ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 302
[FR Doc. 2019–20190 Filed 9–2–19; 8:45 am]
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,
UNEP United Nations Environment Programme
U.S. United States
WWTP Wastewater treatment plant

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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 Proprietary 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:

<table>
<thead>
<tr>
<th>NAICS code</th>
<th>List of potentially affected U.S. industrial entities</th>
</tr>
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<tbody>
<tr>
<td>488119</td>
<td>Aviation operations.</td>
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<td>Chrome electroplating, anodizing, and etching services.</td>
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<td>325999</td>
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<td>562212</td>
<td>Medical Devices.</td>
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<tr>
<td>339112</td>
<td>Municipal fire departments and firefighting training centers, including Federal agencies that use, trained with, and tested firefighting foams.</td>
</tr>
<tr>
<td>922160</td>
<td>Paper mills.</td>
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<tr>
<td>322121 and 322130</td>
<td>Pesticides and Insecticides.</td>
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https://www.epagov/dockets
A. Executive Summary

EPA is proposing to designate two perfluoroalkyl substances (PFAS)—specifically PFOA and PFOS including their salts and structural isomers—as hazardous substances because evidence indicates that these chemicals may present substantial danger to public health or welfare of 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 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 (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 arctic snow and air.

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 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.

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

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1 All references to PFOA and PFOS in this notice are meant to include their salts and 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.


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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 conduct cleanup of 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 threatenized releases without making the imminent and substantial danger finding that is required for responses now.

- 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.

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.

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. 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.

PFOA and PFOS have been produced within the United States (U.S.) 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). 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

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6 Ibid.


8 Ibid.

(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.
- Finishing 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


13 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

14 For additional information on release reporting requirements, see https://www.epa.gov/epcra/definition-immediate-epcra-and-cercla-release-notification.
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 Remedia 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”
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 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. 31 (2014). For CERCLA 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.”)

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

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

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 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. 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 EPA is able to consider costs (and other factors) before imposing 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.

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
“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. 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 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

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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)).

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”.25 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 PFOA28 and PFOS29 and other published peer reviewed science. The weight of scientific evidence presented in the Health Effects Support Documents for PFOA30 and
PFOS and PFOA 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. Because of their resistance to metabolic degradation, PFOA and PFOS are eliminated from mammals primarily unchanged.

Numerous epidemiology studies have observed associations 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 alanine aminotransferase and conjugated bilirubin, increased maternal and infant body weight, and increased birth weight and birth length in infants born to PFOA-exposed mothers were found in a study of 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, and 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. 32

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

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 but is often transient, 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

34 Ibid.
39 Ibid.
40 Ibid.
42 Ibid.
43 Ibid.
44 Ibid.
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 also support the finding that PFOA is tumorigenic (i.e., capable of producing tumors).\(^{56,57}\)

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.\(^{58}\) 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.\(^{59,60}\) 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.

PFOS and PFOS that are deposited, 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.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 repellent 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 developer or as a component of an anti-reflective coating, used in a photomicro lithography 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.59

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. The WWTP 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. 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

Biologids from wastewater treatment plants and some industrial wastewater treatment plants 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/m³) in air samples collected in the urban locations in Albany, New York, Fukushima, Japan, and Morioka, Japan and in the rural locations in Kjeller, Norway, and Mace Head, Ireland. However, higher mean concentrations (101–552 pg/m³) were measured at the urban locations in Oyama, Japan, and Manchester, United Kingdom (UK), and semirural locations in Hazelrigg, UK. Maximum reported concentrations at Oyama and Hazelrigg were 919 and 828 pg/m³, 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 PFOS 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. meeting 26–30 May 2019 (pp. 357). Helsinki, Finland: Society of Environmental Toxicology and Chemistry.


77 Ibid.

78 Ibid.

79 Ibid.
producers phased out these two substances.\(^8\)

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.\(^9\)

PFAS can be inadvertently released to soils when biosolids are applied as fertilizer to help maintain productive agricultural soils and stimulate plant growth.\(^10\) 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.\(^11\)

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 (PWSSs). Of the 4,920 PWSSs with results for PFOA and PFOS, PFOA were detected above the minimum reporting level (minimum reporting level = 20 nanogram/liter (ng/L)) in 117 PWSSs. Detections exceeded above the MRL for PFOS (MRL = 40 ng/L) at 95 PWSs.\(^8\)

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.\(^12\) For example, PFOA has been found in snack foods, vegetables, meat, dairy products and fish, and PFOS has been found in eggs, milk, meat, and root vegetables.\(^8\)

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 PFOS 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

 PFOS bioaccumulates in animals. A fish kinetic bioconcentration factor for PFOS has been estimated to range from 1,000 to 4,000.\(^9\) The time to reach 50% clearance of PFOS in fish has been estimated to be around 100 days. Bioaccumulation has been demonstrated for fish, birds, crustaceans, worms, plankton, and alligators, among others.\(^10\)

PFOA bioaccumulates as well, but not to the same degree as PFOS.\(^13\)

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.\(^10\)

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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.

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.
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 analysis, 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 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 2018 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

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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 CRRA 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 CRRA 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 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 x 10^-5 mg/kg/day. Following peer review, this information will be used to inform updates to 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. The ATSDR has final intermediate duration (15-364 days) MRLs (2021) for PFOA and PFOS which are 3 x 10^-6 mg/kg/day and 2 x 10^-5 mg/kg/day, respectively.


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 commercial 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

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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’s 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, and PFOS parent constituents, and perfluorooctanoic 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 (PFHxS), 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

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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. Kansas Department of Health and Environment. (2021). PFAS statewide health drinking water MCLs are 8 ppt for PFOA and 16 ppt for PFOS, effective in August 2020. The Kansas Department of Health and Environment has coordinated many actions across the state. Kansas Department of Health and Environment. (2021). PFAS statewide health drinking water MCLs are 8 ppt for PFOA and 16 ppt for PFOS. The governor created a task force to mobilize state agencies and other stakeholders to review the prevalence of PFAS in Maine.

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. 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. Also, PFAS are considered to be hazardous material subject to the notification, assessment and cleanup requirements of the Massachusetts Waste Site Cleanup Program.

Michigan derived a toxicity value of 3.9 × 10⁻² mg/kg-day for PFOA and 2.89 × 10⁻² mg/kg-day for PFOS. Michigan’s public health drinking water MCLs for PFOA and PFOS are 6 ppt. Michigan Department of Health and Environment. (2021). PFAS statewide health drinking water MCLs are 8 ppt for PFOA and 16 ppt for PFOS, effective in August 2020. The Michigan Department of Health and Environment 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


- 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 residual soil.167 Exceedance of a basic comparison level does not automatically trigger a response action but warrants further evaluation of health risks.

- New Hampshire’s Department of Environmental Services recommended RIDs of 6.1 x 10^-6 mg/kg/day and 3.0 x 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, landfill sites, 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 RIDs of 2 x 10^-6 mg/kg-day for PFOA and 1.8 x 10^-6 mg/kg-day for PFOS.171 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.172 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 2019.173 New Mexico regulates PFOA and PFOS as hazardous substances. New Mexico 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 of 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


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.state.nh.us/soy/Regs/ss_85963187372379209068.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/watersupply/pdf/pfoa-dep.pdf.


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., RIDs) will result in sufficiently protective environmental media (e.g., soil) cleanup concentrations based on available data. Texas’s RIDs for PFOA and PFOS are 1.2 $\times$ 10^{-6} and 2.3 $\times$ 10^{-6} 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 and soil cleanup 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 It also directed the Agency of Natural Resources to potentially regulate PFAS and report on various monitoring activities.186

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.187

Wisconsin identified a toxicity value (acceptable daily intake) of 2 $\times$ 10^{-6} mg/kg-day for PFOA and recommended the ATSDR value of 2 $\times$ 10^{-6} mg/kg-day for PFOS.188 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.189 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.190

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 by the Wisconsin PFAS Action Plan that will replace 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 2002 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...
was based on available science at that time.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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 perfluoroalkyl group with the moiety (C\textsubscript{n}F\textsubscript{2n+1}C) as one of the structural elements, for example: (i) Polymers with ≥C\textsubscript{8} based perfluoroalkyl side chains; 8:2 fluorotelomer compounds; and (iii) 10:2 fluorotelomer compounds”.\textsuperscript{197} \textsuperscript{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.\textsuperscript{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.\textsuperscript{200} At the 2009 Stockholm Convention COP–4 meeting, parties to the convention agreed to DuPont 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 sulfuronilid, which is known to degrade into PFOS and PFOA.\textsuperscript{201} \textsuperscript{202}


Council in December 2019 on the recast
of the Drinking Water Directive includes
a limit of 0.5 micrograms per liter for all
PFAS.\textsuperscript{206} In December 2020, the
European Parliament formally adopted
the revised Drinking Water Directive.\textsuperscript{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.\textsuperscript{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\textsuperscript{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 issuing drinking water and
recreational water guideline values for
use in site investigations in Australia.
TDI were derived from animal studies
and pharmokinetic 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.

<table>
<thead>
<tr>
<th>Health based guidance value</th>
<th>Total</th>
<th>PFOA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tolerable daily intake (nanograms/kilogram of body weight per day)</td>
<td>20</td>
<td>160</td>
</tr>
<tr>
<td>Drinking water quality guideline value (nanograms per liter)</td>
<td>70</td>
<td>560</td>
</tr>
<tr>
<td>Recreational water quality guideline value (nanograms per liter)</td>
<td>2,000</td>
<td>10,000</td>
</tr>
</tbody>
</table>

\textsuperscript{206} EEA. (2019). Emerging chemical risks in
Europe—PFAS. European Environment Agency.
problemOverview/02a-chemRiskPFAS>
\textsuperscript{207} EC. (2020). Review of the drinking water
\textsuperscript{208} EU. (2019). Outcome of proceedings: Subject:
Towards a sustainable chemicals policy strategy of
the Union—Council conclusions. Council of the
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guidance values for PFAS. Australian Government.
\textsuperscript{210} 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/long-chain-
perfluorocarboxylic-acids.html.
\textsuperscript{211} Environment and Climate Change Canada.
(2021). Guidelines for Canadian Drinking Water Quality:
Guideline technical document—perfluorooctanoic
publications/healthy-living/guidelines-canadian-
drinking-water-quality-technical-document-
perfluorooctanoic-acid/document.html.
\textsuperscript{212} Health Canada. (2018). Guidelines for
Canadian drinking water quality: Guideline
technical document—perfluorooctane sulfonate
publications/healthy-living/guidelines-canadian-
drinking-water-quality-technical-document-
perfluorooctane-sulfonate/document.html.
\textsuperscript{213} 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.
Perfluoralkylated 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-
93283-91-5.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 PFOA 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.

Norway—Norway listed PFOA and PFOS on its national list of priority substances\(^{220}\) 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.

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 it 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) requires EPA to consider early life exposures and lifelong health consistently and explicitly in all human health decisions. The EPA believes that the

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. 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

References:

• Plastics material and resin manufacturing firms identified as having produced PFOS and/or PFOA, and
• 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 12898225 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:


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 “Perfluoroctanesulfonic 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


DEPARTMENT OF THE INTERIOR
Office of the Secretary

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:

- Email: DOI_Privacy@ios.doi.gov. Include docket number [DOI–2022–0007] or RIN 1090–AB16 in the subject line of the message.


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 retrievable 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 Systems and Networks 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

### TABLE 302.4—LIST OF HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES

[All comments/notes are located at the end of this table]

<table>
<thead>
<tr>
<th>Hazardous substance</th>
<th>CASRN</th>
<th>Statutory code †</th>
<th>RCRA waste No.</th>
<th>Final RQ [pounds (kg)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perfluorooctanesulfonic acid, &amp; salts, &amp; structural isomers</td>
<td>1763–23–1</td>
<td>1763–23–1</td>
<td>5</td>
<td>## (0.454)</td>
</tr>
<tr>
<td>Perfluorooctanoic acid, &amp; salts, &amp; structural isomers</td>
<td>335–67–1</td>
<td>335–67–1</td>
<td>5</td>
<td>## (0.454)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>CASRN</th>
<th>Hazardous substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>335–67–1</td>
<td>Perfluorooctanoic acid, &amp; salts, &amp; structural isomers.</td>
</tr>
<tr>
<td>1763–23–1</td>
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