toxicity, dose-range finding, and sub-acute toxicity studies by inhalation exposure; based on the guidelines cited, these studies would use approximately 177 animals. While results of the NAMs-based approach for estimating toxicokinetics being evaluated in the NTP partnership have not yet been reported, such approaches could replace *in vivo* studies in future orders. Further, "in the absence of evidence that either rats or mice are more human-relevant for PFAS inhalation exposure," both species are to be tested in the toxicokinetics and acute toxicity studies to inform species selection for subsequent testing. [It is worth noting that because the elimination half-lives of studied PFAS in mice and rats are generally much closer to each other than they are to those in humans (and often far lower),[11] the added value of selecting one species over the other is questionable.] Mechanistic insights from NAMs-based approaches could potentially inform species selection, reducing the number of animals used by half, as well as providing additional opportunities for reduction by combining preliminary studies.

In its order, EPA determined that vertebrate testing was necessary because "no scientifically valid non-vertebrate test method of equivalent or better scientific quality and relevance currently exists" to measure inhalation exposure dosimetry and toxicity for this chemical. This is not the case. Appropriately, EPA considered available *in vitro* respiratory tract cell culture toxicity models, but found they were relevant to only water-soluble and gaseous substances. Elsewhere, EPA cites a report that PFAS modify lung surfactant function and pro-inflammatory responses in human bronchial epithelial cells as a basis for its concern that PFAS can cause adverse effects on the respiratory system following acute inhalation exposure.[12] While this method does not currently apply to poorly soluble substances, the value EPA places in its results suggests that expanding its applicability to such poorly soluble substances using alternative exposure systems (for example, at the air-liquid interface) could eventually replace some *in vivo* inhalation toxicity studies.

Importantly, EPA's implementation of its testing strategy is already underway and, pending EPA's evaluation of first-tier biosolubility testing or future revision of its first test order, the tests described above will likely be conducted. The more rapidly NAMs-based approaches are implemented, the fewer animals will be used in the testing of PFAS, and the more species-relevant will be the information developed. **One way in which OSTP, and its interagency strategy team,**

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[10] Alice Gilliland, Laura Carlson, Avanti Shirke and Phillip Potter. EPA Tools and Resources Webinar PFAS Strategic Roadmap: Research Tools and Resources. US EPA Office of Research and Development, August 17, 2022; presentation, accessed August 28, 2022. https://www.lawbc.com/uploads/docs/PFAS_Tools_Webinar_081722_%28final%29.pdf.

[11] Ankley, et al., 2021.

[12] Sørli JB, Låg M, Ekeren L, Perez-Gil J, Haug LS, Da Silva E, Matrod MN, Gützkow KB, Lindeman B. Per- and polyfluoroalkyl substances (PFASs) modify lung surfactant function and pro-inflammatory responses in human bronchial epithelial cells. *Toxicol In Vitro*. 2020 Feb;62:104656. doi: 10.1016/j.tiv.2019.104656.

can accelerate their implementation is by establishing a workgroup where representatives of agencies evaluating PFAS toxicity share experience with NAMs as well as coordinate and report metrics of animal use and reduction. To benefit from stakeholder and public participation, these efforts should be transparent and accessible, and include regular public meetings with opportunity for comment. Existing interagency committees, such as the Scientific Advisory Committee on Alternative Toxicological Methods and Interagency Coordinating Committee on the Validation of Alternative Methods, could provide guidance or administrative support.[13]

When animal testing is conducted, current international testing guidelines, referenced by EPA, incorporate several recommendations that can significantly reduce animal use. **Along with ensuring that animal testing is never duplicated, OSTP should promote their acceptance whenever such testing is conducted.** In addition to combining preliminary species and dose selection studies, mentioned above, the *in vivo* micronucleus and comet genotoxicity assays can be combined and integrated into repeated-dose toxicity studies.[14] Pending the results of first-tier *in vitro* genotoxicity testing, EPA identifies *in vivo* testing as a potential second-tier test. Among potential third-tier tests, EPA identifies extended one-generation reproductive toxicity testing, which uses fewer animals than two-generation testing; however, even fewer animals can be used in guidelines that combine reproductive toxicity testing with sub-chronic or developmental toxicity testing.[15] In addition, for substances expected to be virtually non-toxic, a single group of animals can first be exposed at a limit concentration, and if mortality or moribundity is observed, the results of the limit test can inform further testing at other concentrations.[16]

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[13] U.S. Department of Health and Human Services; National Toxicology Program web site, accessed August 28, 2022. https://ntp.niehs.nih.gov/whoweare/advisory/index.html.

[14] OECD (2016), Test No. 474: Mammalian Erythrocyte Micronucleus Test, OECD Publishing, Paris; accessed August 28, 2022. https://doi.org/10.1787/9789264264762-en.

[15] OECD (2015), Test No. 422: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test, OECD Publishing, Paris; accessed August 28, 2022. https://doi.org/10.1787/9789264242715-en.

[16] OECD (2009), Test No. 403: Acute Inhalation Toxicity, OECD Publishing, Paris; accessed August 28, 2022. https://doi.org/10.1787/9789264070608-en.

August 29, 2022

Dr. Alondra Nelson
Acting Director
White House Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue NW
Washington, DC 20502

Re: Request for White House Office of Science and Technology Policy; Identifying Critical Data Gaps and Needs To Inform Federal Strategy Plan for PFAS Research and Development; Document Number 2022-14862, 87 Fed. Reg. 41749 (July 13, 2022)

Dear Dr. Nelson:

The undersigned organizations are pleased to comment on the White House Office of Science & Technology Policy (OSTP) Request for Information on developing a federal research and development agenda on Per-and Polyfluoroalkyl Substances (PFAS). We commend OSTP for raising many pertinent issues in addressing the statutory obligations under the National Defense Authorization Act for FY 2021 to develop an interagency research approach. The business community is committed to working with you to accelerate appropriate cleanup activities and ensure that policymakers consider the best science and risk-based actions in addressing the environmental, public health, and economic challenges presented by PFAS.

The following are key principles that we believe should guide your research and development approach:

All PFAS are not the same and should not be treated for regulatory or research purposes as a class. PFAS, as defined in the RFI, are a broad class of chemistries with very diverse physical and chemical properties, and widely varying toxicity profiles. It is crucial that regulatory actions and risk communications recognize this diversity, calibrate the risk that any specific PFAS chemistry or groups of related chemistries may pose, and prioritize regulatory and research action on the PFAS chemistries that pose the greatest potential human health and environmental risk.

In addition, it is important to recognize that PFAS are used in many societally valuable ways by a wide variety of industries, including—but not limited to—first responder services and safety equipment, aerospace, energy, automotive, medical devices and pharmaceuticals, telecommunications, textiles, and electronics. Examples of products enabled by PFAS technologies include greenhouse gas filters, medical products and garments, coatings for medical devices, semiconductors, solar panels, high-performance electronics, and fuel-efficient technologies. Certain fluorinated firefighting foams are still needed for emergency response, public safety, and national security purposes.

Prioritization of federal research and regulatory activities is critical. The development and implementation of a systematic, science-based prioritization scheme may be the single most important step the federal government can take to ensure that finite research and remediation resources are directed at substances and scenarios that present the most significant risks and, conversely, that finite resources are not squandered on substances and scenarios that do ***not*** present significant risks. Any prioritization scheme for research and regulation should prioritize categories of PFAS compounds that present the greatest potential for risk, and de-prioritize categories of compounds with low potential for risk. In particular, substances and products such as pharmaceuticals, which are already highly regulated and the subject of robust risk assessment by federal regulators, should be a low priority for separate regulation as "PFAS" even if they may fall under the broad definition currently used in the RFI.

EPA's PFAS Strategic Roadmap focuses on ensuring science-based decision-making. Policies should be developed based on the best science and risk to address any identified concerns to protect public health and the environment. The recent health advisories issued by EPA in June 2022 seem inconsistent with this concept and were released prior to completion of peer review and without adequate public engagement.

OSTP should include requirements for sound scientific assessments and public participation consistent with the APA and other statutes. We propose that the Office of Management and Budget (OMB) — in consultation with OSTP; in coordination with the federal interagency community and leading national scientific experts from academia and the private sector; and after soliciting public comment —provide further guidance on processes for conducting sound and consensus-based scientific assessments and other scientific determinations that include public engagement and input consistent with the requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, the Information Quality Act, and other statutes, and consistent with OMB's Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005). This should include an open and transparent peer review process that includes a broad representation of subject matter experts, including representatives from industry.

Performance metrics should be based on risk. Measurement must assist in improving our insight on whether a chemistry poses a significant risk and whether a proposed action or solution will address such significant risk.

The interagency research agenda should address the need for timely development of analytical methods to measure PFAS. OSTP and agency counterparts should consider how research will help shape appropriate methods and provide guidance on how analytical detection limit of existing methods (e.g., EPA HALs) must be considered in establishing appropriate regulatory approaches. OSTP should also consider that the dearth of validated methods makes it almost impossible for states, PRPs, consultants, technology vendors, and others to have clarity with respect to taking cleanup actions.

There are several scientific and practical questions OSTP should ask in developing potential categories. Members of our coalition provided questions to the EPA Science Advisory Board last year in connection with grouping substances (not just PFAS) for regulatory purposes. We suggest that OSTP utilize these priorities as the interagency process debates the importance of PFAS categories.

We propose using the consensus-based definition developed in Delaware legislation that was enacted late last year. According to the new Delaware law: "PFAS" means non-polymeric perfluoroalkyl and polyfluoroalkyl substances that are a group of man-made chemicals that contain at least 2 fully fluorinated carbon atoms, excluding gases and volatile liquids. "PFAS" includes PFOA and PFOS.

Health and environmental pathways research should consider whether PFAS is intentionally added and is identified as potential essential uses. It is first important to recognize the ubiquitous nature of PFAS in the environment. More and more recent studies and information has demonstrated that PFAS can be found, not only in surface waters, groundwater, and soils, but in rainwater, detergents and products that utilize municipal water as an ingredient, and other sources where PFAS is not intentionally added. Because of this, low or trace levels of PFAS will be present in products and environmental media even in instances where no PFAS source was present. The impacts of such low or trace levels of PFAS is exacerbated through the implementation of ppt level advisories and limitations that impact wastewater discharges, remedial activities, and drinking water management.

The Chamber therefore recommends that research activities are also focused on how background levels and sources of PFAS may impact regulations and how those background levels and sources can be taken into consideration when developing regulations and permitting conditions and limitations.

Additionally, the Chamber recommends consideration of the essentiality of certain products that provide certain key benefits to safety, health, and the environment, as well as the PFAS that provide those benefits.

Performance of alternatives to PFAS should also be prioritized and assessing viable alternatives should be based on reducing risks, optimizing costs, and ensuring consistent and effective performance. Research into PFAS alternatives will require not only issues related to toxicity, exposure potential, and removal, but also whether the alternative provides the same level of performance (e.g., durability, surfactancy, chemical, heat, and water resistance) as the PFAS it is intended to replace.

Alternatives analysis should be considered or required only when a particular, existing use of a PFAS substance is found to present an unreasonable risk, and only when other measures to limit risk (e.g., through emissions controls or other limitations on exposure) are not possible. When an alternatives assessment is warranted, an alternative should be considered feasible only if it provides performance that is equivalent to the performance of the PFAS chemistry that is used for the specific applications at issue.

End-of-life issues should be considered with maximum flexibility for safe and long-term disposal and destruction. The coalition submitted our feedback on EPA's interim guidance for disposal and destruction and urged the agency to include the most effective options based on the data and science. OSTP should examine issues relating to measurement and toxicity of chemistries to establish priorities. Research related to disposal, destruction, and degradation of PFAS should focus more on the conditions and methods required to break and destroy the strong chemical bonds that are part of all PFAS. Research should also explore whether and how to manage residuals and byproducts and how much is permitted and practicable. For instance, there should be an end-of-life pathway for all media and waste streams (e.g., gas, liquid, and solid).

We look forward to working with you to create a beyond federal research and development plan to address public-sector and private-sector concerns and to ensure a consistent approach to PFAS treatment and risk communications.

We stand ready to answer any questions you may have.

Sincerely,

Aerospace Industries Association
Alliance for Automotive Innovation
American Apparel and Footwear Association
American Forest & Paper Association
American Petroleum Institute
Council of Industrial Boiler Owners
Flexible Packaging Association
National Council of Textile Organizations
National Mining Association
PRINTING United Alliance
U.S. Chamber of Commerce

RFI Response: PFAS Strategic

Question 1. Should the USG consider identifying priority PFAS when developing a strategic plan for PFAS research and development?

Yes, the most important consideration in developing a strategic PFAS plan includes the development of a systematic, science-based prioritization scheme that focuses on substances and scenarios that present the most significant risks. Specifically, there are specialty applications where fluorinated materials enhance product safety, increase efficiency, extend product life, and improve product efficacy. By focusing research for industrial non-dispersive applications for safety critical, military, and critical US infrastructure we continue to support national critical/strategic priorities while protecting the environment. Any prioritization scheme should prioritize categories of PFAS compounds that present the greatest potential for risk, and de-prioritize categories of compounds with low potential for risk. Criteria to be applied in assessing potential for risk include:

i. The amount of a substance generated and used
ii. Solubility and mobility in the environment (water, air, land – soil, sediment, sludge for example)
iii. Bioavailability and persistence
iv. Evidence of release into the environment and volume of release
v. Evidence of severe toxicity
vi. Ability to contain, capture and destroy when needed?

1a) If so, what criteria should be used to identify priority PFAS for research and development (e.g., tonnage used per year; releases to the environment per year; toxicology or other human or environmental health concerns; national security or critical infrastructure uses)?

The priority should consider.

- *The criteria list above for the first question.*
- *Tonnage produced per year in that it is easy to gather and is representative of the level of risk from a specific substance.*
- *Materials that present an unreasonable risk where other controls are not effective and viable alternatives to a material meeting the current definition of PFAS do not exist. In many cases, our customers have not found a replacement that is as effective and efficient as our oil, grease and/or wax in specialty industrial applications. Some applications are in safety / environmental protective critical services. Some applications require years of application reviews to be qualified such as in electronic applications and medical devices. Priority for review should be given to these specialty industrial applications, safety critical applications, and applications that require these extensive reviews.*
- *The end use of materials that fall in the current definition of PFAS products and how the material could possibly enter the environment. Non-dispersive and many industrial applications of materials meeting the PFAS definition are often used in closed / restricted processes or non-environmentally dispersive applications. These applications can be used safely while preserving environmental goals. Materials such as fluorinated lubricants are self-limiting in use due to extremely high product cost.*
  Is the use of this material a priority to another US government department such as the Department of Defense (DOD) and/or materials with national security implications?
- *Toxicity of the specific material. Prioritize toxicity research of specific compounds (covered under the definition) used in industrial, non-environmentally dispersive applications (products not used in food contact applications.) There is historical evidence of low toxicity on some of these specific compounds. More research / study is needed for these specialized industrial, non-environmentally dispersive applications that can be used in environmentally protective ways that have no or few safe alternatives.*

Question 2. Are there criteria which could be applied across the five research goals identified above, or should specific criteria be developed for each individual research goal?

The five research goals should be prioritized ideally using the risk criteria proposed in question 1. Goal (B), the safe destruction or degradation is a logical priority. If this can be accomplished, it allows safe use of specific manufactured PFAS chemicals that are not used in contact applications (no anticipated toxicity to humans, animals, or the environment) or applications that are not environmentally dispersive. Goal (E) is understanding the actual toxicity of PFAS materials before we ban chemicals are beneficial to the US economy (Goal (A)). Once we know the toxicity, goal (D) is significant. Goal (C) of alternative substances where there is no or minimal impact to the environment would have a disproportionate and devastating effect on small manufacturing companies invested in chlorinated and fluorinated chemicals solutions.

Question 3. Based on the definition of PFAS in this RFI, what are the scientific, technological, and human challenges that must be addressed to understand and to significantly reduce the environmental and human impacts of PFAS and to identify cost-effective: a. Alternatives to PFAS that are designed to be safer and more environmentally friendly; b. Methods for removal of PFAS from the environment; and c. Methods to safely destroy or degrade PFAS?

3 a) Alternatives analysis should only be considered or required when a particular, existing use of a PFAS substance is found to present an unreasonable risk and when other measures to limit that risk (e.g., through emissions controls or other limitations on exposure) are not possible.
When an alternatives assessment is warranted, an alternative should be considered feasible only if it provides performance that is equivalent to the performance of the PFAS substance(s) that are actually used, for the specific applications at issue. Some chemicals that fall under the current definition are used for hazardous operations including high-performance, chemically-inert, and non-flammable lubricants that ensure safe and reliable operations. Many industrial applications are already blanketed under many current legislative / regulatory controls with lower risk for environmental impact. Specific industrial applications require a multi-year evaluation periods to be tested and approved. Manufacturing cost and effectiveness of alternative materials must be included in PFAS reviews/research priorities. The approach of regulating a class of chemicals rather that specific chemicals make it difficult to include toxicological information already researched on specific materials. Where data is available, it should be used in consideration of the application for further research and approval for use for acceptable materials.

3(b & c) *The development of scientifically sound and practicable clean-up levels for priority PFAS is a prerequisite for identifying, developing, and deploying suitable removal technologies. The US has a national shortage of incinerator capacity as was acknowledged by the EPA. Incineration is currently a preferred method of destruction for materials that meet the working definition of PFAS. This shortage will force industries, counties, and cities to use other currently approved disposal methods that do not destroy the material. Recently, the news published articles outlining research on using caustic to destroy some materials defined as PFAS. Further scientific and practicable research to validate or develop new methods of removing/destroying materials defined as PFAS is critical as currently there is a shortage of effective / cost effective choices.*

Question 4. Are there specific chemistries and/ or intended uses that PFAS provide for which there are no known alternatives at this time?

Yes, examples include A) DOD (National Defense) applications where no alternative material has been identified. B) Oxygen safe lubricants and sealants C) Strong acid and base compatibility lubricants and sealants D) Automotive NVH elimination E) High temperature (>200C) industrial bearing lubrication F) Low temperature non-flammable fluid applications (Example. Calibration baths). There are other applications where other substances included under the current definition of PFAS are the not the only solution but are the preferred solution for many reasons. Consideration of

alternatives should be predicated on a determination that a particular PFAS and application presents an unreasonable risk that cannot be adequately mitigated.

Question 5. What are alternatives to the definition of PFAS provided in this RFI? What are the implications of these alternative definitions on possible remediation strategies?

It is important to recognize and explicitly acknowledge that all substances that fall within the definition are not the same and must not be evaluated and regulated as one single group. One current alternate is the OECD definition that considers molecular weight, whether the substance is a polymer or non-polymeric and the industry branch (type of use). This definition is complicated and requires more chemistry training to understand and apply. Further, there is confusion in scholarly/consortium communities as versions/details/footnotes explaining parts of the OECD definition are included in some references but excluded in others which significantly confuses/modifies the applicability/understanding of the definition. Differing regulatory definitions will result in confusion in marking, labeling, SDS nomenclature, end user training, etc. The currently proposed definition should also consider uses in closed systems where the material is contained (unlikely to enter the environment) and the disposal is already under regulatory controls such as use in specialized fuel cells or batteries.

Question 6. What should be the research and development priorities for accelerating progress, improving efficiency, and reducing the cost of: analytical methods, detection limits, non-targeted detection?

Validated and verified analytical methods are critical. Significant improvements are needed in both targeted methods as well as NTA (non-target analyses). Significant NTA advances are needed to make them affordable and widely accessible. Currently we have received feedback that there are only a few labs nationally that have stated they have methods of detection in the range of proposed limits. It will be very difficult to determine analytical methods to quantify PFAS chemicals below ppt (parts per trillion) as suggested in the legislation. Analytical methods will need to meet EPA defined standards, sample prep, analytical equipment, and detectors. In addition, these few labs would be overwhelmed by demand nationally. Research is needed to develop cost effective methods and sampling techniques that can be used and cost effectively implemented widely in industry. The proposed limits are magnitudes lower compared to other contaminants. Research and training is need to ensure robust/repeatable analytical methods and produce confident results.

Question 7. What studies would yield the most useful information and address the current gaps in understanding PFAS health effects in humans (e.g., in vitro, animal toxicological, and epidemiological studies)?

Testing strategies would be difficult to determine for a class of chemicals. Substance specific animal toxicity and environmental toxicity determinations are ideal, but this would be financially restrictive and not always definitive. Mandatory testing is not practicable, huge financial burden to smaller companies, and is contradictory to the US TSCA regulations. Any consideration of impacts beyond human health must fully account for the socioeconomic benefits provided by PFAS technologies.

7a) Which health effects should be prioritized?

Any evidence of CMR (cancer, mutagen or reproductive).

7b) What additional impacts beyond health should be prioritized?

Risk of impact to the environment that evaluate industrial non-environmentally dispersive applications. Environmental persistence (biodegradability, bioaccumulation, mobility, PBT and vBvT) for specific substances.

Question 8. One challenge across all research goals is PFAS mixtures and formulations. Currently, more information is needed to understand the identity, composition, occurrence, source, or effects on human health and the environment for mixtures of PFAS found in environmental media. Additionally, more information is needed to understand the best way to remediate or destroy media contaminated with multiple PFAS. What should be the research and development priorities for accelerating progress in these areas?

Research and development priorities would be to look at specific materials rather than by class. There is too much variation and variables to accurately assess the impact by class. The effects from miss classifying a material as being high risk could have significant negative impacts to society. More research and time is needed to resolve this question.

Question 9. What goals, priorities, and performance metrics would be valuable in measuring the success of National, federally funded PFAS research and development initiatives relating to: a. The removal of PFAS from the environment; b. Safely destroying or degrading PFAS; and c. Developing safer and more environmentally-friendly alternatives to PFAS? d. Mitigating negative human effects of PFAS, whether related to health or additional domains?

The criteria list above for the first question should be incorporated in the prioritization scheme. Other goals include:

- *Define a set of exemptions to help balance the unwanted negative societal consequences of regulating by a class of chemicals vs individual chemicals. For example, including exemptions for materials that are self-contained or there are no known acceptable alternatives. Areas with no known acceptable alternatives include: Military/DOD applications; semi-conductor applications; Oxygen, strong acid and base safe lubricants and sealants; Automotive NVH elimination; High temperature (>200C) industrial bearing lubrication; Low temperature non-flammable fluid applications (Example. Calibration baths).*
- *Increase the number of certified PFAS disposal/recycle facilities for PFAS materials. Developing incinerators that can be used without harm to the environment. Alternatively, increasing the number of economical incineration alternative PFAS disposal methods is advised.*
- *Development of reliable cost-effective water and soil monitoring standardized methods and reasonable detection limits.*
- *Development of an information repository for data collection including PFAS CAS structure, health and environmental toxicology and all other analytical data.*