information, please see the information provided in the **ADDRESSES** section of this document.

Dated: August 26, 2022.

Daniel Blackman

Regional Administrator, Region 4.

[FR Doc. 2022–19202 Filed 9–2–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 302

[EPA–HQ–OLEM–2019–0341; FRL–7204–02–OLEM]

RIN 2050–AH09

Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (''CERCLA'' or ''Superfund''), the Environmental Protection Agency (EPA or the Agency) is proposing to designate perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), including their salts and structural isomers, as hazardous substances. CERCLA authorizes the Administrator to promulgate regulations designating as hazardous substances such elements, compounds, mixtures, solutions, and substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. Such a designation would ultimately facilitate cleanup of contaminated sites and reduce human exposure to these ''forever'' chemicals.

DATES: Comments must be received on or before November 7, 2022. Under the Paperwork Reduction Act, comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before October 6, 2022.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OLEM–2019–0341, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov (our preferred method).* Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, OLEM Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michelle Schutz, Office of Superfund Remediation and Technology Innovation (5202T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number 703–346–9536; email address: *schutz.michelle@epa.gov.*

SUPPLEMENTARY INFORMATION:

Acronyms and Abbreviations: We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of the preamble and for reference purposes, the EPA defines the following terms and acronyms here:

ADEC Alaska Department of Environmental Conservation
AFFF Aqueous film-forming foam
APFO Ammonium perfluorooctanoate
ATSDR Agency for Toxic Substances and Disease Registry
CDC Center for Disease Control and Prevention
CDR Chemical Data Reporting
CERCLA Comprehensive Environmental Response, Compensation, and Liability Act
CFR Code of Federal Regulations
COP–9 9th Conference of Parties
DoD Department of Defense
DOE Department of Energy
DNA Deoxyribonucleic acid
EA Economic Analysis
EALs Environmental action levels
ECF Electrochemical fluorination
EJ Environmental justice
EPA Environmental Protection Agency
EPCRA Emergency Planning and Community Right-to-Know Act
EU European Union
FAA Federal Aviation Administration
FDA Food and Drug Administration
FR Federal Register
FSANZ Food Standards Australia New Zealand
IARC International Agency for Research of Cancer
ICR Information Collection Request
ILs Initiation levels
LEPC Local Emergency Planning Committee
LHA Lifetime health advisories
MAC Maximum acceptable concentration
MCL Maximum contaminant level
MDH Minnesota Department of Health
mg/kg milligram per kilogram
mg/kg/day milligram per kilogram per day
MRL Minimal risk level
MSC Medium-specific concentration
NAICS North American Industrial Classification System
NCP National Oil and Hazardous Substances Pollution Contingency Plan
ng/g nanograms per gram
ng/L nanograms per liter
NHANES National Health and Nutrition Examination Survey
NJDEP New Jersey Department of Environmental Protection
NPL National Priorities List
NRC National Response Center
OMB Office of Management and Budget
PADEP Pennsylvania Department of Environmental Protection
PBI Proprietary business information
PCBs Polychlorinated biphenyls
PCL Protective concentration level
PER Perimeter Well Study
PFAS Per- and polyfluoroalkyl substances
PFBS Perfluorobutanesulfonic acid
PFDA Perfluorodecanoic acid
PFHpA Perfluoroheptanoic acid
PFHxA Perfluorohexanoic acid
PFHxS Perfluorohexanesulfonic acid
PFNA Perfluorononanoic acid
PFOA Perfluorooctanoic acid
PFOS Perfluorooctanesulfonic acid
PFOSA Perfluorooctanesulfonamide
pg/m^3 picogram per cubic meter
PHGs Public health goals
POSF Perfluorooctanesulfonyl fluoride
ppt parts per trillion
PRG Preliminary remediation goal
PWS Public water system
RAGs Remedial action guidelines
RCRA Resource Conservation and Recovery Act
REACH Registration Evaluation, Authorisation and Restriction of Chemicals
RFA Regulatory Flexibility Act
RfD Reference dose
RIDEM Rhode Island Department of Environmental Management
RML Regional removal management level
RQ Reportable quantity
RSL Regional screening level
SAB Science Advisory Board
SALs State action levels
SDWA Safe Drinking Water Act SERC State Emergency Response Commission
SNURs Significant New Use Rules
TDI Tolerable daily intake
TEPC Tribal Emergency Planning Committee
TERC Tribal Emergency Response Commission
TRI Toxic Release Inventory
TSCA Toxic Substances Control Act
UCMR Unregulated Contaminant Monitoring Rule
UK United Kingdom
UMRA Unfunded Mandates Reform Act

UNEP United Nations Environment Programme
U.S. United States
U.S.C. United States Code
WQCC Water Quality Control Commission
WWTP Wastewater treatment plant

Table of Contents

I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2019–0341, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Propriety Business Information (PBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud or other file sharing system). For additional submission methods, the full EPA public comment policy, information about PBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

The EPA continues to monitor information carefully and continuously from the Centers for Disease Control and Prevention (CDC), local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19.

II. Does this action apply to me?

The purpose of this proposed rulemaking is to designate PFOA and PFOS, including their salts and structural isomers, as hazardous substances under CERCLA section 102(a). Upon designation, any person in charge of a vessel or an offshore or onshore facility, as soon as they have knowledge of any release of such substances at or above the reportable quantity (RQ) must immediately report such releases to the Federal, state, tribal and local authorities (CERCLA section 103(a), Emergency Planning and Community Right-to-Know Act (EPCRA) section 304). The RQ for these designations is 1 pound or more in a 24-hour period. Once EPA has collected more data on the size of releases and the resulting risks to human health and the environment, the Agency may consider issuing a regulation adjusting the reportable quantities for these substances.

The five broad categories of entities potentially affected by this action include: (1) PFOA and/or PFOS manufacturers (including importers and importers of articles); (2) PFOA and/or PFOS processors; (3) manufacturers of products containing PFOA and/or PFOS; (4) downstream product manufacturers and users of PFOA and/or PFOS products; and (5) waste management and wastewater treatment facilities. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this action applies to them. Potentially affected entities may include:

NAICS code	List of potentially affected U.S. industrial entities
488119	Aviation operations.
314110	Carpet manufacturers.
811192	Car washes.
325	Chemical manufacturing.
332813	Chrome electroplating, anodizing, and etching services.
325510	Coatings, paints, and varnish manufacturers.
325998	Firefighting foam manufacturers.
562212	Landfills.
339112	Medical Devices.
922160	Municipal fire departments and firefighting training centers, including Federal agencies that use, trained with, and tested firefighting foams.
322121 and 322130	Paper mills.
325320	Pesticides and Insecticides.

NAICS code	List of potentially affected U.S. industrial entities
324	Petroleum and coal product manufacturing.
324110 and 424710	Petroleum refineries and terminals.
352992	Photographic film manufacturers.
325612	Polish, wax, and cleaning product manufacturers.
325211	Polymer manufacturers.
323111 and 325910	Printing facilities where inks are used in photolithography.
313210, 313220, 313230, 313240, and 313320.	Textile mills (textiles and upholstery).
562	Waste management and remediation services.
221320	Wastewater treatment plants.

III. General Information

A. Executive Summary

EPA is proposing to designate two per- and polyfluoroalkyl substances (PFAS)—specifically PFOA and PFOS including their salts and structural isomers [1] as hazardous substances because evidence indicates that these chemicals may present substantial danger to public health or welfare or the environment when released into the environment. All references to PFOA and PFOS in this notice are meant to include their salts and linear and branched structural isomers. Linear and branched structural isomers of PFOA and PFOS maintain the carboxylic acid and sulfonic acid functional groups, respectively, but have different arrangements of the carbon atoms in the fluorinated carbon chain.

PFOA and PFOS have historically been found in or used in making a wide range of consumer products including carpets, clothing, fabrics for furniture, and packaging for food and cookware that are resistant to water, grease or stains. They are also used for firefighting at airfields and in a number of industrial processes. PFOA and PFOS are persistent and mobile in the environment, and exposure can lead to adverse human health effects, including high cholesterol, changes in liver enzymes, decreased immune response to vaccination, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney for PFOA, liver and thyroid cancer for PFOS). In June 2022, EPA released interim updated health advisories for PFOA and PFOS based on human epidemiology studies in populations exposed to these chemicals. Based on the new data and EPA's draft analyses, the levels at which negative health effects could occur are much lower than previously understood when EPA issued the 2016 health advisories for PFOA and PFOS (70 parts per trillion or ppt).

EPA believes the totality of evidence about PFOA and PFOS described here demonstrates that they can pose substantial danger to public health or welfare or the environment. This level of evidence is more than sufficient to satisfy the CERCLA section 102(a) standard. EPA believes that this amount and type of evidence exceeds the minimum required under CERCLA section 102(a).

PFOA and PFOS are common contaminants in the environment because of their release into the environment and their resistance to degradation. PFAS generally, and PFOA and PFOS specifically, are sometimes referred to as ''forever'' chemicals because their strong carbon-fluorine bonds cause PFOA and PFOS to be extremely resistant to degradation in the environment. PFAS are found in outdoor air at locations in the United States, Europe, Japan, and over the Atlantic Ocean. PFAS are also found in the artic snow and air.[2]

PFOA and PFOS are found worldwide in many environmental media and in wildlife. For example:

- PFOA and PFOS are widely detected in surface water samples collected from various rivers, lakes, and streams in the United States.
- PFOA and PFOS have been detected in surface and subsurface soils.
- PFOA and PFOS have been detected in groundwater in monitoring wells, private drinking water wells, and public drinking water systems across the country. PFOA and PFOS have been found in wild and domestic animals such as fish, shellfish, alligators, deer and avian eggs.

Environmental sources can include industrial, and inadvertent municipal and agricultural discharges of PFOA and PFOS directly. PFOA and PFOS precursors can be converted to PFOA and PFOS, respectively, by microbes in soil, sludge, and wastewater and through abiotic chemical reactions. PFOA and PFOS that are deposited or created by the degradation of their precursors in industrial and consumer waste, in a landfill without environmental controls, can discharge via leachates, groundwater pollution/migration and atmospheric releases.

The principal worldwide manufacturers of PFOA and PFOS and related chemicals phased out their production in the early 2000's although PFOA and PFOS may still be produced domestically for certain uses and by international companies that export treated products to the United States. Environmental contamination and resulting human exposure to PFOA and PFOS are anticipated to continue for the foreseeable future due to its environmental persistence, formation from precursor compounds, continued production by international manufacturers and possible domestic production, and as a result of the large legacy production in the United States. Although PFOA and PFOS levels have been decreasing in human serum samples since the phase out, they are still detected in a high percentage of the U.S. population.[3]

The adverse human health effects, mobility, persistence, prevalence, and other factors related to these PFAS combine to support EPA's proposed finding that PFOA and PFOS, when released into the environment may present substantial danger to the public health or welfare or the environment and, as a result, warrant designation as CERCLA hazardous substances.

The potential dangers posed by PFOA and PFOS specifically, and more generally by PFAS, have been recognized by numerous Federal, state, and international governmental entities that have taken a wide variety of actions to address these dangers to public health and welfare and the

[1] All references to PFOA and PFOS in this notice are meant to include their salts and linear and branched structural isomers. Linear and branched structural isomers of PFOA and PFOS maintain the carboxylic acid and sulfonic acid functional groups, respectively, but have different arrangements of the carbon atoms in the fluorinated carbon chain.

[2] Scientific Reports (2016) Natural Poly-/perfluoroalkyl Substances in Air and Snow from the Artic *https://www.nature.com/articles/srep08912*.

[3] CDC. (2021). National Health and Nutrition Examination Survey: NHANES questionnaires, datasets, and related documentation. Centers for Disease Control and Prevention. *https://wwwn.cdc.gov/nchs/nhanes/Default.aspx*.

environment. For example, the Department of Defense has been providing alternative drinking water to local residents near military bases with elevated PFOA and PFOS levels from DoD activities. Many states, including California, Michigan, and Vermont have drinking water standards for PFOA and PFOS. And numerous international bodies, such as the European Union, and individual countries, such as Australia, China, and Canada, have taken measures to address PFOA and PFOS. Designating PFOA and PFOS as hazardous substances will add to the set of tools already available under CERCLA to protect the public health and welfare and the environment.

If finalized, the direct effects of this proposed CERCLA designation would include requiring that any person in charge of a vessel or facility report releases of PFOA and PFOS of one pound or more within a 24-hour period. This would give the Agency, state, Tribal, and local governments, and the public a better understanding of where releases occur and the quantities involved.

In addition, when selling or transferring Federally-owned real property, Federal agencies would be required to meet all of the property transfer requirements in CERCLA section 120(h), including providing notice when any hazardous substance ''was stored for one year or more, known to have been released, or disposed of'' and providing a covenant warranting that ''all remedial action necessary to protect human health and the environment with respect to any [hazardous substances] remaining on the property has been taken before the date of such transfer, and any additional remedial action found to be necessary after the date of such transfer shall be conducted by the United States.'' This would ensure that any entity receiving Federal land is informed of the presence of PFOA or PFOS, and that these substances will be addressed as required under CERCLA. There would also be an obligation for DOT to list and regulate PFOA and PFOS as hazardous materials under the Hazardous Materials Transportation Act (HMTA) (see CERCLA Section 306(a)).

In addition to those direct effects, if finalized, these designations would provide some additional tools that the government and others could use to address PFOA/PFOS contamination and, thus, could facilitate an increase in the pace of cleanups of PFOA/PFOS contaminated sites. Furthermore, there will likely be additional response actions beyond those that are simply undertaken before designating PFOA/PFOS a hazardous substance, although the quantity of such an increase is indeterminable. The Federal government is already authorized to cleanup PFOA/PFOS contamination under some circumstances, including when it finds that a release may present an imminent and substantial danger to public health or welfare. A faster pace of cleanups would provide public health protection for affected communities sooner and could reduce the cost of individual cleanups (generally, the sooner contamination is addressed, the less it spreads and the smaller the area that needs to be cleaned). The indirect, downstream effects of these designations could include the following:

- EPA and other agencies exercising delegated CERCLA authority could respond to PFOA and PFOS releases and threatened releases without making the imminent and substantial danger finding that is required for responses now.
- EPA and delegated agencies could require potentially responsible parties to address PFOA or PFOS releases that pose an imminent and substantial endangerment to public health or welfare or the environment.
- EPA and delegated agencies could recover PFOA and PFOS cleanup costs from potentially responsible parties, to facilitate having polluters and other potentially responsible parties, rather than taxpayers, pay for these cleanups.
- Private parties that conduct cleanups that are consistent with the National Oil and Hazardous Substances Contingency Plan (NCP) could also recover PFOA and PFOS cleanup costs from potentially responsible parties.

These impacts from the proposed rule will result in meaningful public health benefits, including by increasing transparency around PFOA/PFOS releases and offering additional tools that EPA and other government agencies could use to conduct faster cleanups at contaminated sites.[4]

In addition to this action, in 2022, the EPA will be developing an advance notice of proposed rulemaking seeking comments and data to assist in the development of potential future regulations pertaining to other PFAS designation as hazardous substances under CERCLA.

[4] See the *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances* in the rulemaking docket for a discussion of indirect benefits and costs.

B. What are PFOA and PFOS, and how have they been used?

PFAS, including PFOA and PFOS, are human-made chemicals that have been used in industry and consumer products since the 1940s because of their useful properties, including their resistance to water, grease, and stains. In terms of their chemistry, they exist as linear and branched isomers, depending on the methods by which they are produced. Both PFOA and PFOS have been manufactured in numerous salt forms.[5] In considering toxicity and fate and transport processes, the salts are deemed the same as the commonly referenced acid versions because, once added to water, the salts dissociate to the component ions (there are two ions, the cation and the anion). Hence, if any of the salt or acid forms of PFOA or PFOS are released into the environment, the anionic form will generally be found in environmental media; all references to PFOA and PFOS in this preamble are meant to include all salts and structural isomers.[6]

PFOA and PFOS have been produced within the United States (U.S.)[7] as well as imported. Although PFOA and PFOS production may be ending in the United States, their continued use in certain applications and persistence in the environment means that their historical production and use will continue to be a concern in the future.

PFOA and PFOS can also be formed by chemical or biological degradation from a large group of related PFAS (*i.e.,* precursor compounds).[8] [9] The nature of PFOA and PFOS (*i.e.,* reactivity as both a base and acid) has led to their use in a variety of manufactured goods, industrial applications, or the environment, including the following:

- Food packaging and preparation, including PFAS-containing materials

[5] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237*.

[6] Ibid.

[7] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237*.

[8] Ibid.

[9] UNEP. (2006). Report of the Persistent Organic Pollutants Review Committee on the work of its second meeting. Addendum: Risk profile on perfluorooctane sulfonate. Stockholm Convention on Persistent Organic Pollutants. (UNEP/POPS/POPRC.2/17/Add.5). United Nations Environment Programme. *https://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC2/POPRC2ReportandDecisions/tabid/349/Default.aspx*.

(*e.g.,* sandwich wrappers, and other paper and paperboard food packaging) and processing equipment that uses PFAS. This can lead to migration of PFAS into food that contacts such surfaces.

- Commercial household products, including stain- and water-repellent fabrics, nonstick products, polishes, waxes, paints, and cleaning products.
- Certain firefighting foams. PFAS can be found in groundwater and surface water at airports, military bases and other facilities where PFAS-containing firefighting foam was used for training, incident response, or where foam was stored.
- Manufacturing and production, including chrome plating, electronics manufacturing, textile manufacturing or oil recovery.
- Drinking water, typically because of localized contamination associated with a specific facility (*e.g.,* manufacturer, landfill, wastewater treatment plant, firefighter training facility).
- Living organisms, including plants, animals and humans due to the above-mentioned sources.
- Plating processes, such as a wetting agent/fume suppressant.
- Non-stick cookware and food processing equipment.
- Processing aids in fluoropolymer production.
- Processing aids in textile coating applications.
- Insecticides.
- Certain types of adhesives.
- Cleaning products, such as carpet cleaners, auto washes and electronics.
- Coating products, paints, varnishes and inks.
- Surfactants for oil extraction and mining.
- Photo lithography, photographic coatings
- Hydraulic fluids for aviation.[10] [11]
- Certain explosives and pyrotechnics as binders and oxidizers.

The most common processes for making fluorinated chemicals, including PFOA and PFOS, are electrochemical fluorination (ECF) and telomerization. Production sites that produced PFAS by means of ECF were located in the U.S., including Decatur, Alabama. International production sites include Belgium (Zwijndrecht near Antwerp) and Italy (Miteni in Vicenza)).

Although PFOA and PFOS production may be ending in the United States, their continued use in certain applications and persistence in the environment means that their historical production and use will continue to be a concern in the future.

Domestic production and import of PFOA has been phased out in the United States by the companies participating in the 2010/2015 PFOA Stewardship Program. Small quantities of PFOA may be produced, imported, and used by companies not participating in the PFOA Stewardship Program and some uses of PFOS are ongoing (see 40 Code of Federal Regulations (CFR) 721.9582).[12] The EPA Chemical Data Reporting (CDR) rule under the Toxic Substance Control Act (TSCA) requires manufacturers (including importers) to report certain data about chemicals in commerce in the United States, including information on PFOA and PFOS (subject to a 2,500 pound reporting threshold at a single site). The last time PFOA and PFOS manufacturing information was reported to EPA pursuant to CDR was in 2013 and 2002, respectively. However, Toxics Release Inventory (TRI) data for 2020 shows that small amounts of PFOA and PFOS continue to be released into the environment. Pursuant to TRI reporting requirements, facilities in regulated industry sectors must report annually on releases and other waste management of certain listed toxic chemicals that they manufacture, process, or otherwise use above certain threshold quantities (100 pounds for PFOA and PFOS).

C. What action is the Agency taking?

The EPA is proposing to designate PFOA and PFOS, including their salts and structural isomers, as hazardous substances under section 102(a) of CERCLA.

The designation of PFOA and PFOS, including their salts and structural isomers, as hazardous substances, if finalized, would result in a default RQ of one pound pursuant to CERCLA section 102. CERCLA section 103(a) requires any person in charge of a vessel or facility, as soon as they have knowledge of any release [13] (other than a federally permitted release) of a hazardous substance from such vessel or facility in quantities equal to or greater than the RQ (one pound) or more in a 24-hour period, to immediately notify the National Response Center (NRC) of such a release. The reporting requirements are further codified in 40 CFR 302.6(a). Section 304 of EPCRA (42 (United States Code) U.S.C. 11004) also requires facility owners or operators to immediately notify their community emergency coordinator for local emergency planning committee (LEPC) (or Tribal emergency planning committee (TEPC)), if established, for any area likely to be affected by the release and to notify the State Emergency Response Commission (SERC) (or Tribal Emergency Response Commission (TERC)) of any state or Tribal region likely to be affected by the release. EPCRA section 304 also requires facilities to submit a follow-up written report to their SERC (or TERC) and the LEPC (or TEPC) as soon as practicable after the release. EPA published a guidance on July 13, 2010 (75 **Federal Register** (FR) 39852) defining the phrase, ''as soon as practicable'' to be 30 days after a release. (Note: Some states or Tribal Nations provide less than 30 days for submitting a follow-up report.) EPCRA section 304 requirements are codified in 40 CFR 355.30 to 355.43.[14]

In addition, when Federal agencies sell or transfer real property they must provide notice of the presence of hazardous substances in certain circumstances as required by CERCLA section 120(h). Furthermore, in certain circumstances, CERCLA 120(h) requires Federal agencies to provide a covenant warranting that ''all remedial action necessary to protect human health and the environment with respect to any [hazardous substances] remaining on the property has been taken before the date of such transfer, and any additional remedial action found to be necessary after the date of such transfer shall be conducted by the United States.''

While these are the only direct and automatic consequences of designating PFOA and PFOS hazardous substances for purposes of CERCLA, there are other, indirect impacts described above that should facilitate cleanups and reduce

[10] U.S. EPA. (2014). Certain perfluoroalkyl sulfonates. U.S. Environmental Protection Agency. Code of Federal Regulations. 40 CFR 721.9582. *https://www.govinfo.gov/content/pkg/CFR-2014-title40-vol31/pdf/CFR-2014-title40-vol31-sec721-9582.pdf.*

[11] Glüge, J; Scheringer, M; Cousins, IT; DeWitt, JC; Goldenman, G; Herzke, D; Lohmann, R; Ng, CA; Trier, X; Wang, Z. (2020). An overview of the uses of per-and polyfluoroalkyl substances (PFAS). Environ Sci Process Impacts 22: 2345–2373. *https://www.ncbi.nlm.nih.gov/pubmed/33125022.*

[12] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[13] *See* Office of Regulatory Enforcement, EPA, *Enforcement Response Policy for Sections 304, 311 and 312 of EPCRA and Section 103 of CERCLA* at 12 (Sept. 30, 1999), *available at https://www.epa.gov/enforcement/enforcement-response-policy-epcra-sections-304-311-312-and-cercla-section-103. See also https://www.epa.gov/epcra/definition-immediate-epcra-and-cercla-release-notification.*

[14] For additional information on release reporting requirements, see *https://www.epa.gov/faqs/search/topics/emergency-planning-and-community-right-know-304487/topics/release-notification-epcra-304cercla-103-30450.*

human and environmental exposure to these hazardous chemicals.

IV. Legal Authority

A. Background

CERCLA was enacted to promote the timely cleanup of contaminated sites and to ensure that parties responsible for the contamination bear the costs of such cleanups. CERCLA provides the Federal government with the authority to respond to releases or threatened releases of hazardous substances, and pollutants and contaminants in order to protect public health, welfare, and the environment. The statute confers considerable discretion upon the EPA in its exercise of these authorities. Other than the reporting requirements in the statute, CERCLA is not a traditional regulatory statute that prospectively regulates behavior; rather it is remedial in nature, generally designed to address contamination on a site-specific basis.

CERCLA required a significant update to the NCP, which provides the ''procedures and standards for responding to releases of hazardous substances, pollutants, and contaminants . . . .'' CERCLA section 105(a). The NCP is the blueprint for all aspects of the cleanup process, from the discovery of releases of contaminants, to responding to releases or threatened releases that require prompt response, and to prioritizing and developing longer-term remedial actions.

Once a Federal agency learns of a release or potential threat of a release of a hazardous substance, pollutant and/or contaminant, CERCLA authorizes response in one of three ways: by determining no action at the Federal level is warranted; by undertaking a removal action (if the situation presents a more immediate threat); or by assessing the relative risk of the release to other releases via the NPL listing process that is the first step towards a longer-term remedial action. Superfund cleanups typically begin with a preliminary assessment/site inspection, which includes reviews of historical information and site visits to evaluate the potential for a release of hazardous substances. EPA determines whether the site poses a threat to people and the environment and whether hazards need to be addressed immediately or additional site information will be collected. Federal entities other than EPA that respond to releases or threatened releases of hazardous substances, pollutants, or contaminants at Federal sites must similarly act consistent with CERCLA and the NCP. Finally, private parties responding to a release or threatened release at their facility must act consistent with CERCLA and the NCP in order to maintain CERCLA claims for recovery of response costs.

The nature of the subsequent response action depends upon the site-specific circumstances. Short-term ''removals'' are response actions that EPA and other Federal agencies may take to address releases or threatened releases requiring prompt action and are limited in cost and duration unless specific criteria are met. Long-term ''remedial'' actions permanently and significantly reduce the risks associated with releases or threats of releases that are serious and are typically associated with chronic exposures, but not immediately life-threatening. EPA can only conduct remedial actions at sites listed on EPA's National Priorities List (NPL). Additions to the NPL undergo notice-and-comment rulemaking. The NPL sites are among the worst hazardous substance sites identified by EPA. Only about 3% of the 53,400 assessed sites have been placed on the NPL. If a site is placed on the NPL, a Remedial Investigation/Feasibility Study is conducted to assess risks posed by releases of a hazardous substance, pollutant, or contaminant at the site by evaluating soil, surface water, ground water, and other media, and waste samples, and to analyze potential treatment methods or cleanup alternatives. EPA then summarizes those alternatives and offers its recommendation in a Proposed Plan, which undergoes a public comment process. The final decision on the cleanup is memorialized in a Record of Decision, which is accompanied by a responsiveness summary addressing the public comments. The specific details of the cleanup are then planned in the Remedial Design and finally carried out in the Remedial Action. Ultimately, the remedy must be one ''that is protective of human health and the environment, that is cost effective, and that utilizes permanent solutions and alternative treatment technologies or resource recovery technologies to the maximum extent practicable.'' CERCLA section 121(b)(1).

CERCLA provides authority for response actions to address releases of hazardous substances as well as releases of pollutants and contaminants. The authority conferred by CERCLA with regard to hazardous substances differs in a few respects from the authority with regard to pollutants and contaminants. With respect to *hazardous substances,* the Agency can conduct response actions if there is a release or threatened release without having to establish an imminent and substantial danger. In addition, the EPA can also recover costs from potentially responsible parties and require potentially responsible parties to conduct the cleanup themselves. CERCLA also authorizes persons (including private parties) that conduct cleanup activities that are consistent with the NCP to seek to recover cleanup costs from potentially responsible parties. With respect to releases or substantial threat of releases of *pollutants and contaminants,* EPA can respond if the Agency finds that the release or threat of release may present an imminent and substantial danger to the public health or welfare, and, generally, cannot require a private party to pay for or conduct the removal action.

Accordingly, CERCLA already provides significant authority to Federal agencies to address PFOA and PFOS releases because these two chemicals are pollutants and contaminants. Nonetheless, designating PFOA and PFOS as hazardous substances will likely increase the pace at which cleanups occur because it will allow the Federal government to require responsible private parties to address releases of PFOS and PFOA at sites without other ongoing cleanup activities, and allow the government and private parties to seek to recover cleanup costs from potentially responsible parties assuming relevant statutory criteria are met. As a result, risks from releases of PFOA and PFOS may be mitigated.

B. Explanation of Criteria for Designation Decisions

CERCLA section 101(14) sets out the definition of ''hazardous substance.'' There are two ways that a substance may be defined as a ''hazardous'' substance under CERCLA. The first is automatic where the substance is identified as hazardous or toxic pursuant to other specified environmental statutes (*e.g.,* chemicals listed as air toxics by Congress or EPA under section 112 of the Clean Air Act). The second is where the substance is designated as hazardous pursuant to CERCLA section 102. In this action, the Administrator is exercising his authority to designate under section 102.

1. Statutory Factors To Be Considered Under Section 102

The EPA Administrator is authorized under CERCLA section 102(a) to promulgate regulations designating as a hazardous substance:

(1) ''such elements, compounds, mixtures, solutions, and substances''

(2) ''which, when released into the environment''

(3) ''may present substantial danger''

(4) ''to the public health or welfare or the environment.''

The term ''hazardous substance'' is defined in section 101(14) of CERCLA primarily by reference to other environmental statutes and includes substances designated pursuant to CERCLA section 102. Pursuant to CERCLA section 101(14) the term hazardous substance means (A) any substances designated pursuant to section 311(b)(2)(A) of the Federal Water Pollution Control Act [33 U.S.C. 1321(b)(2)(A)], (B) any element, compound, mixture, solution, or substances designated pursuant to section 9602 of this title, (C) any hazardous waste having the characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act [42 U.S.C. 6921], (but not including any waste the regulation of which under the Solid Waste Disposal Act {42 U.S.C. 6901 *et seq.*] has been suspended by Act of Congress). (D) any toxic pollutant listed under section 307(a) of the Federal Water Pollution Control Act {33 U.S.C. 1317(a)], (E) any hazardous air pollutant listed under section 112 of the Clean Air Act [42 U.S.C. 7412], and (F) any imminently hazardous chemical substance or mixture with respect to which the Administrator has taken action pursuant to section 7 of the Toxic Substances Control Act [15 U.S.C. 2606]. The term does not include petroleum, including crude oil or any fraction thereof which is not otherwise specifically listed or designated as a hazardous substance under paragraphs (A) through (F) of this paragraph, and the term does not include natural gas, natural gas liquids, liquified natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas).

Because EPA has not exercised its authority under CERCLA section 102(a), it has not previously issued an interpretation of the standard for designating hazardous substances.

EPA proposes to interpret ''may present'' in the statutory language as indicating that Congress did not require certainty that the substance presents a substantial danger or require proof of actual harm. In assessing whether a substance, when released, may present ''substantial danger,'' [15] the EPA proposes to consider information such as the following: the potential harm to humans or the environment from exposure to the substance (*i.e.,* hazard), and how the substance moves and degrades when in the environment (*i.e.,* environmental fate and transport). To further inform its decision about whether the statutory factors have been met, the Agency proposes to also consider other information that may be relevant when evaluating releases of the substance, such as the frequency, nature and geographic scope of releases of the substances. The Agency proposes to weigh this information to determine whether the substance, when released, may present a ''substantial danger.''

2. CERCLA Section 102(a) Precludes Consideration of Cost

Given the specific standard Congress established for determining whether a substance is hazardous (*i.e.,* whether it ''may present substantial danger to the public health or welfare or the environment''), EPA proposes to interpret the language of CERCLA section 102(a) as precluding the Agency from taking cost into account in designating hazardous substances. Congress did not list cost as a required or permissible factor, and none of the Congressionally-listed statutory factors encompass a consideration of cleanup costs. Moreover, as a matter of common sense and straightforward reading, determining whether something is ''hazardous'' does not naturally lend itself to considerations of cost. A substance is or is not hazardous based on scientific and technical considerations. Subsequent determinations of *whether and how to address* something hazardous may involve considerations of cost, as CERCLA does in the context of response actions, as discussed below.

a. Consistency With Case Law

Reading CERCLA as precluding consideration of costs in hazardous substance designations is consistent with relevant Supreme Court precedent on cost consideration in rulemaking decisions. CERCLA section 102(a) is similar to Clean Air Act section 109(b)(1),[16] which governs EPA's setting of national ambient air quality standards (NAAQS) and which the Supreme Court said precludes consideration of costs. *Whitman* v. *American Trucking,* 531 U.S. 457 (2001). In his majority opinion, Justice Scalia explained,

> The EPA, ''based on'' the information about health effects contained in the technical ''criteria'' documents compiled under section 108(a)(2), 42 U.S.C. 7408(a)(2), is to identify the maximum airborne concentration of a pollutant that the public health can tolerate, decrease the concentration to provide an ''adequate'' margin of safety, and set the standard at that level. Nowhere are the costs of achieving such a standard made part of that initial calculation.

American Trucking, 531 U.S. at 465.

Similarly, CERCLA section 102(a) establishes a standard for designation that is tied exclusively to whether the release of a substance ''may present substantial danger to the public health or welfare or the environment.'' 42 U.S.C. 9602(a). Congress did not mention cost in this language that sets the standard for designation of hazardous substances.

Section 102(a)'s specific designation standard and its statutory context differentiate it from the broader statutory standard in Clean Air Act section 112(n)(1)(A), which the Supreme Court held requires EPA to consider costs in determining whether to regulate air toxic emissions from power plants in *Michigan* v. *EPA,* 576 U.S. 743 (2015). Clean Air Act section 112(n)(1)(A) states, in part,

> The Administrator shall regulate electric utility steam generating units under this section, if the Administrator finds such regulation is appropriate and necessary after considering the results of the study required by this paragraph.

42 U.S.C. 7412(n)(1)(A). The Supreme Court explained that ''appropriate'' is a broad term that ''includes consideration of all the relevant factors'' and when read in the context of Clean Air Act section 112(n)(1)(A) requires ''at least some attention to cost.'' *Michigan,* 576 U.S., at 752. In particular, the Court pointed to a study that was required by

[15] The EPA notes that the ''substantial danger'' language in CERCLA section 102(a) is similar to language in other parts of CERCLA but is interpreted in a different manner due to the contexts in which the language appears. Those other provisions (*see, e.g.,* CERCLA sections 104, 105, 106, and 128) concern enforcement and response actions and apply to and require analyses of site-specific circumstances relevant to a particular facility or person, and to an event. By contrast, the statutory objectives associated with designating hazardous substances under CERCLA section 102(a) warrant a different implementation strategy because of its broader applicability and analytical requirements. The standard for CERCLA section 102(a) in this notice is based on the specific language and purpose of section 102(a) and does not affect EPA's interpretations of other CERCLA provisions. *See Utility Air Regulatory Group* v. *EPA,* 573 U.S. 302, 320 (2014) (finding that statutory terms, even those that are defined in the statute, ''may take on distinct characters from association with distinct statutory objects calling for different implementation strategies.'').

[16] ''National primary ambient air quality standards, prescribed under paragraph (a) shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such primary standards may be revised in the same manner as promulgated.'' 42 U.S.C. 7409(b)(1).

the same paragraph (*i.e.,* Clean Air Act section 112(n)(1)), and noted both that Congress required that this study address cost (among other factors), and that EPA said that study helped provide a ''framework'' for EPA's decision under Clean Air Act section 112(n)(1). Given this context, in interpreting the Clean Air Act section 112(n)(1)'s ''appropriate and necessary'' standard for triggering regulation of air toxics from power plants, the Court held that EPA must consider cost in deciding whether to regulate power plants.

The standard for designation in CERCLA section 102(a) is significantly more circumscribed than the standard at issue in *Michigan.* As noted above, in CERCLA section 102(a), Congress specified a public health and welfare and environment standard governing EPA's designation decisions that did not include cost. In these circumstances, *Michigan* acknowledged that:

American Trucking thus establishes the modest principle that where the Clean Air Act expressly directs EPA to regulate on the basis of a factor that on its face does not include cost, the Act normally should not be read as implicitly allowing the Agency to consider cost anyway.

Id. at 755–56. Because CERCLA section 102(a) specifies the standard that EPA is to use, and it wholly relates to danger to public health, welfare, or the environment, cost should not be read in as an additional consideration. Furthermore, CERCLA section 102(a) is lacking provisions that indicate Congressional intent to take cost into account—unlike CAA section 112(n)(1), which had cost elements in provisions that the Court and EPA said were relevant to interpreting the ''appropriate and necessary'' standard.

CERCLA section 102(a) does use the word ''appropriate'' (the Administrator shall ''promulgate and revise as may be appropriate'' regulations designating hazardous substances), but significantly, the word ''appropriate'' is not used in the context of what EPA should consider when assessing whether a substance is hazardous. And as the Michigan Court noted, ''appropriate and necessary'' does not always encompass cost, context matters. See *Michigan,* 576 U.S. at 752. Under CAA section 112(n)(1), the substantive standard is nothing more than whether regulation is ''appropriate and necessary'' and, to the extent Congress provided a contextual indication about the meaning of that capacious phrase, it indicated that cost was relevant. In contrast, under CERCLA section 102(a), the Administrator is to promulgate and revise as may be appropriate regulations that accomplish the statutory goal of designating hazardous substances—and the guidance Congress provided was that the Administrator should look to specific criteria that do not include cost. Thus, EPA's authority to designate a substance as hazardous is tied solely to a finding that, when released, the substance may present a substantial danger to public health or welfare or the environment.

In addition, the Court in both *American Trucking* and *Michigan,* looked to the overall statutory scheme to determine whether cost should be considered as part of the Agency's determination. The role of a hazardous substance designation in the overall structure of CERCLA is much closer to the role of a national ambient air quality standard in the overall structure of the NAAQS program than it is to the role of the appropriate and necessary finding in regulating air toxic emissions from power plants.

Under CERCLA, the only automatic, private party obligation that flows from designation as a CERCLA hazardous substance under section 102(a) is the obligation to report releases (a relatively small cost). As discussed above, designation does not lead automatically to any response action obligations. CERCLA response actions, which include investigations of hazardous substance releases and determining if removal or remedial action is necessary, are contingent, discretionary, and site-specific actions.[17] EPA prioritizes the highest-risk sites under CERCLA (and that listing process is open to public comment); the process for selecting remedies includes public notice and comment (such as on the remedial action objectives and the consideration of remedial alternatives); and cost considerations, among other important factors such as protectiveness, are part of CERCLA's site-specific cleanup approach.

For both the hazardous substance designation in CERCLA and the setting of a NAAQS, there are later steps in the program where cost can be taken into account before specific requirements are imposed on entities subject to the programs. In contrast, in *Michigan,* the Court seemed to weigh heavily the fact that, if regulations are ''appropriate and necessary'' under section 112(n)(1)(A), then, without regard to cost, ''the Agency must promulgate certain minimum emission regulations, known as floor standards.'' *Michigan,* 576 U.S., at 748.

Furthermore, the designation of a hazardous substance under CERCLA section 102(a) in some cases does not create *new* costs, but rather allows costs to be shifted from the taxpayer to parties responsible for pollution under CERCLA. Even in those circumstances, where the government is able to transfer costs, a private party's ability to pay response costs is taken into account under the statute and in EPA's implementation of the statute.[18]

The interpretation that section 102(a) precludes the consideration of cost in designation decisions is also supported by the Court of Appeals for the D.C. Circuit. In *Utility Solid Waste Activities Group* v. *EPA,* 901 F.3d 414 (D.C. Cir. 2018), the D.C. Circuit, relying on *Michigan* and *American Trucking,* upheld EPA's decision that it should not have considered cost in establishing requirements under the Resource Conservation and Recovery Act (RCRA) for disposing of coal combustion residuals because the statutory standard only addresses ''adverse effects on health or the environment'' without mentioning costs or including other language that could encompass cost.

Based in part on Supreme Court decisions addressing statutory interpretation and the D.C. Circuit's application of those decisions, EPA proposes to interpret CERCLA section 102(a) as precluding consideration of costs in hazardous substance designations.

b. Consistency With Statutory Structure

The way CERCLA initially established the list of hazardous substances shows that Congress did not intend for costs to be considered in designation decisions. As noted above, CERCLA offers two ways for a substance to be designated as hazardous. One is a finding pursuant to CERCLA section 102. Another is the list of other statutory provisions in CERCLA section 101(14) that identify hazardous and toxic substances. In that section, Congress directed that the definition of

[17] As noted below in section IV.B.2.c. and the *Economic Assessment,* the multiple, contingent, discretionary and site-specific steps between designation of a hazardous substance and the incurrence of cleanup costs contribute to the inability to quantify costs at the designation stage. The uncertainty at this stage, when contrasted with the greater certainty and explicit consideration of costs during the later cleanup selection process, further supports EPA's proposed interpretation that CERCLA precludes consideration of costs when designating a hazardous substance.

[18] *See* Memorandum from Susan Shinkman, Director, Office of Civil Enforcement, and Cynthia Mackey, Director, Office of Site Remediation Enforcement, US EPA (June 29, 2015) (Guidance on Evaluating a Violator's Ability to Pay a Civil Penalty in an Administrative Enforcement Action); Memorandum from Barry Breen, Director, Office of Site Remediation Enforcement, US EPA (Sep. 30, 1997) (General Policy on Superfund Ability to Pay Determinations).

''hazardous substance'' includes all substances identified as hazardous or toxic by Congress or EPA under other specified environmental statutes:

- Clean Water Act section 311(b)(2)(A) hazardous substances;
- Resource Conservation and Recovery Act section 3001 hazardous wastes;
- Clean Water Act section 307(a) toxic pollutants;
- Clean Air Act section 112 hazardous air pollutants; and
- Toxic Substances Control Act section 7 imminently hazardous chemical.

When EPA adds a substance or chemical for regulation under any of those other statutory provisions, it also becomes a CERCLA hazardous substance—without considering the resulting costs under CERCLA.

In addition to the other statutory provisions listed above, CERCLA section 101(14) also includes CERCLA section 102(a), which suggests it should be interpreted in a manner similar to the other authorities on the list. Under the other statutory provisions, that program's compliance costs are not considered a factor or criteria in making listing decisions,[19] and the Agency proposes to interpret CERCLA section 102(a) as similarly excluding consideration of cost.

c. Costs

While EPA proposes to interpret CERCLA section 102(a) as excluding consideration of cost in a designation decision, the Agency is soliciting comment on that interpretation and, if costs should be considered, how they should be considered. See section IV.B.2.d. below.

EPA has estimated parties' potential direct costs associated with this designation decision (from reporting releases); they are relatively small and would not impede a designation decision even if the Agency were required to consider costs.

It is impractical, however, to quantitatively assess the indirect costs (for response actions) associated with a designation decision because of the uncertainty about such costs at this early stage in in the process. However, a qualitative discussion of indirect costs and benefits, as well as details explaining the impracticality of quantitative estimates are contained in the *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances*.[20] Possible indirect costs could arise from an increased number of sites identified, assessed and/or remediated, and from associated research and development. In addition, economic costs could be offset by savings from faster and more efficient response actions. Possible indirect benefits could include reduced health effects such as cancer, immunological problems, high cholesterol, and thyroid disorders resulting from earlier and greater numbers of response actions due to release reporting, and application of enhanced response authority.

A designation alone does not require the EPA to take response actions, does not require any response action by a private party, and does not determine liability for hazardous substance release response costs.

Response actions are contingent, discretionary, and site-specific decisions made after a hazardous substance release or threatened release. They are contingent upon a series of separate discretionary actions and meeting certain statutory and regulatory requirements, as explained above. In addition, future discretionary decisions about cleanup and response are difficult to quantify due to numerous, significant uncertainties such as: (1) How many sites have PFOA or PFOS contamination at a level that warrants a cleanup action; (2) the extent and type of PFOA and PFOS contamination at/near sites; (3) the extent and type of other contamination at/near sites; (4) the incremental cost of assessing and remediating the PFOA and/or PFOS contamination at/near these sites; and (5) the cleanup level required for these substances.

d. Request for Comment

EPA proposes to interpret CERCLA section 102(a) as prohibiting the Agency from considering cost as part of its decision to designate hazardous substances, EPA is taking comment on its approach to the consideration of costs, including: (1) Whether CERCLA section 102(a) precludes, allows, or requires consideration of cost in designation decisions, and, if so, (2) which costs and benefits of those discussed in the EA should be considered, (3) whether additional benefits and costs not identified in the EA should be considered, (4) if indirect benefits and costs are considered, how they should be assessed in light of the discretion and uncertainties described above, (5) how benefits and costs could be incorporated into the designation decision, and (6) whether designation would be justified if costs were to be considered in the Agency's designation decision. In addition, the *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances* includes requests for comments on several topics related to indirect costs that EPA does not currently have robust information about. Please see Section ES–5 of the *Economic Assessment* for specific details.

V. Designation of PFOA, PFOS, and Their Salts and Structural Isomers as Hazardous Substances

A. Introduction

The EPA is proposing to designate PFOA and PFOS as hazardous substances because significant evidence indicates that they satisfy the statutory criteria set forth in CERCLA section 102(a):

(1) They are ''substances'' as described in section IV.B.;

(2) They may be ''released into the environment'' as described in section IV.B.;

(3) They may present substantial danger as described in section V; and

(4) That danger is ''to the public health or welfare or the environment'' as described in section V.

While EPA acknowledges that the science regarding PFOA and PFOS human health and environmental effects is still evolving, a significant body of scientific evidence shows that PFOA and PFOS are persistent and mobile in the environment, and that exposure to PFOA and PFOS may lead to adverse human health effects. Assessments conducted by EPA, other Federal, state, Tribal and international agencies, academia, non-profit organizations and the private sector support the conclusion that PFOA and PFOS warrant a hazardous substance designation. This conclusion is based on the factors considered by EPA in this proposal, which, as noted above, included the potential human health or environmental hazards associated with exposure to PFOA and PFOS and the environmental fate and transport of PFOA and PFOS. The evidence for concern about PFOA and PFOS includes:

- Chemical/Physical Characteristics
- Toxicity and Toxicokinetics

[19] *See, e.g.,* 42 U.S.C. 6921(a) (RCRA section 3001(a)); 42 U.S.C. 7412(b)(2) (Clean Air Act section 112(b)(2).

[20] U.S. EPA (2022) Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances.

- Environmental Prevalence

Each of the above evidence categories are discussed in more detail below. PFOA and PFOS hazardous substance designation would be consistent with and supportive of many other actions taken by EPA, other Federal agencies, states, Tribal Nations and international bodies. These entities have set PFOA and PFOS benchmarks and standards and have undertaken PFOA- and PFOS-based regulatory activities and enforcement actions. Details are provided below.

B. What is the evidence for designation of PFOA and PFOS as hazardous substances?

A significant collection of evidence and actions support designating PFOA and PFOS as hazardous substances under CERCLA section 102(a). EPA is proposing that, when released into the environment, PFOA and PFOS may present substantial danger to the public health or welfare or the environment. What follows are brief summaries and not a comprehensive review of the available literature.

1. Chemical/Physical Characteristics

PFOA and PFOS are persistent chemicals that bioaccumulate, and exposure to PFOA and PFOS may cause adverse human health effects. PFOA and PFOS are distinctive from many other bioaccumulative chemicals because their water-solubility allows them to migrate readily from soil to groundwater. If PFOA and PFOS are released into the environment, they can contaminate surface water and groundwater used as drinking water sources and persist for long periods of time, thereby posing a direct threat to human health and the environment.

PFOA is comprised of eight carbons, seven of which are fully fluorinated, and the eighth carbon is part of a carboxylic acid group. PFOA is considered a surfactant (*i.e.,* a substance that tends to reduce the surface tension of a liquid in which it is dissolved) due to its chemical structure consisting of a hydrophobic perfluorinated alkyl ''tail group'' and a hydrophilic carboxylate ''head group''.[21] [22] As a result of the head group, PFOA is water soluble, which contributes to its tendency to be found in groundwater.

PFOA is produced and used mainly as ammonium perfluorooctanoate (APFO), a salt of PFOA, that may include both linear and branched isomers. APFO's isomeric composition depends on the manufacturing processes used. The APFO that is produced through the perfluorooctyl iodide oxidation process, commonly called telomerization, is >99 percent linear, and the APFO that is produced by the ECF process is >70 percent linear with the remaining <30 percent a mixture of branched isomers.[23] [24] As a result, there are different PFOA structural isomers that may be released and found in the environment. Analytical chemistry methods used to detect and measure PFOA may measure the different isomers separately.

PFOS has a fully fluorinated eight-carbon linear or branched tail, with a hydrophilic sulfonate functional head group attached to the carbon tail. PFOS is manufactured from perfluorooctanesulfonyl fluoride (POSF), which is produced through ECF. This process results in linear and branched isomers of PFOS.[25] PFOS is often produced as its potassium salt. Like PFOA, PFOS is water soluble, which is why it can be found in groundwater.

As noted above, PFOA and PFOS contain carbon atoms bonded to fluorine atoms. These carbon-fluorine bonds are strong, causing PFOA and PFOS to be extremely resistant to degradation in the environment (including biodegradation, photolysis and hydrolysis) and, thus, likely to persist for long periods of time.[26] [27]

These chemical and physical characteristics of PFOA and PFOS, when viewed in combination with the information that follows, supports this proposed designation of these chemicals as CERCLA hazardous substances.

2. Toxicity and Toxicokinetics

Exposure to PFOA and PFOS is associated with a variety of adverse human health effects. Human studies have found associations between PFOA and/or PFOS exposure and effects on the immune system, the cardiovascular system, human development (*e.g.,* decreased birth weight), and cancer. EPA continues to conduct extensive evaluations of human epidemiological and experimental animal study data to support the development of a PFAS National Primary Drinking Water Regulation. In November 2021, EPA released draft updated health effects analyses for PFOA and PFOS; these analyses are undergoing Science Advisory Board (SAB) review. EPA evaluated over 400 peer-reviewed studies published since 2016 and used new approaches, tools, and models to identify and evaluate the information. Based on the new data and draft analyses, the levels at which negative health effects could occur are much lower than previously understood when EPA issued the 2016 Health Advisories for PFOA and PFOS (70 ppt).

The following discussion is based on information and conclusions from the EPA 2016 Health Effects Support Documents for PFOA [28] and PFOS [29] and other published peer reviewed science. The weight of scientific evidence presented in the Health Effects Support Documents for PFOA [30] and

[21] ChEBI. (2017). ChEBI:35549—perfluorooctanoic acid. Chemical Entities of Biological Interest. European Molecular Biology Laboratory, European Bioinformatics Institute. *https://www.ebi.ac.uk/chebi/searchId.do?chebiId=CHEBI:35549.*

[22] Lindstrom, AB; Strynar, MJ; Libelo, EL. (2011). Polyfluorinated compounds: past, present, and future. Environ Sci Technol 45: 7954–7961. *https://www.ncbi.nlm.nih.gov/pubmed/21866930.*

[23] European Commission. (2015). Analysis of the risks arising from the industrial use of perfluorooctanoic acid (PFOA) and ammonium perfluorooctonate (APFO) and from their use in consumer articles. Evaluation and risk reduction measures for potential restrictions on the manufacture, placing on the market and use of PFOA and APFO. (TOX08.7049). European Commission, Enterprise and Industry Directorate—General. *https://ec.europa.eu/docsroom/documents/13037/attachments/1/translations/en/renditions/pdf.*

[24] Buck, RC; Franklin, J; Berger, U; Conder, JM; Cousins, IT; de Voogt, P; Jensen, AA; Kannan, K; Mabury, SA; van Leeuwen, SP. (2011). Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins. Integr Environ Assess Manag 7: 513–541. *https://www.ncbi.nlm.nih.gov/pubmed/21793199.*

[25] OECD. (2002). Hazard assessment of perfluorooctane sulfonate (PFOS) and its salts. Environment Directorate, Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, Co-operation on Existing Chemicals. (ENV/JM/RD(2002)17/FINAL. JT00135607). Organisation for Economic Co-operation and Development. *https://www.oecd.org/env/ehs/risk-assessment/2382880.pdf.*

[26] U.S. EPA. (2016). Drinking water health advisory for perfluorooctanoic acid (PFOA). (EPA822R16005). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_health_advisory_final_508.pdf.*

[27] U.S. EPA. (2016). Drinking water health advisory for perfluorooctane sulfonate (PFOS). (EPA822R16004). U.S. Environmental Protection Agency. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_health_advisory_final_508.pdf.*

[28] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

[29] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[30] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

PFOS [31] and supporting documents for the Regulatory Determination 4 process [32] supports the conclusion that exposure to PFOA and PFOS can lead to adverse human health effects. As part of the final Regulatory Determination 4 process, the Agency concluded that exposure to PFOA and PFOS may have adverse health effects.[33]

Data from human and animal studies indicate that PFOA and PFOS are well absorbed via the oral route and are distributed throughout the body by noncovalent binding to serum albumin and other plasma proteins. PFOA and PFOS are slowly eliminated from the human body as evidenced by the half-life of 2.1–10.1 years for PFOA and 3.3–27 years for PFOS.[34] Because of their resistance to metabolic degradation, PFOA and PFOS are eliminated from mammals primarily unchanged.

Human epidemiology studies observed associations between PFOA exposure and high cholesterol, changes in liver enzymes, decreased immune response to vaccination, thyroid effects, pregnancy-induced hypertension and preeclampsia, low birth weight, and cancer (testicular and kidney).[35] Epidemiology studies have generally found a positive association between increasing serum PFOA and total cholesterol levels in PFOA-exposed workers and residents of high-exposure communities. In addition, associations between increasing serum PFOA concentrations and elevations in serum levels of alanine aminotransferase and gamma-glutamyl transpeptidase were consistently observed in occupational cohorts, high-exposure communities and the U.S. general population. This could indicate the potential for PFOA to affect liver function. A decreased response to vaccines was found to be associated with PFOA exposure in studies in adults in a highly exposed community and in studies of children in the general population. A study of a community with high exposure to PFOA observed an association between serum PFOA and risk of pregnancy-related hypertension or preeclampsia, conditions that are related to renal function during pregnancy. An association between increasing maternal PFOA or cord blood PFOA concentrations and decreasing birth weight was seen in several studies.[36]

Numerous epidemiology studies have examined occupational populations at large-scale PFOS production plants in the United States and the residential populations living near the PFOS production facilities to evaluate the association between increasing PFOS concentrations and various health outcomes. Data also suggest associations between higher PFOS levels and increases in total cholesterol and high-density lipoproteins, decreases in female fecundity and fertility, in addition to decreased offspring body weights and negative effects on other measures of postnatal growth. Evidence of an association between PFOS exposure and cancer is less conclusive.[37]

Perfluoroalkyl acids are transferred to the fetus during pregnancy and to breast milk through distribution due to their slow elimination from the human body through excretion.[38] Toxicity studies conducted in laboratory animal models demonstrate that the developing fetus is particularly sensitive to PFOA- and PFOS-induced toxicity. Some studies in laboratory animal models indicate that gestation and/or lactation periods are critical exposure windows that may lead to developmental health effects including decreased offspring survival, low birth weight, accelerated puberty and skeletal variations.[39] [40] [41]

Numerous animal toxicity studies for PFOA and PFOS are available and provide information about the potential for similar effects in humans. Animal studies and epidemiology studies indicate that PFOA and PFOS are well absorbed orally; absorption may also occur via the inhalation and dermal routes. Absorbed PFOA and/or PFOS are widely distributed in the body, with the highest concentrations typically found in the blood, liver and/or kidney. Across species, the highest extravascular concentrations of PFOA and PFOS are found in the liver, however, PFOA and/or PFOS have also been detected in many other tissues (*e.g.,* lung, kidney, spleen and bone). Though not readily, PFOS can cross the blood-brain barrier and has been detected at low levels in the brains of humans and rodents.[42] [43] [44]

PFOA and PFOS in blood bind to plasma albumin and other plasma proteins. Absorbed PFOA and PFOS are not metabolized and are eliminated by excretion primarily in urine. Active transport mechanisms mediate renal tubular reabsorption and secretion of PFOA and PFOS. Some excretion occurs through cord blood in pregnant women, and through lactation and menstrual blood loss. Although PFOA and PFOS are found in the bile of humans, they are reabsorbed from the bile and thus, fecal excretion is substantially lower than urinary excretion; levels in fecal matter represent both unabsorbed material and that discharged with bile.[45] [46] [47] [48] [49]

[31] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[32] U.S. EPA. (2021). Final regulatory determination 4 support document. (EPA815R21001). U.S. Environmental Protection Agency.

[33] Ibid.

[34] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[35] Ibid.

[36] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

[37] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[38] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[39] Ibid.

[40] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

[41] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[42] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[43] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

[44] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[45] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[46] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

[47] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[48] NJDWQI. (2017). Appendix A: Health-based maximum contaminant level support document perfluorooctanoic acid (PFOA). New Jersey Drinking Water Quality Institute, Health Effects

Continued

For PFOA, oral studies of short-term (subchronic) and chronic duration are available in multiple species including monkeys, rats and mice. The animal studies report developmental effects, liver and kidney toxicity, immune effects and cancer (liver, testicular and pancreatic). The developmental effects observed in rodents include decreased survival, delayed eye opening, reduced ossification, skeletal defects, altered puberty (delayed vaginal opening in females and accelerated puberty in males) and altered mammary gland development.

For PFOS, numerous animal studies are available in multiple species including monkeys, rats and mice. Short-term and chronic exposure studies in animals demonstrate increases in liver weight, changes in cholesterol, hepatic steatosis, lower body weight and liver histopathological changes. One- and two- generation rodent toxicity studies also show decreased pup survival and body weights. Additionally, developmental neurotoxicity studies in rodents show increased motor activity, decreased habituation and increased escape latency in the water maze test (tests spatial learning and memory) following *in utero* and lactational exposure to PFOS. Gestational and lactational exposures were also associated with higher serum glucose levels and evidence of insulin resistance in adult offspring. Evidence suggests immunological effects in animal models.[50] [51]

The International Agency for Research on Cancer (IARC) concluded that PFOA is possibly carcinogenic to humans.[52] Study findings are mixed. While a mutagenic mode of action has not been established for PFOA or PFOS, studies indicate that PFOA (the more extensively studied of the two compounds) can induce deoxyribonucleic acid (DNA) damage.[53] In 2016, the EPA determined there is suggestive evidence that PFOA and PFOS may contribute to tumor development in humans.[54] [55] Epidemiology studies show an association between exposure to high levels of serum PFOA and testicular and kidney cancer in humans; two chronic bioassays in rats [56] [57] also support the finding that PFOA is tumorigenic (*i.e.,* capable of producing tumors).[58] Epidemiology studies establishing a correlation between PFOS exposure and the incidence of cancer are limited; however, a chronic toxicity and carcinogenicity study in rats provides some evidence of tumorigenicity.[59]

This information does not reflect recent scientific data that has been collected to support EPA's ongoing PFAS National Primary Drinking Water Regulation. The Agency's draft new analyses, released in November 2021 for independent scientific review by the EPA Science Advisory Board (SAB), indicate that negative health effects may occur at much lower levels of exposure to PFOA and PFOS than previously understood and that PFOA is likely carcinogenic to humans. The draft documents present EPA's initial analysis and findings with respect to this newly available updated information.[60] [61] Following SAB peer review, the final documents will be used to inform the development of Maximum Contaminant Level Goals and ultimately a National Primary Drinking Water Regulation for PFOA and PFOS. While this preliminary data was not used for this proposal, it appears to support designating PFOA and PFOS as hazardous substances.

In sum, studies have shown that exposure to PFOA and PFOS is associated with numerous and varied adverse effects to human health. This evidence plays a major role in the EPA's proposal to designate PFOA and PFOS as hazardous substances.

3. Environmental Prevalence

PFOA and PFOS are common contaminants in the environment because of their release into the environment since the 1940s and their resistance to degradation. PFOA and PFOS are found in many environmental media and in wildlife worldwide, including in remote polar regions. As an example, the polar bear, the top predator of arctic marine ecosystems, bioaccumulates high concentrations of PFAS (especially PFOS), which may be harmful to their health.[62]

Environmental sources can include direct industrial discharges of PFOA and PFOS to soil, air, and water. Precursors can also degrade to PFOA and/or PFOS (*e.g.,* perfluorooctanesulfonamide (PFOSA) can be transformed to PFOS in the environment). PFOA and PFOS precursors can be converted to PFOA and PFOS, respectively, by microbes in soil, sludge, and wastewater and through abiotic chemical reactions. PFOA and PFOS that are deposited, created by the degradation of their precursors in industrial and consumer

Subcommittee. *https://www.state.nj.us/dep/watersupply/pdf/pfoa-appendixa.pdf*.

[49] NJDWQI. (2018). Appendix A: Health-based maximum contaminant level support document perfluorooctane sulfonate (PFOS). New Jersey Drinking Water Quality Institute, Health Effects Subcommittee. *https://www.state.nj.us/dep/watersupply/pdf/pfos-recommendation-appendix-a.pdf*.

[50] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237*.

[51] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf*.

[52] IARC. (2021). Agents classified by the IARC monographs, volumes 1–129. List of classifications. International Agency for Research on Cancer. *https://monographs.iarc.who.int/list-of-classifications*.

[53] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237*.

[54] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf*.

[55] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf*.

[56] NTP. (2020). NTP Technical report on the toxicology and carcinogenesis studies of perfluorooctanoic acid (CASRN 335–67–1) administered in feed to Sprague Dawley (Hsd:Sprague Dawley® SD®) rats. (NTP TR 598). Research Triangle Park, NC: National Toxicology Program. *https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr598_508.pdf?utm_source=direct&utm_medium=prod&utm_campaign=ntpgolinks&utm_term=tr598*.

[57] Butenhoff, J.L.; Kennedy, G.L.; Chang, S.; Olsen, G.W. (2012). Chronic dietary toxicity and carcinogenicity study with ammonium perfluorooctanoate in Sprague Dawley rats. Toxicology 298: 1–13.

[58] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf*.

[59] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf*.

[60] U.S. EPA. (2021). Proposed approaches for deriving maximum contaminant level goals for PFOA in drinking water. (EPA822D21001). U.S. Environmental Protection Agency.

[61] U.S. EPA. (2021). Proposed approaches for deriving maximum contaminant level goals for PFOS in drinking water. (EPA822D21002). U.S. Environmental Protection Agency.

[62] Tartu, S.; Bourgeon, S.; Aars, J.; Andersen, M.; Lone, K.; Jenssen, B.M.; Polder, A.; Thiemann, G.W.; Torget, V.; Welker, J.M.; Routti, H. (2017). Diet and metabolic state are the main factors determining concentrations of perfluoroalkyl substances in female polar bears from Svalbard. Environ Pollut 229: 146–158. *https://www.ncbi.nlm.nih.gov/pubmed/28587979*. Tartu et al. (2017) found that the concentration of PFAS increased with the trophic level of female polar bears, which is consistent with other studies showing biomagnification of PFAS in Arctic marine ecosystems.

waste, in a landfill without environmental controls can discharge via leachates, groundwater pollution/migration and atmospheric releases.[63] [64] [65] The discharge of aqueous film-forming foam (AFFF) starting in the 1970s is also an important source for some locations. AFFF is a foam containing many PFAS, including PFOA and PFOS, which is effective at extinguishing petroleum fueled fires. PFAS, including PFOA and PFOS, were found in the soil and groundwater where AFFF was used to fight fires or for training and storage. Concrete where AFFF has been repeatedly discharged, such as for training activities, can absorb PFAS, including PFOA and PFOS, and then release PFAS to groundwater and soils during precipitation events.[66]

Industrial uses that have led to PFOA and PFOS in the soil and groundwater include, but are not limited to, chrome plating facilities where PFAS were used as a wetting agent/fume suppressant and industries where textiles and other materials are coated with PFAS. PFAS manufactured for use as a stain or water repellant may be released from these facilities into the air and wastewater.[67]

The principal worldwide manufacturers of PFOA and PFOS and related chemicals phased out their production in the early 2000's. PFOA and PFOS may still be produced domestically for certain uses and by international companies that import treated products to the United States.[68] Some uses of PFOS are ongoing, such as use as a component of a photoresist substance, including a photo acid generator or surfactant, or as a component of an anti-reflective coating, used in a photomicrolithography process to produce semiconductors or similar components of electronic or other miniaturized devices. Environmental contamination and resulting human exposure to PFOA and PFOS are declining, but are anticipated to continue for the foreseeable future due to their environmental persistence, formation from precursor compounds, continued production primarily by international manufacturers and their long history of production in the United States.[69]

Wastewater treatment plants (WWTPs) may receive wastewater that contains PFOA, PFOS or their precursors, from a variety of sources, including industries that manufacture or use these PFAS and their precursors. Some companies may operate onsite wastewater treatment facilities, but typically they are not designed to remove PFAS. PFOA and PFOS are the most widely detected PFAS in wastewater, and generally treatment units at conventional WWTPs do not remove PFAS efficiently.[70] Certain PFAS can be volatilized into the atmosphere from wastewater treatment plant operations, such as aeration chambers.[71] [72] Although effluent discharged to receiving water bodies may contain PFOA or PFOS, much of these substances may concentrate in the WWTP biosolids. Biosolids are also commonly applied to land as fertilizers or soil amendments but can also be sent to a landfill. The use of biosolids on farmland and home gardens can lead to the uptake of PFOA and PFOS in the food chain, as acknowledged by the U.S. Food and Drug Administration (FDA).[73] Biosolids from wastewater treatment plants and some industrial wastewater that is land applied are also potential sources of contamination.[74] [75]

PFAS have been found in outdoor air at locations in the United States, Europe, Japan, and over the Atlantic Ocean.[76] Concentrations are not generally correlated with rural or urban environments, but rather, around PFAS production industries and industries that use PFAS. Mean PFOA levels ranged from 1.54 to 15.2 picograms per cubic meter (pg/m^3) in air samples collected in the urban locations in Albany, New York, Fukuchiyama, Japan, and Morioka, Japan and in the rural locations in Kjeller, Norway, and Mace Head, Ireland. However, higher mean concentrations (101–552 pg/m^3) were measured at the urban locations in Oyamazaki, Japan, and Manchester, United Kingdom (UK), and semirural locations in Hazelrigg, UK. Maximum reported concentrations at Oyamazaki and Hazelrigg were 919 and 828 pg/m^3, respectively. Thus, there is no correlation between higher concentrations and urban versus rural locations; rather, high concentrations in certain locations may be attributable to a specific industrial plant.[77]

PFOA and PFOS are widely detected in surface water samples collected from various rivers, lakes, and streams in the United States.[78] Therefore, municipalities and other entities that use surface water sources for drinking water may face challenges treating and removing PFOA and PFAS from their finished drinking water. The most vulnerable drinking water systems are those in close proximity to sites contaminated with PFOA and PFOS.[79] Levels of these substances in surface water are declining since the major U.S.

[63] Lindstrom, A.B.; Strynar, M.J.; Libelo, E.L. (2011). Polyfluorinated compounds: past, present, and future. Environ Sci Technol 45: 7954–7961. *https://www.ncbi.nlm.nih.gov/pubmed/21866930*.

[64] Buck, R.C.; Franklin, J.; Berger, U.; Conder, J.M.; Cousins, I.T.; de Voogt, P.; Jensen, A.A.; Kannan, K.; Mabury, S.A.; van Leeuwen, S.P. (2011). Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins. Integr Environ Assess Manag 7: 513–541. *https://www.ncbi.nlm.nih.gov/pubmed/21793199*.

[65] Oliaei, F.; Kriens, D.; Weber, R.; Watson, A. (2013). PFOS and PFC releases and associated pollution from a PFC production plant in Minnesota (USA). Environ Sci Pollut Res Int 20: 1977–1992. *https://www.ncbi.nlm.nih.gov/pubmed/23128989*.

[66] Baduel, C.; Paxman, C.J.; Mueller, J.F. (2015). Perfluoroalkyl substances in a firefighting training ground (FTG), distribution and potential future release. J. Hazard Mater 296: 46–53. *https://www.ncbi.nlm.nih.gov/pubmed/25966923*.

[67] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237*.

[68] Ibid.

[69] (ATSDR) Per- and Polyfluoroalkyl Substances (PFAS) and Your Health U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html*.

[70] Rainey, M.; Beecher, N. (2018). PFAS in wastewater residuals. National Pretreatment & Pollution Prevention Workshop & Training. North East Biosolids & Residuals Association. *https://www.nacwa.org/docs/default-source/conferences-events/2018-pretreatment/18pret-m-rainey.pdf?sfvrsn=2*.

[71] Ma, R.; Shih, K. (2010). Perfluorochemicals in wastewater treatment plants and sediments in Hong Kong. Environ Pollut 158: 1354–1362. *https://www.ncbi.nlm.nih.gov/pubmed/20153098*.

[72] Ahrens, L.; Shoeib, M.; Harner, T.; Lee, S.C.; Guo, R.; Reiner, E.J. (2011). Wastewater treatment plant and landfills as sources of polyfluoroalkyl compounds to the atmosphere. Environ Sci Technol 45: 8098–8105. *https://www.ncbi.nlm.nih.gov/pubmed/21466185*.

[73] Genualdi, S.; deJager, L.; South, P.; Sheehan, J.; Begley, T. (2019). Investigation of PFAS concentrations in US food products. Center for Food Safety and Applied Nutrition, Food and Drug Administration. In SETAC Europe 29th annual meeting 26–30 May 2019 (pp. 357). Helsinki, Finland: Society of Environmental Toxicology and Chemistry.

[74] NJDWQI. (2018). Appendix A: Health-based maximum contaminant level support document perfluorooctane sulfonate (PFOS). New Jersey Drinking Water Quality Institute, Health Effects Subcommittee. *https://www.state.nj.us/dep/watersupply/pdf/pfos-recommendation-appendix-a.pdf*.

[75] NJDWQI. (2017). Appendix A: Health-based maximum contaminant level support document perfluorooctanoic acid (PFOA). New Jersey Drinking Water Quality Institute, Health Effects Subcommittee. *https://www.state.nj.us/dep/watersupply/pdf/pfoa-appendixa.pdf*.

[76] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://www.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237*.

[77] Ibid.

[78] Ibid.

[79] Ibid.

producers phased out these two substances.[80]

PFOA and PFOS have been detected in surface and subsurface soils. Levels of PFOA and PFOS generally increased with increasing depth at sampled locations, suggesting a downward movement of the contaminants and the potential to contaminate groundwater.[81] PFAS can be inadvertently released to soils when biosolids are applied as fertilizer to help maintain productive agricultural soils and stimulate plant growth.[82] PFOA and PFOS have been detected in both biosolids and biosolid-amended soils. PFAS can also reach soil due to atmospheric transport and wet/dry deposition.[83]

PFOA and PFOS have been detected in groundwater in monitoring wells, private drinking water wells, and public drinking water systems across the country. The EPA worked with the states and local communities to monitor for six PFAS, including PFOA and PFOS, under the third Unregulated Contaminant Monitoring Rule to understand the nationwide occurrence of these chemicals in the U.S. drinking water provided by public water systems (PWSs). Of the 4,920 PWSs with results for PFOA and PFOS, PFOA were detected above the minimum reporting level (minimum reporting level = 20 nanogram/liter (ng/L)) in 117 PWSs. Detections exceeded above the MRL for PFOS (MRL = 40 ng/L) at 95 PWSs.[84]

As previously stated, PFOA and PFOS are common contaminants in the environment because they and their precursors have been produced and released into the environment since the 1940s, and they are resistant to degradation. In addition to being found in groundwater, surface water, soil, sediment, and air, they have been found in wild and domestic animals such as fish, shellfish, alligators, deer and avian eggs; and in humans.[85] For example, PFOA has been found in snack foods, vegetables, meat, dairy products and fish, and PFOS has been found in eggs, milk, meat, fish and root vegetables.[86] [87] [88] [89] [90] [91] [92] [93] [94] [95] In one study investigating the global distribution of PFAS, wildlife samples were collected on four continents including North America and Antarctica. Wildlife sampled included marine mammals, birds, and polar bears. Only a few samples contained PFOA in concentrations greater than the limit of quantification. However, over 30 different species had measurable levels of PFOS. The study reported PFOS concentrations in mink liver in the midwestern U.S. ranging from 970–3, 680 nanograms per gram (ng/g), river otter liver in northwestern U.S. from 34–990 ng/g, brown pelican liver in Mississippi from 290–620 ng/g, and lake whitefish eggs in Michigan waters from 150–380 ng/g.[96] [97]

PFOS bioaccumulates in animals. A fish kinetic bioconcentration factor for PFOS has been estimated to range from 1,000 to 4,000.[98] The time to reach 50% clearance of PFOS in fish has been estimated to be around 100 days.[99] Bioaccumulation has been demonstrated for fish, birds, crustaceans, worms, plankton, and alligators, among others.[100] [101] [102]

PFOA bioaccumulates as well, but not to the same degree as PFOS.[103]

The prevalence of PFOA and PFOS in environmental media, wild animals, livestock, and plants not only affects the environment but can also lead to human exposure. PFOA and PFOS can also enter the drinking water supply from contamination in groundwater and surface water sources for drinking water. Contaminated drinking water or groundwater can also be used to irrigate or wash home-grown foods or farm-grown foods, thereby providing another means for human exposure. Wild animals are contaminated through environmental exposure, and some wild animals are caught or hunted and eaten by humans, thus, increasing human exposure. Contaminated water also results in the contamination of beef, pork, poultry, etc. Susceptible populations, such as women of reproductive age, pregnant and breastfeeding women, and young children who eat fish may have increased exposure to PFOA and PFOS due to bioaccumulation in fish.[104] [105] [106]

[80] Ibid.

[81] Ibid.

[82] Ibid.

[83] Ibid.

[84] U.S. EPA. (2017). The third Unregulated Contaminant Monitoring Rule (UCMR 3): Data summary, January 2017. (EPA815S17001). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf*.

[85] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html*.

[86] U.S. EPA. (2016). Drinking water health advisory for perfluorooctanoic acid (PFOA). (EPA822R16005). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_health_advisory_final_508.pdf*.

[87] U.S. EPA. (2016). Drinking water health advisory for perfluorooctane sulfonate (PFOS). (EPA822R16004). U.S. Environmental Protection Agency. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_health_advisory_final_508.pdf*.

[88] Holmstrom, K.E.; Jarnberg, U.; Bignert, A. (2005). Temporal trends of PFOS and PFOA in guillemot eggs from the Baltic Sea, 1968–2003. Environ Sci Technol 39: 80–84. *https://www.ncbi.nlm.nih.gov/pubmed/15667078*.

[89] Wang, Y.; Yeung, L.W.Y.; Yamashita, N.; Taniyasu, S.; So, M.K.; Murphy, M.B.; Lam, P.K.S. (2008). Perfluorooctane sulfonate (PFOS) and related fluorochemicals in chicken egg in China. Chinese Science Bulletin 53: 501–507.

[90] Gewurtz, S.B.; Martin, P.A.; Letcher, R.J.; Burgess, N.M.; Champoux, L.; Elliott, J.E.; Weseloh, D.V.C. (2016). Spatio-temporal trends and monitoring design of perfluoroalkyl acids in the eggs of gull (Larid) species from across Canada and parts of the United States. Sci Total Environ 565: 440–450. *https://www.ncbi.nlm.nih.gov/pubmed/27183458*.

[91] Morganti, M.; Polesello, S.; Pascariello, S.; Ferrario, C.; Rubolini, D.; Valsecchi, S.; Parolini, M. (2021). Exposure assessment of PFAS-contaminated sites using avian eggs as a biomonitoring tool: A frame of reference and a case study in the Po River valley (Northern Italy). Integr Environ Assess Manag 17: 733–745. *https://www.ncbi.nlm.nih.gov/pubmed/33764673*.

[92] *Michigan.gov*. (2021). Michigan PFAS Action Response Team: Fish and wildlife. PFAS in deer. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-86512_88981_88982—,00.html*.

[93] Wisconsin DNR. (2020). DNR And DHS issue do not eat advisory for deer liver in five-mile area surrounding JCI/TYCO site in Marinette. Wisconsin Department of Natural Resources. *https://dnr.wisconsin.gov/newsroom/release/37921*.

[94] Falk, S.; Brunn, H.; Schroter-Kermani, C.; Failing, K.; Georgii, S.; Tarricone, K.; Stahl, T. (2012). Temporal and spatial trends of perfluoroalkyl substances in liver of roe deer (Capreolus capreolus). Environ Pollut 171: 1–8. *https://www.ncbi.nlm.nih.gov/pubmed/22868342*.

[95] Bangma, J.T.; Reiner, J.L.; Jones, M.; Lowers, R.H.; Nilsen, F.; Rainwater, T.R.; Somerville, S.; Guillette, L.J.; Bowden, J.A. (2017). Variation in perfluoroalkyl acids in the American alligator (Alligator mississippiensis) at Merritt Island National Wildlife Refuge. Chemosphere 166: 72–79. *https://www.ncbi.nlm.nih.gov/pubmed/27689886*.

[96] Giesy, J.P.; Kannan, K. (2001). Global distribution of perfluorooctane sulfonate in wildlife. Environ Sci Technol 35: 1339–1342. *https://www.ncbi.nlm.nih.gov/pubmed/11348064*.

[97] EFSA. (2008). Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts Scientific Opinion of the Panel on Contaminants in the Food chain. EFSA Journal 6.

[98] Ibid.

[99] Ibid.

[100] Bangma, J.T.; Reiner, J.L.; Jones, M.; Lowers, R.H.; Nilsen, F.; Rainwater, T.R.; Somerville, S.; Guillette, L.J.; Bowden, J.A. (2017). Variation in perfluoroalkyl acids in the American alligator (Alligator mississippiensis) at Merritt Island National Wildlife Refuge. Chemosphere 166: 72–79. *https://www.ncbi.nlm.nih.gov/pubmed/27689886*.

[101] Ng, C.A.; Hungerbuhler, K. (2014). Bioaccumulation of perfluorinated alkyl acids: observations and models. Environ Sci Technol 48: 4637–4648. *https://www.ncbi.nlm.nih.gov/pubmed/24762048*.

[102] Burkhard, L.P. (2021). Evaluation of published bioconcentration factor (BCF) and bioaccumulation factor (BAF) data for per- and polyfluoroalkyl substances across aquatic species. Environ Toxicol Chem 40: 1530–1543. *https://www.ncbi.nlm.nih.gov/pubmed/33605484*.

[103] *https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/etc.5010*.

[104] U.S. EPA. (2019). Fish and shellfish program newsletter. (EPA823N19002). U.S. Environmental

Human exposure is confirmed by measurements of PFOA and PFOS that were detected in human serum as part of the continuous National Health and Nutrition Examination Survey (NHANES), a program of the CDC. PFOA and PFOS were measured in the serum of a representative sample of the U.S. population ages 12 years and older in each two-year cycle of NHANES since 1999–2000, with the exception of 2001–2002. PFOA and PFOS have been detected in 99% of those surveyed in each NHANES cycle. However, the mean concentrations of PFOA and PFOS in the serum have been steadily decreasing since 1999–2000.[107] [108]

Taken together, this information illustrates the prevalence of PFOA and PFOS in water, soil, air, plants, and animals worldwide due to its transportability and persistence. This widespread distribution of these PFAS significantly contributes to the EPA's proposed finding that PFOA and PFOS, when released into the environment may present substantial danger to the public health or welfare or the environment.

EPA's proposal to designate PFOA and PFOS, and their salts and structural isomers, as hazardous substances under CERCLA section 102(a) is based on significant evidence, summarized above, that indicates, when released into the environment, these substances may present substantial danger to the public health, welfare or the environment. Collectively, this information demonstrates that PFOA and PFOS should be designated as hazardous substances under CERCLA.

VI. Effect of Designation

The designation of PFOA and PFOS would have three direct effects—triggering reporting obligations when there is a release of PFOA or PFOS above the reportable quantity, obligations on the U.S. Government when it transfers certain properties, and an obligation on DOT to list and regulate CERCLA designated hazardous substances as hazardous materials.

A. Default Reportable Quantity

Section 102(b) of CERCLA provides that, until superseded by regulation, the reportable quantity for any hazardous substance is one pound. This proposed rule does not include an RQ adjustment for PFOA or PFOS. EPA is setting the RQ by operation of law at the statutory default of one pound pursuant to Section 102(b) of CERCLA. If the Agency chooses to propose adjusting the RQ in the future, it would do so through notice-and-comment rulemaking.

B. Direct Effects of a Hazardous Substance Designation

1. Reporting and Notification Requirements for CERCLA Hazardous Substances

Section 103 of CERCLA requires any person in charge of a vessel or facility to immediately notify the NRC when there is a release of a hazardous substance, as defined under CERCLA section 101(14), in an amount equal to or greater than the RQ for that substance. The reporting requirements are further codified in 40 CFR 302.6. If this action is finalized, any person in charge of a vessel or facility as soon as he or she has knowledge of a release from such vessel or facility of one pound or more of PFOA or PFOS in a 24-hour period is required to immediately notify the NRC in accordance with 40 CFR part 302. EPA solicits comment on the number of small entities affected by and the estimated cost impacts on small entities from these reporting requirements.

In addition to these CERCLA reporting requirements, EPCRA section 304 also requires owners or operators of facilities to immediately notify their SERC (or TERC) and LEPC (or TEPC) when there is a release of a CERCLA hazardous substance in an amount equal to or greater than the RQ for that substance within a 24-hour period. EPCRA section 304 requires these facilities to submit a follow-up written report to the SERC (or TERC) and LEPC (or TEPC) within 30 days of the release. (Note: Some states provide less than 30 days to submit the follow-up written report. Facilities are encouraged to contact the appropriate state or tribal agency for additional reporting requirements.) See 40 CFR part 355, subpart C, for information on the contents for the initial telephone notification and the follow-up written report.

EPCRA and CERCLA are separate, but interrelated, environmental laws that work together to provide emergency release notifications to Federal, state, Tribal, and local officials. Notice given to the NRC under CERCLA serves to inform the Federal government of a release so that Federal personnel can evaluate the need for a response in accordance with the National Oil and Hazardous Substances Contingency Plan, the Federal government's framework for responding to both oil and hazardous substance releases. The NRC maintains all reports of hazardous substance and oil releases made to the Federal government.

Relatedly, release notifications under EPCRA given to the SERC (or TERC) and to the LEPC (or TEPC) are crucial so that these state, Tribal, and local authorities have information to help protect the community.

2. Requirements Upon Transfer of Government Property

Under CERCLA section 120(h), when Federal agencies sell or transfer federally-owned, real property, they must provide notice of when any hazardous substances ''was stored for one year or more, known to have been released, or disposed of'' and covenants concerning the remediation of such hazardous substances in certain circumstances.

3. Requirement of DOT To List and Regulate CERCLA Hazardous Substances

Section 306(a) of CERCLA requires substances designated as hazardous under CERCLA be listed and regulated as hazardous materials by DOT under the Hazardous Materials Transportation Act (HMTA). DOT typically does not undertake a public notice and comment period when adding a CERCLA-designated hazardous substance to the list of regulated hazardous materials under HMTA.

VII. Regulatory and Advisory Status at EPA, Other Federal, State and International Agencies

Designating PFOA and PFOS as hazardous substances would be one additional piece of an extensive, widespread response to address the dangers these chemicals pose. Regulatory requirements, enforcement actions, and other activities of many Federal, state, and international entities together indicate the widespread and serious concern with PFOA and PFOS.

Protection Agency. *https://www.epa.gov/sites/production/files/2019-04/documents/fish-news-mar2019.pdf.*

[105] FDA. (2021). Testing food for PFAS and assessing dietary exposure. U.S. Food and Drug Administration. *https://www.fda.gov/food/chemical-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure.*

[106] Christensen, K.Y.; Raymond, M.; Blackowicz, M.; Liu, Y.; Thompson, B.A.; Anderson, H.A.; Turyk, M. (2017). Perfluoroalkyl substances and fish consumption. Environ Res 154: 145–151. *https://www.ncbi.nlm.nih.gov/pubmed/28073048.*

[107] CDC. (2021). National Health and Nutrition Examination Survey: NHANES questionnaires, datasets, and related documentation. Centers for Disease Control and Prevention. *https://wwwn.cdc.gov/nchs/nhanes/Default.aspx.*

[108] U.S. EPA. (2019). EPA's per- and polyfluoroalkyl substances (PFAS) action plan. (EPA823R18004). U.S. Environmental Protection Agency. *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100W32I.txt.*

A. EPA Actions

The EPA has taken several actions in the past to address risks from PFOA and PFOS. In 2006, the EPA launched the 2010/2015 PFOA Stewardship Program, under which eight major chemical manufacturers and processors agreed to phase out the use of PFOA and PFOA-related chemicals in their products and emissions from their facilities. All companies met the PFOA Stewardship Program goals by 2015.

The TSCA program has taken a range of regulatory actions to address PFAS in manufacturing and consumer products. Since 2002, EPA has finalized a number of TSCA Section 5(a) Significant New Use Rules (SNURs) covering hundreds of existing PFAS no longer in use. These regulatory actions require notice to EPA, as well as Agency review and regulation, as necessary, before manufacture (including import) or processing for significant new uses of these chemicals can begin or resume. The SNURs also apply to imported articles containing certain PFAS, including consumer products such as carpets, furniture, electronics, and household appliances. EPA also has issued SNURs for dozens of PFAS that have undergone EPA's new chemicals review prior to commercialization; these actions ensure that any new uses which may present risk concerns but were not part of the EPA new chemicals review, do not commence unless EPA is notified, conducts a risk review, and regulates as appropriate under TSCA section 5.

In 2009, EPA published provisional drinking water health advisories of 400 ppt for PFOA and 200 ppt for PFOS based on health effects information available at that time. The provisional health advisories were developed for application to short-term (weeks to months) risk assessment exposure scenarios. The provisional health advisories were intended as guidelines for public water systems while allowing time for EPA to develop final lifetime health advisories for PFOA and PFOS. EPA published final lifetime drinking water health advisories for PFOA and PFOS (70 ppt individually, and in combination) in 2016.

New health information has become available since 2016, and in June 2022, EPA replaced the 2016 advisories with interim updated lifetime health advisories for PFOA and PFOS based on human epidemiology studies in populations exposed to these chemicals. Based on the new data and EPA's draft analyses, the levels at which negative health effects could occur are much lower than previously understood when EPA issued the 2016 health advisories for PFOA and PFOS. The interim updated health advisory levels are 0.004 ppt for PFOA and 0.02 ppt for PFOS, which are below the levels at which analytical methods can measure these PFAS in drinking water. The EPA Science Advisory Board is reviewing EPA's analyses, and therefore, the interim health advisories are subject to change. However, EPA does not anticipate changes that will result in health advisory levels that are greater than the minimum reporting levels. The interim health advisories are intended to provide information to states and public water systems until the PFAS National Primary Drinking Water Regulation takes effect. Health advisories provide drinking water system operators, and state, Tribal, and local officials who have the primary responsibility for overseeing these systems, with information on the health risks of these chemicals, so they can take the appropriate actions to protect their residents.

In 2019, EPA issued the *Interim Recommendations to Address Groundwater Contaminated with PFOA and PFOS* to facilitate cleaning up contaminated groundwater that is a current or potential source of drinking water. The recommendations provide a starting point for making site-specific cleanup decisions. The guidance recommends: [109]

- Use the following tapwater screening levels for PFOA and PFOS to determine if PFOA and/or PFOS is present at a site and may warrant further attention.
  - If both are detected in tapwater—PFOS regional screening level (RSL) = 6 parts per trillion (ppt) and PFOS regional removal management levels (RMLs) = 4 ppt.
  - If they are the only contaminant detected in tapwater—PFOA RSL = 60 ppt and PFOS RSL = 40 ppt.
  - Screening levels are risk-based values that are used to determine if levels of contamination may warrant further investigation at a site.
- Using EPA's 2016 PFOA and PFOS LHA level of 70 ppt as the preliminary remediation goal (PRG) for contaminated groundwater that is a current or potential source of drinking water, where no state or tribal maximum contaminant level (MCL) or other applicable or relevant and appropriate requirements are available or sufficiently protective.
  - PRGs are generally initial targets for cleanup that may be adjusted on a site-specific basis as more information becomes available.

In 2020, the EPA issued a final rule strengthening the regulation of PFAS (*i.e.,* PFOA and its salts, long-chain perfluoroalkyl carboxylate chemical substances) by requiring notice and EPA review before the use of long-chain PFAS that have been phased out in the United States could begin again. Additionally, products containing certain long-chain PFAS as a surface coating and carpet containing perfluoroalkyl sulfonate chemical substances can no longer be imported into the United States without EPA review. This action means that articles like textiles, carpet, furniture, electronics, and household appliances that could contain certain PFAS cannot be imported into the United States unless EPA reviews and approves the use or puts in place the necessary restrictions to address any unreasonable risks.

In 2020, the EPA also added 172 PFAS (including PFOA and PFOS) to the TRI, and 3 additional compounds were added in 2021. Additional PFAS will continue to be added to TRI, consistent with the National Defense Authorization Act for Fiscal Year 2020.

In October 2021, the EPA released the PFAS Strategic Roadmap that presents EPA's whole-of-agency approach to addressing PFAS and sets timelines by which the Agency plans to take concrete actions.[110] Several actions described in the roadmap, including this proposed rule, address PFOA and PFOS. Other ongoing EPA actions on PFOA and PFOS include:

- Finalizing a proposed rule that would impose certain reporting and recordkeeping requirements under TSCA for PFAS, including PFOA and PFOS, manufactured at any time since January 1, 2011 (86 FR 33926).
- Finalizing the proposed Unregulated Contaminant Monitoring Rule 5 (UCMR5). As proposed, UCMR5 would collect data on 29 PFAS, including PFOA and PFOS, in public water systems (86 FR 13846).
- Establishing a national primary drinking water regulation for PFOA and PFOS under the Safe Drinking Water Act.
- Publishing recommended aquatic life water quality criteria for PFOA and

[109] U.S. EPA. (2019). USEPA draft interim recommendations to address groundwater contaminated with perfluorooctanoic acid and perfluorooctane sulfonate. (EPA–HQ–OLEM–2019–0229–0002). U.S. Environmental Protection Agency. *https://downloads.regulations.gov/EPA-HQ-OLEM-2019-0229-0002/content.pdf.*

[110] U.S. EPA. (2021). PFAS strategic roadmap: EPA's commitments to action 2021–2024. U.S. Environmental Protection Agency. *https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.*

PFOS (draft criteria were released for public comment in May 2022) and developing human health water quality criteria for PFOA and PFOS.

• Finalizing a risk assessment for PFOA and PFOS in biosolids, which will serve as the basis for determining whether regulation of PFOA and PFOS in biosolids is appropriate.

Further, based on public health and environmental protection concerns, and in response to a petition from the Governor of New Mexico, which requested EPA to take regulatory action on PFAS under RCRA, EPA announced on October 26, 2021, the initiation of two rulemakings. First, EPA will initiate the rulemaking process to propose adding four PFAS as RCRA hazardous constituents under 40 CFR part 261 Appendix VIII, by evaluating the existing data for these chemicals and establishing a record to support such a proposed rule. The four PFAS EPA will evaluate are: PFOA, PFOS, perfluorobutane sulfonic acid (PFBS) and GenX chemicals (hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt). Second, EPA will initiate a rulemaking to clarify in the Agency's regulations that the RCRA Corrective Action Program has the authority to require investigation and cleanup for wastes that meet the statutory definition of hazardous waste, as defined under RCRA section 1004(5). This modification would clarify that emerging contaminants such as PFAS can be addressed through RCRA corrective action.

Recent scientific data and the Agency's new analyses indicate that negative health effects may occur at much lower levels of exposure to PFOA and PFOS than previously understood and that PFOA is likely carcinogenic to humans. The Agency's new analyses were released in November 2021 [111] [112] for independent scientific review by the EPA Science Advisory Board. The draft documents present EPA's initial analysis and findings with respect to this new information. EPA's 2021 draft non-cancer reference doses based on human epidemiology studies for various effects (*e.g.,* developmental/growth, cardiovascular health outcomes, immune health) range from ~10^{-7} to 10^{-9} milligram per kilogram per day (mg/kg/day). These draft reference doses are two to four orders of magnitude lower than EPA's 2016 reference doses for PFOA and PFOS of 2×10^{-5} mg/kg/day. Following peer review, this information will be used to inform updated EPA drinking water health advisories and the development of Maximum Contaminant Level Goals and a National Primary Drinking Water Regulation for PFOA and PFOS.

The EPA routinely updates RSLs and RMLs two times per year. EPA's next regularly scheduled update to the RSL and RML tables will be in November 2022. Since the science of PFAS toxicity is evolving we expect to update the numbers as appropriate during future updates.

B. Actions by Other Federal Agencies

• *ATSDR:* The Agency for Toxic Substances and Disease Registry (ATSDR), in response to a congressional mandate under CERCLA, develops comparison values to help identify chemicals that may be of concern to the public's health at hazardous waste sites. The ATSDR's guideline values are minimal risk levels (MRLs). An MRL is an estimate of the amount of a chemical a person can eat, drink, or breathe each day over a specified duration without a detectable risk to health. MRLs are developed for health effects other than cancer. If someone is exposed to an amount above the MRLs, it does not mean that health problems will happen. MRLs are a screening tool that help identify exposures that could be potentially hazardous to human health. Exposure above the MRLs does not mean that health problems will occur. Instead, it may act as a signal to health assessors to look more closely at a particular site where exposures may be identified.

The ATSDR works closely with EPA at both a national and regional level to determine areas and populations potentially at risk for health effects from exposure to PFAS.[113] The ATSDR has final intermediate duration (15–364 days) MRLs (2021) for PFOA and PFOS which are 3×10^{-6} mg/kg/day and 2×10^{-6} mg/kg/day, respectively.[114]

ATSDR also has a PFAS strategy, exposure assessments, and a multi-site study—PFAS Cooperative Agreement.

• *DoD:* The Department of Defense (DoD) included PFOA and PFOS on its list of emerging chemicals of concern.[115] The DoD defines emerging chemicals as chemicals or materials that the department currently uses or plans to use that present a potentially unacceptable human health or environmental risk; have a reasonably possible pathway to enter the environment; and either do not have regulatory standards based on peer-reviewed science, or their regulatory standards are evolving due to new science, detection capabilities or exposure pathways.[116]

In 2017, the DoD updated their military specification for AFFF to include no more than 800 parts per billion, the quantitation limit by DoD Quality Systems Manual 5.1, of PFOA and PFOS in the concentrate.[117] The DoD is working to remove AFFF containing PFOA and PFOS from the supply chain.[118] ''In January 2016, the Office of the Assistant Secretary of Defense for Energy, Installations and Environment issued a policy requiring the DoD components to: (1) issue Military Service-specific risk management procedures to prevent uncontrolled land-based releases of AFFF during maintenance, testing and training activities, and (2) remove and properly dispose of AFFF containing PFOS from the local stored supplies for non-shipboard use to prevent future environmental response action costs, where practical''.[119] Under this policy,

[111] U.S. EPA (U.S. Environmental Protection Agency). 2021a. External Peer Review Draft: Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335–67–1) in Drinking Water. EPA–822–D–21–001. EPA, Office of Water, Washington, DC. Accessed April 2022. *https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601.*

[112] U.S. EPA (U.S. Environmental Protection Agency). 2021b. External Peer Review Draft: Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) CASRN 1763–23–1 in Drinking Water. EPA–822–D–21–002. EPA, Office of Water, Washington, DC. Accessed April 2022. *https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601.*

[113] ATSDR. (2018). Minimal risk levels (MRLs). Atlanta, GA: Agency for Toxic Substances and Disease Registry. *https://www.atsdr.cdc.gov/minimalrisklevels/.*

[114] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[115] DoD. (2019). DoD instruction 4715.18: Emerging chemicals (ECs) of environmental concern. U.S. Department of Defense. *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/471518p.pdf?ver=2017-12-13-110558-727.*

[116] Ibid.

[117] U.S. Navy. (2017). Performance specification fire extinguishing agent, aqueous film-forming foam (AFFF) liquid concentrate, for fresh and sea water. (MIL–PRF–24385F(SH) w/Amendment 2). U.S. Navy, Naval Sea Systems Command (Ship Systems). *https://quicksearch.dla.mil/Transient/E3EA5BB276A741A292E87C18DE644702.pdf https://quicksearch.dla.mil/Transient/C26F946AAE39463BBFCB321B047611E4.pdf.*

[118] *WH.gov.* (2021). Fact sheet: President Biden signs executive order catalyzing America's clean energy economy through federal sustainability. Washington, DC: The White House. *https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/08/fact-sheet-president-biden-signs-executive-order-catalyzing-americas-clean-energy-economy-through-federal-sustainability/.*

[119] DoD. (2017). Aqueous film forming foam: Report to Congress. U.S. Department of Defense,

Continued

for example, the Air Force funded the removal of AFFF from all fire trucks and crash response vehicles and replaced it with PFOS-free AFFF, which contains only trace quantities of PFOA. All Air Force bases except Thule Air Force Base, Greenland, have received replacement AFFF, and 97 percent of the bases have completed the transition. In addition, the Navy is updating the military specification requirements for AFFF and DoD continues its research efforts to find a PFAS-free alternative to AFFF.[120] DoD has also set up a taskforce to address PFAS on and near military bases from DoD activities.

DoD is investing over $49 million through fiscal year 2025 in research, development, testing, and evaluation in collaboration with academia and industry to identify alternative firefighting material and practices. In the meantime, DoD only uses AFFF to respond to emergency events and no longer uses it for uncontained land-based testing and training.[121]

In addition, DoD has initiated other actions to test for, investigate, and mitigate elevated levels of PFOA and PFOS at or near installations across the military departments. Following the release of EPA's LHAs for PFOA and PFOS in May 2016, each of the military departments issued guidance directing installations to test for PFOA and PFOS in their drinking water and take steps to address drinking water that contained amounts of PFOA and PFOS above EPA's health advisory level. The military departments also directed their installations to identify locations with a known or suspected prior release of PFOA and PFOS and to address any releases that pose a risk to human health.[122] As of December 31, 2021, the DoD was performing the PA/SI for PFAS at 700 DoD installations and National Guard Facilities.

• *DOE:* On September 16, 2021, the Department of Energy (DOE) issued a memo that focused on four main points; discontinue use of AFFF except in emergencies, suspend disposal of AFFF pending further guidance, establish reporting requirements for any release or spill of PFAS and establish a DOE PFAS Coordinating Committee. DOE has completed an assessment of its PFAS usage and inventory across the department and is in the process of developing a department wide report of the results of that assessment. At the request of Council on Environmental Quality, DOE, as well as other agencies and departments, is developing a PFAS Roadmap similar to EPA's that will guide future PFAS related actions for 2022–2025.FAA: On January 17, 2019, the Federal Aviation Administration (FAA) released guidance in the form of a CertAlert to all certificated Part 139 Aircraft Rescue and Firefighting departments regarding safer methods for the required bi-annual testing of AFFF for firefighting. In the guidance, the FAA suggests alternative AFFF testing systems that minimize environmental impact while still satisfying the regulatory requirement for safety testing. The recommendations include addressing environmental concerns such as establishing safe and environmentally effective handling and disposal procedures.[123]

On October 4, 2021, the FAA published a CertAlert which informs Part 139 airport operators about changes to the military specification (MIL–PRF–24385F(SH)) for firefighting foam referenced in Chapter 6 of AC No.: 150/5210–6D. While the performance standard remains the same, the military specification no longer requires the use of fluorinated chemicals. One acceptable means of satisfying 14 CFR part 139 requirements is to continue to use the existing approved foam which does contain fluorinated chemicals. However, FAA encourages certificate holders that have identified a different foam that meets the performance standard to seek approval for such foam from the FAA.[124]

• *FDA:* In 2011, FDA reached voluntary agreements with manufacturers and suppliers of long chain PFAS subject to Food Contact Notification to no longer sell those substances for use in food contact applications. In 2016, the FDA revoked the regulations authorizing the remaining uses of these long-chain PFAS in food packaging (see 81 FR 5, January 4, 2016, and 81 FR 83672, November 22, 2016). As of November 2016, long-chain PFAS are no longer used in food contact applications sold in the United States.[125]

In addition to EPA, a number of agencies including ATSDR, DoD, DOI, DOT, FDA, and USDA Have or are developing PFAS plans outlining how their agencies will address PFAS contamination.

C. State Actions

As concerns have arisen regarding PFOA and PFOS many states have taken regulatory action.

In addition to some of the states discussed in more detail below, Alabama, Arizona, Idaho, Kentucky, Nebraska, and West Virginia have opted to use EPA's 2016 LHAs of 70 ppt for PFOA and PFOS.[126] [127] [128] [129]

• *Alaska:* The Alaska Department of Environmental Conservation (ADEC) promulgated groundwater cleanup levels of 400 ppt and soil cleanup levels of 1.3 to 2.2 milligram per kilogram (mg/kg) (range depending on precipitation zone) for PFOA and PFOS, respectively, in Oil and Other Hazardous Substances Pollution Control Regulations as amended through June 2021.[130] Health-based action levels for drinking water of 70 ppt for PFOA and PFOS, individually or combined, were established by ADEC in 2018 (updated in 2019) based on EPA's 2016 LHAs.[131]

• *California:* In August 2019, the California Office of Environmental Health Hazard Assessment developed PFOA and PFOS toxicity values

---

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics. *https://www.denix.osd.mil/derp/home/documents/aqueous-film-forming-foam-report-to-congress/Aqueous%20Film%20Forming%20Foam%20(AFFF)%20Report%20to%20Congress_DENIX.PDF.*

[120] DoD. (2020). Per- and polyfluoroalkyl substances (PFAS) Task Force progress report. U.S. Department of Defense. *https://media.defense.gov/2020/Mar/13/2002264440/-1/-1/1/PFAS_Task_Force_Progress_Report_March_2020.pdf.*

[121] Ibid.

[122] Ibid.

[123] FAA. (2019). National part 139 CertAlert: Aqueous film forming foam (AFFF) testing at certificated part 139 airports. (No. 19–01). Federal Aviation Administration. *https://www.faa.gov/airports/airport_safety/certalerts/media/part-139-cert-alert-19-01-AFFF.pdf.*

[124] FAA. (2021). National part 139 CertAlert: Part 139 extinguishing agent requirements. (No. 21–05). Federal Aviation Administration. *https://www.faa.gov/airports/airport_safety/certalerts/media/part-139-cert-alert-21-05-Extinguishing-Agent-Requirements.pdf.*

[125] *https://www.fda.gov/food/chemical-contaminants-food/authorized-uses-pfas-food-contact-applications.*

[126] Pontius, F. (2019). Regulation of perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) in drinking water: A comprehensive review. Water 11: 2003.

[127] Idaho DEQ. (2021). PFAS and Idaho drinking water. Idaho Department of Environmental Quality. *https://www.deq.idaho.gov/water-quality/drinking-water/pfas-and-idaho-drinking-water/.*

[128] Kentucky EEC. (2019). Evaluation of Kentucky community drinking water for per- & poly-fluoroalkyl substances. Kentucky Energy and Environment Cabinet, Department for Environmental Protection. *https://eec.ky.gov/Documents%20for%20URLs/PFAS%20Drinking%20Water%20Report%20Final.pdf.*

[129] AWWA. (2020). Per- and polyfluoroalkyl substances (PFAS): summary of state policies to protect drinking water. American Water Works Association. *https://www.awwa.org/LinkClick.aspx?fileticket=nCRhtmGcA3k%3D&portalid=0.*

[130] Alaska DEC. (2021). Oil and other hazardous substances pollution control. (Alaska Admin Code 18 AAC 75). Alaska Department of Environmental Conservation. *https://dec.alaska.gov/commish/regulations/.*

[131] Alaska DEC. (2019). Technical memorandum: Action levels for PFAS in water and guidance on sampling groundwater and drinking water. Alaska Department of Environmental Conservation. *https://dec.alaska.gov/media/15773/pfas-drinking-water-action-levels-technical-memorandum-10-2-19.pdf.*

(acceptable daily doses) of 4.5×10^{-7} mg/kg-day and 1.8×10^{-6} mg/kg-day, respectively, and reference levels based on cancer effects of 0.1 ppt and 0.4 ppt, respectively. They noted that the levels are lower than the levels of PFOA and PFOS that can be reliably detected in drinking water using currently available technologies. Thus, they recommended that the State Water Resources Control Board set notification limits at the lowest levels at which PFOA and PFOS can be reliably detected in drinking water using available and appropriate technologies.[132] The California State Water Resources Control Board issued new drinking water notification limits for local water agencies to follow for finding and reporting PFOA and PFOS of 5.1 ppt for PFOA and 6.5 ppt for PFOS. As part of these guidelines, California also established a response level of 10 ppt for PFOA and 40 ppt for PFOS.[133] [134] If this level is exceeded in drinking water provided to consumers, California recommends that the water agency remove the water source from service.[135]

In July 2021, the California Office of Environmental Health Hazard Assessment released draft Public Health Goals (PHGs) for PFOA of 0.007 ppt based on human kidney cancer data and PFOS of 1 ppt based on liver and pancreatic tumor animal data. PHGs are not regulatory requirements and are based solely on protection of public health without regard to cost impacts or other factors.[136]

California is also conducting sampling efforts targeting airports, chrome plating facilities, landfills, WWTPs and nearby water supply wells.[137]

- *Colorado:* To address known contamination in El Paso County, the Colorado Water Quality Control Commission (WQCC) adopted a site-specific groundwater quality standard of 70 ppt for PFOA and PFOS combined in 2018 based on the EPA 2016 LHAs.[138] [139] By 2019, the Colorado Department of Public Health and Environment adopted a PFAS Action Plan outlining methods by which the state planned to protect residents from PFAS. As part of this initiative, a survey was conducted regarding the use of firefighting foams that resulted in rules with respect to the registration and use of PFAS-containing foams.[140] The Colorado WQCC approved a policy interpreting the existing narrative standards for PFAS in 2020. This policy outlines the use of translation levels of 70 ppt for PFOA, PFOS, PFOA and PFOS parent constituents, and perfluorononanoic acid (PFNA), individually or combined, based on the EPA's 2016 LHAs.[141]
- Connecticut has issued a drinking water action level of 70 ppt for PFOA, PFOS, PFNA, perfluorohexanesulfonic acid (PFHxS) and perfluoroheptanoic acid (PFHpA) individually or combined. The action level is based on risk and similar health effects of the five PFAS. An interagency task force was formed that has recommended actions including take-back and safe disposal of AFFF containing PFAS from state and municipal fire departments.[142]
- *Delaware:* Based on Delaware's Department of Natural Resources and Environmental Control Hazardous Substance Cleaning Act Screening Level Table Guidance (last updated in November 2021), a screening/reporting level for PFOA and PFOS, individually or combined, of 70 ppt in groundwater is based on EPA's 2016 LHAs; and a reporting/screening level for PFOA and PFOS in the soil (of 0.13 mg/kg based on screening document and 1.3 mg/kg based on the reporting level table) is based on EPA's Regional Screening Level Calculator.[143] [144]
- Florida issued guidance identifying provisional groundwater target cleanup levels of 70 ppt for PFOA and PFOS combined, provisional soil cleanup target levels of 1.3 mg/kg for PFOA and PFOS, and surface water screening levels of 500 ppt for PFOA and 10 ppt for PFOS; these values were last updated in 2020.[145]
- *Hawaii:* In 2020, Hawaii published a memorandum identifying interim soil and water and soil environmental action levels (EALs) for PFAS. For groundwater that is a current potential source of drinking water, groundwater EALs are 40 ppt for PFOA and PFOS. Soil EALs are 0.0012 mg/kg for PFOA and 0.0075 mg/kg for PFOS.[146]
- *Illinois:* By July 2021, Illinois EPA issued statewide health advisories for six PFAS: PFOA, PFOS, PFNA, perfluorohexanoic acid (PFHxA), PFHxS and PFBS. A health advisory is a regulatory action that provides guidance to local officials and community water supply operators in protecting the health of their customers. Illinois EPA is authorized to issue a health advisory when there is a confirmed detection in a community water supply well of a chemical substance for which no

[132] OEHHA. (2019). Notification level recommendations: Perfluorooctanoic acid and perfluorooctane sulfonate in drinking water. California Office of Environmental Health Hazard Assessment. *https://oehha.ca.gov/media/downloads/water/chemicals/nl/final-pfoa-pfosnl082119.pdf.*

[133] California Water Boards. (2020). Notification level issuance: Contaminant(s): perfluorooctanoic acid (PFOA). State Water Resources Control Board. California Water Boards. *https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/pfos_and_pfoa/pfoa_nl_issuance_jan2020.pdf.*

[134] California Water Boards. (2020). Notification level issuance: Contaminant(s): perfluorooctanesulfonic acid (PFOS). State Water Resources Control Board. California Water Boards. *https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/pfos_and_pfoa/pfos_nl_issuance_jan2020.pdf.*

[135] California Water Boards. (2020). Perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). State Water Resources Control Board. California Water Boards. *https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/PFOA_PFOS.html.*

[136] OEHHA. (2021). Public health goals: First public review draft: Perfluorooctanoic acid and perfluorooctane sulfonic acid in drinking water Office of Environmental Health Hazard Assessment. California Environmental Protection Agency. *https://oehha.ca.gov/sites/default/files/media/downloads/crnr/pfoapfosphgdraft061021.pdf.*

[137] California Water Boards. (2021). GeoTracker PFAS map. State Water Resources Control Board. California Water Boards. *https://geotracker.waterboards.ca.gov/map/pfas_map.*

[138] CDPHE. (2017). Site-specific groundwater standard: PFOA/PFOS. Colorado Department of Public Health & Environment. *https://www.colorado.gov/pacific/sites/default/files/WQ_GWStandard_PFOA_100417%20FINAL.pdf.*

[139] CDPHE. (2020). Policy 20–1. Policy for interpreting the narrative water quality: Standards for per- and polyfluoroalkyl substances (PFAS). Colorado Department of Public Health & Environment, Water Quality Control Commission. *https://drive.google.com/file/d/119FjO4GZVaJtw7YFvFqs9pmlwDhDO_eG/view.*

[140] Coleman, C. (2020). Colorado enacts arsenal of laws to stop ''forever chemicals''. Water Education Colorado. *https://www.watereducationcolorado.org/fresh-water-news/colorado-enacts-arsenal-of-laws-to-stop-forever-chemicals/.*

[141] CDPHE. (2020). Policy 20–1. Policy for interpreting the narrative water quality: Standards for per- and polyfluoroalkyl substances (PFAS). Colorado Department of Public Health & Environment, Water Quality Control Commission. *https://drive.google.com/file/d/119FjO4GZVaJtw7YFvFqs9pmlwDhDO_eG/view.*

[142] CT Interagency PFAS Task Force. (2019). PFAS action plan. Connecticut Interagency PFAS Task Force. Department of Public Health & Department of Energy and Environmental Protection. *https://portal.ct.gov/-/media/Office-of-the-Governor/News/20191101-CT-Interagency-PFAS-Task-Force-Action-Plan.pdf.*

[143] DNREC. (2021). Hazardous Substance Cleanup Act: Screening level table guidance. Delaware Department of Natural Resources and Environmental Control. *https://documents.dnrec.delaware.gov/dwhs/remediation/HSCA-Screening-Level-Table-Guidance.pdf.*

[144] DNREC. (2021). Sortable HSCA reporting level table (Excel). Delaware Department of Natural Resources and Environmental Control. *https://dnrec.alpha.delaware.gov/waste-hazardous/remediation/laws-regs-guidance/.*

[145] Florida DEP. (2020). Provisional PFOA and PFOS cleanup target levels & screening levels. Florida Department of Environmental Protection. *https://floridadep.gov/waste/district-business-support/documents/provisional-pfoa-and-pfos-cleanup-target-levels-screening.*

[146] Hawai'i DOH. (2020). Interim soil and water environmental action levels (EALs) for perfluoroalkyl and polyfluoroalkyl substances (PFASs). Hawaii State Department of Health. *https://health.hawaii.gov/heer/files/2020/12/PFASs-Techncal-Memo-HDOH-Dec-2020.pdf.*

numeric groundwater standard exists. The health-based guidance level for PFOA is 2 ppt and PFOS is 14 ppt.[147] Illinois EPA is conducting a statewide investigation into the prevalence and occurrence of PFAS in finished water at entry points to the distribution system representing 1,749 community water supplies across Illinois.[148]

- *Iowa:* The Iowa Department of Natural Resources issued Statewide Standards for PFOA and PFOS in 2016. The standards were set at 70 ppt for PFOA and PFOS for a protected groundwater source, and 50,000 ppt for PFOA and 1,000 ppt for PFOS for a non-protected groundwater source. Statewide standards for soil are 35 mg/kg for PFOA and 1.8 mg/kg for PFOS.[149]
- *Kansas:* The Kansas Department of Health and Environment, the Bureau of Environmental Remediation, and the Bureau of Water are working together to address PFAS in drinking water. The process involves the development of a statewide inventory and prioritization of potential PFAS sources. This information will be used to develop a public water supply monitoring program.[150]
- Maine's Department of Environmental Protection requires the testing of all sludge material licensed for land application in the state for PFAS (including PFOA and PFOS). The governor created a task force to mobilize state agencies and other stakeholders to review the prevalence of PFAS in Maine.[151] Maine Remedial Action Guidelines (RAGs) for Sites Contaminated with Hazardous Substances (2018) identified a water RAG of 400 ppt for PFOA and PFOS and a soils (residential) RAG of 1.7 mg/kg for PFOA and PFOS.[152] In June 2021, the Governor also signed an emergency resolution establishing an interim drinking water standard of 20 ppt for 6 PFAS. The resolution also requires that the Maine Department of Health and Human Services promulgate an MCL for PFAS by June 1, 2024.
- *Massachusetts:* In December 2019, the Massachusetts Department of Environmental Protection Office of Research and Standards reassessed the toxicity information for a subgroup of longer chain PFAS. They applied a revised reference dose (RfD) of 5×10^{-6} mg/kg-day to PFOA, PFOS, PFNA, PFHxS, PFHpA and perfluorodecanoic acid (PFDA). This reassessment resulted in an MCL of 20 ppt, promulgated in October 2020.[153] [154] Also, PFAS are considered to be hazardous material subject to the notification, assessment and cleanup requirements of the Massachusetts Waste Site Cleanup Program.[155]
- Michigan derived a toxicity value of 3.9×10^{-6} mg/kg-day for PFOA and 2.89×10^{-6} mg/kg-day for PFOS.[156] Michigan's public health drinking water MCLs are 8 ppt for PFOA and 16 ppt for PFOS, effective in August 2020. The Michigan PFAS Action Response Team has coordinated many actions across the state. Michigan Department of Health and Human Services has recommended people avoid contaminant-induced foam occurring on certain PFAS-contaminated surface water bodies and has initiated a PFAS Exposure and Health Study. The Michigan Department of Environment, Great Lakes, and Energy began a statewide initiative to test drinking water from all community water supplies for PFAS and has been testing watersheds. Do not eat advisories have also been issued for deer, fish, and other wildlife in certain parts of the state.[157] [158] [159] [160] [161] [162]
- Minnesota's Department of Health (MDH) identified RfDs of 1.8×10^{-5} milligram/kilogram-day (mg/kg-day) for PFOA, adopted as Rule in August 2018 [163] and 3.1×10^{-6} mg/kg-day for PFOS, adopted as Rule in August 2020.[164] MDH developed guidance values in drinking water of 35 ppt for PFOA and 15 ppt for PFOS. The MDH is helping with drinking water well testing in certain areas of the state. Due to PFAS contamination in surface water bodies and levels of PFOS found in fish, the MDH has issued fish advisories for certain surface water bodies. Minnesota's Pollution Control Agency Toxics Reduction and Pollution Prevention program is working to reduce PFAS in firefighting foam, chrome plating, and food packaging, with related efforts in state and local government purchasing.[165]

[147] Illinois EPA. (2021). PFAS statewide health advisory. Illinois Environmental Protection Agency, Office of Toxicity Assessment. *https://www2.illinois.gov/epa/topics/water-quality/pfas/Pages/pfas-healthadvisory.aspx.*

[148] Illinois EPA. (2021). PFAS statewide investigation network: Community water supply sampling. Illinois Environmental Protection Agency, Office of Toxicity Assessment. *https://www2.illinois.gov/epa/topics/water-quality/pfas/Pages/pfas-statewide-investigation-network.aspx.*

[149] Iowa DNR. (2021). Cumulative risk calculator: Statewide standards. Iowa Department of Natural Resources. *https://programs.iowadnr.gov/riskcalc/Home/statewidestandards.*

[150] KDHE. (2021). Per- and polyfluoroalkyl substances (PFAS). Kansas Department of Health and Environment. *https://www.kdheks.gov/pws/PFAS.htm.*

[151] Maine EPA. (2021). Per- and polyfluoroalkyl substances (PFAS). Maine Department of Environmental Protection Agency. *https://www.maine.gov/dep/spills/topics/pfas/index.html.*

[152] Maine DEP. (2018). Maine remedial action guidelines (RAGs) for sites contaminated with hazardous substances. Maine Department of Environmental Protection. *https://www.maine.gov/dep/spills/publications/guidance/rags/ME-Remedial-Action-Guidelines-10-19-18cc.pdf.*

[153] MassDEP. (2019). Technical support document: Per- and polyfluoroalkyl substances (PFAS): An updated subgroup approach to groundwater and drinking water values. Massachusetts Department of Environmental Protection. *https://www.mass.gov/files/documents/2019/12/27/PFAS%20TSD%202019-12-26%20FINAL.pdf.*

[154] MassDEP. (2020). 310 CMR 22: The Massachusetts drinking water regulations. Massachusetts Department of Environmental Protection, Drinking Water Program. *https://www.mass.gov/doc/310-cmr-2200-the-massachusetts-drinking-water-regulations/download.*

[155] MassDEP. (2019). Final PFAS-related revisions to the MCP. Massachusetts Department of Environmental Protection, Drinking Water Program. *https://www.mass.gov/lists/final-pfas-related-revisions-to-the-mcp-2019.*

[156] *Michigan.gov.* (2022). Health-based drinking water value recommendations for PFAS in Michigan. Michigan Department of Environment, Great Lakes, and Energy. Science Advisory Workgroup. *https://www.michigan.gov/documents/pfasresponse/Health-Based_Drinking_Water_Value_Recommendations_for_PFAS_in_Michigan_Report_659258_7.pdf.*

[157] *Michigan.gov.* (2021). Michigan PFAS Action Response Team: Investigations. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-86511---,00.html.*

[158] *Michigan.gov.* (2021). Michigan PFAS Action Response Team: Investigations: Watershed investigations. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-86511_95792---,00.html.*

[159] *Michigan.gov.* (2018). Michigan PFAS Action Response Team: Drinking water: Public drinking water: Statewide sampling initiative: Statewide testing initiative. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-95571_95577_95587---,00.html.*

[160] *Michigan.gov.* (2021). Michigan PFAS Action Response Team: Fish and wildlife. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-86512---,00.html.*

[161] *Michigan.gov.* (2021). Michigan PFAS Action Response Team: MPART: Press releases: MDHHS recommends Michiganders avoid foam on lakes and rivers. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-86513_96296-563821--y_2018,00.html.*

[162] *Michigan.gov.* (2020). Michigan PFAS Action Response Team: MPART: Press releases: MDHHS announces launch of new PFAS health study in impacted West Michigan communities. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-86513_96296-544808--y_2018,00.html.*

[163] MDH. (2020). Toxicological summary for: Perfluorooctanoate. Minnesota Department of Health. *https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfoa.pdf.*

[164] MDH. (2020). Toxicological summary for: Perfluorooctane sulfonate. Minnesota Department of Health. *https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfos.pdf.*

[165] Minnesota PCA. (2022U.S.Navy). What is Minnesota doing about PFAS? Minnesota Pollution Control Agency. *https://www.pca.state.mn.us/waste/what-minnesota-doing-about-pfas.*

• Montana Department of Environmental Quality set a Groundwater Quality Standard for PFOA and PFOS, individually or combined, of 70 ppt in 2019.[166]

• Nevada Division of Environmental Protection identified basic comparison level values of 667 ppt for PFOA and PFOS in residential water and 1.56 mg/kg in residential soil.[167] Exceedance of a basic comparison level does not automatically trigger a response action but warrants further evaluation of health risks.[168]

• New Hampshire's Department of Environmental Services recommended RfDs of 6.1×10^{-6} mg/kg/day and 3.0×10^{-6} mg/kg/day for PFOA and PFOS, respectively, in June 2019.[169] New Hampshire has undertaken sampling for PFAS at water supplies (including drinking water sources), wastewater treatment plants, fire stations, landfills and contaminated waste sites to better understand the scope of contamination in the state. The New Hampshire Department of Environmental Services filed and finalized its rulemaking to establish MCLs for PFOA of 12 ppt and PFOS of 15 ppt, as well as 11 ppt for PFNA and 18 ppt for PFHxS.[170] The MCLs initially became effective on September 30, 2019. However, on December 31, 2019, the Merrimack County Superior Court issued a preliminary injunction barring enforcement of the MCLs. The New Hampshire legislature subsequently amended the New Hampshire Safe Drinking Water Act in July 2020 establishing the 4 PFAS MCLs.

• New Jersey Department of Environmental Protection (NJDEP) identified RfDs of 2×10^{-6} mg/kg-day for PFOA and 1.8×10^{-6} mg/kg-day for PFOS.[171] [172] On June 1, 2020, the NJDEP published a health based MCL for PFOA of 14 ppt and an MCL for PFOS of 13 ppt in the New Jersey Register. New Jersey previously adopted an MCL for PFNA of 13 ppt on September 4, 2018. New Jersey uses a risk assessment approach to protect for chronic drinking water exposure when setting MCLs. The NJDEP also adopted these same levels as formal groundwater quality standards for the purposes of site remediation activities and discharges to groundwater.[173] New Jersey has added PFNA, PFOA and PFOS to its hazardous substances list.

• New Mexico Environment Department issued Risk Assessment Guidance for Site Investigations and Remediation that identified preliminary screening levels of 70 ppt for PFOA, PFOS, and PFHxS, individually or combined, in drinking water and 1.56 mg/kg for PFOA, PFOS, and PFHxS in residential soil in 2019.[174]

• New York regulates PFOA and PFOS as hazardous substances. New York finalized regulations in 2017 that specify storage and registration requirements for Class B firefighting foams containing at least one percent by volume of one or more of four PFAS (including PFOA and PFOS) and prohibits the release of one pound or more of each into the environment during use. If a release meets or exceeds the one-pound threshold, it is considered a hazardous waste spill and must be reported, and cleanup may be required under the state's Superfund or Brownfields programs. In August 2020, New York adopted MCLs of 10 ppt for both PFOA and PFOS.[175] [176]

• North Carolina's Department of Environmental Quality determined an Interim Maximum Allowable Concentration for groundwater of 2,000 ppt for PFOA (table last updated in June 2021).[177]

• Ohio Environmental Protection Agency and Ohio Department of Health released a Polyfluoroalkyl Substances Action Plan for Drinking Water in 2019. Objectives included gathering sampling data, providing private water system owners with guidelines and resources to identify and respond to PFAS contamination, identifying resources to assist public water systems in the implementation of preventative and long-term measures to reduce PFAS-related risks, increasing awareness of PFAS and associated risks, ongoing engagement, and establishing Action Levels for drinking water systems in Ohio that are protective for human health. As part of this initiative, Ohio indicated that Action Levels of 70 ppt for PFOA and PFOS, singly or combined, would be established.[178]

• Oregon Department of Environmental Quality set initiation levels (ILs) for PFOA and PFOS of 24,000 ppt and 300,000 ppt, respectively (last amended in 2019). The rule indicated that ILs referred to concentrations in effluent, that, if exceeded, requires preparation of a pollutant reduction plan.[179] [180]

[166] Montana DEQ. (2019). Circular DEQ–7. Montana numeric water quality standards. Montana Department of Environmental Quality. *https://deq.mt.gov/files/Water/WQPB/Standards/PDF/DEQ7/DEQ-7.pdf.*

[167] NDEP. (2017). Nevada Division of Environmental Protection basic comparison levels. Nevada Division of Environmental Protection. *https://ndep.nv.gov/uploads/documents/july-2017-ndep-bcls.pdf.*

[168] Pontius, F. (2019). Regulation of perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) in drinking water: A comprehensive review. Water 11: 2003.

[169] NHDES. (2019). Technical background report for the June 2019 proposed maximum contaminant levels (MCLs) and ambient groundwater quality standards (AGQSs) for perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA), and perfluorohexane sulfonic acid (PFHxS) and letter from Dr. Stephen M. Roberts, Ph.D. dated 6/25/2019—findings of peer review conducted on technical background report. New Hampshire Department of Environmental Services. *https://www4.des.state.nh.us/nh-pfas-investigation/wp-content/uploads/June-PFAS-MCL-Technical-Support-Document-FINAL.pdf.*

[170] NHDES. (2019). New Hampshire Code of Administrative Rules: Section Env-Dw 701.03—Units of measure for maximum contaminant levels (MCLs) and maximum contaminant level goals (MCLGs). New Hampshire Department of Environmental Services. *https://services.statescape.com/ssu/Regs/ss_858637087377920900 8.pdf.*

[171] NJDWQI. (2017). Maximum contaminant level recommendation for perfluorooctanoic acid in drinking water basis and background. New Jersey Drinking Water Quality Institute. *https://www.nj.gov/dep/watersupply/pdf/pfoa-recommend.pdf.*

[172] NJDWQI. (2017). Appendix A. Health-based maximum contaminant level support document: perfluorooctanoic acid (PFOA). New Jersey Drinking Water Quality Institute. *https://www.nj.gov/dep/watersupply/pdf/pfoa-appendixa.pdf.*

[173] NJDEP. (2020). Ground water quality standards and maximum contaminant levels (MCLs) for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). New Jersey Department of Environmental Protection. *https://www.nj.gov/dep/rules/adoptions/adopt_20200601a.pdf.*

[174] NMED. (2019). Risk assessment guidance for site investigations and remediation. Volume I. Soil screening guidance for human health risk assessments. New Mexico Environment Department. *https://www.env.nm.gov/wp-content/uploads/sites/12/2016/11/Final-NMED-SSG-VOL-I_-Rev.2-6_19_19.pdf.*

[175] NYSDOH. (2020). Amendment of subpart 5–1 of title 10 NYCRR (maximum contaminant levels (MCLs)) notice of revised rulemaking. New York State Department of Health. *https://regs.health.ny.gov/sites/default/files/proposed-regulations/Maximum%20Contaminant%20Levels%20%28MCLs%29_0.pdf.*

[176] DEC. (2017). Fact sheet: Storage and use of Class B firefighting foams under new hazardous substance regulations. New York State Department of Environmental Conservation. *https://www.dec.ny.gov/docs/remediation_hudson_pdf/affffactsheet.pdf.*

[177] NCDEQ. (2021). Appendix #1: Interim maximum allowable concentrations (IMACs). North Carolina Department of Environmental Quality. *https://files.nc.gov/ncdeq/Water%20Quality/Planning/CSU/Ground%20Water/APPENDIX_I_IMAC_2-01-21.pdf.*

[178] *Ohio.gov.* (2019). Ohio per- and polyfluoroalkyl substances (PFAS) action plan for drinking water. Ohio Environmental Protection Agency. Ohio Department of Health. *https://content.govdelivery.com/attachments/OHOOD/2019/12/02/file_attachments/1335154/PFAS%20Action%20Plan%2012.02.19.pdf.*

[179] OAR. (2019). Division 45. Regulations pertaining to NPDES and WPCF permits 340–045–0100 Effect of a permit: Initiation level rule. Oregon Administrative Rule. *https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=256058.*

[180] OAR. ([2010]). OAR 340–045–0100: Table A—Persistent pollutants. Oregon Administrative Rule.

Continued

• Pennsylvania Department of Environmental Protection (PADEP) adopted a medium-specific concentration of 70 ppt in groundwater for PFOA and PFOS, individually or combined, based on EPA's 2016 LHAs. MSCs are 4.4 mg/kg for PFOA and PFOS in residential soil. PADEP has proposed rulemaking to incorporate groundwater and soil cleanup standards for PFOA, PFOS, and PFBS, and has initiated the process to set drinking water MCLs for PFOA and PFOS.[181]

• Rhode Island Department of Environmental Management (RIDEM) set Groundwater Quality Standards for PFOA and PFOS, individually or combined, of 70 ppt. RIDEM indicated that EPA's 2016 LHAs are used to determine the response to protect human health when these substances are detected in groundwater known or presumed to be suitable for drinking water use without treatment.[182]

• Texas has developed toxicity factors for PFOA and PFOS (using appropriate adjustments and uncertainty factors) for use at remediation sites. When combined with reasonable maximum long-term exposure assumptions for standard receptors (*e.g.,* residents, commercial/industrial workers) and multiple simultaneous routes of exposure (*e.g.,* incidental soil ingestion, dermal exposure), the Texas Commission on Environmental Quality believes these toxicity factors (*e.g.,* RfDs) will result in sufficiently protective environmental media (*e.g.,* soil) cleanup concentrations based on available data. Texas's RfDs for PFOA and PFOS are 1.2×10^{-05} and 2.3×10^{-05} mg/kg/day, respectively.[183] Tier 1 Protective Concentration Level (PCL) tables, released in January 2021, identified PCLs of 290 ppt for PFOA and 560 ppt for PFOS. PCLs are the default cleanup standards in the Texas Reduction Program.[184]

• Vermont's drinking water health advisory is 20 ppt for a combination of five (PFOA, PFOS, PFHxS, PFHpA and PFNA) compounds based on a combined risk assessment. Vermont has issued final rules amending a number of regulations pertaining to groundwater to set cleanup levels of 20 ppt for PFOA, PFOS, PFHxS, PFHpA and PFNA. These rules became effective on July 6, 2019. Vermont passed a law in 2019 requiring public water systems to monitor for PFAS.[185] [186] It also directed the Agency of Natural Resources to potentially regulate PFAS and report on various monitoring activities.[187]

• Washington is developing rule language to establish proposed state action levels (SALs) of 10 ppt for PFOA and 15 ppt for PFOS (also levels for 3 other PFAS). SALs are levels set for long-term daily drinking water to protect human health; systems that exceed SALs would be required to notify their customers.[188]

• Wisconsin identified a toxicity value (acceptable daily intake) of 2×10^{-6} mg/kg-day for PFOA and recommended the ATSDR value of 2×10^{-6} mg/kg-day for PFOS.[189] The Wisconsin Department of Health Services has sent to Wisconsin Department of Natural Resources recommended groundwater standards of 20 ppt for PFOA and PFOS individually and combined.[190] The Wisconsin PFAS Action Council has developed statewide initiatives to address PFAS in Wisconsin. The council led the development of a comprehensive Wisconsin PFAS Action Plan that will serve as a roadmap for how state agencies will address these emerging chemicals.[191]

D. Enforcement

Enforcement actions, both by states and EPA, have been taken to mitigate risks from PFOA and PFOS. To date, EPA has addressed PFAS in 16 cases using a variety of enforcement tools under the Safe Drinking Water Act (SDWA), TSCA, RCRA, and CERCLA,[192] as well as overseeing PFAS response actions by Federal agencies at National Priorities List sites.

For example, in 2002 the EPA entered into an emergency administrative order on consent under SDWA with E. I. du Pont de Nemours and Company. DuPont agreed to provide alternative drinking water or treatment for public or private water users living near the Washington Works facility in Washington, West Virginia, if the level of PFOA detected in their drinking water was greater than the PFOA screening level established by a C–8 Assessment of Toxicity team. The C–8 Assessment team was formed pursuant to a state order and established the screening level for PFOA at 150,000 ppt. In 2006, after the science on health effects of PFOA evolved, the EPA entered into a second emergency administrative order under SDWA with DuPont that replaced the 2002 order and established a site-specific action level equal to or greater than 500 ppt.[193]

In 2009, after EPA scientists established a provisional health advisory for PFOA of 400 ppt to address short-term exposure to PFOA, EPA entered into a third emergency administrative order under the SDWA with DuPont that replaced the 2006 order and lowered the allowable concentration of PFOA in drinking water from 500 ppt to 400 ppt in communities near the facility. The provisional health advisory for PFOA

https://secure.sos.state.or.us/oard/viewAttachment.action;JSESSIONID_OARD=kx0KPdcNidFhJyQctRxEOn3fLasJ_U1SHXoqfYc80w8WtuLnSAlk!-888754201?ruleVrsnRsn=256058.

[181] Schena, R. (2021). New Pennsylvania PFOS and PFOA cleanup standards reach final major regulatory hurdle. JD Supra. *https://www.jdsupra.com/legalnews/new-pennsylvania-pfos-and-pfoa-cleanup-3985880/.*

[182] RIDEM. (2017). Rhode Island Department of Environmental Management determination of a groundwater quality standard for: Perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). Rhode Island Department of Environmental Management. *https://www.dem.ri.gov/programs/benviron/water/quality/pdf/pfoa.pdf.*

[183] TCEQ. (2016). Perfluoro compounds (PFCs): Various CASRN numbers. Texas Commission on Environmental Quality. *https://www.tceq.texas.gov/assets/public/implementation/tox/evaluations/pfcs.pdf.*

[184] TCEQ. (2021). TRRP Protective concentration levels. Texas Commission on Environmental Quality. *https://www.tceq.texas.gov/remediation/trrp/trrppcls.html.*

[185] HealthVermont. (2018). Memorandum: Drinking water health advisory for five PFAS (per- and polyfluorinated alkyl substances). Vermont Department of Health. *https://www.healthvermont.gov/sites/default/files/documents/pdf/ENV_DW_PFAS_HealthAdvisory.pdf.*

[186] Vermont ANR. (2019). Chapter 12 of the environmental protection rules: Groundwater protection rule and strategy. Vermont Agency of Natural Resources. *https://dec.vermont.gov/sites/dec/files/dwgwp/DW/2019.07.06%20-%20GWPRS.pdf.*

[187] Vermont ANR. (2019). ACT 21 (S. 49): Vermont 2019 PFAS law factsheet. Vermont Agency of Natural Resources. *https://dec.vermont.gov/sites/dec/files/PFAS/Docs/Act21-2019-VT-PFAS-Law-Factsheet.pdf.*

[188] WA DOH. (2021). PFAS and drinking water: What is a state action level? Washington State Department of Health. *https://www.doh.wa.gov/CommunityandEnvironment/Contaminants/PFAS#StateActionLevels.*

[189] Wisconsin DHS. (2019). Recommended public health groundwater quality standards: Scientific support documents for cycle 10 substances. Wisconsin Department of Health Services. *https://www.dhs.wisconsin.gov/publications/p02434v.pdf.*

[190] Wisconsin DHS. (2021). Per- and polyfluoroalkyl substances (PFAS). Wisconsin Department of Health Services. *https://www.dhs.wisconsin.gov/chemical/pfas.htm.*

[191] WisPAC. (2020). Wisconsin PFAS Action Plan. Wisconsin PFAS Action Council. Department of Natural Resources. *https://dnr.wisconsin.gov/topic/Contaminants/ActionPlan.html.*

[192] Where PFAS are commingled with CERCLA hazardous substances, EPA can require PRPs to address the PFAS. Additionally, CERCLA Section 120 federal facility agreements for federal facilities listed on the NPL require federal agencies to investigate and clean up hazardous substances, pollutants and contaminants which includes PFAS.

[193] U.S. EPA. (2021). E.I. DuPont de Nemours and Company PFOA settlements. U.S. Environmental Protection Agency. *https://www.epa.gov/enforcement/ei-dupont-de-nemours-and-company-pfoa-settlements.*

was based on available science at that time.[194]

In 2017, EPA issued an amendment to the 2009 emergency administrative order with DuPont by adding The Chemours Company as a respondent and lowering the allowable concentration of PFOA in drinking water from 400 ppt to 70 ppt in communities near the facility. The amendment, issued on May 19, 2016, was based upon current science, changed circumstances, site-specific information, and EPA's health advisories for PFOA and PFOS.[195]

Designating PFOA and PFOS as CERCLA hazardous substances will allow EPA to use its CERCLA enforcement authorities, in appropriate circumstances and where relevant statutory elements are met, which could allow a transfer of the cost-burden of response activities at privately owned sites from the taxpayers/fund to potentially responsible parties.

E. International Actions

PFAS, including PFOA and PFOS, are subject to international treaties and individual country regulations on their production, use, and release to the environment.

PFOA is identified by the United Nations Environment Programme (UNEP) as ''a substance of very high concern with a persistent, bioaccumulative and toxic structure for the environment and living organisms'' and is listed under Annex A of the Stockholm convention.[196] (Parties must take measures to eliminate production and use of the chemicals listed in Annex A.)

In November 2017, the Persistent Organic Pollutants Review Committee adopted a risk management evaluation for PFOA, its salts and PFOA-related compounds, defined as ''any substances that degrade to PFOA, including any substances (including salts and polymers) having a linear or branched perfluoroheptyl group with the moiety (C_7F_{15})C as one of the structural elements, for example: (i) Polymers with ≥C8 based perfluoroalkyl side chains; 8:2 fluorotelomer compounds; and (iii) 10:2 fluorotelomer compounds''.[197] [198] In 2019, at the 9th Conference of Parties (COP–9) meeting, the Stockholm Convention agreed to a global ban on PFOA and some related compounds for criteria including health effects such as kidney cancer, testicular cancer, thyroid disease, ulcerative colitis and pregnancy-induced hypertension. This action also included five-year exemptions for use in semiconductor manufacturing, firefighting foams, worker-safety textiles, photographic coatings for films and medical devices. While a signatory to the Stockholm Convention, the U.S. has not ratified and is therefore not a Party to the convention however; additional exemptions were requested by China, Iran and the European Union.[199]

PFOS, along with its salts and precursor POSF have been classified as a persistent, highly bioaccumulative organic pollutant and listed under Annex B of the Stockholm Convention.[200] At the 2009 Stockholm Convention COP–4 meeting, parties to the convention restricted PFOS production and use, but also included exemptions. The 2019 COP–9 meeting tightened PFOA and PFOS restrictions, but left an exemption for the pesticide sulfluramid, which is known to degrade into PFOS and PFOA.[201] [202] This pesticide is no longer registered for use in the United States.

The European Union (EU) has taken steps to regulate PFOA, its salts and related substances in a wide range of products.[203] PFOA and APFO are also required to be classified, labelled, and packaged under regulation EC No 1272/2008 [204] and there is a ban on placing these chemicals on the market as substances, constituents of other substances, or in mixtures for supply to the general public. PFNA and PFDA have been proposed for similar classification and labelling by Sweden.

In July 2020, the European Food Safety Authority [205] modified its 2018 decision to set safety levels for PFOA and PFOS to include PFNA and PFHxS, based on their observed human bioaccumulation and toxicity. A combined safety threshold or group tolerable weekly limit in food and water of 4.4 nanograms/kilogram of body weight was set for these four PFAS.

Because there are thousands of PFAS widespread in the environment and substance-by-substance risk assessments, environmental monitoring and regulation would be extremely lengthy and resource-intensive, an alternative approach has been proposed to regulate PFAS as a class, or as subgroups, based on toxicity or chemical similarities. The agreement by the European Parliament and the

[194] Ibid.

[195] U.S. EPA. (2017). News releases from Region 03 EPA amends drinking water order to DuPont. U.S. Environmental Protection Agency. *https://archive.epa.gov/epa/newsreleases/epa-amends-drinking-water-order-dupont.html*.

[196] UNEP. (2019). POPs chemicals Mandeeps. Stockholm Convention on Persistent Organic Pollutants. United Nations Environment Programme. *https://chm.pops.int/DNNADMIN/DataEntry/MandeepsHiddenModules/POPsChemicalsMandeeps/tabid/754/Default.aspx*.

[197] UNEP. (2017). Report of the Persistent Organic Pollutants Review Committee on the work of its thirteenth meeting: Addendum: Risk management evaluation on pentadecafluorooctanoic acid (CAS No: 335–67–1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds. Stockholm Convention on Persistent Organic Pollutants. (UNEP/POPS/POPRC.13/7/Add.2). United Nations Environment Programme. *https://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC13/MeetingDocuments/tabid/6024/Default.aspx/*.

[198] UNEP. (2018). Report of the Persistent Organic Pollutants Review Committee on the work of its fourteenth meeting—Addendum to the risk management evaluation on perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds. Stockholm Convention on Persistent Organic Pollutants. (UNEP/POPS/POPRC.14/6/Add.2). United Nations Environment Programme. *https://chm.pops.int/theconvention/popsreviewcommittee/meetings/poprc14/overview/tabid/7398/default.aspx*.

[199] UNEP. (2019). Recommendation by the Persistent Organic Pollutants Review Committee to list perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds in Annex A to the Convention and draft text of the proposed amendment. Stockholm Convention on Persistent Organic Pollutants. (UNEP/POPS/COP.9/14). United Nations Environment Programme. *https://chm.pops.int/TheConvention/ConferenceoftheParties/Meetings/COP9/tabid/7521/Default.aspx*.

[200] UNEP. (2019). POPs chemicals Mandeeps. Stockholm Convention on Persistent Organic Pollutants. United Nations Environment Programme. *https://chm.pops.int/DNNADMIN/DataEntry/MandeepsHiddenModules/POPsChemicalsMandeeps/tabid/754/Default.aspx*.

[201] UNEP. (2009). Listing of perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride. Stockholm Convention on Persistent Organic Pollutants. (UNEP–POPS–COP.4–SC–4–17). United Nations Environment Programme. *https://chm.pops.int/TheConvention/ConferenceoftheParties/Meetings/COP4/COP4Documents/tabid/531/Agg3187_SelectTab/4/Default.aspx*.

[202] UNEP. (2019). Evaluation of perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride pursuant to paragraphs 5 and 6 of part III of Annex B to the Convention. Stockholm Convention on Persistent Organic Pollutants. (UNEP/POPS/COP.9/7). United Nations Environment Programme. *https://chm.pops.int/TheConvention/ConferenceoftheParties/Meetings/COP9/tabid/7521/Default.aspx*.

[203] EU. (2017). Commission regulation (EU) 2017/1000 of 13 June 2017 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) as regards perfluorooctanoic acid (PFOA), its salts and PFOA-related substances. (Official J Eur Union L150/14). European Union. *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32017R1000*.

[204] EU. (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. (Official J Eur Union L353/1). European Union. *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1272*.

[205] EFSA. (2020). Risk to human health related to the presence of perfluoroalkyl substances in food. EFSA Journal 18: e06223. *https://www.ncbi.nlm.nih.gov/pubmed/32994824*.

Council in December 2019 on the recast of the Drinking Water Directive includes a limit of 0.5 micrograms per liter for all PFAS.[206] In December 2020, the European Parliament formally adopted the revised Drinking Water Directive.[207] Based on the widespread occurrence of PFAS in the environment and their risk properties, in June 2019 the European Council of Ministers called for an action plan to eliminate all non-essential uses of PFAS.[208]

A number of countries have issued standards and guidance values for PFOA, PFOS, and other PFAS individually or cumulatively. These are summarized below.

Australia and New Zealand [209]—The Food Standards Australia New Zealand (FSANZ), a statutory authority in the Australian Government health portfolio, and the National Medical Research Council have developed health-based guidance values for PFOA, PFOS, and PFHxS for exposure from food, drinking water and surface water used for recreation. The guidance values give tolerable daily intake (TDI) for lifetime exposure levels from food or drinking water that will not result in significant risk to human health. Based on the TDI, FSANZ recommended tolerable daily intake and issued drinking water and recreational water guideline values for use in site investigations in Australia. TDI were derived from animal studies and pharmacokinetic modeling used to extrapolate to humans. For PFHxS, FSANZ concluded that the available data were insufficient to develop a TDI and that the PFOS TDI should be applied to PFHxS and a combined concentration of PFOS plus PFHxS should be used to evaluate exposure.

Health based guidance value	Total PFOS+PFHxS	PFOA
Tolerable daily intake (nanograms/kilogram of body weight per day)	20	160
Drinking water quality guideline value (nanograms per liter)	70	560
Recreational water quality guideline value (nanograms per liter)	2,000	10,000

Canada—PFOA, its salts and precursors, as well as long-chain perfluorocarboxylic acids, their salts and precursors were assessed in 2012. These substances are prohibited for import and use with a limited number of exemptions under the *Prohibition of Certain Toxic Substances Regulations, 2012*. In 2018 additional proposed amendments to the Canadian Environmental Protection Act, 1999, to regulate additional PFAS were postponed to late 2021. The proposed amendments include PFOS, its salts and precursors that contain one of the following groups: $C_8F_{17}SO_2$, $C_8F_{17}SO_3$ or $C_8F_{17}SO_2N$ (PFOS), PFOA and its salts and precursors. It also includes all longer chain perfluorocarboxylic acids having the molecular formula $C_nF_{2n+1}CO_2H$ in which $8 \leq n \leq 20$, their salts and precursors.[210] [211]

Guidelines for Canadian Drinking Water Quality set the maximum acceptable concentration (MAC) for PFOA in drinking water at 200 ppt [212] and PFOS in drinking water at 600 ppt.[213] These MACs are based on exposure to individual chemicals. Because the toxicological effects of PFOA and PFOS are additive they should be evaluated together, and the ratio of the observed concentration for PFOS to its MAC plus the ratio of the observed concentration for PFOA to its MAC should be below 1 for drinking water to considered safe.[214] [215] For other PFAS with a more limited database, drinking water screening values were developed.

Peoples Republic of China—The ''Industrial Recon-structuring Guide Directory'' [216] restricted the production of PFOS and PFOA. In 2014, the Ministry of Environmental Protection announcement No. [2014]21, banned ''production, transportation, application, imports and exports of PFOS, its salts, and POSF, except for specific exemptions and acceptable use.''

Denmark—Based on toxicity the Danish Environmental Protection Agency [217] has identified health-based criteria or limit values for drinking water, groundwater used for drinking water and soil. Criteria or limit values for drinking water and groundwater used for drinking water are 100 nanograms per liter for PFOS and/or PFOSA (a PFOS precursor) and 300

[206] EEA. (2019). Emerging chemical risks in Europe—'PFAS'. European Environment Agency. European Union. *https://www.eea.europa.eu/ds_resolveuid/a8da291194084d2eaa5bb0a9147e793a.*

[207] EC. (2020). Review of the drinking water directive. European Commission. *https://ec.europa.eu/environment/water/water-drink/review_en.html.*

[208] EU. (2019). Outcome of proceedings: Subject: Towards a sustainable chemicals policy strategy of the Union—Council conclusions. Council of the European Union. *https://www.consilium.europa.eu/media/40042/st10713-en19.pdf.*

[209] Australian Government. (2019). Health based guidance values for PFAS. Australian Government, Department of Health. *https://www1.health.gov.au/internet/main/publishing.nsf/Content/2200FE086D480353CA2580C900817CDC/$File/HBGV-Factsheet-20190911.pdf.*

[210] Environment and Climate Change Canada. (2021). Toxic substances list: long-chain perfluorocarboxylic acids. Environment and Climate Change Canada, Government of Canada. *https://www.canada.ca/en/environment-climate-change/services/management-toxic-substances/list-canadian-environmental-protection-act/long-chain-perfluorocarboxylic-acids.html.*

[211] Environment and Climate Change Canada. (2021). Toxic substances list: PFOS. Environment and Climate Change Canada, Government of Canada. *https://www.canada.ca/en/environment-climate-change/services/management-toxic-substances/list-canadian-environmental-protection-act/perfluorooctane-sulfonate.html.*

[212] Health Canada. (2018). Guidelines for Canadian drinking water quality: Guideline technical document—perfluorooctanoic acid (PFOA). Health Canada. Minister of Health. *https://www.canada.ca/en/health-canada/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-technical-document-perfluorooctanoic-acid/document.html.*

[213] Health Canada. (2018). Guidelines for Canadian drinking water quality: Guideline technical document—perfluorooctane sulfonate (PFOS). Health Canada. Minister of Health. *https://www.canada.ca/en/health-canada/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-guideline-technical-document-perfluorooctane-sulfonate/document.html.*

[214] Health Canada. (2018). Guidelines for Canadian drinking water quality: Guideline technical document—perfluorooctanoic acid (PFOA). Health Canada. Minister of Health. *https://www.canada.ca/en/health-canada/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-technical-document-perfluorooctanoic-acid/document.html.*

[215] Health Canada. (2018). Guidelines for Canadian drinking water quality: Guideline technical document—perfluorooctane sulfonate (PFOS). Health Canada. Minister of Health. *https://www.canada.ca/en/health-canada/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-guideline-technical-document-perfluorooctane-sulfonate/document.html.*

[216] OECD. (2021). Portal on per and poly fluorinated chemicals: Country information: People's Republic of China. Organisation for Economic Co-operation and Development. *https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/china.htm.*

[217] Danish Ministry of the Environment. (2015). Perfluoroalkylated substances: PFOA, PFOS and PFOSA: Evaluation of health hazards and proposal of a health based quality criterion for drinking water, soil and ground water. (Environmental project No. 1665). Copenhagen, Denmark: The Danish Environmental Protection Agency. *https://www2.mst.dk/Udgiv/publications/2015/04/978-87-93283-01-5.pdf.*

nanograms per liter for PFOA. For cumulative exposure the ratio of the sum of concentration/limit value ratios for PFOA, PFOS and PFOSA should be below 1.

The health-based criteria or limit value for soil is 390 micrograms per kilogram for PFOS and PFOSA and 1,300 micrograms per kilogram for PFOA and its salts. Cumulatively the sum of concentration/limit value ratios for PFOA, PFOS and PFOSA should be below 1.[218]

The Danish Ministry of the Environment and Food [219] banned food contact paper and cardboard in which per and polyfluoro chemicals, including PFOA and PFOS and their salts and precursors, have been used unless they incorporate a barrier to prevent migration into food.

Japan—In 2010, Japan designated PFOS, its salts, and POSF as Class I Specified Chemical Substances following their addition to the Stockholm Convention on Persistent to Organic Pollutants Annex B regulating manufacture, use, export, and import of PFOA and its salts.[220]

Norway—Norway listed PFOA and PFOS on its national list of priority substances [221] based on monitoring data that showed high levels of these substances in the environment as well as their toxicological profiles. In 2014, Norway banned manufacturing, production, import and retail of consumer products containing PFOA.[222]

VIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

[218] Ibid.

[219] *PackingLaw.com.* (2020). Denmark's PFAS ban in paper and cardboard effective in July 2020. Keller and Heckman LLP. *https://www.packaginglaw.com/news/denmarks-pfas-ban-paper-and-cardboard-effective-july-2020.*

[220] Ministry of the Environment of Japan. (2013). Summary of the guideline on the treatment of wastes containing perfluorooctane sulfonic acid (PFOS), and its salts in Japan. Ministry of the Environment of Japan. *https://www.env.go.jp/en/focus/docs/files/201304-89.pdf.*

[221] OECD. (2021). Portal on per and poly fluorinated chemicals: Country information: Norway. Organisation for Economic Co-operation and Development. *https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/norway.htm.*

[222] UL. (2013). Norway introduces restrictions on PFOA. UL, LLC. *https://www.ul.com/news/norway-introduces-restrictions-pfoa.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the OMB for review. While EPA is not considering costs in its hazardous substance designation decisions in this proposed rule, and despite that there is still significant uncertainty and lack of data as discussed in the economic analysis (EA), OMB designated this proposed rulemaking as an economically significant action. Any changes made in response to the OMB recommendations have been documented in the docket. Although CERCLA section 102(a) precludes EPA from taking cost into account in the designation of a hazardous substance, to inform the public, EPA prepared an EA of the potential costs, benefits, and impacts associated with this action. This analysis, *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances* is available in the docket for this action. The EA includes request for comments on several topics that EPA does not currently have robust information about. Please see Section ES–5 of the EA for specific details.

If finalized, this proposed CERCLA designation is estimated to have a quantifiable direct annual social cost of approximately $370,000 from reporting releases at or above the RQ. Additional, unquantifiable future costs may occur when Federal agencies sell or transfer real property where PFOA or PFOS was stored, released or disposed of as specified by CERCLA section 120(h). There is also the direct effect resulting in an obligation of DOT to list and regulate CERCLA-designated hazardous substances as hazardous materials under the Hazardous Materials Transportation Act (see CERCLA Section 306(a)). EPA estimates these incremental costs associated with the DOT rulemaking as zero or negligible. This action's direct benefits from release reporting include improved quality of information providing a more comprehensive understanding of the number and location of PFOA and PFOS releases meeting or exceeding the RQ. An important benefit of this information is that it may lead to more efficient property and capital markets. Another potential direct benefit from the proposed reporting requirement is better waste management and/or treatment by facilities handling PFOA or PFOS. Greater transparency provided by release reporting can lead to fewer releases to the environment and thus to health benefits associated with avoided exposure.

Designating PFOA and PFOS as hazardous substances may also have indirect, indeterminate impacts associated with potential increases in the speed of response activity and in the total number of response actions taken to address PFOA and PFOS releases. Both potential increases may lead to health benefits associated with avoided risks. Other indirect effects may be experienced as a result of the movement forward in time of assessment and cleanup costs. The proposed designation would also improve the Agency's ability to transfer response costs from the public to polluters contingent upon specific statutory requirements being met and discretionary actions by EPA. These indirect costs, benefits, and transfers cannot be quantified due to significant uncertainties about each. The full discussion of these impacts can be found in the EA.

B. Paperwork Reduction Act

The information collection activities in this proposed rule have been submitted for approval to the OMB under the Paperwork Reduction Act. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2708.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

If finalized, the designation of PFOA and PFOS, and their salts and structural isomers, as hazardous substances would require any person in charge of a vessel or facility that identifies a release of one pound or more within a 24-hour period of these substances to report the release to the NRC under section 103 of CERCLA and to the SERC (or TERC) and LEPC (or TEPC) under section 304 of EPCRA. The implementing regulations of CERCLA section 103 and EPCRA section 304 are codified at 40 CFR parts 302 and 355, respectively.

Respondents/affected entities: Any person in charge of a vessel or facility from which there is a release of PFOA or PFOS and their salts and structural isomers, equal to or greater than the RQ of one pound within 24 hours.

Respondent's obligation to respond: Mandatory under section 103 of CERCLA and section 304 of EPCRA.

Estimated number of respondents: From 0 to 660 releases per year.

Frequency of response: Varies.

Total estimated burden: 6,415 hours (per year) maximum. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $370,000 (per year) maximum, includes $3,503 annualized operation and maintenance costs (and no capital costs).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than October 6, 2022. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are: (1) producers and importers of PFOA and PFOS, (2) producers and users of PFOA or PFOS-containing articles, and (3) waste management and wastewater facilities. The Agency has estimated that there may be up to 660 reported releases of PFOA or PFOS in any one year and that an indeterminate number, but small percentage, of the annual reports will be submitted by small entities. The estimated cost of $561 to report a release of PFOA or PFOS is not greater than 1% of the annual revenues per small entity in any impacted industry. Details of this analysis are presented in the *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances.* We have therefore concluded that this action will not have a significant regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action is expected to result in reporting costs of $561 per release that meets or exceeds the RQ, and the estimated annual cost of the proposed rule is not expected to exceed $370,000 per year.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 because it does not have substantial direct effects on one or more Tribal Nations, on the relationship between the Federal Government and Tribal Nations, or on the distribution of power and responsibilities between the Federal Government and Tribal Nations. EPA does not expect that it would result in any adverse impacts on tribal entities. Thus, Executive Order 13175 does not apply to this action.

Consistent with the EPA Policy on Consultation with Tribal Nations, the EPA intends to consult with and request comments from tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action, which proposes to designate PFOA and PFOS as hazardous substances, does not itself address environmental health or safety risks. Beyond the requirements of E.O. 13045, EPA's *2021 Policy on Children's Health* (October 5, 2021) [223] requires EPA to consider early life exposures and lifelong health consistently and explicitly in all human health decisions. The EPA believes that the environmental health or safety risk posed by exposure to PFOA and/or PFOS may have a disproportionate effect on children. A discussion of health and risk assessments related to PFOA and PFOS, including developmental and reproductive health effects, are contained in EPA's Health Effects Support Documents for PFOA and PFOS (2016).

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. This action proposes to designate PFOA and PFOS as hazardous substances, and thus, does not involve the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act

This action does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA is unable to determine if this action does or does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

Several key demographic categories were analyzed relative to facilities with known historical use and/or releases of PFOA and PFOS.[224] Because the location of future releases of PFAS is uncertain, this analysis considers populations around facilities in sectors associated with widespread historical uses and releases of PFAS as proxies for facilities that may have future releases of the PFAS considered in the proposed rule. This analysis examines the following site types as proxies for facilities that are known to have commonly used PFAS:

- Operating Department of Defense (DOD) facilities
- Operating U.S. airports and airfields

[223] U.S. EPA. (2021). The administrator: 2021 policy on children's health. Washington, DC: U.S. Environmental Protection Agency. *https://www.epa.gov/system/files/documents/2021-10/2021-policy-on-childrens-health.pdf.*

[224] U.S. EPA. ([2021]). Assessment of the potential costs and other impacts of the proposed rulemaking to designate perfluorooctanoic acid and perfluorooctanesulfonic acid as hazardous substances. U.S. Environmental Protection Agency.

- Plastics material and resin manufacturing firms identified as having produced PFOS and/or PFOA,
- 2020 PFOS and PFOA releases reported to EPA's Toxic Release Inventory (TRI)

On average, airports across the U.S. are surrounded by populations that reflect national averages in relevant demographic categories. Large airports, however, are more likely to be surrounded by minority and low-income populations than medium or small airports. Some DOD sites are surrounded by populations with higher concentrations of minority and low-income residents, but the majority of these sites are below the national averages for these metrics. In contrast, areas around plastics material and resin manufacturer sites and/or sites reporting releases to TRI, on average, are in areas with higher concentrations of minority residents and households experiencing poverty than the U.S. averages for these demographics, suggesting that releases related to manufacturing facilities could have environmental justice implications. A complete discussion of the analysis behind these findings is available in Section 4.3 of the EA accompanying this rulemaking. These findings, combined with the uncertainty surrounding the location of future releases, are indicative of potential impacts but do not provide a clear indication of the type of disparities related to potential exposure to PFAS. Consistent with the priorities outlined in Executive Orders 12898 [225] and 14008,[226] it is unclear whether this proposed regulation will have a significant impact on disadvantaged populations or communities with environmental justice (EJ) concerns relative to other communities. While the locations that may report releases are unknown, to the extent that these proxy locations are representative of likely reporting locations, this screening analysis suggests that the reporting required under the rule may provide better information to nearby populations potentially at risk of exposure, including communities with EJ concerns. To the extent that PFAS releases are consistent with the broader releases reported to TRI and typically involve disposal or manufacturing sites, demographic data around plastics material and resin manufacturer sites and historical releases may be a more reliable predictor of the type of community potentially affected by this proposed rulemaking. Specific site conditions and demographic patterns may become clear as reporting occurs following completion of a final rule. Once available, this information would improve EPA's ability to examine disparate impacts on EJ communities. This improved information would not increase risk for communities with EJ concerns and may improve the speed and design of remediation. EPA is committed to minimizing and/or eliminating existing barriers and burdens that communities with EJ concerns may encounter related to accessing data and information collected as a result of this rulemaking, if finalized. EPA seeks comment on strategies to improve access to the reporting data expected to be collected, if designation of PFOA and PFOS as hazardous substances is finalized, for communities with environmental justice concerns.

Further, the documentation for this decision is contained in the following sections in the preamble to this action: II.C., VI.A. and B. These sections explain that the designation of PFOA and PFOS as hazardous substances, if finalized, and the required reporting and notification requirements, will result in more information about the location and extent of releases. This improved information does not increase risk or result in any adverse environmental justice impacts.

List of Subjects in 40 CFR Part 302

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 302 as follows:

PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

■ 1. The authority citation for part 302 continues to read as follows:

Authority: 33 U.S.C. 1251 *et. seq.,* 42 U.S.C. 9601, *et seq.,* 42 U.S.C. 9602, 42 U.S.C. 9603.

■ 2. Amend § 302.4 by:

■ a. Revising in paragraph (b) the Note II to Table;

■ b. Adding in the Table—List of Hazardous Substances and Reportable Quantities in alphabetical order the following new entries for ''Perfluorooctanesulfonic acid, salts, & structural isomers'' and ''Perfluorooctanoic acid, & salts, & structural isomers'';

■ c. Adding in Appendix A—Sequential CAS Registry Number List of CERCLA Hazardous Substances in numerical order the new entries for ''335–67–1'' and ''1763–23–1''.

The revisions read as follows:

§ 302.4 [Amended]

* * * * *

(b) * * *

Note II to Table 302.4

Hazardous substances are given a Statutory Code based on their statutory source. The ''Statutory Code'' column indicates the statutory source for designating each substance as a CERCLA hazardous substance. Statutory Code ''1'' indicates a Clean Water Act (CWA) Hazardous Substance. Statutory Code ''2'' indicates a CWA Toxic Pollutant. Statutory Code ''3'' indicates a CAA HAP. Statutory Code ''4'' indicates Resource Conservation and Recovery Act (RCRA) Hazardous Wastes. Statutory Code ''5'' indicates a hazardous substance designated under section 102(a) of CERCLA. The ''RCRA waste No.'' column provides the waste identification numbers assigned by RCRA regulations. The ''Final RQ [pounds (kg)]'' column provides the reportable quantity for each hazardous substance in pounds and kilograms.

* * * * *

[225] The White House. (1994). Presidential documents: Executive order 12898 of February 11, 1994: Federal actions to address environmental justice in minority populations and low-income populations. **Federal Register** 59: 7629. *https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf.*

[226] *WH.gov.* (2021). Executive order on tackling the climate crisis at home and abroad. Washington, DC: The White House. *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/executive-order-on-tackling-the-climate-crisis-at-home-and-abroad/.*

TABLE 302.4—LIST OF HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES
[All comments/notes are located at the end of this table]

Hazardous substance	CASRN	Statutory code †	RCRA waste No.	Final RQ [pounds (kg)]
* * * * * * * *				
Perfluorooctanesulfonic acid, & salts, & structural isomers	1763–23–1	5	.....	## (0.454)
Perfluorooctanoic acid, & salts, & structural isomers	335–67–1	5	.....	## (0.454)
* * * * * * * *				

* * * * *

Appendix A to § 302.4—Sequential CAS Registry Number List of CERCLA Hazardous Substances

CASRN	Hazardous substance
335–67–1	Perfluorooctanoic acid, & salts, & structural isomers.
1763–23–1	Perfluorooctanesulfonic acid, & salts, & structural isomers.

[FR Doc. 2022–18657 Filed 9–2–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 2

[DOI–2022–0007; 223D0102DM, DLSN00000.000000, DS65100000, DX.65101]

RIN 1090–AB16

Privacy Act Regulations; Exemption for the Personnel Security Program Files System

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of the Interior (DOI) is proposing to amend its regulations to exempt certain records in the INTERIOR/DOI–45, Personnel Security Program Files, system of records from one or more provisions of the Privacy Act of 1974 because of criminal, civil, and administrative law enforcement requirements.

DATES: Submit comments on or before November 7, 2022.

ADDRESSES: You may submit comments, identified by docket number [DOI–2022–0007] or [Regulatory Information Number (RIN) 1090–AB16], by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for sending comments.
- *Email: DOI_Privacy@ios.doi.gov.* Include docket number [DOI–2022–0007] or RIN 1090–AB16 in the subject line of the message.
- *U.S. Mail or Hand-Delivery:* Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240.

Instructions: All submissions received must include the agency name and docket number [DOI–2022–0007] or RIN 1090–AB16 for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240, *DOI_Privacy@ios.doi.gov* or (202) 208–1605.

SUPPLEMENTARY INFORMATION:

Background

The Privacy Act of 1974, as amended, 5 U.S.C. 552a, governs the means by which the U.S. Government collects, maintains, uses and disseminates personally identifiable information. The Privacy Act applies to information about individuals that is maintained in a ''system of records.'' A system of records is a group of any records under the control of an agency from which information about an individual is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. See 5 U.S.C. 552a(a)(4) and (5).

Individuals may request access to records containing information about themselves under the Privacy Act, 5 U.S.C. 552a(b), (c) and (d). However, the Privacy Act authorizes Federal agencies to exempt systems of records from access by individuals under certain circumstances, such as where the access or disclosure of such information would impede national security or law enforcement efforts. Exemptions from Privacy Act provisions must be established by regulation, 5 U.S.C. 552a(j) and (k).

The DOI Office of Law Enforcement and Security (OLES) maintains the INTERIOR/DOI–45, Personnel Security Program Files, system of records. This system supports the DOI bureau and office Personnel Security Program functions to determine suitability, eligibility, and fitness for service of applicants for Federal employment and contract positions who require access to Departmental facilities and information systems and networks. The system also helps OLES manage a National Security Program to document and support decisions regarding clearance access to classified information and implement provisions that apply to Federal employees and contractors who access classified information or materials and participate in classified activities that impact national security, and ensure the safety, storage of classified information and security of Departmental facilities, information systems and networks, occupants, and users.

The Personnel Security Program Files system will contain records created and managed by DOI bureaus and offices to support personnel security activities and document evaluations and decisions regarding suitability, eligibility, and fitness for service of applicants for Federal employment and contract positions to the extent necessary to manage secure access to Departmental facilities, information systems and networks, and to manage access to classified information and reciprocity. These records may include information about individuals related to possible violations of Federal laws and