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

INSTITUTE OF SCRAP RECYCLING INDUSTRIES, INC., d/b/a RECYCLED MATERIALS ASSOCIATION, Petitioners, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and MICHAEL S. REGAN, in his official capacity as Administrator, United States Environmental Protection Agency, Respondents.	)	Case No. 24-1261

PETITION FOR REVIEW

Pursuant to Section 113 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. § 9613(a), Section 702 of the Administrative Procedure Act, 5 U.S.C. § 702, Rule 15(a) of the Federal Rules of Appellate Procedure, and Rule 15(a) of the D.C. Circuit Rules, the Institute of Scrap Recycling Industries, Inc., d/b/a Recycled Materials Association, hereby petitions the United States Court of Appeals for the District of Columbia Circuit for review of the United States Environmental Protection Agency's final rule entitled "Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances," published in the Federal Register at 89 Fed. Reg. 39,124 (May 8, 2024). A copy of the final rule is attached as Exhibit A. This Court has jurisdiction and is a proper venue for this action pursuant to 42 U.S.C. § 9613(a).

Dated: July 30, 2024

Respectfully submitted,

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Petitioner makes the following disclosures:

The Institute of Scrap Recycling Industries, Inc., doing business as the Recycled Materials Association (ReMA), is a trade association representing over 1,400 companies engaged in the recycling industry in the United States, as well as well as around the globe, that process, broker, and consume recyclable materials, including metals, paper, plastics, glass, electronics, and textiles. ReMA provides advocacy, education, safety, and compliance training, and promotes public awareness of the vital role recycled materials play in the U.S. economy, global trade, the environment, and sustainable development. ReMA represents the interest of its members in matters before Congress, the Executive Branch and the courts. ReMA states that it is a non-profit, tax-exempt organization incorporated in Delaware. ReMA has no parent corporation and no publicly held company has 10% or greater ownership in ReMA.

Dated: July 30, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on July 30, 2024, I caused filed-stamped copies of the foregoing Petition for Review and Corporate Disclosure Statement to be sent to the following parties by certified United States mail, return receipt requested:

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July 30, 2024

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EXHIBIT A

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 302

[EPA–HQ–OLEM–2019–0341; FRL–7204–03–OLEM]

RIN 2050–AH09

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA'' or ''Superfund''), the Environmental Protection Agency (EPA) is designating two per- and polyfluoroalkyl substances (PFAS)—perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), including their salts and structural isomers—as hazardous substances. The Agency reached this decision after evaluating the available scientific and technical information about PFOA and PFOS and determining that they may present a substantial danger to the public health or welfare or the environment when released. The Agency also determined that designation is warranted based on a totality of the circumstances analysis, including an analysis of the advantages and disadvantages of designation.

DATES: Effective July 8, 2024.

ADDRESSES: EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OLEM–2019–0341. All documents in the docket are listed in *https://www.regulations.gov/.* Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. With the exception of such material, publicly available docket materials are available electronically in *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Sicy Jacob, Office of Emergency Management (5104A), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number 202–564–8019; email address: *jacob.sicy@epa.gov* or Linda Strauss, Office of Superfund Remediation and Technology Innovation, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number 202–564–0797; email address: *strauss.linda@epa.gov.*

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

AFFF Aqueous film-forming foam
ARARs Applicable or Relevant and Appropriate Requirements
ATSDR Agency for Toxic Substances and Disease Registry
CDC Centers for Disease Control and Prevention
CASRN Chemical Abstracts Service Registry Number
COC Contaminant of Concern
CDR Chemical Data Reporting
CERCLA Comprehensive Environmental Response, Compensation, and Liability Act
CFR Code of Federal Regulations
DoD Department of Defense
DOE Department of Energy
EA Economic Analysis
ECF Electrochemical fluorination
EJ Environmental justice
EPA Environmental Protection Agency
EPCRA Emergency Planning and Community Right-to-Know Act
EU European Union
FAA Federal Aviation Administration
FDA Food and Drug Administration
FR Federal Register
ICR Information Collection Request
LEPC Local Emergency Planning Committee
MCL Maximum contaminant level
MCLG Maximum Contaminant Level Goals (MCLGs)
NAICS North American Industrial Classification System
NCP National Oil and Hazardous Substances Pollution Contingency Plan
NECI National Enforcement Compliance Initiative
NHANES National Health and Nutrition Examination Survey
NPDWR National Primary Drinking Water Regulation
NPL National Priorities List
NRC National Response Center
OMB Office of Management and Budget
PCBs Polychlorinated biphenyls
PFAS Per- and polyfluoroalkyl substances
PFOA Perfluorooctanoic acid
PFOS Perfluorooctanesulfonic acid
PFOSA Perfluorooctanesulfonamide
PHGs Public health goals
ppt parts per trillion
PRG Preliminary remediation goal
PRP Potentially responsible party
PRSC Post-Removal Site Control
PWS Public water system
RCRA Resource Conservation and Recovery Act
RFA Regulatory Flexibility Act
RfD Reference dose
RQ Reportable quantity
SAB Science Advisory Board
SDWA Safe Drinking Water Act
SERC State Emergency Response Commission
SNURs Significant New Use Rules
TEPC Tribal Emergency Planning Committee
TERC Tribal Emergency Response Commission
TRI Toxic Release Inventory
TSCA Toxic Substances Control Act
UCMR Unregulated Contaminant Monitoring Rule
UMRA Unfunded Mandates Reform Act
U.S. United States
WWTP Wastewater treatment plant

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I. Executive Summary

A. Overview

Pursuant to section 102(a) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), EPA is designating perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), including their salts and structural isomers, as hazardous substances.[1] Each of the actions adding PFOA, PFOS, and their salts and structural isomers, to CERCLA's hazardous substances list is independent, and severable from the others. The Agency evaluated the available scientific and technical information about those substances and concluded that designation of each substance is warranted under the criteria in section 102(a) because both PFOA and PFOS, and their salts and isomers, may present substantial danger to public health or welfare or the environment. Exercising its discretion with respect to when to make a finding under section 102(a), EPA as part of its decision-making process went beyond considering whether PFOA and PFOS ''may present a substantial danger to public health welfare or the environment'' within the meaning of section 102(a), and also performed an additional analysis that weighed the advantages and disadvantages of designation, including quantitative and qualitative benefits and costs. As part of that additional discretionary analysis, EPA determined that the advantages of designation outweigh the disadvantages. Among other advantages, designation best serves CERCLA's two primary objectives—the timely cleanup of contaminated sites and holding polluters accountable for contamination they caused (*i.e.,* the ''Polluter Pays'' principle). Designation provides necessary tools to address the challenge of PFOA and PFOS contamination in the environment. Designation will allow EPA to utilize all CERCLA's authorities, which will enable EPA to address more sites, take earlier action, and to expedite eventual cleanup. Designating PFOA and PFOS as CERCLA hazardous substances is thus critical to addressing PFOA and PFOS releases in the environment and to protecting public health.

B. ''May Present Substantial Danger to Public Health or Welfare or the Environment''

EPA is taking final action on the proposed finding that both PFOA and PFOS ''may present substantial danger to public health or welfare or the environment'' when released into the environment after considering the available scientific and technical information and after considering comments on the proposed determination. Available information indicates that human exposure to PFOA and/or PFOS is linked to a broad range of adverse health effects, including developmental effects to fetuses during pregnancy or to infants (*e.g.,* low birth weight, accelerated puberty, skeletal variations), liver effects (*e.g.,* tissue damage), immune effects (*e.g.,* antibody production and immunity), and other effects (*e.g.,* cholesterol changes). Both PFOA and PFOS are known to be transmitted to the fetus via the placenta and to the newborn, infant, and child via breast milk.

In addition, toxicity assessments in support of EPA's 2024 National Primary Drinking Water Regulation for PFAS (*2024a*) indicate that PFOA and PFOS may cause carcinogenic effects in humans and animals (*Barry et al., 2013; Bartell & Vieira, 2021; Goodrich et al., 2022; Shearer et al., 2021; Vieira et al., 2013*). In the final toxicity assessments, EPA assessed the weight of the evidence for the available cancer data and determined that PFOA and PFOS are *Likely to Be Carcinogenic to Humans* consistent with the Guidelines for Carcinogen Risk Assessment (*U.S. EPA, 2005, 2024b, 2024c, 2024d*). Additionally, in November 2023, the International Agency for Research on Cancer (IARC) evaluated the carcinogenicity of PFOA and PFOS and classified PFOA as carcinogenic to humans (Group 1) and PFOS as possibly

[1] PFOA and PFOS are part of a group of human-made chemicals known as per- and polyfluoroalkyl substances (PFAS). All references to PFOA and PFOS in this notice include their salts and structural isomers.

carcinogenic to humans (Group 2b) (Zahm, et al., 2023).

The potential for adverse health effects is exacerbated by the fact that PFOA and PFOS are persistent in the environment, which can cause long-term exposure. PFAS, including PFOA and PFOS, are sometimes referred to as ''forever'' chemicals because of their strong carbon-fluorine bonds in the ''tail group'' that cause them to be extremely resistant to degradation and to remain in the environment for long periods of time. This means that the potential for human exposure continues long after an immediate release has ended. PFOA and PFOS are also highly mobile in the environment and can migrate away from the point of initial release. Studies also show that PFOA and PFOS persist in humans and animals (*i.e.,* bioaccumulate) with estimated elimination half-lives [2] in humans ranging from about two to three years for PFOA to four or five years for PFOS [3] (*ATSDR, 2021*). Because PFOA and PFOS can remain in the human body for these long durations, individuals who have consistent ongoing exposures to elevated concentrations of PFOA and PFOS (*e.g.,* individuals exposed by drinking contaminated well water) can have elevated concentrations of these compounds in their bodies which may contribute to adverse health effects (Hall et al., 2023; Hoffman et al., 2011; Kotlarz et al., 2020; Steenland et al., 2009).

PFOA and PFOS are prevalent in the environment and can be found in surface water, groundwater, soil, and air. PFOA and PFOS are prevalent because they have been produced and used since the 1940s, were among the most widely used of the PFAS constituents and persist in the environment for a long time. PFOA and PFOS have historically been used in a wide range of consumer products including carpets, clothing, fabrics for furniture, packaging for food and cookware, and firefighting foam, in addition to being used in a wide range of industrial processes. *See* Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances, 87 FR 54415, 54417 (proposed Sept. 6, 2022) (hereinafter ''Proposed Rule'' or ''Proposal'') (providing a brief history of PFOA and PFOS production and use). Domestic production and import of PFOA has been phased out by the companies participating in the 2010/2015 PFOA Stewardship Program (*U.S. EPA, 2023c*). Some uses of PFOS are ongoing. The sustained and broad use of PFOA and PFOS by industries means that many sites may be contaminated with high levels of PFOA and PFOS. Furthermore, these substances may still be released into the environment through use and disposal of legacy products and through limited ongoing uses.

PFOA and PFOS have been detected in the drinking water of millions of Americans and are widely detected in surface water samples collected from various rivers, lakes, and streams in the United States (*ATSDR, 2021; Cadwallader et al., 2022; U.S. EPA, 2017, 2024a*). This exposure potential is exacerbated by their persistence and mobility in the environment (*Langenbach & Wilson, 2021*). The prevalence of PFOA and PFOS is further demonstrated by the fact that these chemicals were detected in the blood of nearly all of the participants in the latest U.S. Centers for Disease Control and Prevention's (CDC) National Health and Nutrition Examination Survey (NHANES) for which data is available from 2017–2018. (*CDC, 2022*). This information indicates widespread though generally declining exposure to PFOA and PFOS in the U.S. population. From 1999–2000 to 2017–2018, blood PFOS levels declined by more than 85%. From 1999–2000 to 2017–2018, blood PFOA levels declined by more than 70%. While serum concentrations of PFOA and PFOS in the general population are declining, there is evidence that PFOA and PFOS releases continue to result in elevated environmental concentrations and the potential for human exposure. For example, under the 2018–2019 National Rivers and Streams Assessment (NRSA) PFOS was detected in 91% of the 290 fish fillet composite samples analyzed, corresponding to PFOS being detected in 92% of the sampled population of 41,099 river miles (a statistically significant decrease of 6.7% from NRSA 2013–14) (U.S. EPA, 2023i).

In consideration of the evidence of adverse effects to human health and the environment from PFOA and PFOS exposure, their persistence and mobility in the environment, and the significant potential for human exposure due to their prevalence in the environment, EPA concludes that PFOA and PFOS may present a substantial danger to public health or welfare or the environment when released into the environment. EPA further finds that populations located near highly contaminated sites are of particular concern because they are at risk of a disproportionately high potential of repeat exposure to PFOA and PFOS as compared to the general population and across demographic characteristics and repeated exposures increase the likelihood of adverse health effects, as discussed further in the Preamble, Section VI.A,2. d. For these reasons, designation of PFOA and PFOS as hazardous substances is warranted.

C. ''Totality of the Circumstances'' Analysis

Along with concluding that PFOA and PFOS each, when released, ''may present a substantial danger'' to public health or welfare or the environment and therefore meet the statutory designation criteria, EPA also exercised discretion to conduct an additional totality of the circumstances analysis. The analysis looks to CERCLA section 102(a), and its broader context, to help identify the information to weigh and how to balance multiple considerations. In conducting the analysis as to PFOA and PFOS, EPA identified and weighed the advantages and disadvantages of designation relative to CERCLA's purpose alongside the formal benefit-cost analysis, including quantitative and qualitative benefits and costs, provided in the Regulatory Impact Analysis [4] accompanying this final rule. That ''totality of the circumstances'' analysis confirmed EPA's conclusion that designation is warranted because the advantages of designation outweigh the disadvantages.

EPA considered how designation supports CERCLA's primary objectives to clean up contaminated sites and ensure the ''Polluter Pays.'' EPA concluded that designation best serves those objectives and that CERCLA is the best tool to address the legacy of sites contaminated with these substances and to address additional releases of these chemicals in the future. EPA considered that designation would allow EPA to deploy the full suite of CERCLA tools to identify, characterize, and clean up the most contaminated sites expeditiously. It allows EPA to ensure that those parties responsible for significant

[2] Elimination half-life is the length of time required for the concentration of a particular substance to decrease to half of its starting dose in the body.

[3] Data from two studies in Table 3–5 of ATSDR 2021 (Seals et al., 2011 and Zang et al., 2013) were not included in EPA's estimate of elimination half-life because their findings were significantly different for the other studies, and may not be the most representative.

[4] The RIA was conducted in a consistent manner with economic principles and governmental guidance documents for economic analysis (*e.g.,* OMB Circular A–4 and EPA's Guidelines for Preparing Economic Analyses) and summarized monetized costs and benefits. The RIA is a neutral analysis tool that allows the federal government to consider potential benefits and costs that may result from designation. It does not consider whether designation is warranted.

contamination bear the costs of cleaning it up. The use of these authorities will allow EPA to address more sites and to do so earlier in time than it otherwise could in the absence of designation. The ability to address more contaminated sites will provide meaningful health benefits to the communities near these sites by reducing the risk of exposure and the potential adverse health and environmental effects associated with such exposure. EPA expects these cleanups will have meaningful health benefits similar to health benefits typically associated with CERCLA actions. EPA also considered the potential quantifiable and qualitative costs and benefits of designation and the comments expressing concerns about widespread liability and litigation after designation. As explained below, EPA finds that the advantages of designation outweigh the disadvantages and that designation is warranted.

EPA's totality of the circumstances analysis considered the adverse health impacts and environmental challenges posed by PFOA and PFOS contamination. PFAS, including PFOA and PFOS, are a nationwide concern because exposure to these chemicals is linked to significant adverse human health impacts, they were in wide use, and they persist and are mobile once released into the environment. CERCLA provides the tools for addressing such contamination and provides a framework to allow EPA, and other delegated Federal agencies,[5] to make site-specific determinations and response decisions to address instances of PFOA and PFOS releases that pose unacceptable risk. Specifically, CERCLA provides authority to respond to releases of hazardous substances (including legacy releases). CERCLA's cleanup process is comprehensive in that it can address contamination to air, water, groundwater, and soil. EPA's CERCLA response authority also extends from initial investigations to cleanup. No other statute that EPA administers provides the breadth of authority to fully address highly contaminated sites. Thus, CERCLA is the best authority to address existing contamination to mitigate the disproportionate risk borne by communities impacted by those sites. Furthermore, CERCLA is a liability statute. The CERCLA cost recovery and enforcement provisions ensure that those parties responsible for significant contamination can be held accountable to pay for or conduct clean up. Designation is the best way for EPA to effectuate CERCLA's objectives with respect to releases of PFOA and PFOS.

EPA also considered whether designation is warranted considering EPA's existing CERCLA authority, which allows the Agency to address PFOA and PFOS as ''pollutants or contaminants.'' CERCLA's authority to address pollutants or contaminants is much more circumscribed than the authority to address hazardous substances. Specifically, CERCLA's notification requirements for releases do not attach to pollutants or contaminants; EPA cannot address a release of pollutants or contaminants unless the Agency demonstrates that the release may present an ''imminent and substantial danger''; CERCLA does not provide cost recovery authority for actions taken solely in response to releases or threats of releases of pollutants or contaminants; and CERCLA authority to compel potentially responsible parties (PRPs) to conduct or pay for response work does not extend to pollutants or contaminants. Designating PFOA and PFOS as CERCLA hazardous substances eliminates those limitations. Elimination of those limitations provides meaningful advantages.

EPA also considered the advantages of designation. The most significant direct costs associated with designation stem from the requirement for facilities to report releases of PFOA and PFOS that occur after designation. EPA determined these costs were fairly minimal and reasonable in light of the benefits of release notifications. Notification ensures transparency about new releases of PFOA and PFOS, and it allows EPA and affected States and communities to immediately evaluate a release and quickly respond, as necessary, to address risks to human health or the environment. Without notice, EPA is less able to obtain key information to help protect affected communities. Thus, the notification requirement is an advantage that is necessary to adequately protect the public from future releases. Designation also allows EPA to streamline the Federal government's response authority to address releases of PFOA and PFOS, which will allow EPA to take action sooner. EPA can also begin the lengthy process of identifying, characterizing, and cleaning up the most contaminated sites without delay, either through enforcement or EPA-funded action.

Another key advantage to designation is that it best effectuates the Polluter Pays principle underpinning CERCLA. Designation improves equities by transferring costs of cleaning up PFOA and PFOS from the Superfund (''the Fund''),[6] which has been historically funded by taxpayer dollars, to those responsible for contamination. Absent designation, costs incurred for addressing PFOA and PFOS as pollutants or contaminants are paid for by the Fund, rather than responsible parties. Preservation of the Superfund is critical because the monies in it are insufficient to clean up all the existing contamination across the country from the more than 800 CERCLA hazardous substances as well as additional/emerging pollutants and contaminants. The ability to require PRPs to pay for PFOA and PFOS response costs means that more money will be available in the Fund to address a multitude of priorities, particularly at those sites where there is no viable PRP. It also allows EPA to address more releases earlier than it otherwise could absent designation. Further, cleanup to address PFOA/PFOS supported by designation may allow for incidental cleanup of co-contaminants, including other types of PFAS, which would also benefit human and environmental health. Because contaminated sites often have multiple contaminants of concern (''COCs''), the benefits from addressing co-contaminants may be substantial for some sites to the extent this occurs. It is critical to initiate more CERCLA actions to address PFOA and PFOS contamination now because the process from investigations to cleanups can take many years, if not decades. And, because PFOA and PFOS are persistent in the environment and highly mobile, further delay increases the extent of contamination, potentially increasing the number of individuals exposed to these substances, and also potentially increasing costs associated with cleanup.

EPA's ability to address PFOA and PFOS contamination through enforcement *and* EPA-funded action means more communities will be protected from disproportionate and unacceptable health risks, including communities with environmental justice

[5] Executive Order 12580 (Jan. 23, 1987, as amended) delegates CERCLA response authority to EPA, as well as the Secretaries of Defense, Interior, Agriculture, Commerce, and Energy with respect to releases from a facility or vessel under their jurisdiction, custody or control and to the U.S. Coast Guard with respect to releases involving the coastal zone, Great Lakes waters, ports, and harbors.

[6] Congress established the Hazardous Substances Trust Fund, otherwise known as the Superfund, to provide funding to address contamination. CERCLA also established liability for parties that contributed to releases of hazardous substances, CERCLA section 107(a), which allows EPA to shift costs from the Fund to PRPs.

(EJ) concerns. Published literature [7] supports the conclusion that certain communities with EJ concerns have a higher likelihood of exposure to PFAS, including PFOA/PFOS. For more information, see RIA Section 6.3 *Impacts on Communities with EJ concerns: Analysis.* Cleaning up more sites with PFOA and PFOS contamination will help to decrease their exposure to PFOA and PFOS, thus reducing their risk of detrimental health effects, such as decreased immune response to vaccination, decreased birthweight, increased total cholesterol, and cancer. Cleaning up sites also promotes economic benefits, such as improved property values and making land available for reuse. Improving environmental quality can improve local economies by supporting local business, such as recreation companies or industries that rely on natural products like agriculture. Improved quality of natural resources can also contribute to ecosystem services.[8]

EPA also considered the quantitative and qualitative direct and indirect costs and benefits evaluated in the RIA as part of its totality of the circumstances analysis.[9] EPA recognizes that designation will lead to both direct and indirect costs. The only quantifiable direct cost associated with designation is the notification requirement, for releases of PFOA and PFOS at or above 1 pound within a 24-hour period. EPA estimates that the notification requirement will cost $2,658 per release and that the total cost of the notification requirement is not anticipated to exceed $1,630,000 per year.[10] Notification is critical to ensuring that new releases are identified, evaluated, and addressed to the extent necessary to protect human health and the environment. EPA considers both the individual and total notification costs to be generally reasonable because of the value notification provides to impacted communities and regulatory agencies. Notification can avoid delays in evaluation of a new release. This is particularly important for persistent and mobile substances like PFOA and PFOS because early evaluation can determine whether the release poses an unacceptable risk that requires a response before PFOA and PFOA migrate away from the release. Such migration without intervention can lead to an increase in both the scope of the contamination and the costs necessary to address any identifiable risks.

With respect to indirect costs, EPA considered the costs associated with responding to releases of PFOA and PFOS at contaminated sites and with responding to future releases, either through direct EPA action with cost recovery or through enforcement. As stated above, EPA considers the ability to use the full suite of CERCLA authorities—including cost recovery and enforcement—to be an advantage of the rule. Designation eliminates current barriers to timely cleanup of contaminated sites and enables EPA to pursue parties responsible for significant contamination, these are the parties that should bear the costs of cleaning it up. When parties responsible for contamination are required to bear the cost of cleanup, more resources are made available to address additional cleanups. For example, EPA can compel a PRP to take action to address PFOA and PFOS pursuant to CERCLA section 106(a), which will then allow EPA to use Superfund monies and human resources to address other releases at other sites. Further, every contaminated site that is addressed can reduce the disproportionate burden borne by some of the communities at risk of exposure to PFOA and PFOS from the contamination. EPA's totality of the circumstances analysis included an evaluation of the benefit-cost analysis in the RIA (including indirect costs) as well as additional qualitative considerations related to designation, such as how CERCLA functions.

EPA is required to take a measured approach in responding to contamination. For instance, CERCLA ensures that costs are considered when determining the remedy. In addition, EPA, as well as other Federal agencies, have resource constraints that require CERCLA response actions to be prioritized to address the most urgent and highest risks as specified by the National Priorities List (NPL). The NPL is the list of sites of national priority among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States and its territories. It is intended primarily to guide EPA in determining which sites warrant further investigation. Eligibility for the NPL includes identifying priority sites based upon relative risk or danger that may be posed to public health or welfare or the environment, considering the population, the hazard potential of the hazardous substances at issue, the potential for contamination of drinking water supplies, the potential for direct human contact, the potential for destruction of sensitive ecosystems, and the damages to natural resources that may affect the human food chain when determining priority. Thus, CERCLA provides EPA with the ability to identify the sites with the highest human health and environmental risks and address those sites first, and the costs of addressing contamination are considered relative to the risks the contamination poses before a remedy is selected. before a remedy is selected.

Between FY 2003 and FY 2022, only about four percent of all contaminated sites added to EPA's Active Site Inventory were placed on the NPL. Since 2013, EPA has, on average, added 11 sites [11] per year to the NPL, and EPA

[7] Northeastern University—The PFAS Project Lab, ''PFAS Contamination Is an Equity Issue, and President Trump's EPA Is Failing to Fix It'' October 31, 2019. Available at: *https://pfasproject.com/2019/10/31/pfas-contamination-is-an-equity-issue-and-president-trumps-epa-is-failing-to-fix-it/.*

Lee, Susan, Avinash Kar, and Dr. Anna Reade, *Dirty Water: Toxic ''Forever'' PFAS Chemicals are Prevalent in the Drinking Water of Environmental Justice Communities.* Natural Resources Defense Council, New York. 2021. *https://www.nrdc.org/sites/default/files/dirty-water-pfas-ej-communities-report.pdf*

Stoiber, T., Evans, S., & Naidenko, O.V. (2020). Disposal of products and materials containing per- and polyfluoroalkyl substances (PFAS): A cyclical problem. *Chemosphere 260,* Accessed at: *https://doi.org/10.1016/j.chemosphere.2020.127659.*

[8] Ecosystem services produce the life-sustaining benefits we receive from nature—clean air and water, fertile soil for crop production, pollination, and flood control.

[9] The terms ''direct'' and ''indirect'' as used to describe potential impacts of this rule are based on established definitions used for analyses under the Regulatory Flexibility Act (RFA). EPA is aware that ''direct'' and ''indirect'' costs have distinct definitions for CERCLA purposes; those CERCLA-specific definitions were not used for estimating costs for the purpose of designation. Both EPA and SBA have applicable RFA guidance documents that were considered in developing this rule. For this rule, reporting requirements are direct effects because upon designation of PFOA and PFOS as hazardous substances, entities that release a reportable quantity within a 24-hour period are required to use established procedures to report the release immediately by telephone and provide a follow-up written report. Potential liability for response costs for addressing PFOA and PFOS releases or threatened releases is an indirect effect of designation. This is because CERCLA response actions are not required by this rule, and are discretionary and contingent upon a series of many site-specific determinations. See RIA Section 1.4 *Scope of Analysis* and RIA Section 6.2 *Small Entity Analysis* for more detail.

[10] The designation may also result in minimal costs to federal agencies associated with CERCLA section 120(h) notice requirements when selling or transferring federally owned real property where PFOA/PFOS may be present. Future federal property sales and transfers involving property where PFOA and/or PFOS may be present is unknowable and therefore such costs are unquantifiable.

[11] This estimate is based on data from EPA's SEMS database with respect to non-federal NPL sites. EPA determined that it was appropriate to assess the designation's impact with respect to non-federal NPL sites only, because federal sites are generally expected to address PFOA and PFOS in the absence of designation consistent with CERCLA section 104. As discussed in Chapter 2 of the RIA, federal sites are addressing PFAS in the baseline as authorized by CERCLA section 104 and corresponding Executive Orders, as required by the

does not expect the rate at which annual additions to the NPL occur to increase as a result of this rule. Moreover, NPL listing does not trigger any immediate actions, liability, or requirements for the site.[12]

CERCLA ensures that the most significant releases that pose the most risks to human health and the environment are prioritized, and designation will allow EPA to ensure more sites are evaluated sooner, thereby protecting more communities from PFOA and PFOS contamination. In Chapter 5 of the Regulatory Impact Analysis (RIA) for this rulemaking, EPA presents quantified potential response costs [13] that may occur after designation despite the uncertainty of future response actions. Every site is unique and the extent of action necessary to mitigate risks depends on many factors, which leads to uncertainties regarding response activities and associated costs. Notwithstanding these uncertainties, EPA used existing data to estimate response costs for PFOA and PFOS. Specifically, EPA used response costs data for EPA-lead response actions, potential costs associated with cleanup methods and technologies available to address PFOA and PFOS, and information about conditions at contaminated sites. EPA then used that data to assess the incremental costs of cleanup associated with addressing PFOA/PFOS contamination. Data available to EPA demonstrates that PFOA and PFOS generally are not found in isolation; rather, those substances are typically co-located or commingled with other ''contaminants of concern'' that on their own support a remedy. The estimated incremental costs to address PFOS and/or PFOS releases at NPL sites are those that the Agency believes it would incur absent the designation, which can be transferred to viable, liable parties as a result of designation. As EPA's funds would then be used for additional fund-led efforts to address contamination not addressed under the baseline, there will be a net increase in spending on response activities. This ability to transfer costs enables EPA to investigate and clean up additional NPL sites to address potential risks posed by any of the more than 800 hazardous substances, including PFOA and PFOS. EPA estimated the potential transfer of response costs associated with NPL sites range from $10.3M to $51.7M per year (at a 2% discount rate), depending on the cost premium associated with the response work to address PFOA and/or PFOS in addition to other Contaminants of Concerns (COCs) [14] at a given NPL site. Because EPA would use these funds for additional fund-led efforts to address contamination not addressed under the baseline, the transfer of $10.3M to $51.7M would result in additional costs of this same amount. Additionally, indirect costs associated with potential enforcement actions that may result in additional response activities for PFOA and PFOS at non-NPL sites are estimated to range from $327,000 to $18,100,000 per year (at the 2% discount rate), depending on the type of response actions taken at a given site. See RIA *Section.*

5.1 Indirect Costs and Transfers

EPA expects response costs to address PFOA and PFOS to represent an incremental increase above the cost of addressing other substances at NPL sites because, more often than not, PFOA and PFOS are likely to be co-located with or commingled with other substances. EPA also expects that costs to address PFOA and PFOS will fall within typical response cost ranges for actions to address other hazardous substances. This is because many of the same response and cleanup methods available, as noted in the *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances—Version 2 (2024),*[15] to address other hazardous substances can be used to address PFOA and PFOS (*e.g.,* dig and haul for soil and granulated activated carbon for water). Moreover, EPA expects that response and cleanup costs may decrease over time as associated methods improve. Finally, by addressing PFOA and PFOS releases earlier, EPA can mitigate the spread of contamination, which likely mitigates the costs of an otherwise more wide-spread cleanup.

EPA also considered liability and litigation that may arise after designation. CERCLA is designed to ensure that those responsible for contamination pay to clean it up. For PRPs that have significantly contributed to contamination, imposing CERCLA liability is wholly consistent with CERCLA and necessary to address the public health threat posed by PFOA and PFOS. However, EPA also gave serious consideration to potential liability for parties that have not played a significant role in contamination. Those parties include entities that did not generate PFOA- or PFOS-contaminated materials. EPA evaluated CERCLA liability limitations, EPA's enforcement policies, settlement protections for settling and non-settling parties, and parameters for CERCLA lawsuits to resolve who should pay and how much. Those mechanisms, combined with decades of historical practice, show that CERCLA liability is not unlimited; enforcement is targeted; and parties' ability to recover costs from other PRPs is constrained.

Although CERCLA's liability structure is broad, both the statute and EPA enforcement discretion policies may constrain a party's ability to secure reimbursement of response costs.[16] CERCLA includes liability exemptions as well as affirmative defenses against liability. *See, e.g.,* CERCLA section 101(10), 107(b), (d), (k). Parties must incur response costs before they can recover those costs from other viable, liable parties. And parties must prove that response costs incurred are consistent with the National Contingency Plan, CERCLA's implementing regulations. *Id.* section 107(a)(4)(B). EPA's enforcement authorities and policies can serve as a deterrent for responsible parties to pursue entities that did not contribute

NDAA, and consistent with federal facilities agreements under CERCLA section 102(a). Therefore, EPA expects that federal sites will address PFOA and PFOS contamination in the absence of the final rule. With federal sites taking action to address PFAS in the baseline, indirect impacts of the final rule will likely be related to actions taken at non-federal sites. For additional context, since FY 2000 EPA has added 8 federal sites to the NPL.

[12] EPA considered the portion of non-federal NPL sites that may be impacted by designation depending on site-specific circumstances. Of final, proposed, or deleted non-federal NPL sites that have been tested for PFOA and/or PFOS, an estimated 33.1% of NPL sites have detectable levels of PFOA and/or PFOS. See Section 3.3 of the RIA for more details about this estimate. In evaluating the designation's impact non-federal NPL sites, this estimate is instructive and serves as a benchmark for assessing designation's potential impact to those sites. There are currently 5 sites where either PFOA or PFOS contributed to NPL listing.

[13] The term ''response'' may include actions including but not limited to: site assessment, investigation, remedial action, and removal action. See CERCLA section 101(25). For a description of details on the differences between remedial and removal actions and other response activities under CERCLA, please see Section 2.1 of the RIA.

[14] Contaminants of Concerns (COCs) are chemicals identified during in-depth site studies (Remedial Investigation/Feasibility Study) that need to be addressed by a cleanup action because they pose a potential threat to human health or the environment.

[15] *Interim PFAS Destruction and Disposal Guidance; Notice of Availability for Public Comment* was published in the **Federal Register** on April 16, 2024 (89 FR 26879) *https://www.govinfo.gov/content/pkg/FR-2024-04-16/pdf/2024-08064.pdf.*

[16] Other Federal agencies including DOD, DOE, USDA, and DOI have delegated CERCLA authority. EPA's policies apply only to EPA and its exercise of enforcement discretion. Please note that EPA's policies are not regulations and do not create new legal obligations or limit or expand obligations under any Federal, State, Tribal or local law.

significantly to contamination.[17] EPA has a well-proven track record of developing enforcement discretion policies that have been effective and well-received.[18] EPA's enforcement policies, such as its policy regarding de minimis or de micromis parties and innocent landowner policies, have proven to be useful tools in convincing responsible parties not to pursue entities covered by these enforcement discretion policies. Finally, the statute provides that a party that resolves its potential liability with the United States or a State in a judicially approved settlement is entitled to contribution protection—the ability to block third-party claims for matters addressed in the settlement. These liability limitations and mitigation tools are more fully discussion in Section VI.B.2. EPA concludes that designation is not expected to result in excessive litigation and that CERCLA will continue to operate as it has for decades. Indeed, CERCLA's liability framework, coupled with EPA enforcement policies, has operated in a rational way for the more than 800 CERCLA hazardous substances already within its purview, some of which are similar to PFOA and PFOS in terms of ubiquity, mobility, and persistence. Heavy metals, such as arsenic and chromium, are persistent, and in at least some places, prevalent in the environment. Although EPA understands that designation will result in new litigation regarding PFOA and PFOS releases for responsible parties, forty years of CERCLA experience indicates that designation should not result in unusual CERCLA liability or litigation outcomes for parties who did not significantly contribute to the contamination as a result of this designation, and, therefore, the potential for litigation should not be a barrier to designation.

EPA aims to further support reasonable liability and litigation outcomes through the implementation of its CERCLA enforcement program. EPA will continue to implement its ''Enforcement First'' policy (''*Guidelines for Using the Imminent Hazard, Enforcement and Emergency Response Authorities of Superfund and Other Statutes,*'' *1982*)—in which EPA aims to compel viable PRPs to conduct and pay for investigation and cleanup before resorting to the Fund—which supports the Polluter Pays principle. EPA has a proven track record of developing and applying enforcement discretion policies that are effective and well-received by the public and interested parties, and courts have sanctioned this approach. Enforcement discretion policies historically have given EPA the needed flexibility to offer liability comfort or protections when circumstances warrant. For example, for more than 30 years, EPA has maintained its ''Policy Towards Owners of Residential Property at Superfund Sites,'' which generally provides that EPA will not take action against residential property owners provided their own actions do not cause a release that requires a response action.

Although EPA believes existing limitations in CERCLA coupled with existing CERCLA enforcement policies mitigate concerns about liability that may arise after designation, EPA recognizes that some parties that do not bear primary responsibility for litigation may be sued and face uncertain litigation costs as a consequence. EPA believes that the statutory safeguards described above will likely limit this type of litigation, or at a minimum, limit adverse outcomes. Even if litigation costs are incurred by parties that do not bear primary responsibility, EPA does not believe that these potential costs will outweigh the substantial advantages from the rule.

While some commenters shared concerns that these mechanisms may not mitigate concerns, these commenters did not support their concerns with any specific data or evidence. Generally, in enforcement matters, the facts, circumstances, and equities of a case help dictate which parties the Agency will pursue. EPA, intends to develop a policy, consistent with those limitations and policies, that explains EPA's priorities for enforcement in the context of PFOA and PFOS releases.[19] As EPA states in the FY 2024–2027 National Enforcement and Compliance Initiatives (NECI), the Agency expects to ''focus on implementing EPA's PFAS Strategic Roadmap and holding responsible those who significantly contribute to the release of PFAS into the environment . . . much as [EPA] exercises CERCLA enforcement discretion in other areas.''.[20] Available at *https://www.epa.gov/system/files/documents/2023-08/fy2024-27necis.pdf.*

In sum, EPA's additional ''totality of the circumstances'' analysis affirms that designation is warranted. The totality of the circumstances analysis gave particular weight to the scientific basis for designation—that PFOA and PFOS may present substantial danger when released into the environment. EPA also concluded that designation best addresses the problem posed by PFOA and PFOS in the environment, particularly for those communities living in and around highly contaminated sites, and that designation meaningfully furthers CERCLA's purposes. Designation ensures that EPA has the full suite of CERCLA tools necessary to address contamination and that EPA is able to take more timely response actions, including those necessary to address immediate risks. EPA's analysis shows that designation results in quantitative and qualitative benefits, including significant health

[17] CERCLA is designed to achieve the cleanup of contaminated sites by ensuring that those responsible for the contamination pay to clean it up, which EPA supports through its longstanding ''enforcement first'' policy. (''*Guidelines for Using the Imminent Hazard, Enforcement and Emergency Response Authorities of Superfund and Other Statutes,*'' 1982.) Furthermore, CERCLA's settlement provisions are designed to support and achieve those outcomes by making it efficient for EPA to secure clean up from those that have significantly contributed to contamination. *See, e.g.* Section 122(a) (''Whenever practical and in the public interest, . . . [EPA] shall act to facilitate agreements . . . that are in the public interest and minimize litigation.''); Section 122(g)(1) (allowing for ''expedited'' *de minimis* settlements for ''minor portions of the response costs''). In practice, CERCLA's settlement parameters incentivize PRPs that likely bare a large share of responsibility to settle with EPA, which in turn can deter those same parties from pursuing other PRPs. Ultimately, settlement is generally less expensive than litigation and can serve as an effective mechanism for achieving the true goal of CERCLA—that the parties most responsible for contamination pay to clean it up.

[18] While EPA's enforcement discretion policies themselves are not regulations and do not create new legal obligations or limit or expand obligations under any federal, state, tribal or local law, such policies have influenced Congress to create new laws that have been upheld by courts. The Small Business Liability Relief and Brownfields Revitalization Act of 2002 (''Brownfields Amendments'') illustrate how EPA's policies have influenced Congressional action. The Brownfields Amendments amended CERCLA and promoted the cleanup, reuse, and redevelopment of sites by addressing potential liability concerns associated with contaminated, potentially contaminated, and formerly contaminated properties. The Brownfields Amendments provided important self-implementing liability limitations for certain categories of landowners, enabling private parties to save time and costs, in part, by reducing EPA involvement in most private party transactions. EPA launched the Brownfields Initiative in the 1990s and developed guidance and tools to help further the Initiative's goals to empower states, communities, and other stakeholders to assess, safely clean up, sustainably reuse, and prevent future brownfield sites. EPA's Brownfields Initiative established a number of practices, policies, and guidances to support cleanup and reuse at contaminated property. In 2002, many elements of EPA's Brownfields Initiative were codified into CERCLA by the Brownfields Amendments.

[19] EPA received valuable public input that EPA is considering in drafting a CERCLA PFAS enforcement discretion policy. EPA held two public listening sessions in March 2023 and several stakeholder meetings in 2023 with the agriculture sector, water sector, pulp and paper sector, solid waste management sector, and NGOs to hear stakeholder concerns regarding potential CERCLA PFAS enforcement concerns.

[20] *https://www.epa.gov/enforcement/national-enforcement-and-compliance-initiatives.*

benefits. EPA's analysis accounts for potential direct and indirect costs that may result from designation. Direct costs, particularly for release notifications, are minimal and reasonable in light of the substantial benefits notification provides. EPA assessed the potential for litigation and liability costs, particularly for parties that have not significantly contributed to contamination. EPA was unable to quantify those costs with reasonable certainty but conducted a qualitative assessment of CERCLA's liability provisions and enforcement policies to assess the potential magnitude of such costs. EPA's analysis shows that designation should not result in excessive or unreasonable liability and litigation outcomes. Rather, CERCLA will continue to operate as it has for decades. EPA concludes that the substantial advantages of designation outweigh potential disadvantages, and that designation is warranted based on its additional totality of the circumstances analysis.

D. Conclusion

EPA concludes that designation is warranted based solely on its finding that PFOA and PFOS may present a substantial danger to the public health or welfare or the environment when released into the environment. Additionally, EPA believes designation is warranted based on its totality of the circumstances analysis. The latest science is clear: human exposure to PFOA and PFOS is linked to significant health risks. CERCLA provides the tools necessary to address those risks posed by significant contamination of PFOA and PFOS in the environment. CERCLA is designed to target and prioritize sites that present unreasonable risk to human health and the environment and serves those communities that are most vulnerable to potential adverse health risks from exposure. Designation eliminates barriers to cleanup and enables EPA to secure more timely actions. It streamlines response authority, provides a mechanism for parties to recover response costs from PRPs, and makes available CERCLA enforcement authority to compel PRPs to conduct or pay for cleanup. Designation also requires facilities to notify Federal, State, local, and Tribal authorities, as well as potentially injured parties, of significant releases. EPA considered the potential costs that may arise after designation, including both quantified and unquantified costs, and finds that they are outweighed by the substantial advantages of designation. Further delay in accessing CERCLA's complete suite of tools to address contamination will allow PFOA and PFOS more time to migrate within the environment and exacerbate existing contamination. Thus, designation best achieves CERCLA's primary objectives—the timely cleanup of contaminated sites and ensuring that those responsible for contamination pay to clean it up. Designation will help protect communities near contaminated sites from potential health risks. For all these reasons, discussed in detail below, EPA concludes that designation of both PFOA and PFOS as CERCLA hazardous substances is warranted under the statute.

II. General Information

A. What action is the Agency taking?

As proposed on September 6, 2022, EPA is designating PFOA and PFOS, including their salts and structural isomers, as hazardous substances under section 102(a) of CERCLA. *See Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances,* 87 FR 54415 (Sept. 6, 2022). The list of hazardous substances in Table 302.4 of 40 CFR part 302 is amended to include PFOA, PFOS and their salts and structural isomers. (*Note: EPA's CompTox Chemicals Dashboard (https://comptox.epa.gov/dashboard/) is a resource that can be used to identify salts and structural isomers of PFOA and PFOS. EPA periodically updates the CompTox Chemicals Dashboard to include new information on PFAS, including PFOA and PFOS.)*

B. What are the direct effects of this Action?

The designation of PFOA and PFOS, including their salts and structural isomers, as hazardous substances, can trigger the applicability of release reporting requirements under CERCLA sections 103 and 111(g), and accompanying regulations, and section 304 of the Emergency Planning and Community Right-to-Know Act (EPCRA). Facilities must report releases of hazardous substances at or above the reportable quantity (RQ) within a 24-hour period. For PFOA and PFOS, a default [21] reportable quantity (RQ) of one pound is assigned to these substances pursuant to CERCLA section 102(b). Therefore, consistent with CERCLA section 103(a), any person in charge of a vessel or facility is required, as soon as they have knowledge of any release (other than a federally permitted release) of any PFOA, PFOS, their salts or structural isomers from such vessel or facility in quantities equal to or greater than the RQ of one pound or more within 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). *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-J/part-302/section-302.6.*

In addition to CERCLA 103(a), EPCRA section 304 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 of these substances. These entities may have specific release reporting requirements under the State, Tribal, and local EPCRA program. *https://www.epa.gov/epcra/state-contact-information-epcra-section-304-emergency-release-notification.*

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. EPCRA section 304 requirements are codified in 40 CFR 355.30 to 355.43. *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-J/part-355/subpart-C.*

CERCLA section 111(g) requires that owners or operators of any vessel or facility ''provide reasonable notice to potential injured parties by publication in local newspapers serving the affected area'' of any release of these substances.

CERCLA section 120(h) requires Federal agencies that sell or transfer real property to provide notice of the presence of hazardous substances in certain circumstances. CERCLA section 120(h) also 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.''

As provided by CERCLA section 306, the Department of Transportation (DOT) is required to regulate any substance added to the CERCLA list as hazardous materials in accordance with the Hazardous Materials Transportation Act (HMTA).

[21] 42 U.S.C. 9602(b). *https://www.govinfo.gov/content/pkg/USCODE-2021-title42/pdf/USCODE-2021-title42-chap103-subchapI-sec9601.pdf.*

While these are the only direct, automatic requirements of designating PFOA and PFOS as CERCLA hazardous substances, EPA has also considered other, indirect impacts in the *Regulatory Impact Analysis (RIA) of the Final Rulemaking to Designate Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances,* available in the docket, including those that are expected to facilitate cleanups and reduce human and environmental exposure to these hazardous substances.

C. Does this Action apply to me?

The seven broad categories of entities that may potentially be affected by this action include, but are not limited to: (1) PFOA and/or PFOS manufacturers (including importers and importers of articles that contain these substances); (2) PFOA and/or PFOS processors; (3) manufacturers of products containing PFOA and/or PFOS; (4) downstream users of PFOA and PFOS; (5) downstream users of PFOA and/or PFOS products; (6) waste management facilities; and (7) wastewater treatment facilities.[22] (*Note: PFOA and PFOS noted here include their salts and structural isomers.*) The following list of North American Industrial Classification System (NAICS) codes identifies entities that may be directly or indirectly affected by this action. It is not intended to be exhaustive, but rather a guide to help readers determine whether this action applies to them. Potentially affected entities may include:

BILLING CODE 6560–50–P

[22] The proposed rule listed 5 broad categories of entities potentially affected by this designation. This action separated two of these categories to be clearer. Entities listed as downstream product manufacturers and users of PFOA and/or PFOS products in the proposed rule are split into two separate categories in the final rule (see (4) and (5)). Entities listed as waste management and wastewater treatment facilities in the proposed rule are split into two categories in the final rule (see (6) and (7)).

Sector	Industry Group	6-Digit NAICS	6-Digit NAICS Description
Oil and Gas Extraction	Oil and Gas Extraction	211120	Crude Petroleum Extraction
		211130	Natural Gas Extraction
Mining (except Oil and Gas)	Metal Ore Mining	212221	Gold Ore Mining
		212230	Copper, Nickel, Lead, and Zinc Mining
		212291	Uranium-Radium-Vanadium Ore Mining
Utilities	Water, Sewage and Other Systems	221320	Sewage Treatment Facilities
Textile Mills	Fiber, Yarn, and Thread Mills	313110	Fiber, Yarn, and Thread Mills
	Fabric Mills	313210	Broad Woven Fabric Mills
		313220	Narrow Fabric Mills and Schiffli Machine Embroidery
		313230	Nonwoven Fabric Mills
		313240	Knit Fabric Mills
	Textile and Fabric Finishing and Fabric Coating Mills	313310	Textile and Fabric Finishing Mills
		313320	Fabric Coating Mills
Textile Product Mills	Textile Furnishings Mills	314110	Carpet and Rug Mills
	Other Textile Product Mills	314910	Textile Bag and Canvas Mills
		314999	All Other Miscellaneous Textile Product Mills
Leather and Allied Product Manufacturing	Leather and Hide Tanning and Finishing	316110	Leather and Hide Tanning and Finishing
	Other Leather and Allied Product Manufacturing	316998	All Other Leather Good and Allied Product Manufacturing
Paper Manufacturing	Pulp, Paper, and Paperboard Mills	322121	Paper (except Newsprint) Mills
		322130	Paperboard Mills
	Converted Paper Product Manufacturing	322219	Other Paperboard Container Manufacturing
		322220	Paper Bag and Coated and Treated Paper Manufacturing
Printing and Related Support Activities	Printing and Related Support Activities	323111	Commercial Printing (except Screen and Books)
		323120	Support Activities for Printing
Petroleum and Coal Products Manufacturing	Petroleum and Coal Products Manufacturing	324110	Petroleum Refineries
		324191	Petroleum Lubricating Oil and Grease Manufacturing

Sector	Industry Group	6-Digit NAICS	6-Digit NAICS Description
Chemical Manufacturing	Basic Chemical Manufacturing	325110	Petrochemical Manufacturing
		325120	Industrial Gas Manufacturing
		325130	Synthetic Dye and Pigment Manufacturing
		325180	Other Basic Inorganic Chemical Manufacturing
		325193	Ethyl Alcohol Manufacturing
		325199	All Other Basic Organic Chemical Manufacturing
	Resin, Synthetic Rubber, and Artificial and Synthetic Fibers and Filaments Manufacturing	325211	Plastics Material and Resin Manufacturing
		325212	Synthetic Rubber Manufacturing
		325220	Artificial and Synthetic Fibers and Filaments Manufacturing
	Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing	325320	Pesticide and Other Agricultural Chemical Manufacturing
	Pharmaceutical and Medicine Manufacturing	325411	Medicinal and Botanical Manufacturing
	Paint, Coating, and Adhesive Manufacturing	325510	Paint and Coating Manufacturing
	Soap, Cleaning Compound, and Toilet Preparation Manufacturing	325611	Soap and Other Detergent Manufacturing
		325612	Polish and Other Sanitation Good Manufacturing
		325613	Surface Active Agent Manufacturing
	Other Chemical Product and Preparation Manufacturing	325910	Printing Ink Manufacturing
		325992	Photographic Film, Paper, Plate, and Chemical Manufacturing
		325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing
Plastics and Rubber Products Manufacturing	Plastics Product Manufacturing	326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing
		326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing
		326121	Unlaminated Plastics Profile Shape Manufacturing
		326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing

Sector	Industry Group	6-Digit NAICS	6-Digit NAICS Description
	Rubber Product Manufacturing	326211	Tire Manufacturing (except Retreading)
Nonmetallic Mineral Product Manufacturing	Glass and Glass Product Manufacturing	327215	Glass Product Manufacturing Made of Purchased Glass
	Cement and Concrete Product Manufacturing	327310	Cement Manufacturing
	Other Nonmetallic Mineral Product Manufacturing	327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing
Primary Metal Manufacturing	Steel Product Manufacturing from Purchased Steel	331221	Rolled Steel Shape Manufacturing
	Alumina and Aluminum Production and Processing	331313	Alumina Refining and Primary Aluminum Production
Fabricated Metal Product Manufacturing	Coating, Engraving, Heat Treating, and Allied Activities	332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers
		332813	Electroplating, Plating, Polishing, Anodizing, and Coloring
	Other Fabricated Metal Product Manufacturing	332999	All Other Miscellaneous Fabricated Metal Product Manufacturing
Machinery Manufacturing	Industrial Machinery Manufacturing	333249	Other Industrial Machinery Manufacturing
	Commercial and Service Industry Machinery Manufacturing	333316	Photographic and Photocopying Equipment Manufacturing
		333318	Other Commercial and Service Industry Machinery Manufacturing
Computer and Electronic Product Manufacturing	Communications Equipment Manufacturing	334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing
	Audio and Video Equipment Manufacturing	334310	Audio and Video Equipment Manufacturing
	Semiconductor and Other Electronic Component Manufacturing	334412	Bare Printed Circuit Board Manufacturing
		334413	Semiconductor and Related Device Manufacturing
		334418	Printed Circuit Assembly (Electronic Assembly) Manufacturing
		334419	Other Electronic Component Manufacturing
Electrical Equipment,	Other Electrical Equipment and	335931	Current-Carrying Wiring Device Manufacturing

Sector	Industry Group	6-Digit NAICS	6-Digit NAICS Description
Appliance, and Component Manufacturing	Component Manufacturing	335999	All Other Miscellaneous Electrical Equipment and Component Manufacturing
Transportation Equipment Manufacturing	Motor Vehicle Parts Manufacturing	336399	All Other Motor Vehicle Parts Manufacturing
Miscellaneous Manufacturing	Medical Equipment and Supplies Manufacturing	339112	Surgical and Medical Instrument Manufacturing
Merchant Wholesalers, Nondurable Goods	Chemical and Allied Products Merchant Wholesalers	424690	Other Chemical and Allied Products Merchant Wholesalers
	Petroleum and Petroleum Products Merchant Wholesalers	424710	Petroleum Bulk Stations and Terminals
Furniture and Home Furnishings Stores	Home Furnishings Stores	442291	Window Treatment Stores
Rail Transportation	Rail Transportation	482111	Freight Rail
Truck Transportation	General Freight Trucking	484110	Truck Freight
Support Activities for Transportation	Support Activities for Air Transportation	488119	Other Airport Operations
	Support Activities for Water Transportation	488310	Port and Harbor Operators
Administrative and Support Services	Services to Buildings and Dwellings	561740	Carpet and Upholstery Cleaning Services
Waste Management and Remediation Services	Waste Collection	562112	Hazardous Waste Collection
	Waste Treatment and Disposal	562211	Hazardous Waste Treatment and Disposal
		562212	Solid Waste Landfill
		562213	Solid Waste Combustors and Incinerators
		562219	Other Nonhazardous Waste Treatment and Disposal
Repair and Maintenance	Automotive Repair and Maintenance	811192	Car Washes
	Personal and Household Goods Repair and Maintenance	811420	Reupholstery and Furniture Repair
Personal and Laundry Services	Drycleaning and Laundry Services	812300	Dry Cleaner and Laundry Operators

Sector	Industry Group	6-Digit NAICS	6-Digit NAICS Description
Justice, Public Order, and Safety Activities	Justice, Public Order, and Safety Activities	922160	Fire Protection
National Security and International Affairs	National Security and International Affairs	928110	National Security

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D. What is the Agency's authority for taking this action?

CERCLA section 102(a) authorizes the EPA Administrator to ''promulgate and revise as may be appropriate, 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[.]'' CERCLA section 102(b) establishes a default RQ of one pound for releases of designated hazardous substances. *See Section IV of this document for additional details on EPA's authority, including statutory criteria.*

E. What are CERCLA's primary objectives, and how does it operate to protect human health and the environment?

CERCLA establishes broad Federal authority to address past, current, and future releases or threat of releases of hazardous substances and pollutants or contaminants. The statute's primary objectives are to promote the timely cleanup of contaminated sites and to ensure parties responsible for contamination bear site cleanup costs. CERCLA is unlike traditional environmental statutes that prospectively regulate, among other things, how facilities operate and provide limitations on discharges, emissions, releases, or disposal of certain chemicals into water, air, or land. Instead, CERCLA is designed to address contamination already in the environment on a site-specific basis, which includes evaluating the nature, extent, and risk to human health and/or the environment from the release. CERCLA affords EPA broad discretion as to whether or how to respond to a release. It includes cost-shifting mechanisms and liability provisions that support PRP cleanups rather than relying on the Fund.

1. How does CERCLA authority and causes of action differ in key respects between ''hazardous substances'' and ''pollutants or contaminants''?

For hazardous substances,[23] CERCLA section 103(a) requires reporting of releases. 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 in an amount equal to or greater than the RQ for that substance. 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 pursuant to CERCLA and its accompanying regulations, the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). (40 CFR part 300).

CERCLA response authorities apply to releases or the threat of releases into the environment of ''hazardous substances'' and/or ''pollutants or contaminants'' [24]; however, the CERCLA authorities available to address each type of release differs. With respect to *hazardous substances,* the Agency can conduct response actions if there is a release or threatened release; however, for pollutants or contaminants, EPA can only respond if it establishes that the release may present an imminent and substantial danger. (CERCLA section 104(a)).

In addition, CERCLA's cost recovery and some specific enforcement authorities extend to hazardous substances but not pollutants or contaminants. (CERCLA section 107(a), 106(a)). For hazardous substances, EPA can recover all response costs (*e.g.,* investigation and cleanup costs) from PRPs the Agency incurs that are not inconsistent with the NCP and require PRPs to conduct the response. CERCLA also authorizes non-governmental entities (including private parties) who conduct cleanup activities related to hazardous substance releases to recover response costs from liable parties provided the costs incurred are consistent with the NCP.

2. What response actions does CERCLA authorize?

CERCLA authorizes two types of response actions—removal and remedial. (CERCLA section 101(25)). Removals include ''such actions as may be necessary taken in the event of the threat of release,'' including those ''necessary to prevent, minimize, or mitigate damage to the public health or welfare or the environment.'' (CERCLA section 101(23)). Removals are typically short-term response actions that may be taken to address releases or threatened releases requiring prompt action; they are limited in cost and duration unless specific criteria are met. (CERCLA section 104(c)(1)). Remedial includes those actions consistent with ''permanent remedy taken instead of or in addition to removal actions in the event of a release or threatened release of a hazardous substance into the environment, to prevent or minimize the release of hazardous substances so that they do not migrate to cause substantial danger to present or future public health or welfare or the environment'' (CERCLA section 101(24)). Remedial actions (RAs) entail longer-term and more complex cleanup actions designed to provide permanent solutions to mitigate risks typically associated with chronic exposures often not immediately life-threatening.

[23] CERCLA defines ''hazardous substance'' primarily by reference to other environmental statutes (*i.e.,* the Clean Water Act, Solid Waste Disposal Act, Clean Air Act and the Toxic Substances Control Act) and includes substances designated as hazardous under CERCLA section 102. (CERCLA section 101(14)).

[24] CERCLA defines the term ''pollutant or contaminant'' to include, ''but not be limited to, any element, substance, compound, or mixture . . . which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism . . . will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions . . . or physical deformations.'' (CERCLA 104).

3. What discretionary authority does CERCLA provide and how does CERCLA prioritize cleanup actions?

EPA has broad discretionary authority to decide on a site-specific basis whether to respond to a release or threat of release and to prioritize the order in which it undertakes response actions determined to be necessary. (CERCLA section 105(a)(8)(A)). Site-specific decisions take into consideration factors such as relative risk, hazard potential, population at risk and the potential for drinking water contamination. Those considerations are embodied in the NCP. (*See, e.g.,* 40 CFR 300.410, 300.415, 300.430).

4. What is the CERCLA cleanup process and what role does the National Priorities List (NPL) play in it?

Before identifying an appropriate response action—removal or remedial—EPA or another lead agency, may first identify a release, investigate its scope and extent, and evaluate its potential risk to human health and the environment. 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 (CERCLA section 104(b); 40 CFR 300.410, 300.430(b)). After an initial investigation, EPA has several options, including determining a release does not pose sufficient risk to warrant further action and deciding that the release warrants a CERCLA response action. EPA may also defer the site to the State where it is located.

The NCP provides guidance on the process to determine whether to undertake a removal or a remedial action. For removal actions, the NCP provides that the lead agency may take such an action when it has determined ''that there is a threat to public health or welfare'' based on a set of factors such as actual or potential exposure to drinking water supplies, the potential for hazardous substances to migrate, and the availability of other appropriate Federal or State response mechanisms to address the release. (40 CFR 300.415(b)). For remedial actions, EPA first evaluates a site for consideration as an NPL site, (40 CFR part 300 App. A); only sites added to the NPL are eligible for Superfund monies to conduct remedial actions.

A site's addition to the NPL does not trigger any immediate action but represents an initial step towards a site's potential long-term remedy; NPL sites are among the Nation's worst contaminated sites. EPA has placed on the NPL only about 3 percent of the 53,400 sites assessed since the program's beginning in 1980.

5. What is the process for identifying and selecting remedial actions under CERCLA?

EPA can only begin the process to identify potential remedial actions after completing the careful and deliberate process to add a site to the NPL. CERCLA and the NCP together prescribe a comprehensive and detailed process for evaluating, selecting, and implementing remedies, which includes State and community roles. (40 CFR 300.430). The process' first step is conducting a remedial investigation and feasibility study (RI/FS) to assess site conditions and to evaluate the remedial alternatives identified. (40 CFR 300.430(a)(2)). Next, the NCP mandates consideration of several factors by which to evaluate remedial alternatives. (40 CFR 300.430(e)(9)). At a minimum, all eligible remedies must be protective of human health and the environment and comply with all applicable or relevant and appropriate requirements (ARARs).[25] (CERCLA section 121(a), (d); 40 CFR 300.430(f)(1)(i)(A)). The alternatives satisfying these two threshold criteria are then further evaluated against one another using balancing criteria, including factors such as long-term effectiveness and permanence; toxicity, mobility or volume reduction; implementability; cost; and finally modifying criteria of State acceptance; and community acceptance. (40 CFR 300.430(e)(9), (f)).

A remedial action's selection must include public review and comment on the lead agency's preferred alternative as presented in a proposed plan. (CERCLA section 117; 40 CFR 300.430(f)(2)). EPA documents its selection of a remedy in a record of decision. (40 CFR 300.430(f)(1)(ii)).

A site's selected remedy then enters the remedial design (RD)/remedial action (RA) stage in which the remedy is designed and constructed, followed in some instances by an Operation & Maintenance (O&M) period.[26] (40 CFR 300.435(a), (f)). Five-year reviews (FYR)[27] are required at sites where completed remedial actions result in any hazardous substances, pollutants, or contaminants remaining onsite. (CERCLA section 121(c)). They also must be conducted where remedial actions result in any hazardous substances, pollutants, or contaminants remaining at the site above levels that allow for unlimited use and unrestricted exposure after the initiation of the selected remedial action. (40 CFR 300.430(f)(4)(ii)).

6. How does CERCLA's framework ensure that those responsible for contamination pay for cleanup?

A critical CERCLA component is holding those responsible for the contamination accountable to perform or pay for its cleanup. EPA's preference, and one of CERCLA's main goals, is to have PRPs be responsible for the cleanup of releases of hazardous substances. EPA can compel a PRP to take action pursuant to a CERCLA enforcement instrument. (CERCLA section 106). EPA can also perform the response action using Fund money and then seek reimbursement of costs incurred from liable parties in litigation, (CERCLA section 107(a)), or subsequent cost recovery settlement (CERCLA section 122(a)). Under CERCLA, potentially liable parties include: (1) current owners and operators of facilities, (2) past owners and facility operators in place at the time of hazardous substance disposal, (3) any person who ''arranged for disposal'' of that facility's hazardous substances, and (4) any person that accepts hazardous substances for ''transport to disposal or treatment facilities.'' (CERCLA section 107(a)(1)–(4)). If found liable under the statute, a PRP is financially responsible for the government's response costs incurred not inconsistent with the NCP in addition to other categories of costs. (CERCLA section 107(4)(A)–(D).

[25] ARARs may be waived under certain circumstances. (CERCLA section 121(d)(4)).

[26] O&M is an important component of a Superfund response, ensuring that the remedy continues to perform as intended and remains protective of human health and the environment. O&M activities may include remedy operation, maintenance and monitoring, as well as monitoring of impacted media and monitoring and maintenance of implemented Institutional Controls (IC)s. ICs are non-engineered instruments, such as administrative and/or legal controls, that help minimize the potential for human exposure to contamination and/or protect the integrity of a remedy by limiting land or resource use. Examples include fishing restrictions, deed restrictions, and the posting of warning signs outside of a contaminated site.

[27] Five-year reviews evaluate the implementation and performance of a remedy to determine whether it remains protective.

7. What enforcement discretion is available when exercising CERCLA authority?

EPA has a proven track record of developing and applying enforcement discretion policies that are effective and well-received, and courts have sanctioned this approach. CERCLA's limitations and EPA's enforcement discretion policies historically have given EPA the needed flexibility to provide assurances when circumstances warrant. Although CERCLA's liability scheme is broad, the statutory affirmative defenses and EPA's enforcement discretion policies provide mechanisms to narrow the scope of liability and focus on the significant contributors to contamination.

Both the statute and EPA enforcement discretion policies may constrain a party's ability to secure reimbursement of response costs. CERCLA itself includes liability exemptions as well as affirmative defenses against liability. *See, e.g.,* CERCLA section 101(10), 107(b), (d), (k). Additionally, parties must prove that response costs incurred are consistent with the National Contingency Plan, CERCLA's implementing regulations. *Id.* section 107(a)(4)(B). Parties must also incur response costs before they can recover those costs from other viable, liable parties. EPA's enforcement authorities and policies can serve as a deterrent for responsible parties to pursue parties that did not contribute significantly to contamination. EPA has a well-proven track record of developing enforcement discretion policies that have been effective and well-received by stakeholders. EPA's enforcement policies, such as its policy regarding de minimis or de micromis parties and innocent landowner policies, have proven to be useful tools in convincing responsible parties not to pursue parties covered by these enforcement discretion policies. Finally, the statute provides that a party that resolves its potential liability with the United States or a State in a judicially approved settlement is entitled to contribution protection—the ability to block third-party claims for matters addressed in the settlement. These liability limitations and mitigation tools are more fully discussion in Section VI.B.2.

8. Why is understanding CERCLA's overarching provisions critical to understanding the importance of this rulemaking to EPA's ability to protect human health and the environment?

Understanding CERCLA's basic concepts, particularly its liability scheme and CERCLA's authority to address hazardous substances (versus its authorities to respond to pollutants or contaminants) are essential to understanding this regulatory action's importance in protecting human health and the environment. Designating PFOA and PFOS as hazardous substances is an important step for EPA to take because it makes available the full suite of CERCLA tools to address releases of these substances. Designation provides a more streamlined path to respond to PFOA and PFOS releases. It also makes available CERCLA enforcement authority that EPA can use to compel PRPs to pay for or conduct CERCLA response actions, rather than EPA using the Fund to clean up. Designation is expected to expediate PFOA and PFOS cleanups, and in turn, mitigate risks to public health and the environment from these substances.

III. Background for This Rulemaking

A. Summary of Proposed Designation

On September 6, 2022 (87 FR 54415), EPA proposed to find that PFOA and PFOS and their salts and structural isomers warrant designation as hazardous substances pursuant to CERCLA section 102(a). EPA concluded that significant evidence indicates that PFOA and PFOS may present a substantial danger to public health or welfare or the environment when released. (87 FR 54417, 54423). In reaching the proposed conclusion, the Agency relied on a significant body of evidence showing that PFOA and PFOS are persistent and mobile in the environment and that exposure to such substances may lead to adverse health effects.

The Agency primarily relied on evidence concerning the hazard and fate and transport, as well as other information that may be relevant to whether the statutory criteria are met. EPA looked at scientific and technical data regarding toxicity and toxicokinetics, chemical and physical characteristics, and environmental prevalence of PFOA and PFOS to support the proposed finding that these chemicals may present substantial danger when released into the environment. *See* Proposed Rule, 87 FR at 54423–29. In short, the evidence related to the chemical and physical characteristics indicated that PFOA and PFOS are persistent in the environment and that they bioaccumulate in both humans and wildlife. The evidence also showed that PFOA and PFOS are distinct from many other bioaccumulative chemicals because their water solubility allows PFOA and PFOS to more readily migrate from soil to groundwater; thus, their release into the environment has the potential to contaminate both surface water and groundwater used as drinking water sources.

Concerning the toxicity and toxicokinetics, both human and animal studies supported a conclusion that exposure to PFOA and PFOS may cause adverse health effects, including effects on the immune system, the cardiovascular system, fetus development, and cancer. The evidence also showed that PFOA and PFOS are prevalent in the environment because they have been produced and used since the 1940s and are resistant to degradation. The evidence showed that PFOA and PFOS are not only prevalent in humans, but also prevalent in environmental media, wild animals, livestock, and plants. EPA concluded that the prevalence of these substances impacts the environment directly and increases the likelihood of exposures that may lead to additional human exposure.

The adverse human health effects, mobility, persistence, prevalence, and other information about PFOA and PFOS combined to support EPA's proposed finding that these chemicals may present a substantial danger to public health or welfare or the environment when released such that designation of PFOA and PFOS as CERCLA hazardous substances is warranted.

B. PFOA and PFOS Production and Use

PFOA and PFOS are part of a large family of human-made chemicals known as PFAS that have been in use in the U.S. since the 1940s. PFAS, including PFOA and PFOS, are used in industry and consumer products because of their useful properties, including their resistance to water, grease, and stains. These substances have 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 have also been used for firefighting and various industrial processes. 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. Once dissolved in water, the salt and the acid forms will dissociate into the respective ions. *See* Proposed Rule, 87 FR at 54417 (providing a brief history of PFOA and PFOS production and use).

Production and use of these chemicals have resulted in releases into the

environment for many decades. Historic releases of PFOA and PFOS are significant sources of environmental contamination and present ongoing hazards to human health and the environment. Precursors of PFOA and PFOS can be converted to PFOA and PFOS 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 or in a landfill without environmental controls can discharge via leachates, groundwater pollution/migration, and atmospheric releases.

PFAS have been detected in the ambient environment, in wildlife, and in humans around the globe, and PFOA and PFOS were among the most used PFAS from the beginning of their development in the 1940s (*Blake & Fenton, 2020; Calafat et al., 2007; Domingo & Nadal, 2019; Hanssen et al., 2013; Olsen et al., 2017*). The potential health risks associated with PFAS were first recognized in occupationally exposed workers in the 1980s and community level exposure concerns were first raised in 1998. Since that time, the U.S. government, including EPA, and many other environmental and human health organizations both within the U.S. and internationally have researched PFAS to determine the risks posed by exposure to such chemicals. The additional evaluation since the late 1990s has added support for early concerns that exposure to PFAS may present a risk and that exposure to long chain PFAS, such as PFOA and PFOS, are of particular concern because of, among other things, their prevalence in the environment, mobility, and resistance to degradation.

In response to the growing body of evidence concerning the potential risks, Federal, State, and international agencies have taken steps to mitigate exposure to PFOA and PFOS. For example, in 2016, the FDA revoked a regulation that allowed the use of long chain PFAS in food contact applications in the U.S.; the DoD added PFOA and PFOS to its list of emerging chemicals of concern and is in the process of requiring any of its new firefighting foam it purchases to be made without PFAS per a January 2023 military specification; several States have established groundwater cleanup standards for PFOA and/or PFOS; and PFAS, including PFOA and PFOS, are addressed in several international treaties.[28]

Domestic production and import of PFOA has been phased out in the United States by the companies participating in the 2010/2015 PFOA Stewardship Program (*U.S. EPA, 2023c, 2023d*). Small quantities of PFOA may be produced, imported, and used by companies not participating in the PFOA Stewardship Program and some uses of PFOS are ongoing (*U.S. EPA, 2023a*). The EPA Chemical Data Reporting (CDR) rule (*see* 40 CFR 721.9582) under TSCA requires manufacturers (including importers) to report certain data about chemicals in commerce in the United States, including information on PFOA and PFOS (subject to a 2,500-pound reporting threshold at a single site). The last time PFOA and PFOS manufacturing information was reported to EPA pursuant to CDR was in 2013 and 2002, respectively. The reports showed that these chemicals were still being produced or used in those reporting years, however manufacturers did not report PFOA and PFOS in excess of the reporting limit in subsequent reporting cycles. However, 2020–2022 Toxic Release Inventory (TRI) data show that PFOA and PFOS continue to be released into the environment, which means that there are on-going uses of these substances. Pursuant to TRI reporting requirements, regulated facilities must report annually on releases and other waste management of toxic chemicals that they manufacture, process, or otherwise use above certain threshold quantities. The TRI reporting threshold for PFOA and PFOS is 100 pounds. Between 2020 and 2022, TRI data on releases [29] of PFOA, PFOS, and their salts [30] reported by 21 facilities amount to 71,411 lbs. In 2020, TRI data on releases of PFOA, PFOS, and their salts reported by nine facilities totaled 1,706 lbs. In 2021 and 2022, reported releases increased to 24,351 lbs. and 45,384 lbs., respectively.[31] PFOA is not produced domestically or imported by the companies participating in the 2010/2015 PFOA Stewardship Program. However, based on the TRI report, it is possible that PFOA may still be produced domestically or imported by companies that did not participate in the PFOA Stewardship Program and that PFOS may be as well.

Environmental contamination and resulting human exposure to PFOA and PFOS are anticipated to continue for the foreseeable future due to their past wide-scale manufacture and use, environmental persistence, formation from precursor compounds, and continued limited domestic production and use. 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 (NHANES). This indicates humans are still being exposed to PFOA and PFOS.

C. EPA's PFAS Strategic Roadmap

EPA issued the PFAS Strategic Roadmap (Roadmap) in October 2021, wherein the Agency recognized the potential dangers posed by exposure to PFAS and committed to a comprehensive whole-of-Agency plan to address PFAS (*U.S. EPA, 2021a*). EPA's integrated approach to PFAS is focused on three central directives: (1) *Research.* Invest in research, development, and innovation to increase understanding of PFAS exposures and toxicities, human health and ecological effects, and effective interventions that incorporate the best available science; (2) *Restrict.* Pursue a comprehensive approach to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment; and (3) *Remediate.* Broaden and accelerate the cleanup of PFAS contamination to protect human health and ecological systems. The Roadmap committed to an Agency-wide approach, in which EPA would utilize the tools at its disposal to urgently address PFAS and bring tangible health benefits to communities impacted by PFAS. EPA identified a variety of authorities to address PFAS, including the TSCA, the Safe Drinking Water Act (SDWA), CWA, and RCRA, in addition to CERCLA. The Agency recognized that each authority has a unique set of tools to address discrete and specific environmental challenges posed by PFAS. Since 2021, EPA has taken several actions to address PFAS contamination under the Agency's various regulatory programs. *Visit Agency's website at https://www.epa.gov/pfas/key-epa-actions-address-pfas.*

[28] See Proposed Rule, 87 FR at 54429–39 (providing a list of regulatory and other PFAS related actions at EPA, other Federal Agencies, states, and international agencies).

[29] Facilities are required to report total releases per year of listed toxic chemicals into the environment (*e.g.,* releases to land on-site, discharges to receiving streams or water bodies, etc.). *https://www.ecfr.gov/current/title-40/part-372/subpart-E#p-372.85(b)(14)* (40 CFR 372.85(b)(14).

[30] As of November 2023, the list of toxic chemicals under the TRI program include 8 salts, as well as PFOA and PFOS, that are also listed as CERCLA HSs in this final action.

[31] In addition to these releases, the TRI also includes data on PFOA and PFOS production-related waste. See U.S. Environmental Protection Agency. Toxic Release Inventory (TRI) Search. Available at: *https://www.epa.gov/enviro/tri-search.*

IV. Legal Authority

A. CERCLA Section 102(a) Designation Considerations

In this action, the Administrator is exercising his authority to designate PFOA and PFOS as hazardous substances pursuant to CERCLA section 102(a). CERCLA's definition of ''hazardous substances'' includes any substance designated pursuant to specified provisions in select environmental statutes (CWA, RCRA, CAA, and TSCA) and ''any element, compound, mixture, solution, or substance designation pursuant to [CERCLA section 102]. CERCLA section 101(14).[32] Section 102(a), in turn, provides clear authority to designate hazardous substances in addition to substances designated automatically through the operation of CERCLA section 101(14). In relevant part, section 102(a) provides that, ''[t]he Administrator shall promulgate and revise as may be appropriate, regulations designating as hazardous substances, in addition to those referred to in section 101(14), 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. . . .'' The statutory language delegates to EPA the authority to identify and weigh the scientific, technical, and other factual information relevant to determining whether a substance ''may present a substantial danger,'' and then determine whether to promulgate regulations designating such substances.

Reading Section 102(a) in context, including the broader context of CERCLA as a whole, EPA affirms the factors it proposed to evaluate for determining what constitutes ''substantial danger'' and designating hazardous substances under CERCLA section 102(a). 87 FR at 54421. To inform its decision whether a substance, when released, may present ''substantial danger'' pursuant to CERCLA section 102(a), EPA considers two primary factors: the potential harm to humans or the environment from exposure to the substance (*i.e.,* hazard), and how the substance potentially moves, persists and/or changes when in the environment (*i.e.,* environmental fate and transport). EPA will then weigh this information in deciding whether the substance, when released, may present a substantial danger.

In deciding whether a substance presents potential harm to humans or the environment from exposure to the substance (hazard), EPA may consider such information as human health toxicity, including carcinogenicity, neurotoxicity, developmental toxicity, reproductive toxicity, and other adverse health effects. EPA may also consider toxicity or adverse impacts to non-human organisms or ecosystems, such as adverse effects to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas. Additionally, EPA may consider chemical properties such as combustibility, flammability, reactivity, or corrosiveness. Regarding the environmental fate and transport of a substance, EPA may consider whether a substance moves readily through the environment, and whether it persists and/or changes in the environment.

In weighing this information, EPA will consider the degree or magnitude of the danger posed based on the substance's hazard and environmental fate and transport characteristics. The hazard that a substance presents can be shown in a variety of ways. For example, it could be toxic to humans or other organisms in the environment, or it could exhibit a more physical hazard, such as corrosivity or explosivity.

In assessing a substance's hazard if based on toxicity, EPA could consider whether the substance may be acutely toxic (and thus lead to an immediate health problem or even death) or may have chronic toxicity (and thus lead to detrimental health effects after long-term exposure). For example, there could be a substance that is acutely toxic but does not move far from the point of release. This substance might pose substantial danger due to its ability to immediately harm people and other organisms at the point of release. As another example, there may be a substance that exhibits chronic toxicity and is very persistent. In this case, the substance might also pose substantial danger when released because people and other organisms near the point of release could be exposed to the substance over a long period of time, potentially leading to adverse health effects. Designation may be appropriate if the hazard and fate and transport, when taken together, demonstrate there may be danger and the danger is substantial.

Hazard and environmental fate and transport are the primary factors EPA will assess in evaluating whether to designate a substance under section 102(a). However, EPA may also consider additional information that could inform the degree of danger a substance may pose when released. This includes, but is not limited to, information such as frequency, nature, and geographic scope of releases (*e.g.,* prevalence) and likelihood of human exposure. For example, the Agency may review accident history or other release data (*e.g.,* TRI, UCMR) to determine how frequently a substance is released or found in the environment, and how or if the substance has caused any adverse health effects to the public or the environment. Together with hazard and environmental fate and transport, this additional information will inform EPA's conclusion on whether a substance, when released, may present a substantial danger to public health or welfare or the environment.

EPA interprets section 102(a) as requiring that, at a minimum, there is a possibility the substance, when released into the environment, presents substantial danger. EPA need not have certainty that the substance poses a substantial danger or require proof of actual harm when released into the environment. This reading of CERCLA section 102(a) is consistent with the ordinary meaning of ''may'' which is defined as a term ''used to indicate possibility or probability.'' Merriam-Webster (*https://www.merriam-webster.com/dictionary/may*). It is also consistent with the caselaw interpreting the term ''may'' in the phrase ''may present an imminent and substantial endangerment'' under RCRA, which has been construed as not requiring certainty. *See ME. People's Alliance* v. *Mallinckrodt, Inc.,* 471 F.3d 277, 288 (1st Cir. 2006) (noting that ''at least four of our sister circuits have construed [section 7002(a)(1)(B)] expansively'' and that ''all four courts have emphasized the preeminence of the word 'may' in

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

defining the degree of risk needed to support [section 7002(a)(1)(B)'s] liability standard'' and that certainty of harm is not required); *Price* v. *United States Navy,* 39 F.3d 1011, 1019 (9th Cir. 1994) (reasoning that the term ''may'' ''implies that there must be a threat which is present now, although the impact of the threat may not be felt until later'').

The information that EPA may consider in determining whether the release of a substance may present a substantial danger is consistent with the criteria that the Agency uses in implementing CERCLA through the Hazard Ranking System (HRS) (*U.S. EPA, 2023b*). CERCLA section 105(a)(8)(A) requires EPA to set criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial and removal action, to the extent practicable taking into account the potential urgency of such action. The statute directs EPA to develop criteria based upon relative risk or danger to public health or welfare or the environment, taking into account to the extent possible the population at risk, the hazard potential of the hazardous substances at such facilities, the potential for contamination of drinking water supplies, the potential for direct human contact, the potential for destruction of sensitive ecosystems, the damage to natural resources which may affect the human food chain and which is associated with any release or threatened release, and the contamination or potential contamination of the ambient air which is associated with the release or threatened release. EPA's regulations establishing criteria for placing sites on the National Priorities List are codified in EPA's Hazard Ranking System (HRS), 40 CFR part 300 App. A. Ultimately, the HRS factors are consistent with the information EPA considered in designating PFOA and PFOS under CERCLA section 102(a).

The standard that EPA has adopted for CERCLA section 102(a) is also consistent with EPA's interpretation of similar statutory language. *See, e.g.,* CERCLA section 104(a) (allowing for response to pollutants or contaminants that ''may present an imminent and substantial danger'') and CERCLA section 106(a) (granting enforcement authority ''when there may be an imminent and substantial endangerment'').[33] For example, CERCLA section 106(a) provides EPA with enforcement authority when ''there may be an imminent and substantial endangerment.'' EPA guidance provides that EPA should rely on ''scientific evidence and documentation'' to determine if conditions may present an imminent and substantial endangerment (*Breen et al., 2001*). This may include an evaluation of site-specific conditions that provide a ''reasonable cause for concern that someone or something may be exposed to a risk of harm by a release or a threatened release of a hazardous substance.'' *B.F. Goodrich Co.* v. *Murtha,* 697 F. Supp. 89, 96 (D. Conn. 1988). ''Hazard'' and ''fate and transport'' are inherently a part of that analysis, and courts have long examined such considerations under CERCLA section 106(a). *See, e.g., United States* v. *Northeastern Pharmaceutical and Chemical Co., Inc.,* 579 F. Supp. 823, 832 (W.D. Mo. 1984), aff'd in part, rev'd in part, 810 F.2d 726 (8th Cir. 1986) (examining toxicological properties, hazard, fate and transport, as well as likelihood of exposure in determining whether substances posed an ''imminent and substantial endangerment''); *United States* v. *E.I. du Pont de Nemours & Co., Inc.,* 341 F.Supp.2d 215, 247 (W.D.N.Y. 2004) (collecting cases and concluding endangerment exists where, examining all impacts, ''there is reasonable cause for concern that someone or something may be exposed to a risk of harm by a release or a threatened release''); *see also Cox* v. *City of Dallas, Tex.,* 256 F.3d 281, 300 (5th Cir. 2001) (examining hazard and fate and transport posed from dangerous gases in concluding that old landfill ''may present an imminent and substantial endangerment'' under RCRA).[34]

B. Consistency With Other Methodologies for Identifying CERCLA Hazardous Substances

The two central factors that EPA considers in the context of CERCLA section 102(a)—hazard, as well as fate and transport—are consistent with other methodologies used for identifying CERCLA hazardous substances. CERCLA's list of ''hazardous substances'' includes more than 800 substances identified as hazardous or toxic by Congress or EPA under the following 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 chemicals.

See 40 CFR Table 302.4 (list of hazardous substances).

EPA has applied these authorities in a manner similar to how EPA is interpreting and applying its authority under CERCLA section 102(a) in this action. For this designation, under section 102(a), EPA evaluated toxicity data to assess ''hazard'' from exposure to PFOA and PFOS. Similarly, the statutes cited in CERCLA's definition of hazardous substance consider toxicity in some fashion in their listing or identification decisions. *See* RCRA section 3001 (providing that EPA's criteria for listing RCRA regulated hazardous wastes take into account ''toxicity,'' along with other factors); CWA section 311(b)(2)(A) and 42 FR 10474, 10475 (March 13, 1978) (describing ''toxicological selection criteria'' for hazardous substances designated under the CWA section 311); CWA section 307(a) (providing CWA authority to list ''toxic pollutants'' taking into account ''toxicity of the pollutant''); CAA section 112(b)(2) (providing CAA authority to identify air toxics which ''present, or may present . . . a threat of adverse human health effects (including . . . substances which are known to be, or may reasonably be anticipated to be . . . acutely or chronically toxic)); TSCA section 7 (providing TSCA authority to identify a chemical substance or mixture as imminently hazardous when it ''presents an imminent and unreasonable risk of serious or widespread injury to health or the environment, without consideration of costs or other non-risk factors.'').

EPA also evaluated data regarding the fate and transport of PFOA and PFOS in the environment. This analysis focused primarily on the chemical and physical characteristics of PFOA and PFOS, including mobility, resistance to degradation, and persistence in the

[33] These provisions concern enforcement and response actions and apply to and require analysis of narrow, site-specific circumstances relevant to a particular facility or person, and to a specific event. As a result, the Agency conducts an assessment of the particular situation at each site when it invokes those other authorities. That purpose is distinct from the purpose of CERCLA section 102(a), which requires a more generalized, non-site-specific evaluation.

[34] CERCLA section 106 sets forth a site-specific standard, which differs from the general applicability of CERCLA section 102(a). The language between each section also slightly differs. The phrase ''imminent and substantial endangerment'' in section 106 is different from the phrase ''may present a substantial danger'' in section 102. However, given the similar language, the factors that courts have considered in analyzing whether a substance poses a threat under section 106 are instructive to determining whether a substance ''may pose a substantial danger'' under section 102.

environment. Similarly, the CWA, RCRA, and CAA provisions referenced in CERCLA, also consider persistence and resistance to degradation in their listing and identification decisions. *See* CWA section 307(a) (providing that EPA may list toxic pollutants under the CWA that take into account ''persistence and degradability,'' alongside toxicity); RCRA section 3001 (providing that EPA's criteria for listing RCRA regulated hazardous wastes take into account ''persistence and degradability in nature,'' along with other factors); CAA section 112(b)(2) (identifying ''bioaccumulation'' as a consideration for evaluating whether a pollutant may be identified as a hazardous air pollutant under CAA).

C. CERCLA Section 102(a) and Cost Considerations

EPA proposed interpreting CERCLA section 102(a) as precluding the consideration of cost in designating CERCLA hazardous substances. EPA recognizes that, as a general matter, a statutory assessment of health- and environmental-based criteria like the criteria in section 102 does not typically allow for consideration of costs. *See, e.g., Whitman* v. *American Trucking,* 531 U.S. 457, 471 (2001) (finding that public health criteria provided in the Clean Air Act, interpreted in its statutory and historical context and with appreciation for its importance to the CAA as a whole, unambiguously bars cost considerations.''). EPA is not resolving in this final action whether section 102 is best construed as precluding or requiring consideration of costs in designating a hazardous substance. It need not resolve this question here because designation is appropriate under either construction. Specifically, as discussed in Section V, examining only whether PFOA and PFOS may present a substantial danger to public health or welfare or the environment, without considering costs and benefits, EPA has concluded that designation is warranted. In addition to the analysis of the health- and environmental-based criteria, EPA also conducted a totality-of-the-circumstances analysis, including an evaluation of quantitative and qualitative benefits and costs of designation. This additional analysis confirmed that designation is appropriate. In sum, designation is warranted either by examining the health- and environmental-based criteria alone or by examining these criteria along with the broader totality of the circumstances.

V. PFOA and PFOS May Present a Substantial Danger to the Public Health or Welfare or the Environment When Released Into the Environment

In evaluating hazard with respect to PFOA and PFOS, EPA considered the substantial evidence, based on epidemiological and toxicological studies, indicating that human exposure to PFOA or PFOS is linked to adverse human health effects. Regarding environmental fate and transport, EPA considered evidence that PFOA and PFOS migrate through the environment from the point of release, that they persist in the environment for long durations, and that they bioaccumulate in humans and other organisms.

For PFOA and PFOS, EPA considered other relevant information about the frequency, nature, and geographic scope of releases of the substances (*i.e.,* prevalence) demonstrating that these substances have been widely detected in drinking water, surface water, wild animals, and humans in the United States. This other information about the prevalence of PFOA and PFOS is relevant to EPA's designation decision because widespread detections of these substances in the environment and people demonstrates a greater potential for communities to be exposed to the substances at concentrations that could result in adverse health effects. EPA weighed all of this information—hazard, environmental fate and transport, prevalence—in evaluating the degree or magnitude of danger posed. EPA concluded that PFOA and PFOS may present a substantial danger when released because of the potential for harm to human health, evidence of persistence and bioaccumulation, and high likelihood of exposure.

A. PFOA and PFOS Pose a Hazard

EPA is confirming the proposed finding that exposure to PFOA and PFOS may pose a hazard, after evaluating the available scientific and technical information as well as public comments. There is evidence from both epidemiological and animal toxicological studies that oral exposure to either PFOA or PFOS has been associated with various adverse health effects across many health outcomes. Numerous health studies support a finding that PFOA and PFOS exposure can lead to adverse human health effects, including cancer (testicular and kidney for PFOA, liver cancer for PFOS), pregnancy-induced hypertension and preeclampsia, and decreased immune response to vaccination (*ATSDR, 2021*). Toxicology studies suggest that PFOA and PFOS exposure is associated with decreases in serum thyroid hormone levels [35] and adverse effects to the endocrine system (ATSDR, 2021; USEPA, 2024b; 2024c).

Based on studies of PFOA and PFOS, in 2021, EPA found that PFOA and PFOS may have adverse effects on public health (''*Announcement of the Final Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List,*'' *2021*). EPA determined that studies indicate human exposure to PFOA and/or PFOS is linked to a broad range of adverse health effects, including developmental effects to fetuses during pregnancy or to infants (*e.g.,* low birth weight, accelerated puberty, skeletal variations), liver effects (*e.g.,* tissue damage), immune effects (*e.g.,* antibody production and immunity), and other effects (*e.g.,* cholesterol changes). Both PFOA and PFOS are known to be transmitted to the fetus via the placenta and to the newborn, infant, and child via breast milk or formula made with contaminated water. Both compounds were also associated with carcinogenic effects in human epidemiological and long-term animal studies (*NTP, 2020; U.S. EPA, 2016a, 2016b*). In November 2023, the International Agency for Research on Cancer (IARC) evaluated the carcinogenicity of PFOA and PFOS and classified PFOA as carcinogenic to humans (Group 1) and PFOS as possibly carcinogenic to humans (Group 2b) (Zahm, et al., 2023).

These adverse health effects of PFOA and PFOS were further described in the final toxicity assessments and Final Maximum Contaminant Level Goals (MCLGs [36]) for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS) in Drinking Water (*U.S. EPA, 2024b, 2024c, 2024d*). These toxicity assessments indicate that PFOA and PFOS are associated with adverse health effects at lower levels than previously recognized. In the final toxicity assessments, EPA assessed the weight of the evidence for the available cancer data and determined that PFOA and PFOS are *Likely to Be Carcinogenic to Humans* consistent with the Guidelines for Carcinogen Risk Assessment (*U.S. EPA, 2005*). For PFOA, this determination is based on

[35] Decreased thyroid hormone levels are associated with effects such as changes in thyroid and adrenal gland weight, hormone fluctuations, and organ histopathology (ATSDR, 2021; USEPA, 2024b; USEPA, 2024c).

[36] Maximum Contaminant Level Goal (MCLG)—the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. (*https://www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants.*)

the evidence of kidney and testicular cancer in humans and Leydig cell tumors, pancreatic acinar cell tumors, and hepatocellular adenomas in rats. (*U.S. EPA, 2024c, 2024d*). For PFOS, this determination is based on the evidence of hepatocellular tumors in humans and rats, pancreatic islet cell carcinomas in male rats, and mixed but plausible evidence of bladder, prostate, kidney, and breast cancers in humans as described by U.S. EPA (*2024b, 2024d*).

The EPA's 2024 PFOA and PFOS toxicity assessments prioritized the following five health endpoint categories with the strongest weight of evidence and indicating that oral PFOA and PFOS exposure is associated with adverse health effects: immunological, hepatic, developmental, cardiovascular, and cancer effects. This prioritization was based on findings from conducting systematic review (including the study quality evaluation, evidence synthesis and evidence integration) on the available and relevant human epidemiological and animal toxicity studies (*U.S. EPA, 2024b, U.S. EPA, 2024c*). EPA evaluated sixteen non-cancer health outcomes as part of the 2024 toxicity assessments and, in accordance with recommendations from the SAB {U.S. EPA, 2022, 10476098} and the IRIS Handbook {U.S. EPA, 2022, 10367891}, EPA's toxicity assessments prioritized the five categories of health outcomes above with either *evidence demonstrating* or *evidence indicating* associations between PFOA and PFOS exposure and adverse health effects. Accordingly, to support EPA's finding in this final rule that both PFOA and PFOS each individually pose a human health hazard, EPA gave weight to immunological, hepatic, developmental, cardiovascular, and cancer effects.

For this final rule, EPA considered a wide range of potential health effects associated with exposure to PFOA and PFOS using five comprehensive peer-reviewed Federal government documents that summarize the recent literature on PFAS (mainly PFOA and PFOS) exposure and its health impacts: (1) EPA's 2016 Health Effects Support Documents for PFOA *(U.S. EPA, 2016c)*; (2) EPA's 2016 Health Effects Support Documents for PFOS (*U.S. EPA, 2016d)*; (3) U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry's (ATSDR) 2021 Toxicological Profile for Perfluoroalkyls (*ATSDR, 2021)*; (4) EPA's 2024 Final Human Health Toxicity Assessment for Perfluorooctanoic Acid *(PFOA)* (*U.S. EPA, 2024b*); and (5) EPA's 2024 Final Human Health Toxicity Assessment for Perfluorooctane Sulfonic Acid (PFOS), (*U.S. EPA, 2024c*). Each source presents comprehensive, systematic reviews of relevant, peer-reviewed literature on adverse health effects associated with PFOA and PFOS. The EPA assessments were prepared by the Office of Water.

Data from human and animal studies indicate that PFOA and PFOS are well absorbed in the human body after being ingested and are distributed throughout the body by binding to proteins. PFOA and PFOS bioaccumulate in the human body as evidenced by the elimination half-lives from about two to three years for PFOA and four to five years for PFOS (*ATSDR, 2021*). There is no evidence that humans or animals are able to break down these substances, and they can be distributed to tissues throughout the human body and are not readily eliminated, resulting in long elimination half-lives in the human body and bioaccumulation. Available evidence supports urine as the primary route of excretion in most species, though fecal elimination is prominent in rats. In rats, hair is another route of elimination in both males and females. In females, elimination pathways include menstruation, pregnancy (cord blood, placenta, amniotic fluid, and fetal tissues) and lactation (breast milk) (PFOA Toxicity Assessment 2024, PFOS Toxicity Assessment 2024). Thus, PFOA and PFOS remain in the body after exposure has ended and can potentially cause detrimental health effects even after an initial exposure has ceased. Continued exposures to PFOA and PFOS can lead to significantly elevated concentrations in the human body and result in adverse health effects due to this bioaccumulation (Ballesteros et al., 2017; Barry et al., 2014; Dhingra et al., 2016; Frisbee et al., 2010; Gallo V et al., 2012; Hall et al., 2023; Hoffman et al., 2011; Kotlarz et al., 2020; Savitz et al., 2012; Steenland et al., 2009; Steenland et al., 2018a; Steenland et al., 2018b).

EPA's 2024 Final Human Health Toxicity Assessments for PFOA and PFOS integrated the available data on absorption, distribution, metabolism and elimination into the derivation of reference values for PFOA and PFOS. Collectively the adverse health effects evidence demonstrates that each PFOA and PFOS individually pose a human health hazard, and the substantial body of evidence for several individual adverse health effects also supports EPA's human health hazard finding for each of these substances. A discussion of some of the detrimental health effects follows.

Developmental Effects: Adverse developmental effects can increase the likelihood of difficulties during labor through post-delivery. Evidence indicates that exposure to PFOA and PFOS is likely associated with developmental effects such as lower infant birth weight, lower birth length, smaller head circumference at birth, and other effects (Verner et al., 2015; U.S. EPA, 2016e; U.S. EPA, 2016f; Negri et al., 2017; ATSDR, 2018; Waterfield et al., 2020; U.S. EPA, 2023b; U.S. EPA, 2024c). Research suggests that exposure to PFOA and PFOS is associated with developmental effects, including decreased infant birth weight (*ATSDR, 2021; Negri et al., 2017; U.S. EPA, 2016c, 2016d, 2024b, 2024c; Verner et al., 2015; Waterfield et al., 2020*). Low birth weight is linked to a number of health effects that may be a source of economic burden to society in the form of medical costs, infant mortality, parental and caregiver costs, labor market productivity loss, and education costs (*Behrman & Rosenzweig, 2004; Chaikind & Corman, 1991; Colaizy et al., 2016; Institute of Medicine, 2007; Joyce et al., 2012; Klein & Lynch, 2018; Kowlessar et al., 2013; Nicoletti et al., 2018*).

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 animals 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 (*ATSDR, 2021; U.S. EPA, 2016c, 2016d*). The embryo and fetus are exposed prenatally to PFOA and PFOS through maternal blood via the placenta (*ATSDR, 2021*). Several epidemiological studies of the association between maternal serum PFOA/PFOS and birth weight have found evidence for decreased body weight of infants exposed in utero (*Chu et al., 2020; Darrow et al., 2013; Dzierlenga et al., 2020; Govarts et al., 2016; Negri et al., 2017; Sagiv et al., 2018; Starling et al., 2017; Verner et al., 2015; Wikstrom et al., 2020; Yao et al., 2021*). Other developmental associations with PFOA and PFOS include small for gestational age (SGA), decreased birth length, decreased head circumference at birth, and other effects (*ATSDR, 2021; Negri et al., 2017; U.S. EPA, 2016c, 2016d, 2024b, 2024c; Verner et al., 2015; Waterfield et al., 2020*). Epidemiology evidence for SGA related to PFOA/PFOS exposure was mixed; some studies reported increased risk of SGA with PFOA/PFOS exposure, while other studies observed null results (USEPA,

2024b; USEPA, 2024c). SGA is a developmental health outcome of interest when studying potential effects of PFOA/PFOS exposure because SGA infants have increased health risks during pregnancy and delivery as well as post-delivery (*Osuchukwu & Reed, 2022*).

Cardiovascular Effects: Cardiovascular Disease (CVD) is one of the leading causes of premature mortality in the United States (*D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017*). Changes in total cholesterol and blood pressure are associated with changes in incidence of CVD events such as myocardial infarction (*i.e.,* heart attack), ischemic stroke, and cardiovascular mortality occurring in populations without prior CVD event experience (*D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017*). Evidence indicates that exposure to PFOA and PFOS is likely associated with increased low-density lipoprotein cholesterol (LDLC), total cholesterol, and high-density lipoprotein cholesterol (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). High levels of LDLC lead to the buildup of cholesterol in the arteries, which can raise the risk of heart disease and stroke. Epidemiology studies showed a positive association between PFOA or PFOS exposure and LDLC or total cholesterol levels in children (*U.S. EPA, 2024b, 2024c*). In particular, the evidence suggested positive associations between serum PFOA and PFOS levels and LDLC levels in adolescents ages 12–18, while positive associations between serum levels and LDLC levels in younger children were observed only for PFOA (*ATSDR, 2021*). Other epidemiology studies have generally found a positive association between increasing serum PFOA and total cholesterol levels (*ATSDR, 2021*).

Cancer Effects: PFOA and PFOS are Consistent with the Guidelines for Carcinogen Risk Assessment (*U.S. EPA, 2005*), EPA determined that both PFOA and PFOS are *Likely to Be Carcinogenic to Humans* based on sufficient evidence of carcinogenicity in humans and animals (U.S. EPA, 2024b, USEPA 2024c). Additionally, in November 2023, the International Agency for Research on Cancer (IARC) evaluated the carcinogenicity of PFOA and PFOS and classified PFOA as carcinogenic to humans (Group 1) and PFOS as possibly carcinogenic to humans (Group 2b) (Zahm, et al., 2023). For PFOA, cancer evidence in epidemiological studies is primarily based on the incidence of kidney and testicular cancer, as well as some evidence of breast cancer, which is most consistent in genetically susceptible subpopulations or for particular breast cancer types (*U.S. EPA, 2024c*). Epidemiology studies indicated that exposure to PFOA was associated with an increased risk of renal cell carcinoma (RCC) (*ATSDR, 2021; California EPA, 2021; U.S. EPA, 2016d, 2024d*). For PFOS, the available epidemiology studies report elevated risk of liver cancer, consistent with increased incidence of liver tumors reported in long-term rat exposure studies. There is also mixed but plausible evidence of bladder, prostate, kidney, and breast cancers in humans after chronic exposure and evidence of pancreatic islet cell tumors in rats (*U.S. EPA, 2024b*).

Liver Effects: High levels of the enzyme alanine transaminase (ALT) in the bloodstream may indicate liver damage. Evidence indicates that exposure to PFOS and PFOA is associated with increased liver enzymes (U.S. EPA, 2024b; 2024c). Epidemiology data provides evidence of a positive association between PFOS/PFOA exposure and ALT levels in adults (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). Studies of adults showed consistent evidence of a positive association between PFOA exposure and elevated ALT levels at both high exposure levels and exposure levels typical of the general population (*U.S. EPA, 2024c*). Associations between increasing serum PFOA concentrations and elevations in different serum enzyme levels were consistently observed in occupational cohorts, high-exposure communities and the U.S. general population that could indicate the potential for PFOA to affect liver function (*ATSDR, 2021*). There is also consistent epidemiology evidence of associations between PFOS and elevated ALT levels. A limited number of studies reported inconsistent evidence on whether PFOA/PFOS exposure is associated with increased risk of liver disease (*U.S. EPA, 2024b*). Results reported in animal toxicological studies are consistent with the observed elevated ALT indicative of hepatic damage in epidemiological studies. Specifically, studies in rodents found that oral PFOA or PFOS treatment resulted in biologically significant alterations in levels of at least one serum biomarker of liver injury (*e.g.,* ALT) and evidence of histopathological alterations including hepatocyte degenerative or necrotic changes.

Immune Effects: Proper antibody response helps maintain the immune system by recognizing and responding to antigens. Evidence indicates that exposure to PFOS and PFOA is associated with immunosuppression; (U.S. EPA, 2024b; U.S. EPA, 2024c); epidemiology studies showed suppression of at least one measure of the antibody response for tetanus and diphtheria among people with higher prenatal, childhood, and adult serum concentrations of PFOA (*U.S. EPA, 2024c*). Data reporting associations between PFOA exposure and antibody response to vaccinations other than tetanus and diphtheria are limited (*ATSDR, 2021; USEPA, 2024c*). Several epidemiological studies have shown a relationship between increased PFOA and PFOS serum concentrations and decreased response to vaccinations in children (*Budtz-Jorgensen & Grandjean, 2018; Grandjean et al., 2012; Grandjean, Heilmann, Weihe, Nielsen, Mogensen, & Budtz-Jorgensen, 2017; Grandjean, Heilmann, Weihe, Nielsen, Mogensen, Timmermann, et al., 2017; Timmermann et al., 2022; Zhang et al., 2023*). Epidemiology evidence suggests that children with preexisting immunological conditions are particularly susceptible to immunosuppression associated with PFOA exposure (*U.S. EPA, 2024c*). Available studies supported an association between PFOS exposure and immunosuppression in children, where increased PFOS serum levels were associated with decreased antibody production (*U.S. EPA, 2024b*). Studies reporting associations between PFOA or PFOS and immunosuppression in adults are less consistent; there is a lack of high confidence data. (*U.S. EPA, 2024b*).

In addition to the adverse health effects listed above, there was suggestive evidence that exposure to PFOS and PFOA is associated with the additional health effects summarized below.

Endocrine Effects: Elevated thyroid hormone levels can accelerate metabolism and cause irregular heartbeat; low levels of thyroid hormone can cause neurodevelopmental effects, tiredness, weight gain, and increased susceptibility to the common cold. There is suggestive evidence of a positive association between PFOA/PFOS exposure and thyroid hormone disruption (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). Toxicology studies in animals indicated that PFOA and PFOS exposure can affect thyroid function [37] (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). Changes to serum thyroid hormone levels in animals lead to adverse effects to the endocrine system (*U.S. EPA, 2024b, 2024c*). Despite uncertainty around the applicability of animal studies in this area, changes in serum

[37] Decreased thyroid hormone levels are associated with effects such as changes in thyroid and adrenal gland weight, hormone fluctuations, and organ histopathology (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*).

thyroid hormone levels in animals did indicate adverse effects after PFOS and PFOA exposure that is relevant to humans (U.S. EPA, 2024b; 2024c).

Metabolic Effects: Leptin is a hormone that controls hunger, and high leptin levels are associated with obesity, overeating, and inflammation (*e.g.,* of adipose tissue, the hypothalamus, blood vessels, and other areas). Animal studies showed increases in serum leptin levels in mice that were exposed to low levels of PFOA (ATSDR, 2021). Based on a review of 69 human epidemiology studies, evidence of associations between PFOS and metabolic outcomes appears inconsistent, but in some studies, suggestive evidence was observed between PFOS exposure and leptin levels (*U.S. EPA, 2024b*).

Reproductive Effects: Studies of the reproductive effects from PFOA/PFOS exposure have focused on associations between exposure to these pollutants and increased risk of gestational hypertension and preeclampsia in pregnant women (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). Gestational hypertension (high blood pressure during pregnancy) can lead to fetal health outcomes such as poor growth and stillbirth. Preeclampsia—instances of gestational hypertension where the mother also has increased levels of protein in her urine—can similarly lead to fetal problems and maternal complications. The epidemiology evidence yields mixed (positive and non-significant) associations, with some suggestive evidence supporting positive associations between PFOA/PFOS exposure and both preeclampsia and gestational hypertension (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). A study of a community with high exposure to PFOA observed an association between serum PFOA and risk of pregnancy-related hypertension or preeclampsia, conditions that are related to renal function during pregnancy (*U.S. EPA, 2016d*).

Musculoskeletal effects: Adverse musculoskeletal effects such as osteoarthritis and decreased bone mineral density impact bone integrity and cause bones to become brittle and more prone to fracture. There is limited evidence from studies pointing to effects of PFOS on skeletal size (height), lean body mass, and osteoarthritis (*U.S. EPA, 2024b*). Epidemiology evidence suggested that PFOA exposure may be linked to decreased bone mineral density, bone mineral density relative to bone area, height in adolescence, osteoporosis, and osteoarthritis (*ATSDR, 2021; U.S. EPA, 2024c*). Evidence from four PFOS studies suggests that PFOS exposure has a harmful effect on bone health, particularly measures of bone mineral density, with greater statistically significance of effects occurring among females (*U.S. EPA, 2024b*).

Taken together, the technical/scientific information above demonstrate that both PFOA and PFOS individually are each associated with considerable and varied adverse health effects.

EPA also considered potential effects on children's health. EPA's Policy on Children's Health requires the Agency to consider early life exposures (from conception, infancy, early childhood and through adolescence until 21 years of age) and lifelong health consistently and explicitly in all human health decisions through identifying and integrating children's health data and information. As described throughout this section, information on PFOA and PFOS shows exposure to PFOA and/or PFOS is linked to adverse health effects relevant to children. These adverse health effects include developmental effects to fetuses during pregnancy or to infants, cardiovascular effects and immune effects in children and endocrine and reproductive effects that impact development. Suggestive evidence of associations found in human epidemiological studies between PFOA and PFOS and adverse development effects of include decreased infant birth weight (*ATSDR, 2021; Negri et al., 2017; U.S. EPA, 2016c, 2016d, 2024b, 2024c; Verner et al., 2015; Waterfield et al., 2020*). Animal studies have shown developmental health effects including associations with decreased offspring survival, low birth weight, accelerated puberty and skeletal variations (*ATSDR, 2021; U.S. EPA, 2016c, 2016d*). Cardiovascular effects include positive associations between serum PFOA and PFOS levels and LDLC levels in adolescents ages 12–18 (*ATSDR, 2021*). Several epidemiological studies have shown a relationship between increased PFOA and PFOS serum concentrations and decreased response to vaccinations in children (*Budtz-Jorgensen & Grandjean, 2018; Grandjean et al., 2012; Grandjean, Heilmann, Weihe, Nielsen, Mogensen, & Budtz-Jorgensen, 2017; Grandjean, Heilmann, Weihe, Nielsen, Mogensen, Timmermann, et al., 2017; Timmermann et al., 2022*). There is suggestive evidence of a positive association between PFOA and/or PFOS exposure and thyroid hormone disruption (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). The epidemiology evidence yields mixed (positive and non-significant) associations, with some evidence suggesting positive associations between PFOA and/or PFOS exposure and both preeclampsia and gestational hypertension which can lead to fetal health outcomes such as poor growth, stillbirth and maternal complications (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*).

EPA also considered the hazards associated with salts and structural isomers of PFOA and PFOS. The hazards associated with PFOA and PFOS can be associated with their respective salts and both their linear and branched isomers. Salts are deemed to have the same toxicity as the commonly referenced acid versions because, once put in water (and likewise when in the human body), the acid and salt forms will dissociate to the ionic form. Further, many toxicity studies on PFAS were often performed using the salt form. For example, while *Emmett et al.* (*2006*) toxicity studies were performed on the acid version of PFOA, *Butenhoff et al.* (*2012*) used the ammonium salt of PFOA. The potassium salt of PFOS was generally used in animal toxicity studies such as *Ankley et al.* (*2004*).

Additionally, PFOA and PFOS exist as linear and branched isomers, and the linear and branched isomers have been found in environmental media and in human sera. For example, in the last NHANES for which results are available (*2017–2018*), branched PFOS was detected in 99% of those sampled, while branched PFOA was found in 10%. Most animal toxicity studies using isomeric mixtures do not state the ratio of linear and branched isomers in the test material, and, therefore, it is not feasible to distinguish the toxicity of the individual isomers. However, in a few studies, including *Butenhoff et al.* (*2012*), *Lau et al.* (*2006*), and *Lou et al.* (*2009*) for PFOA, and *Ankley et al.* (*2004*) for PFOS, the authors stated that the PFAS test substance was not 100% linear, and thus, any effects indicated in these studies can only be associated with the isomeric mixture of linear and branched and not specifically with linear isomers or branched isomers. Further, *Loveless et al.* (*2006*) compared the toxicity of linear ammonium PFOA, branched ammonium PFOA, and a mixture of linear and branched ammonium PFOA in rodents and demonstrated that both linear and branched isomers exhibit similar types of toxicity.

B. Information About the Fate and Transport of PFOA and PFOS Demonstrate That They Are Persistent and Mobile in the Environment

Available information about the fate and transport of PFOA and PFOS

support EPA's conclusions that these substances remain in the environment for many years (*i.e.,* persistency) and that they can move through air, land, and water (*i.e.,* mobility) after release. Both PFOA and PFOS are considered surfactants due to their chemical structures that consists of a hydrophobic perfluorinated alkyl ''tail group'' and a hydrophilic carboxylate (for PFOA) or sulfonate (for PFOS) ''head group.'' Surfactants decrease the surface tension between two liquids (*i.e.,* oil and water), a gas and a liquid, or a solid and a liquid. This attribute means they increase mixing and transport between soil and groundwater or air and water, and thus PFOA and PFOS move between environmental media more easily.

These chemicals are sometimes referred to as ''forever'' chemicals because of their strong carbon-fluorine bonds in the ''tail group'' that cause PFOA and PFOS to be extremely resistant to degradation through biological degradation and also through chemical degradation (*i.e.,* photooxidation and hydrolysis). Photooxidation describes the process of oxidation through light exposure and hydrolysis describes the chemical breakdown of compound due to reaction with water. Degradation data from 3M for PFOA states ''Hydrolysis half-life >92 years @ pH 7 & 25 °C (ammonium salt tested); Photolysis in water: half-life > = 342 days; neither direct nor indirect photolysis in water observed based on loss of PFOA; Biodegradation-OECD 301C, 28 days, 5% BOD/ThOD; Biodegradation-Aerobic sludge, 18 days, no degradation observed (ammonium salt tested); Biodegradation-Anaerobic sludge, 94 days, no degradation observed.'' Degradation date from 3M for PFOS states ''Biodegradation-Anaerobic sludge, 105 days, no degradation observed; Biodegradation-OECD 301C (MITI–I), 28 days, 0% BOD/ThOD (3M 2021).'' The resistance to degradation causes PFOA and PFOS to remain in the environment for long periods of time. This means that the potential for human exposure continues long after a release has ended.

PFAS are mobile in the environment and have been found in remote locations, indicating they are widespread in the environment (*Giesy & Kannan, 2001*). PFAS have been found in outdoor air at locations in the United States, Europe, Japan, and over the Atlantic Ocean (*ATSDR, 2021*). PFOA and PFOS are water soluble and thus may be found in groundwater and surface water (*U.S. EPA 2024a*). Further, PFOA and PFOS have water-soil/sediment partition coefficients of 15–708 L/kg and 7–120 L/kg, respectively (*3M, 2021*). These values are on the order of many metals, indicating that PFOA and PFOS are fairly mobile and will move from soil and sediment to water. Experimental data indicates in the marine environment, where suspended solid concentrations are generally low, PFOA and PFOS are mainly transported in the dissolved phase rather than being adsorbed to suspended solids (*Ahrens et al., 2011*). Their presence in the water column means that they will be transported further and are available for long range transport and bioaccumulation (*Ahrens et al., 2011*).

In a 2001 study investigating the global distribution of PFAS, wildlife samples were collected on four continents including North America and Antarctica and PFAS was found to be widely distributed on a global scale.[38] [39] Over 30 different species had measurable levels of PFOS (*European Food Safety Authority, 2008; Giesy & Kannan, 2001*). PFOA and PFOS have been shown to persist in humans and animals, with estimated half-lives in humans ranging from about two to three years for PFOA to four or five years for PFOS (*ATSDR, 2021*). Organisms that are exposed to PFOA and PFOS cannot break them down inside the body and excrete very little. Because PFOA and PFOS can remain in human and animal bodies for long durations, individuals with consistent ongoing exposures to PFOA and PFOS (*e.g.,* individuals consistently exposed by drinking contaminated water or eating contaminated food) can have elevated concentrations of these substances in their bodies (*Bangma et al., 2017; Burkhard, 2021; Ng & Hungerbuhler, 2014*).

C. Other Information Considered

Other information that EPA considered includes, the frequency, nature, and geographic scope of releases of these substances. This information demonstrates that PFOA and PFOS are prevalent, including in the U.S., and there is likelihood of exposure to humans and the environment. PFOA and PFOS are prevalent throughout the environment because of their widespread use since the 1940s in a wide range of commercial and consumer products and because of their persistence. Currently, the public can be exposed to PFOA and PFOS through a variety of sources, including water, food, and environmental media. *See Proposed Rule, 87 FR at 54418–19* (Discussion on the uses of PFOA and PFOS).

Major causes of PFOA and PFOS environmental contamination include historical uses, limited ongoing uses, and ongoing uses of precursors. These activities include past direct industrial discharges of PFOA and PFOS to soil, air, and water and disposal of these substances or products that contain these substances. Precursor chemicals 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. *See Proposed Rule, 87 FR at 54426* (providing a brief history of sources of PFOA and PFOS to the environment).

PFOA and PFOS have been detected in groundwater in monitoring wells, private drinking water wells, and public drinking water systems across the country. The most vulnerable drinking water systems are those in close proximity to sites contaminated with PFOA and PFOS (*ATSDR, 2021*). Under the third Unregulated Contaminant Monitoring Rule (UCMR), EPA worked with the States and local communities to monitor for six PFAS, including PFOA and PFOS, to understand the nationwide occurrence of these chemicals in the U.S. drinking water provided by public water systems (PWSs). Of the 4,920 PWSs with results for PFOA and PFOS, PFOA was detected above the minimum reporting level (minimum reporting level = 20 nanogram/liter (ng/L)) in 379 samples in 117 PWSs serving a population of approximately 7.6 million people located in 28 States, Tribes, or U.S. territories. PFOS was found in 292 samples at 95 systems above the UCMR 3 MRL (40 ppt). These systems serve a population of approximately 10.4 million people located in 28 States, Tribes, or U.S. territories (*U.S. EPA, 2017*).

More recent available data collected by States show continued occurrence of PFOA and PFOS in drinking water supplies in multiple geographic locations throughout the country, as well as occurrences at lower concentrations and significantly greater frequencies than were measured under the UCMR3 (''*PFAS National,*'' *2023*). PFOA and PFOS are also widely detected in surface water samples

[38] Global Distribution of Perfluorooctane Sulfonate in Wildlife; John P. Giesy and Kurunthachalam Kannan; Department of Zoology, National Food Safety and Toxicology Center, Institute for Environmental Toxicology; Michigan State University.

[39] *https://www.efsa.europa.eu/en/efsajournal/pub/653.*

collected from various rivers, lakes, and streams in the United States. Municipalities and other entities may use surface water sources for drinking water and that creates an additional potential exposure pathway to PFOA and PFOS.

PFOA and PFOS can reach soil due to atmospheric transport and wet/dry deposition (*ATSDR, 2021*). These substances have been found in outdoor air at locations across the globe around PFAS production facilities and facilities that use PFAS. PFOA and PFOS have been detected in surface and subsurface soils. Levels of PFOA and PFOS generally increased with increasing depth at sampled locations (PFAS manufacturing facilities), suggesting a downward movement of the contaminants and the potential to contaminate groundwater (*ATSDR, 2021*).

PFOA and PFOS can be taken up by plants, as evidenced by their presence in produce analyzed by the U.S. Food and Drug Administration (*2021*). PFOA and PFOS have also been found in wild and domestic animals such as fish, shellfish, alligators, deer, and avian eggs and in humans (*ATSDR, 2021*). For example, PFOA has been found in snack foods, vegetables, meat dairy products and fish, and PFOS has been found in eggs, milk, meat, fish and root vegetables (*Bangma et al., 2017; Falk et al., 2012; Gewurtz et al., 2016; Holmstrom et al., 2005; Michigan PFAS Action Response Team, 2021; Morganti et al., 2021; U.S. EPA, 2016a, 2016b; Wang et al., 2008; Wisconsin DNR, 2020*).

There is a significant potential for human exposure to PFOA or PFOS because of their persistence, mobility, and prevalence in the environment (*Langenbach & Wilson, 2021*). PFOA and PFOS contamination in the environment can lead to human exposure through ingestion of contaminated water, plants, wild animals, and livestock. PFOA and PFOS 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. Human exposure can occur through the consumption of wild animals that have been contaminated by environmental exposure. Several States have issued advisories recommending that hunters and fishers avoid eating deer, turkey, or fish due to high levels of PFOS detected in the animals (*MDIFW, 2023; Michigan PFAS Action Response Team, 2023; NCDHHS, 2023*). Contaminated water also results in the contamination of livestock such as 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 (*Christensen et al., 2017; FDA, 2021; U.S. EPA, 2019b*). Food can also be contaminated through food packaging made with these chemicals. However, in 2016, the Food and Drug Administration revoked the regulations authorizing the remaining uses of long-chain PFAS in food packaging (see 81 FR 5, January 4, 2016, and 81 FR 83672, November 22, 2016). Therefore, PFOA and PFOS should not be in food packaging now. Humans can also be exposed through incidental ingestion of contaminated soil and dust. Numerous studies have shown that PFOA and PFOS can be found in residences, offices, and other workplaces, and in consumer goods (*Gaines, 2023; Hall et al., 2020; Strynar & Lindstrom, 2008*).

PFOA and PFOS have been detected in nearly all of the blood of the participants in the NHANES. This indicates widespread exposure to these PFAS in the U.S. population (*CDC, 2022*). As part of the continuous NHANES, 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. As of the 2017–2018 data, PFOA and PFOS were still detectable in 99% of the population, although the mean concentrations of PFOA and PFOS in the serum have been steadily decreasing since 1999–2000 (*CDC, 2021; U.S. EPA, 2019a*).

Communities drinking water or eating food contaminated with PFAS can have significantly elevated blood levels of PFAS compared to national average concentrations (*Graber et al., 2019; Kotlarz et al., 2020*). Because PFOA and PFOS can remain in the human body and for long durations, individuals who have consistent ongoing exposures to PFOA and PFOS (*e.g.,* those exposed by drinking contaminated water or eating contaminated food) can have high concentrations of these compounds in their bodies. Epidemiological studies measuring PFAS levels in humans have noted that people living near contaminated sites have higher concentrations of these chemicals than the general population and that drinking water is an important contributor to exposure (*Emmett et al., 2006*).

Conclusion

In light of the evidence regarding hazard and the fate and transport of these chemicals, and consideration of the degree or magnitude of danger posed, EPA concludes for several reasons described above that PFOA and PFOS each may present a substantial danger when released into the environment.[40] Furthermore, the other information EPA considered, such as environmental prevalence and the likelihood of exposure, reinforce its conclusion. individuals living in communities located near sites with high levels of PFOA and PFOS (*e.g.,* sites where PFOA and PFOS were manufactured or used in the manufacture of products) are the populations (*i.e.,* non-occupationally exposed populations) most likely to be exposed to PFOA or PFOS and are thus more likely to experience associated adverse health effects.

At the same time, the mobility of PFOA and PFOS means that these substances have the potential to migrate away from a highly contaminated site into sources of drinking water, both groundwater and surface water. And the mobility and persistence combine to create an ever-expanding area of contamination if it is not contained and/or cleaned up. The persistence, mobility, and prevalence of PFOA and PFOS create more opportunities for exposure to humans and the environment, thereby increasing the likelihood of adverse health effects and adverse ecological burdens stemming from the toxicity of these compounds. *See Proposed Rule, 87 FR 54415.* In sum, communities located near sites with the highest concentrations of PFOA and PFOS are subject to a disproportionately higher risk of exposure to those substances as compared to the general population.

For all these reasons, EPA finds that both PFOA and PFOS, and their salts and isomers, each may present a substantial danger to the public health, or welfare, or the environment when released.

[40] EPA need only determine that PFOA and PFOS ''may present'' a substantial danger to designate as hazardous substances pursuant to CERCLA. CERCLA section 102(a). Other actions taken by EPA, pursuant to other statutory authorities, may require a different or more stringent finding. The scientific and technical data that EPA is relying on in this action may be relevant to those determinations and may support a finding under a more stringent standard.

VI. The Totality of the Circumstances Confirms That Designation of PFOA and PFOS as Hazardous Substances Is Warranted

Along with concluding that both PFOA and PFOS ''may present a substantial danger,'' EPA also independently exercised its discretion and conducted an additional ''totality of the circumstances'' analysis to evaluate whether designation was warranted. The analysis looks to the evidence showing that PFOA and PFOS ''may present a substantial danger'' along with CERCLA section 102(a) and its broader context. CERCLA section 102(a) and its broader context help identify the information to weigh and how to balance multiple considerations. In conducting the analysis as to PFOA and PFOS, EPA identified and weighed the advantages and disadvantages of designation. This analysis included consideration of the formal benefit-cost analysis, including quantitative and qualitative benefits and costs provided in the Regulatory Impact Analysis accompanying this final rule.

The totality of the circumstances analysis first considered the evidence that both PFOA and PFOS may present a substantial danger to public health or welfare or the environment when released, *see* CERCLA section 102(a). Specifically, EPA examined the scientific basis for designation. EPA gave the scientific evidence considerable weight. As discussed in Section V above, PFOA and PFOS exposure has been connected to a wide range of adverse human health and environmental effects. PFOA and PFOS bioaccumulate in humans and animals, including the fish and other wild animals we eat. And PFOA and PFOS are persistent and mobile in the environment. If not addressed, PFOA and PFOS will continue to migrate, further exacerbating exposure risk and potential cleanup costs.

EPA then evaluated CERCLA section 102(a) in the broader context of CERCLA. Section 102(a) provides EPA with health- and environmental-based criteria to evaluate whether a substance can be designated as hazardous. A hazardous substance designation, in turn, makes available the full suite of CERCLA authorities. EPA examined the ways in which designation serves CERCLA's express purposes and functions: ensuring that the ''Polluter Pays'' for cleanup (CERCLA sections 107(a), 106(a)); allowing for timely cleanup of contaminated sites (CERCLA sections 104, 106, 121); and authorizing response that protects human health and the environment (CERCLA sections 104, 106, 121).

With these statutory purposes in mind, EPA considered the core problem posed by PFOA and PFOS in the environment and whether designating PFOA and PFOS as hazardous substances would meaningfully improve EPA's ability to address the problem. EPA believes that the likelihood of the public being exposed to PFOA and PFOS is high. The science demonstrates that human exposure to these chemicals is linked to a broad range of adverse health effects. These concerns apply particularly to those communities living near former manufacturing sites, where PFOA and PFOS were produced (and then widely used) since the 1940s. As a result, communities may be exposed to existing contamination at and near sites where those substances were manufactured and used for decades. These contaminated sites have the potential to disproportionately harm nearby communities and ecosystems. Because of this potential risk, such sites need to be investigated, evaluated for risk to human health and the environment, and cleaned up as appropriate. EPA concluded that CERCLA is best suited to address the problem posed by legacy PFOA and PFOS contamination.

EPA next considered whether the hazardous substances designation is warranted considering EPA's existing authority that allows the Agency to address PFOA and PFOS as CERCLA ''pollutants and contaminants.'' EPA weighed how designation may promote cleanups that might otherwise be delayed or not occur. EPA's current authority to is limited in meaningful ways.[41] This rule, however, will allow EPA to utilize the full suite of CERCLA authorities and enable EPA to address more sites, allow for earlier action, and expedite eventual cleanup. This is, in large part, because EPA will be able to employ CERCLA's liability and enforcement provisions to require parties responsible for significant pollution to address existing contamination. As a consequence, designation greatly expands societal resources available (both financial and human capital) for investigation and cleanup that would not be available absent designation.

EPA also weighed the quantitative and qualitative costs and benefits evaluated in the RIA.[42] EPA considered the estimated direct and indirect monetized costs. These costs include direct costs to comply with release notification requirements and indirect costs for response actions, including potential costs for existing and future NPL sites as well as potential costs that may arise from enforcement actions taken at non-NPL sites. EPA also considered qualitative costs, which are those that EPA could not quantify with reasonable certainty. Qualitative costs encompass the potential costs of litigation and liability. Although EPA was unable to quantify these potential costs, EPA evaluated how designation may affect CERCLA liability and litigation. EPA analyzed whether CERCLA's statutory provisions (*e.g.,* liability limitations, cost recovery provisions and settlement authorities) and existing enforcement discretion policies could mitigate those potential costs. Next, in evaluating benefits, EPA considered the quantified baseline benefits associated with transferring response costs from EPA to PRPs as well as quantified health benefits that may result from the designation. These health effects include those associated with birth weight, cardiovascular disease (CVD) and renal cell carcinoma (RCC)-avoided morbidity and mortality associated with reductions in PFOA and/or PFOS. Unquantified health benefits include health effects such as immune, liver, endocrine, metabolic, reproductive, musculoskeletal, as well as certain cancers such as combined hepatocellular adenomas and carcinomas.

EPA also considered the ways in which the accompanying RIA does not fully capture the quantitative costs or benefits of the rule due to data limitations. As discussed throughout this preamble, CERCLA response actions are discretionary, contingent, and site-specific determinations. Whether it is appropriate to take any action—such as through CERCLA

[41] As described in Section II.E., CERCLA authority differs with respect to ''hazardous substances'' and ''pollutants or contaminants.'' Designation of PFOA and PFOS as ''hazardous substances'' streamlines response authority, makes available cost recovery authorities allowing parties to recover response costs from PRPs, and makes available CERCLA enforcement authority to compel PRPs to conduct or pay for cleanup. *See* CERCLA sections 104(a), 106(a), 107(a). Designation also requires facilities to notify federal, state, local, and tribal authorities, as well as potentially injured parties, of significant releases. *See* CERCLA sections 103(a), 111(g); EPCRA section 304.

[42] EPA conducted a Regulatory Impact Analysis (RIA) consistent with E.O. 12866. The E.O. requires, among other things, that the Agency quantify costs and benefits to the extent possible and that it qualitatively address the costs and benefits that cannot be quantified. The analyses required under the E.O. do not determine the appropriate consideration of advantages and disadvantages for EPA final actions. Instead, the EPA statute, in this case CERCLA, must be evaluated to determine the intended benefits of the statute as determined by it terms.

response authority under section 104 or CERCLA enforcement authority under section 106—is based on a myriad of factors and most importantly whether the releases at the site pose unacceptable risk. Because EPA cannot fully assess and characterize the magnitude and number of instances where the rule would reduce impacts associated with PFOA or PFOS exposure, the benefits are difficult to fully ascertain and estimate with certainty. In addition, there is considerable uncertainty regarding the cost of health burdens that may result from exposure to PFOA or PFOS, and associated cost savings from reducing the incidence of these burdens because of designation.

Relatedly, future response costs are also difficult to quantify due to the site-specific nature of CERCLA. Unlike with benefits, though, EPA concluded that it has sufficient information to reasonably estimate anticipated future costs for NPL and non-NPL sites. EPA was able to utilize existing data to estimate a high and low range for response costs at these sites. As explained in Section VI.A, the investigative and remedial technologies available to address PFOA and PFOS are, in large part, the same remedial technologies used to address other hazardous substances (*e.g.,* the costs to pump and treat groundwater; to dig and haul contaminated soil; or to provide alternative drinking water). Therefore, EPA can use historic response cost information to reasonably assess PFOA and PFOS response costs. EPA acknowledges, however, that there remains uncertainty concerning the location and number of sites that will be identified as needing remediation and the extent of contamination at those sites. There is also uncertainty regarding the potential incremental increase in cost (if any) of addressing PFOA or PFOS at a site along with other COCs present.[43]

EPA concluded that a ''totality of the circumstances'' analysis is a useful benchmark for assessing whether action is warranted under a unique statute like CERCLA. Unlike other environmental statutes which are premised on ''command and control'' regulation, CERCLA is a remedial statute. It does not set prospective limits on the amount of permissible contamination. Instead, CERCLA imposes financial liability on those responsible for existing contamination that presents unacceptable risk to public health and the environment. In many instances (*e.g.,* at NPL sites) cost considerations are evaluated on a site-specific basis. A totality of the circumstances analysis best reflects the advantages and disadvantages of designation and allows for a more holistic assessment of designation.

The totality of the circumstances analysis is provided below. Section VI.A discusses the numerous advantages of designation. Designation allows EPA to deploy the full suite of CERCLA tools to identify, characterize, and cleanup the most contaminated sites expeditiously. It also allows EPA to hold responsible those parties that have contributed to significant contamination so that they bear the costs of cleaning it up. This, in turn, makes more resources available, allowing for additional and/or earlier cleanups relative to what could occur absent designation. These additional, earlier cleanups will protect vulnerable populations and communities living near contaminated sites. Further, these cleanups will have meaningful health benefits similar to other CERCLA actions by reducing a broad range of potential adverse human health effects. Thus, cleaning up PFOA and PFOS contamination that is posing unacceptable risk to human health, or the environment will improve quality of life and reduce health care expenditures for the communities living in and around PFOA and PFOS contaminated sites.

Section VI.B evaluates the disadvantages of designation such as direct costs of the rule, the potential for the rule to create hardship for parties that did not significantly contribute to contamination, and the potential for uncertainty for PRPs. EPA estimates that direct costs, particularly release notification costs, are fairly minimal. EPA recognizes that some parties that do not bear primary responsibility for contamination may be sued and face uncertain litigation costs. EPA believes that CERCLA's liability limitations, coupled with EPA enforcement discretion policies, should operate to minimize hardship for parties that did not significantly contribute to contamination. EPA expects that designation should not change CERCLA's liability framework and that CERCLA will continue to operate as it has for decades (with respect to the more than 800 existing hazardous substances) to resolve who should pay for the cleanup and how much.

In Section VI.C, EPA explains the results of the totality of the circumstances analysis to demonstrate that potential costs and disadvantages are not unreasonable when weighed against the numerous advantages of designation.

A. Advantages of Designation

EPA examined the advantages of designation, including its positive impacts on public health, the Superfund program, local economies and ecosystems, and the importance of shifting response costs to parties responsible for significant contamination. Unlike other environmental statutes which are premised on ''command and control'' regulation, CERCLA is a remedial statute. It does not set prospective limits on the amount of permissible contamination. Instead, CERCLA imposes financial liability on those responsible for existing contamination that presents unacceptable risk to public health and the environment. As a consequence, benefits of the designation flow from CERCLA's liability framework—which leads to more cleanups of existing contaminated sites—rather than the prospective regulation of releases at regulated sources.

Designating PFOA and PFOS as CERCLA hazardous substances eliminates barriers to timely cleanup of contaminated sites, enables EPA to shift responsibility for cleaning up certain sites from the Fund to PRPs, and allows EPA to compel PRPs to address additional contaminated sites. Ensuring the timely cleanup of sites, and that the parties responsible for significant contamination bear the costs of cleaning it up, are the primary objectives of CERCLA. EPA gave significant weight to these considerations because, absent designation, the cleanup of PFOA and PFOS contamination would be significantly hampered. PFOA and PFOS contamination is widespread, and EPA's current authority is limited.

Earlier and more timely responses at contaminated sites will better address the urgent public health issue of PFOA and PFOS contamination. As discussed above in Section V, the latest science is clear: human exposure to PFOA and PFOS is linked to a broad range of adverse health effects. EPA gave significant weight to its finding that both PFOA and PFOS may present substantial danger. The potential for harm to public health is unabated if PFOA and PFOS remain in the environment, and designation is necessary to facilitate swift action. EPA also gave significant weight to the substantial health benefits—realized by communities nationwide—that are expected to result from designation. Earlier, expeditious response to PFOA

[43] Designation does not require any specific response actions or confer liability. Whether response costs will be incurred is wholly dependent on site-specific discretionary decisions. Before taking any action, EPA evaluates the level of risk posed by any given release.

and PFOS releases will reduce exposure to PFOA and PFOS across the country and will minimize the likelihood of adverse health effects, particularly for sensitive groups such as pregnant woman and children. As discussed *supra* in Section V, PFOA and PFOS exposure is linked to serious health conditions, including cancer and cardiovascular disease. Reducing PFOA and PFOS exposures can improve community health while potentially saving Americans billions of dollars in health care and other expenses. PFOA exposure alone has been estimated to have caused billions of dollars of health care and other economic costs (*Malits et al., 2018*). EPA also quantified certain potential health benefits associated with reducing PFOA and PFOS exposure in private drinking water wells. Designation allows for earlier, and additional, CERCLA response activities to address areas with high levels of PFOA and PFOS contamination, which translates to lower risk of adverse health effects for the most exposed communities. Ensuring that EPA can utilize CERCLA to the fullest extent is critical to address this serious public health issue.

1. Designation Enables Earlier, Broader, and More Effective Cleanups of Contaminated Sites

Designation of PFOA and PFOS as hazardous substances is critical to EPA's ability to address the public health threats posed by PFOA and PFOS in the environment. CERCLA imposes notification requirements and potential liability on those that release hazardous substances and makes available authorities that promote timely cleanup of hazardous substances. This includes release notification under CERCLA section 103, response authority under CERCLA section 104, enforcement authority under CERCLA section 106, and cost recovery under CERCLA section 107. Thus, designation allows EPA to employ a broader suite of CERCLA authorities to address contamination, which in turn allows EPA to address more sites, enables earlier and more expeditious responses to PFOA and PFOS releases, and makes available additional resources allowing for cleanup of other COCs at NPL sites. It also provides EPA with authority to pursue those responsible for the most significant contamination so that they bear the financial responsibility for cleaning it up.

a. Designation Opens Up CERCLA's Notification, Response, Enforcement and Cost Recovery Authorities, Which Allows EPA to More Timely Address Contaminated Sites

This action will make PFOA and PFOS subject to CERCLA's notification, response, enforcement, and cost recovery authorities. This is because those authorities either do not apply, or are limited, with respect to pollutants or contaminants (which PFOA and PFOS are currently).

A direct consequence of designating PFOA and PFOS as hazardous substances is that, once designated, entities that release PFOA and PFOS at or above the reportable quantity must provide notification of the release. The requirements include notification to the National Response Center for releases that meet or exceed the reportable quantity, CERCLA section 103; newspaper notice to parties potentially injured by a release, CERCLA section 111(g); and State, local, and Tribal notice, as appropriate, for reportable releases, EPCRA section 304. These notifications allow EPA to assess whether CERCLA response actions are necessary to mitigate risks to public health and the environment and to respond promptly where response actions are necessary. Swift action to address harmful releases can prevent further migration of PFOA and PFOS from the source of the release and reduce the need for more expensive, more expansive cleanup in the future.

Designation also allows EPA to streamline the Federal government's response authority under CERCLA section 104 to address releases or threatened releases using removal or remedial authority. Absent designation, EPA (and other Federal agencies) can only address PFOA and PFOS as pollutants or contaminants. This means that, for each individual response, EPA (or another agency) needs to find that a release, or threat of release, ''may present an imminent and substantial danger to the public health or welfare.'' 42 U.S.C. 9604(a)(1). After designation, agencies will be able to respond to a release or threatened release without first making this determination, allowing for action sooner.

Designation also makes CERCLA's enforcement and cost recovery authorities available for PFOA and PFOS. In the absence of designation, CERCLA authority to compel PRPs to conduct or pay for response work does not extend to ''pollutants or contaminants'' and CERCLA does not provide cost recovery for actions taken solely in response to releases or threats of releases of ''pollutants or contaminants.'' Having access to these authorities will allow EPA to hold PRPs responsible for addressing PFOA/PFOS contamination, which can lead to the timely cleanup of more contaminated sites.

Designation will allow EPA to take enforcement actions against PRPs under CERCLA section 106(a) when there may be an imminent and substantial endangerment from an actual or threatened release of PFOA or PFOS. EPA will be able to use CERCLA section 106(a) to compel PRPs to take immediate action to start the time-consuming process of investigating, scoping, and cleaning up PFOA and PFOS releases. This authority also helps to ensure that PRPs are financially accountable for releases of PFOA and PFOS by enabling EPA to compel PRPs to undertake response action. This, in turn, enables earlier and more EPA response work by diversifying EPA's options. Enforcement actions are also complementary to Fund-financed response activities (''*Guidelines for Using the Imminent Hazard, Enforcement and Emergency Response Authorities of Superfund and Other Statutes,*'' *1982*). EPA aims, whenever possible, to seek cleanup by responsible parties prior to recourse to either the Fund or litigation. This allows EPA to preserve the valuable resources of the Fund to address as many priorities as possible.

Enforcement authority contributes to timely response actions at the most contaminated sites. Because PRPs, rather than EPA, are best positioned to know the location and extent of potential contamination at and from their facilities, PRP-led cleanups can be more efficient. PRP-led cleanups can also be faster because EPA need not secure access orders with PRPs if the PRP is conducting the response actions. Also, EPA generally takes enforcement actions to address sites that pose the highest relative risks; therefore, making enforcement authority available supports EPA's ability to target and prioritize existing sites where PFOA and PFOS releases pose substantial risk to public health and the environment.

Additionally, designation will allow EPA to use CERCLA section 107 to recover costs expended by EPA to clean up PFOA and PFOS contamination. CERCLA section 107 provides that liable parties are responsible for the costs associated with responding to hazardous substances. Liable parties under CERCLA include: (1) Current owners and operators of facilities, (2) past owners and facility operators in place at the time of hazardous substance

disposal, (3) any person who ''arranged for disposal'' of that facility's hazardous substances, and (4) any person that accepts hazardous substances for ''transport to disposal or treatment facilities.'' (CERCLA section 107(a)). If a person is liable for a release of hazardous substances, that person may be responsible to pay for response costs, natural resource damages, and assessment costs, and costs pertaining to certain health assessment or health effects studies. CERCLA section 107(a)(4)(A)–(D).

b. The Availability of CERCLA Enforcement and Cost Recovery Authority Ensures That Polluters Are Financially Responsible, Which Is Consistent With CERCLA

This action will allow EPA to hold polluters responsible for addressing significant contamination. After designation, EPA will have authority under CERCLA section 106 to compel PRPs to take response actions at their facilities. This may allow EPA to reach more sites more quickly. After designation, EPA can also rely on authority under CERCLA section 107 to recover costs expended by EPA to clean up PFOA and PFOS contamination.

The availability of CERCLA enforcement authority to address PFOA and PFOS releases aligns with the Polluter Pays principle, a central objective of CERCLA, and is an important advantage of the rule. CERCLA is specifically designed to hold responsible those parties that contributed to dangers to human health and the environment by releasing hazardous chemicals into the environment. *See* H.R. Rep. No. 99–253, pt. 3, at 15 (1985), *as reprinted in* 1978 U.S.C.C.A.N. 3038, 3038 (stating that a goal of CERCLA is ''to hold responsible parties liable'' for cleanup costs); H.R. Rep. No. 96–1016, pt 1, at 1 (1980) (acknowledging that CERCLA establishes ''strict liability to enable the Administrator to pursue rapid recovery of costs . . . and to induce [liable parties] voluntarily to pursue appropriate environmental response actions . . . .''). The ability to require liable parties to pay for cleanup is the cornerstone of ensuring that sites are cleaned up to protect public health from ''one of the most pressing environmental problems.'' *See* H.R. Rep. No. 99–253, pt 1, at 54 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 2835, 2836. In reauthorizing CERCLA, Congress acknowledged that, ''[I]t is clear from the accumulating data on waste sites that EPA will never have adequate monies or manpower to address the problem itself. As a result, an underlying principle . . . is that Congress must facilitate cleanups of hazardous substances by the responsible parties . . . .'' H.R. Rep. No. 99–253 at 55. Consistent with these legislative goals, this rule enables EPA to hold PRPs, particularly those that have contributed significantly to PFOA and PFOS contamination, financially responsible for addressing such contamination. Designation also signals to the market that there is value in the prevention of releases and mitigation of existing releases.

EPA considered the additional costs that PRPs may face and concluded that these potential costs do not outweigh the advantages of designating PFOA and PFOS. Potential costs associated with CERCLA enforcement actions that may occur after designation are difficult to assess. Nonetheless, EPA used historical cost data to assess the potential for additional costs to PRPs associated with response work at non-NPL sites that may result from enforcement actions, *see Chapter 5 of the RIA for more detail.* EPA cannot ascertain with certainty the number of sites that may be subject to a CERCLA enforcement action over the next several years. Depending on the circumstances, EPA may determine that authority provided under a different statute, such as RCRA, SDWA, CWA, or TSCA, may be best suited to address the environmental harm. In addition, the site could be referred to the State for further action rather than EPA; or site activity could be Fund-lead, which may occur when there is no viable PRP or when immediate action is required. Should EPA proceed using CERCLA enforcement, the scope of the enforcement action—including the response activities required and the amount of time it may take to implement them—is also difficult to estimate absent a preliminary assessment of the scope of contamination at a specific site.

Ensuring that the PRPs responsible for significant contamination bear the costs of cleanup is one of the express purposes of CERCLA and can only be realized through designation. This is an important advantage of designation. Bringing PFOA and PFOS into CERCLA's liability framework is a critical and essential advantage of designation, considering that PFOA and PFOS are prevalent in the environment, threaten communities across the country, and PRPs are best situated to address releases from their facilities. And while it cannot be determined with specificity where or when enforcement and response actions will occur, EPA attempted to estimate anticipated expenditures to the best of its ability. Considering all of this together, EPA concluded that designation achieves a principal objective of CERCLA—the polluter pays. The payment of these costs by those responsible for significant contamination represents an improvement in social welfare as a result of the rule.

c. EPA Expects Designation Will Increase Emergency Response and Removal Actions for PFOA/PFOS

EPA expects that designation will result in more removal actions, including emergency actions, to address PFOA and PFOS releases, which in turn may increase health benefits. These removal actions can be taken by EPA (*i.e.,* Fund-lead actions) or a PRP (*i.e.,* PRP-lead actions).[44] Additional removal actions are expected to occur because EPA prioritizes responses to hazardous substances and in particular those with the greatest threat to human health, and EPA expects an increase in State referrals, each of which are explained in turn.

After designation, EPA expects to take more Fund-lead removal actions for PFOA and PFOS contamination because existing limitations on response authority and cost recovery will no longer apply. EPA's removal program, although not limited to responses to hazardous substance releases, prioritizes responses to hazardous substance releases. This is in part because the removal budget is limited, and the administrative burden for addressing hazardous substances is reduced relative to addressing PFOA/PFOS as pollutants or contaminants. Absent designation, to respond to PFOA or PFOS contamination utilizing CERCLA section 104(a), the statute requires EPA to determine the release or threat of release may pose an imminent and substantial endangerment. The statute also does not allow EPA to cost recover for actions exclusive to pollutants or contaminants. A hazardous substance designation removes those statutory limitations, as EPA need not demonstrate on a case-by-case basis that releases of hazardous substances may pose an ''imminent and substantial endangerment.'' Designation thus enables additional Fund-lead removal actions to address immediate risks.[45]

[44] This section only discusses designation impacts on Fund-lead removals. Designation impacts pertaining to PRP-lead actions, including removal orders, are discussed in section VI.1.b.

[45] When a removal action is appropriate, EPA should take action ''as soon as possible,'' (40 CFR 300.415(b)(3)), and may often choose to take a Fund-lead removal rather than pursing a PRP-lead action through use of CERCLA enforcement authority. Negotiating an enforcement order can be a time-consuming effort, which can in turn delay

EPA can then later recover costs for cleanup of these substances. Recovered costs for each removal action that EPA takes to address sites contaminated with PFOA and/or PFOS are costs that would be shifted from taxpayers to PRPs.

Removal actions to address PFOA and PFOS releases may also increase as a result of State referrals, which often trigger a Fund-lead removal action. States refer sites to EPA when they do not have the capacity, technical expertise, or funding to take action under their own authorities. EPA expects an increase in State referrals to EPA for PFOA and PFOS removal actions because State budgets are limited. And because State budgets are limited, Federal involvement may be the only financially viable path toward responding to PFOA and PFOS releases. EPA is not required to initiate a removal in response to referrals; however, EPA must evaluate the need for removal actions as promptly as possible after receiving the notification and determine the appropriate response. (40 CFR 300.405(f)(1), 300.410(b)). EPA may determine that a Fund-lead removal is the appropriate response or, if not, EPA may continue monitoring the situation should EPA involvement be appropriate at a later point in time.

EPA expects that removal costs for addressing PFOA and PFOS releases will likely be roughly similar to removal costs for other substances. The same response methods that exist for addressing other hazardous substances are available for PFOA and PFOS. As one example, in cases where PFOA and PFOS are contaminating drinking water, removal actions would primarily focus on risk reduction for exposure to contaminated drinking water. Methods of addressing exposure may include granulated activated carbon, ion exchange, connecting customers to the nearest public water system, and/or temporarily providing bottled water. Any contamination left in place would be managed using post-removal site controls [46] or referred to a cleanup program (*e.g.,* State, local, or the Superfund remedial program),[47] dependent on relative risk. EPA expects that Fund-led removal actions to address PFOA and PFOS releases may range from $160,000 to $503,000 per site. *See RIA Chapter 5.* Where PFOA and/or PFOS are the sole driver for initiating a removal action, the cost estimate above represents the estimated cost of the action. Where EPA may be responding to multiple COCs, the cost of addressing PFOA/PFOS would represent an incremental increase to the overall cost of response in addition to those other COCs.

An increase in removal actions for PFOA and PFOS releases is expected to produce meaningful health benefits. Fund-lead removal actions are the fastest way for EPA to respond to the most urgent situations. Removal actions are typically quick responses to immediate threats to eliminate or mitigate a threat to the public. Thus, EPA is able to initiate a removal action more quickly than it can remedial action—actions which often take decades to develop and implement. Through removal actions, EPA can more quickly eliminate or mitigate exposure pathways. For example, if it becomes known to EPA that a resident's drinking water is contaminated with PFOA and PFOS above risk-based levels, EPA can take action to eliminate that exposure pathway by providing alternative drinking water or connecting the resident to an alternative water source. Such actions mitigate the risk of adverse health outcomes associated with chronic and cumulative exposures to PFOA and PFOS. *See Section VI.A.2 of this document, discussion of health benefits.*

d. EPA Expects That Shifting Costs to PRPs To Address PFOA/PFOS Contamination at NPL Sites Will Make Fund Money Available for Other Response Work

Through this action, EPA may compel viable PRPs to clean up PFOA/PFOS contamination. EPA may thus conserve use of the Fund for addressing other COCs or sites where there are no viable PRPs, expanding EPA's ability to provide meaningful benefits for public health and the environment across the country. Absent designation, EPA would continue to spend Fund resources to clean up PFOA and PFOS releases at non-Federal facility NPL sites under EPA's authority to address PFOA and PFOS as ''pollutants or contaminants.'' Prior to this rule, EPA evaluated PFOA and PFOS releases as pollutants and contaminants as part of its process to identify potential NPL sites, in its selection of a remedy, and in evaluation of the remedy. *See supra*—Section II.*E.4, 5.* After designation, EPA will continue to evaluate PFOA and PFOS releases as part of the Superfund process, but now EPA can transfer these costs to PRPs—the entities responsible for the contamination and associated hazards to human health and the environment.[48] Designation or not, EPA has been and will continue to evaluate hazardous substances, pollutants or contaminants, at NPL sites and, if necessary, address releases that present unacceptable risk to human health or the environment. A major difference this designation makes for NPL sites is who bears responsibility.

After designation, parties responsible for significant contamination may bear liability. As discussed in Section VI.A.1.b., the transfer of costs from EPA to PRPs directly advances CERCLA's objective that those that contributed to contamination bear the cost of cleaning it up. While these cost transfers at NPL sites are an important outcome of the designation, the designation itself does not lead to greater response costs at particular NPL sites. Absent designation, EPA would incur these costs, which would be paid by the Superfund. After designation, EPA can transfer these costs to viable PRPs by compelling PRPs to implement response actions at NPL sites or through cost recovery.

The transfer of costs to viable PRPs leads to more total resources available for cleanups. Superfund resources that otherwise would have been used for PFOA and PFOS response actions can now be available for other priorities. Such monies could be made available for additional Superfund response activities at NPL sites to be spent addressing any of the more than 800 hazardous substances, including PFOA and PFOS, as well as other pollutants and contaminants. EPA estimates that this will result in $10.3M to $51.7M (at a 2% discount rate) of Fund resources available each year for NPL response work because of designation. While EPA cannot fully quantify the benefits attributable to funds being available for more response work at NPL sites, EPA

a response. When immediate action is required, EPA will use Fund dollars to initiate a removal and later cost recover.

[46] Post-removal site control (PRSC) means ''those activities that are necessary to sustain the integrity of a Fund-financed removal action following its conclusion.'' (40 CFR 300.5). This may include, for example, replacing water treatment system filters or collecting leachate. Once field actions end, and all EPA resources are demobilized, any additional actions required are PRSCs. PRSCs continue until they are no longer necessary or until such time as a PRP, state or local government, or EPA's remedial program implements a remedy. (40 CFR 300.415(l)).

[47] After EPA takes a removal action, it may be appropriate to refer the site back to the state to maintain PRSCs. The NCP provides that EPA should provide for PRSC, to the extent practicable, before the removal action begins. (40 CFR 300.415(l)). EPA often coordinates with states to obtain a commitment that the state will maintain PRSCs after the removal ends. States may not have funding to undertake the initial removal action, but often are able to budget PRSC costs.

[48] As detailed in the RIA accompanying this rule, these ''cost transfers'' from EPA to the PRP do not result in a net increase in economic costs—rather, they just change ''who pays'' for these cleanup costs.

believes these benefits will be meaningful. More money for NPL response work means that EPA will be able to better address threats to public health and our natural environment from contamination.

Addressing PFOA and PFOS contamination may lead to an incremental increase in the costs associated with addressing NPL sites depending on what other COCs are located at a given site. It is unusual for a remedy to address a sole ''contaminant of concern,'' many of which are hazardous substances. Typically, remedial actions address a number of COCs at once. In some cases, the remedy for other COCs will also address PFOA and PFOS contamination; in other cases, there will need to be additional work to address PFOA and PFOS contamination. For instance, if PFOA and PFOS are not already part of a remedy for the site, adding them to the remedy would then have the potential to incrementally increase the overall cost of the remedy (*e.g.,* by increasing the frequency of GAC replacement). Any costs of cleaning up PFOA and PFOS contamination could then be transferred to PRPs, instead of borne by the Fund. EPA estimates that the incremental cost for addressing PFOA and PFOS releases at NPL sites may range from $10.3 million annually to $51.7 million annually (at a 2% discount rate). *See RIA Chapter 5.* These represent estimated response costs that the Fund would incur absent designation; designation is not expected to result in an overall increase in cost to EPA to address NPL sites. However, the recovery of $10.3M to $51.7M (at a 2% discount rate) of Fund resources each year because of designation will result in EPA continuing to spend that same amount on other Superfund response activities. This represents an increase in resources expended on Superfund response as EPA continues to spend as before and parties responsible for PFOA and PFOS contamination also must spend to address contamination at NPL sites. This represents an indirect incremental cost of the rule.

In sum, EPA concludes that significant advantages of designation are that it will enable earlier, broader, and more effective cleanups of contaminated sites. Designation will provide additional or enhanced notification, response, liability, and enforcement authority under CERCLA. This enhanced authority may allow EPA to address more contaminated sites more quickly. Designation will also ensure that polluters pay for cleaning up contamination that poses unacceptable risks to human health and the environment, which is consistent with CERCLA's objectives. EPA expects to conduct more removal and emergency response actions and that more resources will be available for NPL site response actions. These are significant advantages of the rule because it effectuates the two primary objectives of CERCLA's statutory framework—timely cleanup of contaminated sites and polluter pays—by bringing widespread, persistent chemicals—PFOA and PFOS—under the umbrella of CERCLA's liability framework, which in turn makes more resources available to address this widespread public health threat.

2. Designation Brings Broad Health Benefits

EPA also weighed the health benefits that may indirectly result from designation. EPA considered quantified and unquantified health benefits associated with reducing exposure to PFOA and PFOS, as well as from additional response work at NPL sites. While it is hard to determine with certainty the nature and scope of future response actions, EPA expects that reducing PFOA and PFOS exposure will reduce the risk of adverse health effects, as detailed below.

a. Qualitative Potential Benefits From Decreased Exposure After Addressing PFOA/PFOS Contamination

EPA weighed the indirect potential health benefits associated with removing PFOA and PFOS from the environment. When exposure pathways are mitigated or eliminated, communities living around contaminated sites would be expected to have lower rates of adverse health effects because they are exposed to less PFOA and PFOS. Historical data, such as NPL sites with soil lead contamination and cleanups, demonstrates improved health outcomes after Superfund cleanups.[49] So here, one advantage from designation is that EPA expects overall reductions of adverse health outcomes for exposed communities to occur sooner, in addition to wholly avoided exposure in some instances. EPA expects that additional response actions to address PFOA/PFOS at non-NPL sites resulting from more removals and enforcement actions will reduce or in some cases eliminate exposure to PFOA and PFOS from contaminated sites, resulting in several categories of non-quantified health benefits realized as avoided adverse health effects. As described in section V.A. of this document, PFOA and PFOS exposure can be associated with the following adverse health outcomes:

- Developmental birth effects such as low infant birth weight, birth length, and head circumference
- cardiovascular effects such as changes in cholesterol and blood pressure
- cancer, including renal cell carcinoma
- changes in liver enzymes
- decreased immune response to vaccination
- endocrine effects, including thyroid disorders
- reproductive effects (for PFOA)
- nervous system effects (for PFOS).

Designation provides a robust mechanism to minimize the potential for these adverse health effects from PFOA and PFOS exposure. To the extent that adverse health effects are reduced or avoided, healthcare expenditures to address these outcomes could be reduced, and worker productivity and overall quality of life would be enhanced due to reduced illness and chronic health conditions.

Given that PFOA and PFOS are often expected to be co-located and/or commingled with other chemicals, cleanup at non-NPL sites because of enforcement actions may simultaneously clean up co-contaminants other than PFOA and PFOS that would otherwise go unaddressed, potentially including other types of PFAS. This may include cleanup of co-contaminants from private drinking water wells as well as the source water used for public water supply (to the extent contamination entered source waters and will be cleaned up as a result of this rule). As a result, addressing these co-contaminants has the potential to result in additional health and ecological benefits.

Despite the array of adverse health and environmental risks associated with exposure to PFOA and PFOS, it is technically challenging to quantitatively estimate adverse effects from exposure that will occur absent the designation of PFOA and PFOS as hazardous substances. Furthermore, it is challenging to quantitatively estimate the benefits that may result from designation. In fact, many important benefits (including those associated with possible immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal outcomes) of cleaning up PFOA and PFOS can only be

[49] *Heather Klemick, Henry Mason, and Karen Sullivan. 2020. ''Superfund Cleanups and Children's Lead Exposure,'' Journal of Environmental Management,* 100. doi: 10.1016/j.jeem.2019.102289. For more information: *https://www.epa.gov/superfund/lead-superfund-sites#sites.*

described in qualitative terms due to the lack of robust data. They cannot be quantified or monetized due to data gaps, and due to uncertainty regarding where and when cleanups will occur. But that does not mean that these benefits are small, insignificant, or nonexistent, particularly to the communities CERCLA exists to protect. Quantifying benefits from cleanup of PFOA and PFOS requires data to characterize the risk and quantify the magnitude of expected (cancer and noncancer) health outcomes. Generally, robust data needed to quantify the magnitude of expected adverse noncancer impacts are unavailable, and full quantification of these benefits is made even more challenging by the overlap of effects from PFOA and PFOS exposure. For these reasons, EPA was able to estimate only a few of the many potential benefits from reduced exposure to PFOA and PFOS. The quantified illustrative benefits of addressing PFOA/PFOS contamination discussed below are in addition to the potential qualitative benefits discussed above. EPA believes that the advantages of this action outweigh the disadvantages even without consideration of quantified benefits. The quantified benefits account for only a portion of the overall benefits from the designation of PFOA and PFOS as hazardous substances. That is, addressing PFOA and PFOS contamination in private drinking water wells also results in additional health benefits for additional health endpoints that cannot be quantified, and addressing PFOA/PFOS contamination more broadly brings health and ecological benefits well beyond private drinking water wells. The quantitative benefits described below, however, make clear the meaningful health benefits achieved from reduced exposure to PFOA and PFOS.

b. Quantifiable Health Benefits of PFOA and PFOS Exposure Reduction

In the RIA supporting this final regulation, EPA performed an illustrative estimate of benefits calculated using monetized health benefits estimates per unit reduction of PFOA and PFOS derived for 2024 National Primary Drinking Water Regulation (*U.S. EPA, 2024a*). The estimated benefits attributable to this rule due to reduced PFOA and PFOS levels in private wells (which are not subject to the PFAS NPDWR) are distinct from those attributable to the PFAS NPDWR from reduced PFOA and PFOS in public and community water systems. A portion of benefits from this rule derive from reduced PFOA and PFOS in private wells used for drinking water that may result from addressing contaminated sites, both in the baseline (at NPL sites) and under this final rule (at non-NPL sites). The benefits estimation methodology and results are discussed here. Quantified benefits in the PFAS NPDWR were assessed as avoided cases of illness and deaths (or morbidity and mortality, respectively) associated with exposure to PFOA and PFOS. The PFAS NPDWR provided a quantitative estimate of birth weight and cardiovascular disease (CVD)—avoided morbidity and mortality associated with reductions in PFOA and PFOS. A quantitative estimate of renal cell carcinoma (RCC)—avoided morbidity and mortality for reductions in PFOA was also developed. EPA was not able to quantify or monetize other health benefits, including those related to other reported health effects including immune, liver, endocrine, metabolic, reproductive, musculoskeletal, as well as certain cancers such as combined hepatocellular adenomas and carcinomas. EPA assesses potential benefits quantitatively if evidence of exposure and health effects is likely, it is possible to link the outcome to risk of a health effect, and there is no overlap in effect with another quantified endpoint in the same outcome group. Particularly, the most consistent epidemiological associations with PFOA and PFOS include decreased immune system response, decreased birthweight, increased serum lipids, and increased liver enzymes (particularly Alanine Transaminase (ALT)). The available evidence indicates effects across immune, developmental, cardiovascular, and hepatic organ systems at the same or approximately the same level of exposure.

i. Quantified Developmental Effects

Research indicates that exposure to PFOA and PFOS is associated with developmental effects, including infant birth weight (*ATSDR, 2021; Negri et al., 2017; U.S. EPA, 2016c, 2016d, 202bg, 2024c; Verner et al., 2015; Waterfield et al., 2020*). The route through which the embryo and fetus are exposed prenatally to PFOA and PFOS is maternal blood serum via the placenta. Most studies of the association between maternal serum PFOA/PFOS and birth weight report negative relationships (*Dzierlenga et al., 2020; Negri et al., 2017; Verner et al., 2015*). EPA quantified and valued changes in birth weight-related risks associated with reductions in exposure to PFOA and PFOS in drinking water.

Low birth weight is linked to a number of health effects that may be a source of economic burden to society in the form of medical costs, infant mortality, parental and caregiver costs, labor market productivity loss, and education costs (*Behrman & Rosenzweig, 2004; Chaikind & Corman, 1991; Colaizy et al., 2016; Institute of Medicine, 2007; Joyce et al., 2012; Klein & Lynch, 2018; Kowlessar et al., 2013; Nicoletti et al., 2018*). Recent literature also linked low birth weight to educational attainment and required remediation to improve students' outcomes, childhood disability, and future earnings (*Chatterji et al., 2014; Dobson et al., 2018; Elder et al., 2020; Hines et al., 2020; Jelenkovic et al., 2018; Temple et al., 2010*).

EPA's analysis focuses on two categories of birth weight impacts that are amenable to monetization associated with incremental changes in birth weight: (1) medical costs associated with changes in infant birth weight and (2) the value of avoiding infant mortality at various birth weights.

ii. Quantified Cardiovascular Effects

Cardiovascular Disease (CVD) is one of the leading causes of premature mortality in the United States (*D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017*). As discussed in Section V.A above, exposure to PFOA and PFOS is associated with increased serum PFOA and PFOS concentrations and potentially elevated levels of total cholesterol and elevated levels of systolic blood pressure (*U.S. EPA, 2024b; U.S. EPA, 2024c*). Changes in total cholesterol and blood pressure are associated with changes in incidence of CVD events such as myocardial infarction (*i.e.,* heart attack), ischemic stroke, and cardiovascular mortality occurring in populations without prior CVD event experience (*D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017*).

iii. Quantified Kidney Cancer Effects

The strongest evidence of an association between PFOA exposure and cancer in human populations is from studies of kidney cancer (*e.g.,* renal cell carcinoma (RCC)). Epidemiology studies indicated that exposure to PFOA was associated with an increased risk of kidney cancer (*ATSDR, 2021; California EPA, 2021; U.S. EPA, 2016d, 2024c, U.S. EPA 2024d*). The C8 Science Panel (2012) characterized the evidence for PFOA effects on kidney cancer as ''probable'' based on two occupational population studies (*Raleigh et al., 2014; Steenland & Woskie, 2012*) and two high-exposure community studies (*Barry et al., 2013; Vieira et al., 2013*). A recent study of the relationship

between PFOA and RCC in U.S. general populations found a statistically significant positive exposure-response association between prediagnostic serum PFOA concentrations and subsequent risk of RCC within a population-based US prospective cohort (*Shearer et al., 2021*). This study also observed associations with RCC for PFOS and PFHxS in models unadjusted for other PFAS. However, after mutual adjustment for these 3 chemicals, only the association with PFOA remained statistically significant. As such, EPA selected RCC as a key outcome when assessing the health impacts of reduced PFOA exposures.

In the PFAS NPDWR, EPA quantified and valued the changes in RCC risk associated with reductions in serum PFOA levels that are in turn associated with reductions in drinking water PFOA concentrations. For more details regarding the quantification of benefits from potential reduced developmental, CVD, and RCC impacts, as well as key limitations and uncertainties in that analysis, *See Chapter 6 of the EA for the 2024 NPDWR Final Rule.* (*U.S. EPA, 2024a*).

2. Estimated Health Benefits of PFOA and PFOS Exposure Reduction

For this final CERCLA rule, the quantitative benefit estimates from reducing the adverse health effects described throughout this rule are characterized as illustrative because, in addition to several uncertainties regarding potential cleanups at these sites, it is not possible to estimate the precise magnitude of potential health-related benefits from reducing PFOA/PFOS at these sites. Chapter 3 of the RIA supporting this final rule describes other limitations of the benefits-estimate transfer approach adopted from the PFAS NPDWR, including the simplifying assumption of combining PFOA and PFOS concentrations into one metric and the assumption that benefits per person are linear per PFOA and PFOS part per trillion (ppt) removed.[50]

For context of baseline benefits associated with addressing PFOA/PFOS at NPL sites, the low-end annualized baseline benefits under the assumption 10% of wells within one mile of NPL sites are impacted with 10 ppt reduction in PFOA/PFOS exposure are $430,000 (2% discount rate). The high-end annualized baseline benefits under the assumption 30% of wells near NPL sites are impacted with 200 ppt reduction in PFOA/PFOS exposure are $25,800,000 (2% discount rate). Exhibit 1 shows the results of the illustrative baseline benefits estimates under the scenarios analyzed. Note that these estimates are associated with potential cost transfers as described in Section VI.A.1.d. above and are expected to occur in the baseline (absence of the designation), therefore they are not a result of designation. However, these and other health benefits are expected to be conferred earlier than without designation because designation as hazardous substances reduce the administrative burden on the Agency and makes available enforcement authorities that allow EPA to address PFOA/PFOS contamination sooner.

Exhibit 1. Estimated Illustrative Range of Baseline Annualized Human Health Benefits as a Result of Addressing PFOA/PFOS Contamination at NPL sites (2022$)

% of wells with PFOA/PFOS detections	2% Discount Rate Estimates		
	10 ppt reduction	50 ppt reduction	200 ppt reduction
10% of wells	$430,000	$2,150,000	$8,5900,000
20% of wells	$859,000	$4,300,000	$17,200,000
30% of wells	$1,290,000	$6,440,000	$25,800,000

Notes:
1. Values rounded to three significant digits.
2. Results reflect PFOA/PFOS addressed at final, proposed, deleted, and future NPL sites.
3. Benefits estimated are associated with reduced incidence of developmental effects, cardiovascular effects, and renal cell carcinoma for populations served by private drinking water wells.

As noted previously, the final rule is likely to result in enforcement actions brought by EPA to address PFOA and PFOS releases at non-NPL sites, which are expected to reduce exposure thereby mitigating or eliminating adverse health effects for nearby communities. Due to uncertainties regarding the level of contamination at affected sites, the level of exposure avoided, populations near these sites of concern, and response actions taken, it is not possible to estimate the precise magnitude of potential health-related benefits from reducing PFOA/PFOS at these sites. Given this uncertainty, EPA presents a range of *illustrative* potential health benefits associated with this

[50] The extent to which PFOA or PFOS or both will be reduced at any given site where EPA may implement CERCLA response action is unknown at this time. While PFOA and PFOS are typically found together, to the extent that any CERCLA response action only reduces PFOS concentrations and not PFOA concentrations, the potential health benefits associated with reducing renal cell carcinoma presented here would be overestimated because RCC is associated with PFOA exposure and not PFOS. Further limitations and potential bias are described in more detail in Section 3.5 of the accompanying RIA.

designation. Consistent with the assessment of baseline benefits at NPL sites presented above, the analysis presented here is limited to benefits related to reductions in PFOA/PFOS concentrations in private wells that lead to a reduced incidence of developmental effects, cardiovascular effects, and renal cell carcinoma. This analysis focuses on sites where EPA may address PFOA/PFOS contamination at non-NPL sites using enforcement authorities made available by designation. These sites may include those that are owned/operated by plastics material and resin manufacturing firms identified as having produced PFOS/PFOA,[51] and sites owned/operated by companies reporting PFOS/PFOA releases (including PFOA/PFOS salts) to EPA's TRI.[52] [53]

Under the low-end assumptions, estimated annualized benefits range from as low as $8,990 to as high as $539,000. These low-end values reflect an assumption that clean up actions are completed in year 19 for each group of sites analyzed. The corresponding range based on the high-end assumptions is $13,000 to $779,000. These high-end values reflect the assumption that response actions are completed in year 1 for each group of sites. Exhibit 2 below shows the results of the illustrative range of benefits estimates under the low-end and high-end scenarios analyzed. For more information about this analysis, *see Section 5.2.2 of the RIA.*

Exhibit 2. Estimated Illustrative Range of Annualized Human Health Benefits as a Result of Addressing PFOA/PFOS Contamination at non-NPL Sites (2022$)

% of wells with PFOA/PFOS detections	Low-End Estimates			High-End Estimates		
	10 ppt reduction	50 ppt reduction	200 ppt reduction	10 ppt reduction	50 ppt reduction	200 ppt reduction
10% of wells	$8,990	$44,900	$180,000	$13,000	$64,900	$260,000
20% of wells	$18,000	$89,900	$360,000	$26,000	$130,000	$519,000
30% of wells	$27,000	$135,000	$539,000	$39,000	$195,000	$779,000

Notes:
1. Values rounded to three significant digits and reflect a 2% discount rate.
2. Results reflect PFOA/PFOS addressed at certain sites where EPA may use enforcement authorities.
3. Benefits estimated are associated with reduced incidence of developmental effects, cardiovascular effects, and renal cell carcinoma for populations served by private drinking water wells.
4. Benefits realized over a period of 77 years.

c. Cost Estimates of Burden of PFAS-Related Disease

EPA also considered the potential for designation to contribute to reduction in the burden of PFAS-related disease by looking at published studies related to PFAS disease burden. Expanding upon the exposure-response literature for PFAS, a recent study published by *Obsekov et al.* (*2023*) estimated a total United States disease burden of $5.52 billion related to PFOA and PFOS in the U.S. in 2018. Based on PFAS exposure data from the NHANES, the study stratified the population into percentile groups according to PFAS concentrations. The incidence of five adverse health effects was then estimated for each group based on exposure-response relationships from the literature. These health effects include: (1) Low birth weight, (2) Childhood obesity, (3) Kidney cancer, (4) Testicular cancer, and (5) Hypothyroidism in women. These health effects were chosen based on the existence of statistically significant associations for each effect derived from published meta-analyses of epidemiological studies. To value the economic costs associated with these health effects, the study relies on a combination of cost-of-illness data (*e.g.,* the costs of hospitalization), human capital-based metrics (*e.g.,* reduction in lifetime income associated with lost IQ points related to low birth weight), and the value of disability-adjusted life years (related to kidney cancer). The study also includes a sensitivity analysis that expands the scope of health effects examined to include health conditions for which relationships with PFAS had been identified in the literature but had not been meta-analyzed. These additional health effects include adult obesity, type 2 diabetes in females, gestational diabetes due to exposure during pregnancy, endometriosis, polycystic ovarian syndrome, couple infertility, female breast cancer, and pneumonia. With these health effects added, the sensitivity analysis in *Obsekov et al.* (*2023*) estimates a PFOS-

[51] Data acquired from: Environmental Protection Agency, ''Enforcement and Compliance History Online (ECHO).'' Because not all plastic material and resin manufacturers use PFAS, only a fraction of the facilities reported in ECHO as plastics material and resin manufacturers were used in this analysis. To filter facilities involved in the use or manufacture of PFAS, this RIA uses proxy sites identified using sites owned/operated by companies that participated in EPA's PFOA Stewardship Program, under the assumption that the likelihood of PFOA/PFOS contamination is potentially high at these sites.

[52] Environmental Protection Agency, ''Toxics Release Inventory (TRI) Program, 2022 TRI Preliminary Dataset: Basic Data Files,'' July 2023. Accessed at: *https://www.epa.gov/toxics-release-inventory-tri-program/2022-tri-preliminary-dataset-basic-data-files.*

[53] TRI reporting is not currently required for isomers of PFOA and PFOS.

and PFOA-related disease burden of $62.6 billion in 2018. However, the authors recognize ''that some studies for each of the included outcomes might have reported null findings, [and that] the lower bound of economic cost added for this group of outcomes is zero.'' (*Id.*)

e. Environmental Justice (EJ) Analysis

EPA believes that the human health and environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with EJ concerns. The demographic analysis of plastics manufacturers, facilities reporting to the Toxic Release Inventory (TRI), and U.S. airports found that people of color and low-income populations are disproportionately represented (except near small/medium airports). In particular, these sites have higher rates of Black, Asian, and Hispanic people surrounding them relative to the national average. This finding holds whether focusing on all such populations within one or three miles of these sites or only such populations served by private wells.

Consequently, EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with EJ concerns. To the extent that the final rule leads to additional response actions to mitigate or eliminate exposure to PFOA/PFOS, or to actions that mitigate exposure earlier, health risks for populations living near sites where releases occur may decline. Based on the detailed analysis found in *Section 6.3 of the RIA,* the proportion of the population near these sites identified potential communities with EJ concerns, or (in some cases) people living in structures with a higher probability of containing lead paint (built before 1960) exceeds the national average. Thus, EPA expects that the final rule will at least partially mitigate the existing burden of PFOS/PFOA exposure that falls disproportionately on communities with EJ concerns.

As further context for EJ effects potentially associated with the final rule, published literature concludes that communities with potential EJ concerns, and other socio-economic burdens, have a higher likelihood of exposure to PFAS, including PFOA/PFOS. For instance, reported data from Northeastern University's Social Science Environmental Health Institute published in 2019 show that people of color and low-income populations are disproportionately exposed to PFAS as nearly 39,000 more low-income households (15% more than the expected based on U.S. census data) and approximately 295,000 more people of color (22% more than expected) live within five miles of a site contaminated with PFAS (*PFAS Project Lab, 2019*). In addition, information on the broader links between PFAS exposure and communities with EJ concerns continues to emerge. An August 2021 Natural Resources Defense Council (NRDC) report examined exposure to PFAS in drinking water in California and found that at least 69 percent of State-identified disadvantaged communities have PFAS contamination in their public water systems, and a number of these communities have levels of PFAS contamination that are higher than the State average PFAS concentrations. In their report, NRDC examined the relationship between the PFAS results and California's CalEnviroScreen 3.0 (CES) scores, which measure the environmental burden at the census-tract level. CES identifies communities that are disproportionately burdened by and vulnerable to multiple sources of pollution. The top 25 percent most impacted communities are identified as ''disadvantaged communities'' for the purpose of allocating funds from the State's cap-and-trade climate program (Senate Bill 535). By examining the overlap of CES scores and PFAS results at the census level, NRDC identified census tracts that may be the most vulnerable to PFAS contaminated drinking water. (*Lee, Susan, Avinash Kar, and Dr. Anna Reade, Dirty Water: Toxic ''Forever'' PFAS Chemicals are Prevalent in the Drinking Water of Environmental Justice Communities.* Natural Resources Defense Council, New York. 2021). Therefore, this final rulemaking may improve conditions for exposed populations and communities, including communities with EJ concerns that may have greater PFAS exposure than the general population. Designation of PFOA and PFOS as hazardous substances would allow EPA to address more sites and to implement response actions earlier in time at sites contaminated with PFOA/PFOS, including those near exposed populations and communities, than the Agency could otherwise address in the absence of designation.

f. Summary of Potential Health Benefits Resulting From the Designation

EPA estimates that a portion of potential health benefits associated with reduced exposure resulting from addressing PFOA and PFOS contamination in private drinking water around non-NPL sites that may result from EPA exercising enforcement authorities range from $8,900 to $779,000 (2% discount rate) per year, depending on the percentage of private wells impacted, the reduced level of PFOA/PFOS exposure at each well, and when the cleanup is expected to occur. Note that additional health benefits could also arise through other routes of exposure and for other health effects and non-health effects related to PFOA and PFOS that did not have adequate information for monetization in the PFAS NPDWR, which was used to develop estimates of potential indirect benefits of this designation. Remediation of PFOA and PFOS contaminated sites under CERCLA, including sites with contaminated sediment in water bodies, may reduce the transport of these substances to waters that can be sources of water to public water systems (PWS). There are potential health benefits to customers of public PWSs if source waters are cleaned up to levels below the PFAS NPDWR MCLs [54] or are cleaned up before the PWSs take action to comply with the PFAS NPDWR; EPA cannot quantify these potential benefits.

EPA expects that health benefits that would accrue absent this designation through addressing PFOA and PFOS as pollutants or contaminants under CERCLA, and the additional health benefits due to a potential increase in enforcement actions and removal actions, will be realized sooner rather than later because of this designation. Low-end annualized estimated baseline benefits associated with addressing PFOA/PFOS as pollutants or contaminants at NPL sites under the assumption 10% of wells near NPL sites are impacted with 10 ppt reduction in PFOA/PFOS exposure are $430,000 (2% discount rate). The high-end annualized baseline benefits under the assumption that 30% of wells near NPL sites are impacted with 200 ppt reduction in PFOA/PFOS exposure are $25,800,000 (2% discount rate). Designation is expected to result in earlier response actions because the rule will make EPA aware of PFOA/PFOS contamination earlier than in the baseline (at both NPL and non-NPL sites). As described previously, designation allows EPA access to enforcement authorities to investigate potential releases and compel PRPs to address releases and requires notification of releases above the RQ. These factors may allow for

[54] MCL—Once the MCLG is determined, EPA sets an enforceable standard. In most cases, the standard is a maximum contaminant level (MCL). The MCL is the maximum level allowed of a contaminant in water which is delivered to any user of a public water system. (*https://www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants.*)

timelier cleanup relative to a world without the rule. EPA also expects that industry may improve best practices and handling procedures to prevent or mitigate releases of PFOA and PFOS that, in turn, could result in less expensive cleanups over the long run.

3. Property Reuse and Social, Economic, and Ecological Benefits That May Result From Designation

Superfund cleanups have a proven track record of contributing to social, economic, and ecological benefits. EPA expects similar benefits to accrue as a result of more PFOA and PFOS cleanups that will occur after designation. As a first step, EPA considered studies that evaluated property value trends for communities living around contaminated sites that were cleaned up. Some studies evaluated communities surrounding Superfund sites and other RCRA facilities. RCRA studies examining the effects of remediating hazardous waste sites are also illustrative of how cleanups can improve property values for nearby communities. Thus, EPA considered both sets of studies in evaluating how designation may contribute to increased property values.

Many studies demonstrate that cleaning up contaminated sites can positively improve property values. Residential property values within 3 miles (4.8 kilometers) of Superfund sites may increase as much as 18.7 to 24.4 percent when sites are cleaned up and deleted from the NPL. Research specific to RCRA cleanups also suggest that property values may improve from cleanup, perhaps as much as five percent (*Taylor et al., 2016*). Improved property values also have social equity and environmental justice benefits. Communities near Superfund sites tend to be more disadvantaged than those living farther from the sites, and so increased housing values may provide the most benefit to the poorest segments of the population as opposed to other population groups. Cleanup may help correct sociodemographic disparities in access to a clean and safe environment.

EPA also considered the potential for designation to support returning property to beneficial use. Superfund cleanups also make property usable for various purposes. Many Superfund sites—often vacant and underused areas—can become valuable local assets after cleanup. Many once-blighted properties across the country are now in use for a wide range of purposes, including shopping centers, offices, public parks, recreational fields, wildlife habitat, neighborhoods, and renewable energy facilities. Cleanups can also deter blight, vandalism and trespassing. *https://www.epa.gov/superfund/superfund-program-protecting-healthy-communities-advancing-environmental-protection#community_anchor.*

Sites in reuse and continued use can revitalize a local economy with economic benefits such as jobs, new businesses, tax revenues, and local spending. As of FY 2022, more than 1,040 Federal and non-federal [55] NPL sites support new and ongoing uses. EPA has collected data on more than 10,250 businesses at 671 non-Federal NPL sites. In FY 2022, these businesses generated $74.1 billion in sales and employed more than 236,802 people who earned a combined income of more than $18.6 billion. Over the last 12 years (2011–2022), these businesses' ongoing operations have generated over $589 billion (inflation adjusted) in sales. *https://www.epa.gov/superfund/superfund-remedial-annual-accomplishments-metrics#redevelopment.*

EPA considered the potential for designation to contribute to ecological benefits, such as ecological reuse and ecosystem services. Superfund cleanups can reduce or reverse damage to ecosystems and generate ecological or recreational reuse activities. These improvements can contribute to a thriving local community and spark local investment, which can improve local well-being, quality of life, employment rates, property values, and tax revenue generation. While the exact monetary value of ecosystem services and ecological reuse can be challenging to measure, historical evidence shows they provide meaningful benefits to communities. Ecosystem services support all facets of human systems, providing trillions of dollars in amenities and important natural capital. New or restored ecosystems as a result of Superfund actions can generate important economic benefits. See EPA document on the Agency's website, *Ecosystems at Superfund Sites, Reuse and the Benefit to Community. https://semspub.epa.gov/work/HQ/100003256.pdf.* Cleanups can produce a range of ecosystem services—timber, purification of surface water and recreation opportunities, habitat to use for new hives to support pollinators, and enhance flora and fauna, among others. It can lead to ecological and recreational reuse activities, which include waterbodies, wildlife sanctuaries, nature preserves, wetlands, pollinator habitats, forests, grasslands, beaches, and forests. Recreational reuse can also include the installation of athletic fields, parks, playgrounds, and trails. Now there are nearly 2,000 ecological and recreational reuse activities at about 460 Superfund sites. EPA expects that PFOA and PFOS cleanups can contribute to similar benefits.

In summary, past experience shows that cleaning up Superfund sites can restore ecosystems, allow for beneficial reuses of the sites (*e.g.,* shopping centers, parks, ecological or wildlife sanctuaries) spurring and revitalizing local community economies, increase property values and tax revenues, create jobs, and improve the quality of life and well-being those living on or near sites. *EPA expects similar benefits to accrue from designation.* EPA expects, as a result of designation, that these economic, social, and ecological benefits will also be realized sooner rather than later. Designation will bring PFOA/PFOS entirely into the Superfund program, including investigation, cleanup, enforcement, and liability.

4. Some Facilities May Adopt or Improve Best Practices To Prevent Future Releases of PFOA and PFOS

To the extent they have not done so already, some facilities that use or have legacy stocks of PFOA and PFOS and products that contain these substances may adopt best practices to prevent any future releases and adopt best practices to manage waste that contains these substances and products. Other facilities, such as landfills, firefighting training facilities, metal plating facilities and textile coating operations—may improve their best practices as a result of designation.

Congress considered this benefit when enacting CERCLA: ''Expenditures to prevent a threatened release, discharge, or disposal may be necessary if damages are to be avoided while also providing considerable savings when compared to the costs of removal after a release, discharge or disposal has occurred.'' S. Rep. No. 96–848, at 51 (1980). Better waste management practices could result in fewer releases and in cost-savings.

B. Potential Disadvantages of Designation

EPA assessed potential disadvantages of designation and weighed those against the advantages. The disadvantages include direct costs, indirect costs associated with potential response activities, and the potential for uncertainty. For indirect costs, at the outset, EPA acknowledges that there is

[55] While all NPL sites are overseen by the federal government, the term non-federal NPL sites is used in this context to refer to sites that are not federally owned.

uncertainty associated with both quantified and unquantified potential costs; including response costs, costs that may arise from a judgment of liability, and litigation costs. The magnitude of costs arising from liability and litigation are linked to response costs, and future response costs that may arise after designation are uncertain. Additionally, CERCLA is a discretionary statute and decisions are made on a site-by-site basis. 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 described below. In addition, future discretionary decisions about cleanup and response are difficult to quantify due to numerous 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 at each individual site. Designation alone does not require EPA to take response actions, does not require any response action by a private party, and does not determine liability. As such, none of the indirect costs associated with response, liability, or litigation that EPA estimates are costs that are certain to be incurred after designation.

EPA also considered potential liability, including the risk of a judgment of liability and associated litigation costs, that may arise after designation. EPA was unable to quantify these costs. Liability and litigation are directly tied to response actions taken for any given release, and as explained, future response costs are uncertain. EPA assessed data that may inform potential liability and litigation costs, but ultimately determined that such data was insufficient to quantify these costs given the number of variables that inform potential liability and litigation. Nonetheless, EPA gave careful consideration to CERCLA's liability scheme, and the impact designation may have on CERCLA liability. EPA concludes that designation will not change CERCLA's liability framework. Designation does not automatically confer liability, nor does it alter CERCLA's statutory or regulatory framework for liability. This conclusion is supported by an analysis of CERCLA's statutory limitations, EPA's existing enforcement discretion policies, CERCLA settlement authorities, and CERCLA's parameters for cost recovery and contribution actions.

The disadvantages from designation are discussed in turn.

1. Direct Costs

EPA evaluated direct costs that may result from designation and determined that there are three categories of direct effects that result from designation: notification and reporting requirements pursuant to CERCLA section 103(a) and section 111(g), as well as EPCRA section 304(a); Federal property sale and transfer requirements pursuant to CERCLA section 120(h); and designation of these substances as hazardous materials under the HMTA, see CERCLA section 306(a). EPA analyzed direct costs that may arise from those requirements, as explained below.

Direct costs that may result from designation are limited to costs associated with notification requirements and are expected to not exceed $1,630,000 in annualized costs. EPA estimated potential notification costs for facilities that must comply with CERCLA section 103(a), CERCLA section 111(g), and EPCRA section 304. Reporting and notification requirements are only triggered in the event of a PFOA or PFOS release that meet or exceed the reportable quantity. Per release, the estimated cost for a facility is expected to be no more than $2,658. This is a minimal financial burden compared to the benefit of having more immediate information about significant releases of PFOA and PFOS. Reporting will result in increased transparency about releases of PFOA and PFOS, which will inform our understanding of these substances in the environment and allow EPA to respond as necessary. In addition, State, Tribal and local officials will receive immediate notification of these releases so these entities can take actions to protect the community where release occurs.

EPA also considered direct costs that may be associated with DOT regulations under CERCLA section 306 and Federal property sales and transfers under CERCLA section 120(h). EPA has not estimated the cost to DOT to implement this requirement but expects it to be minimal; additionally, EPA estimates the subsequent indirect incremental costs to shippers as zero or negligible. The number and magnitude of future Federal property sales and transfers involving property contaminated with PFOA and/or PFOS is highly uncertain and cannot be known at this time. Due to this uncertainty, EPA does not attempt to quantify these costs.

2. Potential Hardship for Parties That Did Not Contribute Significantly to Contamination

EPA also considered how designation may impact CERCLA liability for PRPs. As discussed in Section VI.A, as an advantage of designation, it ensures that parties that contributed to releases of PFOA and PFOS are responsible for response costs necessary to cleanup those releases. For PRPs that have significantly contributed to PFOA and PFOS contamination, imposing liability is appropriate and necessary to address this public health threat. However, EPA also gave serious consideration to potential liability for parties that have not played a significant role in contamination, such as parties that did not generate PFOA- or PFOS-contaminated waste.

For those parties that have not played a significant role in contamination, EPA examined the role of CERCLA's liability limitations and protections in safeguarding against liability. EPA also considered how EPA's existing CERCLA enforcement discretion and settlement policies may offer protection from litigation in some situations that may arise after designation. EPA also considered the role that CERCLA settlements may play in resolving potential liability and limiting litigation risk. Taken together, EPA expects that designation should not change CERCLA's liability framework and that CERCLA will continue to operate as it has for decades to resolve who should pay for the cleanup and how much. EPA expects that those parties that are primarily responsible for contamination will bear the brunt of costs to address PFOA and PFOS releases while parties that are not primarily responsible can rely on statutory protections to limit liability, settlement with EPA to secure contribution protection, and EPA enforcement discretion to provide additional comfort. Indeed, this is how CERCLA has operated for decades with respect to the more than 800 hazardous substances already covered by CERCLA. Below, EPA examines CERCL's liability framework, including CERCLA's limiting provisions, EPA's enforcement discretion policies, and relief available under CERCLA's primary causes of action.

CERCLA includes a number of provisions that may limit liability or the financial impact of liability. These include:

- *De minimis or de micromis parties:* CERCLA provides EPA the ability to settle with parties whose contribution is

minimal in comparison to other parties and provides a statutory exemption to de micromis parties. CERCLA section 107(o).

- *Third-Party Defense:* Parties may have a defense to liability if they can show that the contamination was solely caused by acts or omissions of a third party. CERCLA section 107(b)(3).
- *Residential, small business and non-profit generators of municipal solid waste (MSW) Exemption:* This exemption provides an equitable methodology for resolving CERCLA liability of certain MSW generators and transporters. CERCLA section 107(p).
- *Bona Fide Prospective Purchasers (BFPP):* Parties that meet the threshold criteria and continuing obligations for a BFPP are provided with CERCLA liability protection. CERCLA section 101(40).
- *Innocent Landowners (ILO):* Certain entities that acquire contaminated property with no knowledge of the contamination at the time of purchase may be protected from CERCLA liability. CERCLA section 101(35).
- *Contiguous Property Owners (CPO):* This provision protects parties that are victims of contamination caused by a neighbor's action. CERCLA section 101(q).
- *Permit Shield Defense:* CERCLA liability is limited for certain releases that fall within the federally permitted release provision of CERCLA. CERCLA section 101(10).
- *Normal Application of Fertilizer:* CERCLA provides that the ''normal application of fertilizer'' does not constitute a release and, therefore, does not trigger liability under the statute. CERCLA section 101(22).22).

EPA also considered the Agency's existing CERCLA enforcement policies that may mitigate liability concerns and litigation risks. EPA will continue to follow its ''Enforcement First'' policy, which provides that EPA will aim to compel viable PRPs to conduct and pay for cleanup before resorting to the Fund. EPA's existing enforcement discretion policies generally reflect EPA's interest in pursuing major PRPs over minor PRPs. For example, EPA's ''Policy Towards Owners of Residential Properties at Superfund Sites'' (*U.S. EPA, 1991*) is designed to relieve residential owners of the fear that they might be subject to an enforcement action involving contaminated property, even though they had not caused the contamination of the property. EPA's ''Final Policy Toward Owners of Property Containing Contaminated Aquifers'' (*U.S. EPA, 1995*) similarly provides assurance to certain property owners that EPA will not take enforcement actions against them when the landowner did not cause, contribute or exacerbate release of the hazardous substances.

CERCLA's limiting provisions and EPA's enforcement policies work together to support equitable outcomes. Residential landowner PRPs provide a helpful example of how these provisions may work together. Residential landowners may avail themselves of statutory protections such as those available to Bona Fide Prospective Purchasers, Contiguous Property Owners, or ''innocent landowners.'' These protections are self-implementing, which means the protections provided under the statute are automatic, and all a landowner must do to be protected is comply with the requirements of the statute. EPA also has policies in place that provide further comfort to residential landowners, such as the residential landowner policy mentioned above.

Existing limitations in CERCLA coupled with existing CERCLA enforcement policies are sufficient to mitigate concerns about liability that may arise after designation. No additional action is necessary to ensure that those limitations and policies continue to operate as they have for decades. Nonetheless, although unnecessary to justify designating PFOA and PFOS as hazardous substances, EPA intends to develop a policy, consistent with those limitations and policies, that explains EPA's priorities for CERCLA enforcement in the context of PFOA and PFOS releases.[56] As EPA states in the FY 2024–2027 National Enforcement and Compliance Initiatives (NECI) (*August 17, 2023*) (*Uhlmann, 2023*), the Agency expects to ''focus on implementing EPA's PFAS Strategic Roadmap and holding responsible those who significantly contribute to the release of PFAS into the environment . . . .'' The NECI also clarifies that EPA ''does not intend to pursue entities where equitable factors do not support CERCLA responsibility, such as farmers, water utilities, airports, or local fire departments, much as [EPA] exercises CERCLA enforcement discretion in other areas.'' EPA may exercise enforcement discretion on a site-by-site basis informed by site-specific circumstances.

CERCLA has additional mechanisms that may operate to temper financial responsibility if a party is potentially liable to equitably resolve how much each party should pay for the costs of cleanup. Under CERCLA section 113(f), liable parties that believe they paid more than their fair share of response costs at a site may, in certain circumstances, seek contribution from other liable parties. In resolving contribution claims, courts consider equitable factors. *See infra-Section VI.B.3.* CERCLA settlements can also operate to balance equities. CERCLA settlements include protection from CERCLA contribution claims by other PRPs related to the matters addressed in the settlement, CERCLA section 122(h)(4), which should help limit litigation and associated costs. In addition, EPA settlements with major PRPs may provide contribution protection for non-settling parties. For example, if EPA settles with a PFAS manufacturer, EPA may secure a waiver of rights providing that the PFAS manufacturer cannot pursue contribution against certain non-settling parties to that settlement. The waiver of rights helps provide some protection to parties that EPA does not intend to pursue from both the costs of litigation and the costs of cleanup. Without such a waiver, settling major PRPs could pursue contribution under CERCLA from those parties for a portion of the CERCLA cleanup.

CERCLA has several mechanisms that can operate to mitigate liability concerns and temper CERCLA's liability scheme. EPA expects these mechanisms to continue to operate as they have for decades to ensure that designation does not result in inequitable outcomes. This conclusion is supported by the fact that PFOA and PFOS are similar to other hazardous substances, and CERCLA's liability scheme has functioned in a rational way as to these hazardous substances. Specifically, several designated hazardous substances have a similar fate and transport to PFOA and PFOS and are similarly ubiquitous. *See* 40 CFR 302.4. CERCLA hazardous substances, such as the chlorinated solvents trichloroethene (TCE) and tetrachloroethene (PCE), as well as heavy metals like mercury and arsenic are prevalent in the environment. TCE and PCE, for example have been found at over 800 NPL sites as well other contaminated sites from their use as industrial solvents including TCE's use for degreasing manufactured metal parts and PCE's use for dry cleaning. Heavy metals, like mercury and arsenic, are

[56] To help EPA develop a CERCLA PFAS enforcement discretion and settlement policy, EPA held two public listening sessions to solicit individual public input on CERCLA PFAS enforcement concerns. The input received will be reviewed and considered by EPA in drafting the policy. EPA's CERCLA PFAS enforcement discretion and settlement policy is aimed at addressing stakeholder concerns and reducing uncertainties by clarifying when EPA intends to use its CERCLA enforcement authorities or its CERCLA enforcement discretion.

commonly found in soil and groundwater. Arsenic has been found at over 1100 NPL sites and mercury at over 600 sites. Some municipalities also encounter these substances on a regular basis from industrial wastewater discharges. Property owners may also handle these substances as a result of home renovations or gardening or normal activities. For example, TCE can be found in some cleaners sold for household use, including paint removers, glue, spot and stain removers, carpet spot removers, metal cleaners, and gun cleaners. Mercury is found in fluorescent light bulbs and is also found in some water bodies as a consequence of pollution from industrial and mining wastes, powerplant emissions, and other sources. This mercury contamination in turn affects fish and those that consume these fish (*U.S. EPA, 2023f*). In addition, americium, a radioactive element that is on the hazardous substances list is found in household smoke detectors. Similarly, PFOA and PFOS were historically manufactured on a broad scale, have past and continued releases to the environment (*e.g.,* through legacy disposal, release of precursors, or manufacture as a byproduct), and are detected widely in multiple environmental media, including groundwater, surface water, wild animals, livestock, and plants. Despite the fact that people come into contact with these hazardous substances on a regular basis, CERCLA has continued to operate in a rational way, generally protecting those that have played little to no role in significant environmental contamination from liability.

3. Potential Litigation, Liability, and Uncertainty

EPA considered the potential for litigation costs, such as attorney's fees and costs associated with negotiating settlements, following the designation. EPA was unable to quantify these costs given the number of variables that inform potential litigation. In addition to threshold issues associated with liability considerations described previously, variables that inform litigation may include, among others: whether EPA takes a response action; whether there are viable PRPs; the number of parties involved in the litigation; whether it is cost effective for a party to pursue litigation; and whether litigation results in settlement or goes to trial. There also remains an open question of how many actions are taken pursuant to CERCLA or taken pursuant to a State Superfund law. Whether an action is taken pursuant to CERCLA or State law creates an additional level of uncertainty that makes it difficult for EPA to fully evaluate and quantify the potential litigation costs associated with designation.

CERCLA is, in part, a liability statute and is designed to ensure that those responsible for the contamination pay to clean it up. Some amount of litigation to resolve ''who should pay'' is an expected, and intended, aspect of CERCLA, and this is true in the context of actions to address PFOA and PFOS releases as well as the more than 800 hazardous substances that are already within CERCLA's scope. EPA considered how CERCLA may operate to minimize the risks posed by litigation. EPA evaluated how CERCLA's primary causes of action—cost recovery and contribution—operate to resolve liability. EPA also considered the role that CERCLA settlements may play in minimizing risks posed by litigation. EPA weighed these considerations against CERCLA's objective of ensuring the polluter pays.

EPA determined that CERCLA cost recovery and contribution provide parameters that safeguard against excessive litigation, and furthermore, that CERCLA settlements may further mitigate future litigation. The presence of a hazardous substance does not create liability under CERCLA. Under section 107, there must be a ''release'' or ''threat of release'' of a hazardous substance and the entity must fall within one of the categories of liable parties. CERCLA section 107(a)(1)–(4). In addition, an entity can only recover response costs that are ''consistent with the NCP.'' Section 107(a)(4)(B). Further, a party's potential liability may be limited as a result of contribution or settlement, CERCLA section 113(f). The statute provides that a party that resolves its potential liability with the United States or a State in a judicially approved settlement is entitled contribution protection—the ability to block third-party claims for matters addressed in the settlement.

In addition to CERCLA's limiting provisions, litigation may also be constrained by the relief available. Private party CERCLA cost recovery actions are limited to relief associated with certain costs and damages. Most notably is the relief permitted for response costs, which is limited to costs incurred ''consistent with the NCP.'' The NCP provides a technical and detailed process for implementing response actions and creates benchmarks that may limit actions that have no discernible human health, welfare, or environmental benefit. Parties also may only receive reimbursement for response costs incurred, and so a party would need to have the financial means to conduct a cleanup before obtaining any recovery. Those parameters may operate to limit frivolous lawsuits or excessive litigation.

Courts' assessment of equitable factors in allocating cleanup costs can also serve as an important limitation on liability. In resolving contribution claims, courts typically allocate a particular party's share of costs based on equitable factors. As a result, courts aim to resolve claims in an equitable manner, which generally results in those that contributed significantly to contamination bearing the most liability; those that did not will bear only a small percentage of response costs, if any. The equitable factors that courts generally apply include: the volume and toxicity of the hazardous substances and their wastes contributed to the contamination by each party; the degree of involvement in generating the hazardous substances or wastes released/deposited; the degree of care exercised in handling the hazardous substances; and the degree of cooperation by the parties with government officials in preventing further harm to public health or the environment.[57] These factors are designed to ensure that those who have contributed significantly to contamination bear financial responsibility for cleanup. Given the information before the Agency, including the comments on the proposal, EPA does not believe that designation is going to result in widespread, significant liability consequences for parties that lack meaningful responsibility for the contamination at issue.

Contribution claims are further limited by CERCLA settlements that provide contribution protection, and such settlements may serve to prevent contribution lawsuits against settling parties. A party that resolves its liability through a CERCLA settlement with the United States will not be liable for third-party contribution claims related to the matters addressed in the settlement. This means that PRPs will not be able to pursue the settling parties for

[57] *See, e.g., United States* v. *A&F Materials Co.,* 578 F. Supp. 1249, 1256 (S.D. Ill. 1984) (establishing equitable factors for apportioning financial responsibility (*i.e.,* the ''Gore Factors'')); *see also In re Bell Petroleum Services, Inc.,* 3 F.3d 889, 894 (5th Cir. 1993) (discussing considerations for apportioning liability among contributors); *Waste Mgmt. of Alameda County, Inc.* v. *East Bat Reg'l Park,* 135 F. Supp. 2d 1071, 1089–90 (N.D. Cal. 2001) (in exercising its discretion on allocation, court does not need to limit itself to any particular set of factors, courts may consider factors appropriate to balance the equities in the totality of circumstances).

contribution costs under CERCLA related to the settlement, thus minimizing litigation costs and discouraging third-party litigation. In certain situations, parties may qualify for *de minimis* or *de micromis* settlements under the terms of the Agency's 2002 enforcement discretion/settlement policy. On a case-by-case basis, EPA may enter into limited ''ability to pay'' settlements with parties to resolve CERCLA response costs, where payment could result in undue financial hardship for the PRP. Further, parties may also be asked to perform actions such as in-kind services, including PFAS monitoring activities and implementing institutional controls.

EPA also considered the potential for CERCLA litigation that may arise as the result of ''voluntary'' private-party cleanup or as the result of cleanup conducted or ordered pursuant to a State program. The safeguards and limitations on CERCLA liability discussed in this section are equally applicable in the context of CERCLA litigation arising from voluntary or state-led cleanups. Such litigation is subject to the same paradigms as litigation that arises out of a Federal-led CERCLA action.

EPA acknowledges though that some parties that do not bear primary responsibility for contamination may be sued and face litigation costs as a consequence. These costs cannot be known at this juncture with reasonable certainty. Notwithstanding this, EPA believes that statutory safeguards described above will likely limit this type of litigation or adverse outcomes. Even if litigation costs are incurred by parties that do not bear primary responsibility, EPA does not believe that the potential for such costs will outweigh the substantial advantages of designation discussed above.

C. Results of Totality of the Circumstances Analysis

Taken together, weighing the advantages and disadvantages of the designation alongside EPA's determination that both PFOA and PFOS may present a ''substantial danger,'' EPA concludes that designation of PFOA and PFOS as hazardous substances is warranted. First, the scientific evidence establishes that PFOA and PFOS releases into the environment pose diverse and serious health hazards to exposed populations. The full scope of the hazards from PFOA and PFOS is not yet known, and scientists continue to gain greater understanding of the effects of these human-made chemicals on public health and the environment. Among other things, the current body of scientific and technical literature establishes that PFOA and PFOS exposure are associated with adverse impacts on pregnant women and developing fetuses, such as an increased likelihood of pregnant women getting preeclampsia and hypertension or that babies will be born with a lower birth weight and smaller head circumference. PFOA and PFOS exposure are associated with increased risk for renal cell carcinoma, a type of kidney cancer. Exposure is associated with an increased risk for many other adverse health effects including cardiovascular effects, such as changes to blood pressure and cholesterol, and thyroid disorders, which in turn can impact heart rate, mood, energy level, metabolism, bone health, pregnancy, and many other functions. *[See section V.A.]* PFOA and PFOS exposure are also associated with decrease immune response to vaccinations, in turn leaving vaccinated individuals more vulnerable to harmful disease. These health risks are documented in an extensive body of scientific and technical literature that is continuing to develop as more is learned about the widespread adverse impacts of PFOA and PFOS exposure.

In addition to the serious potential health hazards posed by these substances, available information about the fate and transport of PFOA and PFOS support EPA's conclusions that these substances remain in the environment for many years (*i.e.,* persistence) and that they can move through air, land, and water (*i.e.,* mobility) after release. These chemicals are sometimes referred to as ''forever'' chemicals because of their strong carbon-fluorine bonds in the ''tail group'' that cause PFOA and PFOS to be extremely resistant to degradation through biological degradation and also through chemical degradation (*i.e.,* photooxidation and hydrolysis).

Other information that EPA considered demonstrates that PFOA and PFOS are prevalent and there is a likelihood of exposure to humans and the environment. PFOA and PFOS are prevalent throughout the environment because they are persistent and have been widely used since the 1940s in a wide range of commercial and consumer products. Currently, the public can be exposed to PFOA and PFOS through a variety of sources, including drinking water, food, and environmental media. PFOA and PFOS have been detected in the drinking water of millions of Americans and are widely detected in surface water samples collected from various rivers, lakes, and streams in the United States (*ATSDR, 2021; Cadwallader et al., 2022; U.S. EPA, 2017, 2024a*). The prevalence of PFOA and PFOS is further demonstrated by the fact that these chemicals were detected in the blood of nearly all of the participants in NHANES. This information indicates widespread exposure to PFOA and PFOS in the U.S. population.

Addressing PFOA and PFOS contamination, including cleaning up contaminated soils and water supplies, can reduce PFOA and PFOS exposure to affected communities, and bring substantial benefits. In particular, individuals living near heavily contaminated sites—that is, those sites that are most likely to be targeted for EPA enforcement action, removal action, or designation on the NPL list for more complex cleanup—often include communities with EJ concerns. These communities are at particular risk from adverse health impacts from PFOA and PFOS exposure as well and so are vulnerable to further cumulative harm.

Designation of PFOA and PFOS as hazardous substances under CERCLA section 102(a) will have concrete, on the ground impact, and reduce serious harm. CERCLA's scheme gives EPA authority to cleanup both pollutants and contaminants (which PFOA and PFOS have long been considered) and hazardous substances. But only once a chemical is designated as a hazardous substance, can EPA employ the full suite of CERCLA authorities. These include: the requirement that authorities be notified of certain releases; the authority to compel PRPs to investigate and cleanup contamination where there may be an imminent and substantial endangerment; and the authority to recover response costs where EPA takes Fund-lead actions. These authorities are critical to addressing existing and future PFOA and PFOS contamination and reducing risk of ongoing exposure to these harmful chemicals.

EPA's analysis shows that designation of PFOA and PFOS as hazardous substances will allow EPA to address more sites and to implement response actions earlier in time than it otherwise could in the absence of designation. This is because designation allows EPA to complement Fund-lead actions with PRP-lead actions. Shifting costs to PRPs to address PFOA and PFOS contamination at NPL sites will make Fund money available for cleanup work at Superfund sites. More cleanups promote economic benefits, such as improved property values and making land available for reuse, which can revitalize a local economy with economic benefits such as jobs, new businesses, tax revenues and local

spending. Designation also removes barriers to taking removal actions, which is expected to result in more short-term actions to address immediate risks. Collectively, these actions are expected to have meaningful benefits to human health and the environment, limit further exposure to PFOA and PFOS, and reduce the spread of PFOA and PFOS contamination. Expeditious response to mitigate PFOA and PFOS releases is particularly important given the chemical properties of these substances which make them persistent and mobile in the environment. While the full extent of health, social, economic, and ecological benefits of the designation cannot be quantified, such benefits are expected to be substantial, bringing particular benefit to vulnerable populations.

Designation also serves CERCLA's key purpose of ensuring that those entities that are primarily responsible for contamination bear the economic burden of cleaning it up. Without designation, EPA actions to address PFOA and PFOS are more limited, and response costs may only be paid for through the Fund. After designation, EPA will have authority to compel action by and recover costs from PRPs, which effectively places financial responsibility on those entities responsible for contamination. When EPA is able to transfer NPL site costs addressing PFOA and PFOS contamination, as described previously, it improves societal equity by ensuring that the Polluter Pays for cleanup rather relying exclusively on Fund resources. Further upholding the Polluter Pays principle of CERCLA, designation allows EPA to compel PRPs to address PFOA and PFOS contamination at sites outside of the NPL. This means that additional sites can be addressed, and contamination can be addressed earlier. ''Polluter pays'' is a central objective of CERCLA as a liability statute. Response costs at NPL sites enabled by transfers from EPA to PRPs are estimated to be $10.3 million annually to $51.7 million annually (2% discount rate). Indirect costs associated with response work at non-NPL sites compelled through enforcement actions is estimated to be $327,000 to $18,100,000 annually (2% discount rate). (*See RIA Chapter 5*). EPA recognizes that designation will result in economic costs borne by PRPs. While CERCLA's primary aim is to ensure that PRPs bear cleanup costs, EPA acknowledges that the costs parties expend to clean up PFOA and PFOS is a burden for them. Notwithstanding this, EPA views the cleanup monies spent by PRPs as an advantage of the rule for the reasons stated above. In addition, EPA believes that these cleanup costs will substantially reduce the hazards posed by exposure to PFOA and PFOS, providing significant health benefits (particularly to sensitive populations) that justify the costs.

EPA recognizes that, under CERCLA, a PRP—including those parties that significantly contributed to contamination and those that did not—may be jointly and severally liable to the government for the entire amount of response costs unless it proves that the harm from the release of hazardous substances is divisible. This is true of all listed hazardous substances. EPA's experience over the past four decades administering CERCLA shows that the statute, combined with EPA's existing enforcement discretion policies, ensure that CERCLA will continue to function in a rational manner, with those primarily responsible for pollution bearing the costs of cleanup.

The decision to designate PFOA and PFOS as CERCLA hazardous substances is supported by CERCLA's legislative aims underpinning CERCLA's enactment. CERCLA was enacted to promote the timely cleanup of contaminated sites and to ensure that those responsible for contamination pay to clean it up. H.R. Rep. No. 99–253, pt. 3, at 15 (1985); *Burlington Northern and Santa Fe Railroad Co.* v. *U.S.,* 556 U.S. 599, 602 (2009) (''The Act was designed to promote the 'cleanup of hazardous waste sites' and to ensure that the costs of such cleanup efforts were borne by those responsible for the contamination.''). Designation ensures that CERCLA activities to address PFOA and PFOS contamination conforms to those objectives. Moreover, CERCLA was enacted to address the challenge of community exposure to hazardous chemicals, like PFOA and PFOS, released into the environment.[58] EPA's decision to designate aligns with Congress's vision for CERCLA as an important Federal tool in removing chemicals from the environment that have the potential to pose serious risks to human health and the environment. Indeed, CERCLA designation is necessary to adequately tackle the threat posed by PFOA and PFOS contamination to communities across the country.

CERCLA authority provides EPA with tools to address immediate and long-term needs for mitigating and eliminating PFOA and PFOS exposures that present unreasonable risk. CERCLA's approach to identifying, investigating, and cleaning up contamination is also designed to promote response for the subset of releases that present the most urgent risks. This is evidenced through CERCLA's removal authorities, NPL listing process, the remedial process, and enforcement authority for imminent and substantial endangerments. CERCLA directs Federal agencies to assess risks by considering the population, the hazard potential of hazardous substances, the potential for drinking water contamination, the potential for direct human contact, the potential for destruction of sensitive ecosystems, and the damages to natural resources that may affect the human food chain. Indeed, with those considerations in mind, a small fraction of sites qualifies for the NPL every year.[59] CERCLA also includes safeguards against excessive cleanup costs relative to the effectiveness of a remedy, and those safeguards are reinforced by CERCLA's cost recovery mechanisms. Collectively, these tools ensure that CERCLA prioritizes and targets releases that pose the most risk to human health and the environment; ensures that EPA can respond quickly when necessary and design durable, long-term remedies that ensure protection for public health and the environment; and that site-specific remedies are cost-effective.

In conclusion, the totality of the circumstances analysis confirms that designation of PFOA and PFOS as CERCLA hazardous substances is warranted. An analysis of the advantages and disadvantages of designation, including weighing of

[58] Congress enacted CERCLA to address contaminated sites across the nation, which was considered one of ''the most serious health and environmental challenge[s] of the decade.'' S. Rep. No. 96–848, at 2 (1980). Congress acknowledged that ''the potential impact of toxic chemicals on the general public and environment through unsound hazardous disposal sites and other releases of chemicals is tremendous.'' *Id.* And in fact, expert testimony solicited by Congress stated that the breadth and scope of the effect of exposure to hazardous chemicals nearly ''extend[ed] to the entire population of the United States.'' *Id.*

[59] The hazardous substance designation is not expected to change the approach EPA uses for identifying potential NPL sites. EPA already has the authority to add PFOA and PFOS releases to the NPL. EPA evaluates a number of options before determining the most effective approach for site cleanup. Alternatives to NPL listing may include: Superfund Alternative Approach, state cleanup, cleanup by other federal agencies, EPA removal, deferral to another EPA program and various enforcement mechanisms. Therefore, releases that contain PFOA or PFOS are more likely to be addressed through non-NPL mechanisms than through the NPL. Between FY 2003 and FY 2022, only about four percent of all contaminated sites evaluated by EPA for placement on the NPL were added to it. Since 2013, EPA has, on average, added 11 non-federal sites per year to the NPL and EPA does not expect the rate at which annual additions to the NPL occur to increase as a result of this rule.

quantitative and qualitative benefits and costs, demonstrates that the advantages outweigh the disadvantages. Further, designation best achieves CERCLA's dual objectives—the timely cleanup of contaminated sites and ensuring that those responsible pay for cleanup. Designation provides additional tools that allow for earlier, broader, more effective cleanups, allowing EPA to protect communities that are exposed to high concentrations of PFOA and PFOS.

VII. Summary of Public Comments and Responses

In this final action, EPA is designating PFOA and PFOS, including their salts and structural isomers, as hazardous substances pursuant to CERCLA section 102(a).

In response to the September 6, 2022, proposed rule (2022 Proposal), EPA received approximately 64,000 comments, including mass mail. EPA received comments from a variety of sources, including the regulated community, trade associations, and State, Tribal and local agencies. The Agency received comments generally supporting and opposing the designation of PFOA and PFOS as CERCLA hazardous substances. EPA also received a number of comments requesting clarity on the various issues that EPA considered in support of the 2022 Proposal. EPA has taken the submitted comments into consideration in preparing this final action. Comments have been summarized and EPA has provided detailed responses to the significant comments either here in this final action or in the *Response to Comments on the Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances,* which is available in the rulemaking docket. This section includes responses to a selection of the significant comments received on various topics addressed in the 2022 Proposal.

A. Legal Authority

1. Consideration of Cost and Section 102(a)

Comment: Several commenters assert that EPA must consider costs when designating a hazardous substance pursuant to CERCLA section 102(a). These commenters disagreed with EPA's proposed interpretation of CERCLA section 102(a) ''as precluding consideration of costs in hazardous substance designations.'' Those commenters generally remarked that EPA's position is inconsistent with U.S. Supreme Court case law on considering costs in regulatory actions. Commenters that disagreed with EPA's position also generally argued in the alternative that, at a minimum, EPA has discretion to consider cost. Conversely, some commenters agreed with EPA's proposed position that CERCLA section 102(a) precludes the consideration of cost.

Commenters that disagreed with EPA's position assert that CERCLA section 102(a) requires the consideration of cost. Commenters assert that the phrase ''as may be appropriate'' in CERCLA section 102(a) means that EPA must consider cost in considering whether to promulgate regulations to designate hazardous substances. Commenters support this interpretation by: (1) Asserting that CERCLA provides no textual basis to preclude cost citing *Michigan* v. *EPA,* 576 U.S. 743, 752 (2015), where the court held that the phrase ''appropriate and necessary'' as used in section 112(n)(1)(A) of the CAA must include some consideration of cost; and (2) distinguishing *Whitman* v. *American Trucking Ass'ns, Inc.,* 531 U.S. 457 (2001), and *Utility Solid Waste Activities Group* v. *EPA,* 901 F.3d 414 (D.C. Cir. 2018), in which the courts upheld EPA determinations that health-based statutory provisions precluded consideration of costs. A few commenters further supported their position by asserting that CERCLA's definition of ''hazardous substance,'' CERCLA section 101(14), incorporates by reference other environmental statutes with listing or identification criteria that include cost considerations.

These commenters also argued in the alternative that even if EPA is not required to consider cost, it at least has discretion to do so. Looking to the Court's decision in *Entergy Corp.* v. *Riverkeeper, Inc.,* one commenter implied that ''. . . silence [as to cost] is meant to convey nothing more than a refusal to tie the agency's hands as to whether cost-benefit analysis should be used, and if so to what degree.'' 556 U.S. 208, 222 (2009).

EPA also received comments agreeing with its proposed interpretation that CERCLA section 102(a) precludes the consideration of cost. As one commenter stated, EPA's proposed interpretation ''accords with CERCLA's unambiguous text, statutory structure, and judicial interpretations of comparable provisions of other environmental laws.'' The commenter notes that ''CERCLA's text contains a single criterion for the designation of a hazardous substance: whether the substance, 'when released into the environment[,] may present substantial danger to the public health or welfare or the environment.' '' The commenter also states that ''[c]ompliance costs do not constitute 'substantial danger to the public health or the environment' and are not attributed to the 'release[ ]' of a hazardous substance into the environment. . . .'' The commenter contrasts CERCLA section 102(a) with other CERCLA provisions that authorize or require cost considerations to conclude that Congress intended a difference in meaning. Finally, the commenter suggests that CERCLA section 102(a) is akin to other ''health-focused provisions of other environmental laws'' that courts have interpreted to exclude cost considerations.

Response: EPA proposed interpreting CERCLA section 102(a) as precluding the consideration of cost in designating CERCLA hazardous substances. EPA recognizes that, as a general matter, a statutory assessment of health and environmental-based criteria like the criteria in section 102 does not generally allow for consideration of costs. As discussed in Section V of this document, examining only the statutory criteria—whether PFOA or PFOS ''may present a substantial danger to public health or welfare or the environment'' and without considering costs and benefits—EPA has concluded that designation is warranted.

EPA considered comments supporting and disagreeing with the position that CERCLA section 102(a) precludes the consideration of cost. In taking final action, EPA decided it need not determine whether section 102(a) precludes consideration of costs and benefits because designation is warranted either by examining the health- and environmental-based criteria alone or by examining these criteria along with the broader totality of the circumstances. The Agency first evaluated the available scientific and technical information about those substances and concluded that designation of each is warranted based solely on a finding that PFOA and PFOS may present substantial danger to public health or welfare or the environment. The Agency next conducted a separate totality-of-the-circumstances analysis, which did consider costs and benefits. EPA considered the available scientific and technical information, along with the advantages and disadvantages of designation, including quantified and unquantified benefits and costs, and concluded this analysis reinforced that designation was warranted as reflected in section VI of this preamble. Because EPA's designation is warranted when considering benefits and costs as part of a totality of the circumstances analysis, EPA need not resolve whether CERCLA

section 102(a) precludes EPA from taking into account costs.

2. Interpretation of the Phrase ''May Present Substantial Danger''

Comment: Commenters posit that the standard for designation proposed by EPA is overbroad, vague, and arbitrary and capricious. Some commenters argue that EPA's alleged vague articulation of this standard provides little guidance on how or why PFOA and PFOS satisfy that standard. Commenters go on to assert that the lack of clarity regarding EPA's proposed interpretation of ''may present a substantial danger'' suggests that the Agency has deprived the public of the ability to meaningfully comment on its proposed rule. Relatedly, these commenters state that EPA must clearly state the level of evidence that is sufficient to demonstrate ''substantial danger'' before proceeding with the designation. Commenters also asserted that EPA failed to demonstrate how PFOA and PFOS qualify as toxic, persistent, and prevalent.

Commenters also argue that EPA must address the likelihood of exposure to PFOA and PFOS in evaluating whether designation of PFOA and PFOS is consistent with section 102(a). Another commenter suggests that EPA propose a standard for designating substances consistent with 102(a) in a separate rulemaking before proceeding with designating any substances.

Commenters further claim that the standard EPA articulated makes it unclear how EPA may apply CERCLA section 102(a) in the future to designate additional substances. A commenter asserts that EPA has not identified an ''intelligible principle'' to apply when making listing decisions, and therefore, any level of risk is sufficient to support a listing of a chemical so long as it is also mobile, persistent, and prevalent. Commenters also argue that there should be a level of predictability for potential future designations; for example, EPA should identify a bright-line risk threshold at which a substance poses ''substantial danger'' for the purposes of section 102(a). One commenter suggests that EPA must explain the characteristics that a substance must exhibit to be designated as a hazardous substance under section 102(a). Another commenter stated that the criteria articulated for CERCLA section 102(a) should have a level of specificity similar to the criteria for listing decisions made under the environmental statutes incorporated by reference through CERCLA's definition of hazardous substances.

Several commenters also suggest that EPA's interpretation of ''substantial danger'' for the purposes of CERCLA section 102(a) is inconsistent with a reading of that phrase offered by EPA in an Advanced Notice of Proposed Rulemaking released on January 14, 2021. Finally, one commenter argues that EPA should explain how ''substantial danger'' aligns with the NCP's risk thresholds for cancer and noncancer risks.

Response: EPA disagrees with the commenters' position that the information the Agency considered in proposing to designate PFOA and PFOS as hazardous substances under CERCLA section 102(a) was overbroad, vague, and arbitrary and capricious. In the final rule, EPA identified the information it considered in evaluating whether a substance satisfies CERCLA section 102(a) and described the information it considered in reaching its conclusion that PFOA and PFOS satisfy CERCLA section 102(a). Specifically, as detailed in section IV.A., the two primary factors the Agency considered in the context of CERCLA section 102(a)—hazard, and fate and transport—are consistent with other statutory methodologies used for identifying CERCLA hazardous substances. Under section 102(a) of CERCLA, EPA has been delegated the authority to identify and weigh information relevant to determining whether a substance, when released, may present a substantial danger and the approach we have adopted is reasonable and consistent with EPA's other authorities. In the final rule, EPA also conducted an additional, discretionary analysis of the totality of the circumstances.

EPA also disagrees with commenters that EPA should identify a bright-line risk threshold at which a substance poses ''substantial danger'' for the purposes of section 102(a). The plain language of CERCLA section 102(a) does not require a ''bright-line'' risk threshold applicable to any and all substances. Further, the Agency does not know how it would establish such a line, including because exposures at different levels are associated with a variety of health effects, carcinogenic and non-carcinogenic risk are calculated separately, risk must consider, acute, sub-chronic, and chronic exposure, and risk is calculated for all site contaminants combined,[60] and the commenters do not provide suggestions for how such an approach would work. Instead, EPA is utilizing the discretion provided in CERCLA section 102(a) to conduct individual analyses of substances that account for all of their characteristics to determine whether, when released, the substances may present substantial danger. Moreover, EPA also finds that a bright-line test is not appropriate because the plain language of CERCLA section 102(a) (''may present a substantial danger'') does not require certainty that a release of a substance in fact presents a substantial danger in any given location it is found.

EPA disputes the commenter's position that the NCP's risk thresholds for cancer are relevant to its interpretation of whether PFOA or PFOS may present a substantial danger to public health or the environment under section 102(a) of CERCLA. EPA's cancer risk thresholds are used on a site-specific basis—during EPA's remedy selection process—to take into account an individual's lifetime cancer risk. By contrast, the analysis of whether a substance ''may present a substantial danger'' for the purposes of designation as a CERCLA hazardous substance does not require certainty and is not site-specific. It would be inconsistent with the plain language of section 102(a) for EPA, at this stage and for the purpose of designating hazardous substances, to evaluate the specific releases in which exposure to PFOA and PFOS pose actual risk. Those determinations are left for later stages in the CERCLA process and evaluated on a site-by-site basis.

EPA also rejects the commenter's assertion that CERCLA section 102(a) requires the Agency to promulgate a standard for designating hazardous substances in advance of today's action. CERCLA section 102(a) includes no such requirement, and neither do the other environmental statutes that authorize EPA to list or designate substances as hazardous. Rather, CERCLA section 102(a) provides that, ''[t]he Administrator shall promulgate and revise as may be appropriate, regulations *designating* . . . hazardous substances . . .'' CERCLA section 102(a) (emphasis added). This language is distinct from other places in CERCLA where Congress directed EPA to promulgate regulations or procedures for various CERCLA activities. For example, CERCLA section 112 explicitly provides that EPA shall ''prescribe appropriate forms and procedures'' for filing CERCLA claims. CERCLA section 112(b)(1). Likewise, CERCLA section 105 directs EPA to ''establish procedures and standards for responding to releases of hazardous substances.'' CERCLA section 105(a). Section 102(a) does not include similar

[60] USEPA. 1986a. *Guidelines for the Health Risk Assessment of Chemical Mixtures.* EPA 630–R–98–002. Available on the internet at: *https://www.epa.gov/risk/guidelines-health-risk-assessment-chemical-mixtures.*

language and does not require that EPA promulgate a standard for designating hazardous substances in advance of doing so. Nonetheless, EPA identified two primary factors—hazard, as well as fate and transport—relevant to the designation of hazardous substances. To further inform its decision, EPA concluded that other information may be relevant to evaluating releases of the substance, such as the frequency, nature, and geographic scope of releases of the substances and likelihood of exposure. EPA's evaluation of the scientific and technical information pertaining to those factors support the Agency's finding that both PFOA and PFOS may present substantial danger to public health and the environment.[61]

EPA further disagrees with the commenter's claim that Congress failed to provide an ''intelligible principle'' to guide EPA's authority to designate hazardous substances pursuant to section 102(a) of CERCLA. The non-delegation doctrine provides that ''Congress generally cannot delegate its legislative power to another Branch.'' *Mistretta* v. *United States,* 488 U.S. 361, 371–72 (1989). This test requires that Congress ''lay down by legislative act some intelligible principle'' to which the recipient must conform. *Id.* (quoting *J.W. Hampton. Jr. & Co.* v. *United States,* 276 U.S. 394, 409 (1928)). Congress's delegation of authority to EPA in the context of CERCLA section 102(a) amply satisfies the constitutional standard set forth in controlling Supreme Court precedent because Congress has clearly provided an ''intelligible principle'' in the provision limiting EPA's discretion in designating substances under the statute. Specifically, section 102(a) provides that the Agency may designate those substances which, ''when released into the environment may present substantial danger to the public health or welfare or the environment.'' 42 U.S.C. 9602(a). Contrary to the commenter's claim, the authority conferred by Congress is neither open-ended nor otherwise so imprecise as to provide no principles for the Agency to apply in designating hazardous substances. Rather, CERCLA section 102(a) requires EPA to base its designation decisions on certain specified principles, including whether the substance in question poses a substantial danger to either public health, welfare, or the environment. These considerations intelligibly confine EPA's discretion to designate substances under the statute and the Agency's listing decision is not only based upon the criteria prescribed by Congress but is firmly within the bounds of the Court's nondelegation precedents. *See, e.g., American Power & Light Co.,* 329 U.S. at 104 (upholding the authority of the Securities and Exchange Commission to modify the structure of holding company systems so as to ensure that they are not ''unduly or unnecessarily complicate[d]'' and do not ''unfairly or inequitably distribute voting power among security holders.''); *Yakus* v. *United States,* 321 U. S. 414, 420, 423–26 (1944) (approving the wartime conferral of agency power to fix the prices of commodities at a level that ''will be generally fair and equitable and will effectuate the [in some respects conflicting] purposes of the] Act.'' (internal quotations omitted); *National Broadcasting Co.* v. *United States,* 319 U.S. 190, 225–26 (1943) (finding an ''intelligible principle'' in the Federal Communication Commission's power to regulate airwaves in the ''public interest.''). In sum, CERCLA section 102(a) provides an intelligible principle that guides the Agency in the exercise of its authority under section 102(a).

EPA also disagrees with the assertion that its interpretation of ''substantial danger'' is inconsistent with its past interpretation of this phrase or EPA's interpretation of similar phrases. In the context of CERCLA section 102(a), EPA has never authoritatively issued an interpretation of ''substantial danger'' prior to this designation. In 2021, EPA issued an Advanced Notice of Proposed Rulemaking (ANPRM) seeking comment and data to assist in the consideration of the development of future regulations pertaining to PFOA and PFOS. *See Addressing PFOA and PFOS in the Environment: Potential Future Regulation Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act* (Jan. 14, 2021). The ANPRM represented a preliminary effort by the Agency to obtain public input on certain issues to inform its thinking on any future proposed rulemaking regarding PFAS. EPA never received feedback on the ANPRM's discussion of ''substantial danger'' as the document was withdrawn shortly after it was issued and never published in the **Federal Register**. Since that time, the Agency has proposed an interpretation of section 102(a) and solicited and obtained comments through this rulemaking process that have informed the development of EPA's final interpretation of ''substantial danger.''[62]

As EPA explained in section IV.A., the Agency's interpretation of CERCLA section 102(a) is consistent with the proposed rule and in harmony with its application of similar language in site-specific provisions. Section 102(a) does not require certainty that the substance poses a substantial danger or require proof of actual harm when released into the environment.

EPA also disagrees with the commenters assertions that the Agency failed to substantiate EPA's conclusion that PFOA and PFOS may present a substantial danger to public health and the environment. The proposed rule established, and this final action confirms that the available scientific and technical information demonstrate that both PFOA and PFOS may present substantial danger to public health and the environment. That conclusion is supported by the scientific and technical evidence of adverse effects to human health and the environment from PFOA and PFOS exposure, their persistence and mobility in the environment, and the significant potential for human exposure due to their prevalence in the environment.

3. Authority To Create Exclusions From the Designation

Comment: Several commenters suggest that section 102(a) grants EPA authority to create exclusions from designation for certain uses of or materials containing PFOA and PFOS. According to one commenter the phrase ''as may be appropriate'' in section 102(a) grants EPA broad authority to include and exclude substances from a designation. Commenters also argue that CERCLA's definition of ''hazardous substance'' in section 101(14) supports this interpretation. CERCLA section 101(14) incorporates substances or chemicals regulated under select provisions of the CWA, RCRA, CAA, and TSCA, and at least some of those statutory provisions include exclusions;

[61] To support EPA's finding in this final rule that both PFOA and PFOS each individually pose a human health hazard, EPA gave weight to immunological, hepatic, developmental, cardiovascular, and cancer effects. These health outcomes had the strongest evidence of associations between PFOA and PFOS exposure and adverse health effects.

[62] Both interpretations of 102(a)—the preliminary interpretation offered in the 2021 ANPRM and today's final rule—allow for consideration of similar information to assess whether a release into the environment may present substantial danger. Hazard can encompass ''the degree of danger posed;'' fate and transport can encompass temporal considerations as in whether a substance remains in the environment ''more than fleeting in terms of time;'' and the consideration of additional information may include a consideration of the ''geographic scope'' of the substance in the environment. The standard that EPA is affirming today more accurately describes the type of scientific information needed to consider whether a substance, when released in the environment, may present substantial danger.

therefore, according to commenters, Congress would have expected EPA to have the authority to create exclusions pursuant to a CERCLA 102(a) designation.

Some commenters suggested that EPA can create exclusions that mirror other exclusions or defenses in CERCLA. For example, some commenters suggested that application of biosolids should be excepted from designation consistent with CERCLA's definition of release in section 101(22), which excludes ''the normal application of fertilizer.'' Another commenter suggested that EPA create an exclusion that reflects the liability defense in CERCLA section 107(d) for government ''actions taken in response to an emergency created by the release . . . of a hazardous substance generated by or from a facility owned by another person.''

Commenters requested that EPA create exclusions for: (1) paper mill residuals that are beneficially land applied as a fertilizer or soil conditioner; (2) land application of municipal biosolids; and (3) PFOA and PFOS contained in AFFF used in response to a fire or other emergency. Another commenter suggested that EPA should only designate PFOA and PFOS contained in specific mixtures or compounds generated by specific sources.

Some commenters suggest that an exclusion for certain materials or uses of PFOA and PFOS is necessary to avoid unintended consequences from the designation or over-broad impacts. For example, commenters expressed concern that designating PFOA and PFOS would result in liability for entities, such as farms applying biosolids or airports using AFFF for fire-fighting activities in emergency situations, that should not bear responsibility for generating or creating the contamination. Finally, one commenter claimed that CERCLA should not be used to designate PFOA and PFOS because designation will have the end-result of negatively impacting ''good actors.''

Response: EPA declines to create exclusions for certain uses of PFOA and/or PFOS in this rulemaking. EPA believes there is a strong argument that section 102(a) does not authorize exclusions for certain uses of a substance where EPA has concluded that the substance (here, PFOA and PFOS) may present substantial danger to the public health or welfare or environment, based on its review and analysis of a significant body of scientific and technical information. In this circumstance, EPA believes that section 102(a) is best read to preclude exclusions for certain uses of PFOA and PFOS—relative to other uses—without a factual or scientific basis showing that a particular use does not meet the standard articulated by Congress. *See* CERCLA section 102(a) (authorizing EPA to designate substances that, when released into the environment, ''may present substantial danger to the public health or welfare of the environment''). Even if EPA had authority to create exclusions for certain uses, it lacks the basis to do so here. Commenters did not provide information or data to support a conclusion that certain types of releases of PFOA and PFOS do not present a substantial danger, including an exclusion for AFFF as used for fire-fighting purposes and an exclusion for PFOA and PFOS contained in biosolids or soil amendments.[63] Given EPA's conclusion that PFOA and PFOS do present a substantial danger, and in the absence of evidence that certain releases of PFOA and PFOS do not present a substantial danger to public health or welfare or the environment, EPA lacks a scientific or factual basis for the exclusions requested.

Commenters also did not provide a persuasive justification for EPA to otherwise carve out specific uses of PFOA and/or PFOS from this designation irrespective of scientific or factual evidence relative to potential public health and environmental impacts. Commenters appear to be proposing that EPA create an exclusion to liability via CERCLA section 102(a); the Agency, however, does not believe that section 102 is the appropriate mechanism to establish liability exclusions, and EPA questions whether it has the authority to do so, through this provision. For example, the D.C. Circuit has held that, in enacting CERCLA, Congress reserved resolution of liability issues to the judiciary, not the Agency.[64] *See Kelley* v. *EPA,* 15 F.3d 1100, 1108 (D.C. Cir. 1994) (''Congress . . . has designated the courts and not EPA as the adjudicator of the scope of CERCLA liability.''). Congress explicitly identified CERCLA's liable parties in section 107. In fact, Congress has enumerated many exclusions to CERCLA's liability scheme over the years—and courts have regularly interpreted and applied those provisions. For example, CERCLA section 107(d) provides a mechanism to account for liability concerns arising out of an emergency response, which appears similar to one commenter's request for an exclusion for the use of AFFF in response to an emergency. *See, e.g.,* CERCLA section 107(d)(1)–(2) (providing a defense to costs and damages in the event of an incident creating danger to public health or in the event of an emergency).). EPA believes this Congressionally-established framework, discussed in further detail below, is more appropriate for the type of exclusions that commenters suggest.

EPA also concludes that the commenter's request for an exclusion for the application of biosolids containing PFOA or PFOS is not appropriate for resolution in this rulemaking under section 102(a). Section 102(a) provides for designation of a substance that, when ''released into the environment,'' may present substantial danger to the public health or welfare or environment. CERCLA section 102(a). As stated above, EPA considered a significant body of scientific and technical information in concluding that both PFOA and PFOS—irrespective of use—may present a substantial danger to public health or welfare or the environment.

Against this backdrop, EPA considered commenters' request for EPA to exclude from designation PFOA and PFOS when contained in biosolids consistent with the language in CERCLA section 101(22). EPA acknowledges that the CERCLA definition of ''release'' explicitly excludes the ''normal application of fertilizer.'' CERCLA section 101(22)(D). EPA believes this language is best read as requiring a site-specific analysis and that a categorical exclusion for all contaminated biosolid application using section 102(a) risks exceeding the limits of the exclusion as envisioned by Congress. *See, e.g., Sierra Club, Inc.* v. *Tyson Foods, Inc.,* 299 F. Supp. 2d 693, 714 (W.D. Ky. 2003) (defendant did not qualify for the normal application of fertilizer

[63] EPA received requests for exclusions from liability from specific sectors—namely, water utilities, municipal landfills, local governments, landowners or utilities that land apply biosolids or paper mill sludge, and landowners adjacent to offsite sources—for the use of certain materials (*i.e.,* biosolids), and for the disposal of particular types of waste, including landfill leachate, research waste, and medical waste. However, the commenters did not present data supporting their claims that certain releases, either from specific types of entities, uses, or kinds of waste, do not present a substantial danger to public health, welfare, or the environment.

[64] Although a court is the final arbiter of whether a party is liable under CERCLA section 107, EPA intends to develop a policy that explains the Agency's priorities for CERCLA enforcement in the context of PFOA and PFOS releases. Enforcement discretion policies are not exclusions from liability but instead describe circumstances in which the Agency may exercise its discretion to not pursue enforcement actions against certain parties that may fall within a category of liable parties under CERCLA section 107. EPA's enforcement discretion is guided by the unique circumstances of each case.

exemption because it was not applying ammonia to farm fields as fertilizer when it vented the ammonia into the atmosphere); *City of Waco* v. *Schouten,* 385 F. Supp. 2d 595, 602 (W.D. Tex. 2005) (defendants' agricultural practices (namely, the improper storage and maintenance of manure waste storage areas) did not fall within the ''normal application of fertilizer'' exclusion)). EPA also does not believe an exclusion under section 102(a) is necessary, because it would be duplicative of the exclusion in section 101(22)(D). And because liability under CERCLA section 107 is tied to a ''release'' or threat of a ''release,'' any entity facing potential liability for the application of biosolids contaminated with PFOA or PFOS will have the opportunity to make site-specific arguments as to whether its actions fall within the ''normal application of fertilizer'' exclusion to the definition of ''release.'' [65]

EPA also rejects the commenters' assertion that creating an exclusion for this designation is necessary to address concerns regarding over-broad or unintended liability, such as for farmers or water utilities. Designation does not alter CERCLA's liability framework, which EPA expects to continue to operate as it has for decades to equitably resolve who should pay, or automatically confer liability. First, potential plaintiffs must establish a legal basis for CERCLA liability; to recover costs from the parties responsible for contamination requires a plaintiff to show that a ''release'' or ''threatened release'' of a ''hazardous substance'' from a ''facility'' has caused it to incur cleanup costs. CERCLA section 107(a). The defendant must also fall within at least one of four classes of covered persons: (1) the owner or operator of the facility, (2) the owner or operator of the facility ''at the time of disposal'' of hazardous substances, (3) persons who ''arranged for disposal'' or treatment of hazardous substances, and (4) certain transporters of hazardous substances. *Id.*

Although liability under CERCLA section 107(a) is strict, subject only to a few limited defenses specified in section 107(b), it is not unlimited, and courts may decide to apportion costs among defendants where the harm is divisible and there is a reasonable basis for doing so. *Burlington N.,* 556 U.S. at 613–15. Further, if a defendant is found jointly and severally liable for response costs under CERCLA section 107(a), the defendant may also seek contribution from other potentially responsible parties pursuant to CERCLA section 113(f).

In addition, CERCLA provides defenses to and exemptions from Superfund liability for certain parties that are otherwise liable. For example, under CERCLA section 107(b), liability is limited in situations in which the release or threat of release of a hazardous substance was caused by an act of God, an act of war, or an act or omission of a third party (or some combination thereof). CERCLA section 107(b)(1)–(4). CERCLA also contains several statutory limitations on liability, which are more fully described in section VI.B. These include liability exemptions for contiguous property owners, innocent landowners under certain circumstances, de minimis or de micromis parties, and ''federally permitted'' releases, among others. And a party may not be subject to CERCLA at all if the release is considered a ''normal application of fertilizer.'' EPA also notes that—as detailed in section VI.B.—it has well-established enforcement policies that help the Agency prioritize sites that pose the most risk.

Finally, the commenters' concerns regarding liability do not account for the intervening steps between designation and site-specific cleanup or enforcement decisions. A designation alone does not require EPA or others to take response actions, does not require any response action by a private party, and does not determine liability. Response actions are contingent, discretionary, and site-specific decisions that are made after a hazardous substance release or threatened release. Site-specific decisions are also the more appropriate opportunity to evaluate unacceptable risk posed by specific releases, rather than a blanket exclusion for certain uses or PFAS-containing materials that may not account for site-specific risk.

The first steps in the CERCLA process are to identify a release, investigate the scope and extent of such a release, and evaluate its potential risk to human health and the environment. CERCLA is a largely discretionary statute that gives EPA leeway to determine whether, after that investigatory stage, it is appropriate to move forward with a cleanup. CERCLA speaks to this evaluation of releases and risk. For example, Congress provided that EPA shall identify ''criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial action and, to the extent practical taking into account the potential urgency of such action, for the purpose of taking removal action.'' CERCLA section 105(a)(8)(A). CERCLA goes on to provide that ''[c]riteria and priorities . . . shall be based upon relative risk or danger to public health or welfare or the environment . . . taking into account to the extent possible the population at risk, the hazard potential of the hazardous substances at such facilities, the potential for contamination of drinking water supplies, the potential for direct human contact,'' among other considerations embodied in the NCP. The NCP provides guidance on when it may be appropriate to cleanup releases either through a removal or remedial action. For example, for removal actions, the NCP provides that the lead agency may take action when the agency has determined ''that there is a threat to public health or welfare'' based on a set of factors such as actual or potential exposure to drinking water supplies, the potential for hazardous substances to migrate, and the availability of other appropriate Federal or State response mechanisms to address the release. 40 CFR 300.415(b).

Even if EPA determines that it is appropriate to move forward with a cleanup and a site is listed on the NPL, a listing does not require any immediate action. Rather, an NPL listing is the initial step towards a potential long-term remedy for a site. Listing also allows EPA to prioritize which sites warrant further investigation to better understand potential risks to human health and the environment. This process identifies less than 10% of CERCLA sites as NPL sites.

Only after those very careful and deliberative steps to investigate and prioritize sites does EPA begin the process of identifying potential cleanup actions. Because of this significant narrowing of sites that will receive EPA attention, it follows that not every instance of contamination by a hazardous substance—including a PFOA and/or PFOS release—will lead to enforcement and liability. And, as previously noted, EPA has a long history of focusing its enforcement on significant polluters, potentially further narrowing the extent of liability. While there may be independent third-party cleanups, those too are not immediately triggered by designation and just like with EPA-focused cleanups, parties

[65] Not all releases warrant response under CERCLA, and not all release lead to litigation and liability for all PRPs. Whether a party may be exposed to any liability in the first instance is ultimately a function of whether a response action is taken to address the release. As an initial matter, EPA has discretion to determine whether to respond to a release and only responds to those releases that pose unacceptable risk to human health and the environment. Even then, EPA may assess relative risk among releases to determine which releases should be prioritized for investigation and, potentially, clean up. Further, whether a PRP may be pursued for costs, found liable by a court, and required to pay some portion of costs remain uncertain for any given release.

would typically have the benefit of CERCLA's liability protections, equitable divisions of responsibility by the courts, and so forth.

EPA also notes that concerns about the cost of liability, the cost of cleanup, and the costs that certain facilities will bear managing PFOA and PFOS in waste to mitigate CERCLA liability risk are costs that Congress had front of mind in enacting CERCLA and chose to proceed anyway. The statutory language of CERCLA clearly provides interconnected response, enforcement and liability authorities that impose costs on PRPs enumerated in the statute. First, CERCLA section 104(a) authorizes EPA to respond to a release (or substantial threat of a release) of a hazardous substance into the environment, or of a pollutant or contaminant that may present an ''imminent and substantial danger to the public health or welfare.'' CERCLA section 104(a). In addition, CERCLA section 106 gives EPA the authority to compel action by liable parties in response to a release or threatened release of a hazardous substance that may pose an ''imminent and substantial endangerment'' to public health or welfare or the environment. CERCLA section 106(a). Finally, under CERCLA section 107, when the United States, states, or Tribes perform cleanup work and incur costs, section 107(a) authorizes them to recover those costs from potentially responsible parties. *See* CERCLA section 107(a).

Legislative history also shows that one of Congress' aims was to incentivize better waste management practices: ''In correcting the historic neglect of hazardous substances disposal, it is essential that this incentive for greater care focus on the initial generators of hazardous wastes since they are in the best position to control the risks. Generators create the hazardous wastes, they have more knowledge about the risks inherent in their wastes and how to avoid them, and they determine whether and how to dispose of these wastes.'' S. Rep. No. 96–848, at 14 (1980). Congress' expectation was that better waste management practices could ultimately result in cost savings by reducing the need for expensive remedies to clean up hazardous waste in the environment: ''Expenditures to prevent a threatened release, discharge, or disposal may be necessary if damages are to be avoided while also providing considerable savings when compared to the costs of removal after a release, discharge or disposal has occurred.'' *Id.* Ultimately, Congress' calculation was that the benefit to human health and the environment to prevent exposure to hazardous chemicals is worth the costs borne by industry to improve waste management practices, prevent releases, and minimize the costs of retroactive efforts to clean up hazardous waste.

EPA concludes that it would be inappropriate to carve out certain uses or materials containing PFOA or PFOS from the designation because any PFOA or PFOS release ''may present substantial danger,'' and subsequent steps in the CERCLA process are more appropriate for determining whether any specific release poses risk sufficient for further investigation and, potentially, cleanup.

4. Designating PFOA and PFOS as ''Hazardous Substances'' Under CERCLA Section 102(a) Does Not Present a ''Major Question''

Comment: Commenters contend that EPA's use of section 102(a) of CERCLA to designate PFOA and PFOS as hazardous substances—as well as the Agency's interpretation of the scope of the authority granted by this provision—run afoul of the ''major questions doctrine'' articulated by the Supreme Court in *West Virginia* v. *EPA,* 142 S.Ct. 2587 (2022). To support this assertion, the commenters argue that the designation will have a substantial ''economic, social, and legal impact'' and point to the fact that EPA is utilizing section 102(a) of CERCLA for the first time to contend that today's action represents a novel and transformative expansion of the Agency's regulatory authority.

Response: EPA disagrees that this rulemaking raises a major question as defined in *West Virginia* v. *EPA,* 142 S. Ct. 2587 (2022).

The designation of PFOA and PFOS pursuant to section 102(a) of CERCLA does not represent a radical change to CERCLA's statutory scheme. Rather, the designation is well within the statutory framework that Congress provided. CERCLA by its express terms authorizes EPA to designate hazardous substances and the designation is consonant with the Agency's longstanding practice of adding other chemicals to CERCLA's hazardous substances list through CERCLA's ''automatic'' designation process in section 101(14). That provision cross-references listing authorities in the CAA, CWA, RCRA, and TSCA. CERCLA's automatic designation process has resulted in the addition of more than 800 hazardous substances to the statute's list of hazardous substances through separate actions. And just like it did when making designations under those other statutes, here EPA examined scientific and technical factors, including hazard and fate and transport, when evaluating whether PFOA and PFOS met the statutory standard and may present substantial danger to the public health or welfare or the environment. *See supra-Section IV.* Further, as discussed in Section VI.B, PFOA and PFOS are not different in kind from the other substances added to CERCLA's hazardous substance list.

While EPA's action today utilizes a different mechanism for designation than the procedure outlined in CERCLA section 101(14)—which defines the term ''hazardous substance'' by reference to provisions in other environmental statutes and to substances designated under CERCLA section 102—Congress specifically provided EPA with multiple pathways to address the varied threats posed by hazardous substances in various media. Although the commenters argue that EPA's approach to PFOA and PFOS represents an unprecedented expansion of EPA's authority, EPA has added similarly ubiquitous substances to CERCLA's hazardous substance list for decades. For example, polychlorinated biphenyls (PCBs) became hazardous substances when EPA initially promulgated its list of hazardous substances on April 4, 1985, *Notification Requirements; Reportable Quantity Adjustments,* 50 FR 13456, 13475 (1985), and are generally considered ''ubiquitous contaminants in the environment.'' Rouzbeh Tehrani and Benoit Van Aken, *Hydroxylated Polychlorinated Biphenyls in the Environment: Sources, Fate, and Toxicities,* 21 Environmental Science and Pollution Research, 6334–6345 (2014); see also U.S. Dept. of Health and Human Services, *Toxicological Profile for Polychlorinated Biphenyls (PCBs),* at 291 (November 2000) (''PCBs are ubiquitous and continuously circulating in the global environment. . . .''); U.S. Environmental Protection Agency, *Remediation of PCBs at Superfund Sites,* at 7 (2001) (noting that as of publication ''[o]f the 1,229 Superfund sites currently on the NPL, PCBs have been detected at 357 sites.''). PCBs, however, are far from the only highly prevalent contaminant of concern that EPA has routinely grappled with at Superfund sites for decades. In fact, at the 1,548 Superfund sites with a selected remedy, arsenic has been identified at 919 facilities, lead at 897, benzene at 885, and trichloroethene at 816. *See* U.S. Environmental Protection Agency, *Contaminant of Concern Data for Decision Documents by Media, fYs 1982–2021 (Final NPL, Deleted NPL, and Superfund Alternative Approach Sites)* (2024), available at *https://*

www.epa.gov/superfund/superfund-data-and-reports. Ultimately, EPA's decision to designate PFOA and PFOS under section 102(a) is not an expansion of the Agency's authority that would cause a ''radical'' or ''fundamental'' shift in CERCLA's statutory scheme.

For these reasons, EPA's regulatory action to designate PFOA and PFOS as CERCLA hazardous substances does not present a major question.

B. Operation of CERCLA

1. Comments Suggesting That Other Authorities Are Better Suited To Address PFAS Contamination

Comment: Several commenters argued that CERCLA is not the appropriate tool to address PFOA and PFOS in the environment. Commenters also argued that EPA already possesses the authority to protect public health, welfare, and the environment from any potential risks posed by PFOA and PFOS without designating these substances as hazardous under section 102(a). Instead, these commenters contend that EPA should utilize existing tools under SDWA, RCRA, CWA, and other laws to address PFAS-contaminated sites.

Multiple commenters also argued that EPA should not use CERCLA to designate PFOA and PFOS as hazardous substances because the Agency has not yet regulated PFOA and PFOS under other statutes (*e.g.,* CWA, RCRA, SDWA), and accordingly—because CERCLA site cleanup standards and responsibilities are informed by other statutes' regulatory frameworks—potentially responsible parties lack the necessary structure to conduct CERCLA cleanups of PFOA and PFOS.

In arguing that CERCLA is not the appropriate tool to address the problem posed by PFOA and PFOS, one commenter also specifically claimed that the statute was designed to address only inactive hazardous waste sites and facilities impacted by groundwater plumes contaminated by specific hazardous substances, rather than ''problematic class[es] of chemicals with widespread contamination across the country.'' Another commenter stated that it appears ARARs do not yet exist and urges EPA to delay this rulemaking until such standards are developed.

Response: EPA disagrees with the commenters' position that CERCLA is not the appropriate tool to address the challenges posed by PFOA and PFOS contamination. Congress enacted CERCLA to provide EPA with the ability to timely clean up contaminated sites that pose risk to human health and the environment. CERCLA is the right tool for addressing wide-spread, existing PFOA and PFOS contamination, which is a nationwide concern. CERCLA includes authorities to investigate and scope releases to better understand the extent of contamination. CERCLA includes response authority to implement short-term and long-term actions to address contamination and risks to public health and the environment. CERCLA removal authority is available to address emergency situations, such as when immediate action is necessary to mitigate consumption of contaminated drinking water. It also includes authority to take remedial actions that are designed to provide a more permanent remedy to mitigate or reduce unacceptable risk from highly contaminated sites. CERCLA also provides mechanisms to ensure that those responsible for the contamination pay to clean it up rather than using Fund resources. By designating PFOA and PFOS as CERCLA hazardous substances, EPA can utilize the full suite of CERCLA tools to address contamination.

CERCLA is the best tool to address the legacy of sites contaminated with these substances and to address additional releases of these chemicals in the future. As EPA noted in its Strategic Roadmap, ''[t]he risks posed by PFAS demand that the Agency attack the problem on multiple fronts at the same time. EPA must leverage the full range of statutory authorities to confront the human health and ecological risks of PFAS.'' The Roadmap looked at a variety of authorities to address PFAS, including TSCA, SDWA, CWA, RCRA, and CAA, and identified CERCLA as a tool to accomplish one of its three central directives: Research, Restrict, Remediate. CERCLA is applicable to address all environmental media: air, surface water, groundwater, and soils. And CERCLA can apply to any type of industrial, commercial, or noncommercial facility, regardless of whether there are specific regulations that affect that type of facility or how that facility might affect the environment.

The Agency also disputes the commenters' assertion that designation under CERCLA is premature in the absence of pre-existing regulatory standards for PFOA and PFOS. The plain language of CERCLA section 102(a) includes no such explicit limitation. The statute requires only that EPA determine that a substance ''may present substantial danger to public health or welfare or the environment'' to designate. Considering the significant, and growing, body of evidence that PFOA and PFOS, when released in the environment, may present substantial danger, designation is warranted. Such a limitation also runs counter to the ''automatic'' designation that occurs through CERCLA section 101(14) when a substance is identified as toxic or hazardous under another statutory authority. When a substance is designated pursuant to the specified CWA, CAA, RCRA, and TSCA authorities, there aren't necessarily pre-existing regulatory standards for that substance. For example, a substance could be listed under RCRA as a regulated hazardous waste, but not be subject to regulatory standards under the Clean Water Act or the Safe Drinking Water Act. The absence of such a regulatory framework is not a bar to listing under RCRA and nor should such a limitation be read into CERCLA section 102(a).

EPA also disagrees that, at present, there is no regulatory framework in place that allows EPA to respond effectively to PFOA and PFOS releases. While it is true that PFOA and PFOS regulations, environmental standards, and remediation technologies are evolving, CERCLA and the NCP provide a process to identify cleanup standards on a site-by-site basis that ensure that a remedy is protective of human health and the environment. CERCLA section 121(a) provides that a remedial action must be ''protective of human health and the environment.'' All remedies selected must satisfy that requirement. Cleanup standards often help define remedy protectiveness. CERCLA cleanup standards are generally those standards that are determined to be ''applicable or relevant and appropriate requirements'' (ARARs).[66] ARARs are Federal, or more stringent State, standards, requirements, criteria, or limitations. CERCLA section 121(d)(2)(A). ARARs apply to hazardous substances or pollutants and contaminants that remain on-site at the completion of a remedy. A final remedy must attain ARARs by the completion of the remedy, unless compliance with the ARAR is waived. CERCLA section 121(d)(2)(A), (d)(4). ARARs frequently are determinant in establishing preliminary remediation goals, which become site cleanup levels.

The current regulatory landscape for PFOA and PFOS is sufficient to inform future remedies, and regulatory actions to address PFOA and PFOS are

[66] The NCP provides that *Fund-financed* removal actions (*or removals under CERCLA section 106*) must comply with ARARs to the extent practicable considering the exigencies of the situation. 40 CFR 300.415. For the sake of discussion, EPA's response focuses on compliance with ARARs in the remedial context.

increasing. Currently, there are certain Federal standards that may be considered as ARARs. For example, a potential ARAR for drinking water cleanups may be the final PFOA and PFOS MCLs. For PFOA and PFOS, the MCLs are 4.0 parts per trillion (PPT) each. A number of States have also promulgated cleanup numbers for PFOA and PFOS, which may be evaluated as potential ARARs at sites. For example, Pennsylvania [67] promulgated an MCL of 14 ppt for PFOA and 18 ppt for PFOS. In addition, New Jersey [68] has adopted an MCL of 14 ppt for PFOA and 13 ppt for PFOS (*NJ DEQ, 2023*).

There are also non-chemical specific ARARs that may be relevant to a potential remedy. Those include ''location-specific'' and ''action-specific'' ARARs. Location-specific ARARs are restrictions placed on the concentration of hazardous substances or the conduct of activities solely because they are in specific locations. Some examples of specific locations include floodplains, wetlands, historic places, and sensitive ecosystem habitats. An example of a location-specific requirement is the substantive CWA section 404 prohibitions regarding unrestricted discharge of dredged or fill material into wetlands. Action-specific ARARs are usually technology- or activity-based requirements or limitations on actions taken with respect to hazardous wastes. These requirements are triggered by particular remedial activities that are selected to accomplish a remedy. Examples of action-specific ARARs include activities such as ground-water diversion, dredging, and landfill closure with waste in place.

EPA has also developed an *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) and Materials Containing PFAS-Substances—Version 2 (2024),* which outlines the current science on techniques and treatments that may be used to destroy or dispose of PFAS and PFAS-containing materials from non-consumer products, along with screening methods to assess vulnerable populations near destruction and disposal sites. In sum, the evolving regulatory landscape with respect to PFOA and PFOS cleanup standards is not a barrier to designation nor is it a barrier to evaluating, identifying, and selecting protective remedies. The Agency is also striving to ensure regulatory actions do not overlap with one another and duplicate efforts. EPA also disagrees with the commenter's claim that CERCLA is designed solely to address inactive hazardous waste sites and facilities subject to groundwater contamination from specific contaminants of concern. The commenter's view of CERCLA runs counter to the plain language of the statute. CERCLA's language does not include any limitation on response authority to only ''inactive'' waste sites. Rather, CERCLA makes clear that authority extends to inactive and active ''facilities.'' CERCLA defines a facility as ''any building, structure, equipment, pipe or pipeline (including any pipe into a sewer or publicly owned treatment works) . . . .'' CERCLA section 101(9)(A). Moreover, CERCLA provides authority to respond to past, current, and future releases. Response authority extends to releases and the threat of release of ''any hazardous substance'' and ''any pollutant or contaminant which may present an imminent and substantial danger to public health or welfare.'' CERCLA section 104(a). CERCLA's definition of the term ''release'' also makes clear that it encompasses past and current releases. *See* CERCLA section 101(22) (defining release to include ''any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment (including the abandonment or discarding of barrels, containers, and other closed receptacles . . .)''). This language is broad enough to encompass inactive and active sites.

Although one impetus for CERCLA was a growing concern about the public health threats posed by improperly disposed toxic waste, Congress's interest in addressing issues associated with environmental contamination was more holistic. Addressing the challenge of widespread community exposure to hazardous chemicals such as PFOA and PFOS—when released into the environment—is the exact kind of environmental threat that Congress sought to ameliorate in enacting CERCLA. Moved to action by the Love Canal incident, Congress crafted CERCLA to address contaminated sites across the nation, which it considered one of ''the most serious health and environmental challenge[s] of the decade.'' S. Rep. No. 96–848, at 2 (1980). Congress acknowledged at that time that ''more than 43,000 chemical substances are in commercial production and thousands of new ones are introduced each year . . . As a result, the potential impact of toxic chemicals on the general public and environment through unsound hazardous disposal sites and other releases of chemicals is tremendous.'' *Id.* Indeed, expert testimony solicited by Congress stated that the breadth and scope of the impact of exposure to hazardous chemicals nearly ''extend[ed] to the entire population of the United States.'' *Id.* Designating PFOA and PFOS is wholly consistent with Congress' vision for CERCLA as an important Federal tool in removing widespread toxic chemicals from the environment that have the potential to pose substantial danger to human health, welfare, and the environment.

2. Addressing PFOA/PFOS as ''Pollutants or Contaminants''

Comment: Several commenters contend that EPA should use its existing authority to address PFOA and PFOS as pollutants or contaminants rather than designate these substances as hazardous under section 102(a) of CERCLA. One commenter also argued that PFOA and PFOS must be specifically designated as pollutants or contaminants before they are designated as hazardous substances. Finally, a commenter claimed that EPA has failed to demonstrate that PFOA and PFOS qualify as pollutants or contaminants under section 101(33) of CERCLA because the Agency has not indicated why these substances ''cause or are reasonably expected to cause death, disease, physiological malfunctions, or any other conditions in the definition of 'pollutant or contaminant' in CERCLA [s]ection 101(33).''

Response: EPA disagrees with the commenters' position that the Agency should treat PFOA and PFOS contamination by relying solely on its authority to address these substances as CERCLA pollutants or contaminants. *See* CERCLA section 101(33) (defining ''pollutants or contaminants''). As EPA has explained, EPA's authority to address ''pollutants and contaminants'' is limited. Designation of hazardous substances provides the Agency with a suite of tools necessary to identify, characterize, and clean up the most contaminated sites without delay, either through PRP- or Fund-lead actions.

EPA also disagrees with the commenters that the Agency must designate PFOA and PFOS as a pollutant or contaminant under section 101(33) of CERCLA before utilizing its authority under section 102(a) to designate PFOA and PFOS as hazardous substances. Section 102(a) requires only a determination that the substance ''may present . . . substantial danger to the

[67] *https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol53/53-2/46.html.*

[68] *https://dep.nj.gov/pfas/standards/.*

public health or welfare or the environment'' when released into the environment. Moreover, a substance's status as a pollutant or contaminant is determined on a site-specific basis. And, in fact, EPA has already identified and treated PFOA and PFOS as pollutants and contaminants at multiple Superfund sites, including the Saint-Gobain Performance Plastics facility in Hoosick Falls, New York, and the Blades Groundwater site in Blades, Delaware.

The Agency further disagrees that PFOA and PFOS do not qualify as pollutants or contaminants because EPA has not shown that these substances either ''cause or are reasonably expected to cause'' human health effects. In fact, the commenter misstates the qualifying criteria for a pollutant or contaminant.

The statute requires only that pollutants or contaminants may ''reasonably be anticipated'' to impact human health. In keeping with this broad standard, multiple courts have consistently reaffirmed the principle that section 101(33) ''. . . refers to, basically, any substance which may reasonably be anticipated to cause harm'' to human health when released into the environment. *Eagle-Picher Industries, Inc.* v. *EPA,* 759 F.2d 922, 931 (D.C. Cir. 1985); *see also APWU, et al.* v. *Potter,* 343 F.3d 619 (2d Cir. 2003) (anthrax); *Lozar* v. *Birds Eye, Inc.,* 678 F.Supp.2d 589 (W.D. Mich. 2009) (iron, manganese, arsenic, chloride, and sodium); *Jastram, et al.* v. *Phillips Petroleum Co., et al.,* 844 F. Supp. 1139 (E.D. La. 1994) (produced water). PFOA and PFOS readily meet the definition of pollutants or contaminants, particularly given the weight of scientific evidence—as discussed in section V—indicating that exposure to PFOA and PFOS is associated with a host of negative health effects. Accordingly, EPA has determined PFOA and PFOS to be pollutants or contaminants on a site-specific basis, further demonstrating that PFOA and PFOS satisfy the definition in section 101(33) of CERCLA.

3. Relationship Between SDWA and CERCLA

Comment: Commenters stated that the 2022 interim Health Advisory Levels (HALs) of 0.004 ppt for PFOA and 0.02 ppt for PFOS are below the value that laboratory methods can accurately quantify, creating uncertainties with the proposed designation. Another commenter stated that EPA should provide additional clarity as to how the Agency's SDWA process will impact the setting of cleanup goals. A few commenters stated that while ''[the health advisories] are not regulations and should not be construed as legally enforceable Federal standards,'' they do shape public perception and almost certainly influence people's (including organizations') behavior. Similarly, there were comments concerning whether EPA was coordinating internally on how the SDWA rule to regulate PFOA and PFOS may impact the CERCLA program.

Response: As stated in the proposed rule, EPA did not rely on the interim PFOA or PFOS HALs or draft toxicity values as support for the proposed designation decision. EPA's 2022 interim PFOA and PFOS HALs are beyond the scope of today's action. EPA HALs are non-enforceable advisory levels that provide information to drinking water systems and officials responsible for protecting public health when emergency spills or other contamination situations occur. Based on the record before the Agency, with today's action EPA is designating PFOA and PFOS as hazardous substances.

EPA's actions establishing NPDWR for PFOA, PFOS, and other PFAS, pursuant to SDWA are beyond the scope of this action. Nonetheless, EPA has closely coordinated these actions to ensure consistency. For information about EPA's PFAS NPDWR, please see *https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas,* or visit regulations.gov under docket id EPA–HQ–OW–2022–0114. The 2024 NPDWR pursuant to the Safe Drinking Water Act, EPA established a maximum contaminant level (MCL) of 4.0 ppt for both PFOA and PFOS and a maximum contaminant level goal (MCLG) of 0 ppt for both PFOA and PFOS. Consistent with CERCLA, EPA may evaluate MCLs and non-zero MCLGs as Applicable or Relevant and Appropriate Requirements (ARARs) cleanup levels on a site-specific basis. 42 U.S.C. 9621(d).

For any Superfund site, EPA evaluates the risk and determines the appropriate cleanup level for the site, including for PFOA and PFOS. The risk is evaluated according to guidance, mainly Risk Assessment Guidance for Superfund using final toxicity information, and exposure information, and according to guidance, mainly Risk Assessment Guidance for Superfund (*https://www.epa.gov/risk/risk-assessment-guidance-superfund-rags-part*). PFOA and PFOS toxicity information used in CERCLA for any risk calculations are based on toxicity values that support EPA's 2024 NPDWR. Once a basis for action has been determined, the risk at a site has been assessed, and the need for a response action is determined, then the MCLs for PFOA and PFOS will potentially be considered as ARARs on a site-specific basis and documented in a decision document. While MCLs, MCLGs, and HAs are potentially appropriate to consider at CERCLA sites, other standards may be considered for other media evaluated at a site, such as soil, air, and biota such as fish.

C. Toxicity, Human Health Effects/ Mobility, Persistence, Prevalence/ Release Into the Environment

1. Data Supporting Designation

Comment: Several commenters argued that EPA has not presented sufficient information regarding the environmental and human health effects of PFOA and PFOS salts and structural isomers to support the designation of such substances as hazardous under CERCLA section 102(a). Multiple commenters contend that additional scientific study is needed prior to designation of PFOA and PFOS as CERCLA hazardous substances to enhance an understanding of the risks posed by these substances to human health and the environment.

Response: EPA believes that the available data clearly supports the conclusion that PFOA and PFOS, as well as their salts and structural isomers, present a hazard to human health and the environment. For further discussion of this issue, see Section V of this document, which describes the scientific and technical information supporting the Agency's conclusion that both PFOA and PFOS may present substantial danger to public health or welfare or the environment when released into the environment.

EPA disagrees with the commenters' position regarding the need for additional data prior to designation. As discussed in detail in Sections I and V, EPA has determined that a robust body of epidemiological and toxicological studies support the Agency's conclusion that exposure to PFOA or PFOS are associated with serious and wide-ranging adverse health effects.

Comment: Several commenters asserted that EPA could not utilize draft toxicity assessments developed as part of the PFAS NPDWR rulemaking process (draft MCLG documents) to substantiate the designation of PFOA and PFOS as CERCLA hazardous substances (See Response to Comment Document, Section 3B). Specifically, these commenters argued that the draft MCLG documents are flawed because the Science Advisory Board identified certain methodological issues with the initial approaches the Agency used to derive PFOA and PFOS MCLGs. Relatedly, one commenter also

challenged EPA's purported reliance on interim Health Advisories (HAs) issued by the Agency in 2021, arguing that the underlying toxicity assessments supporting the interim HAs are flawed and have not been finalized by the Agency.

Finally, several commenters critiqued the reliability of several studies cited by EPA as part of this rulemaking, including certain epidemiological studies conducted in the Faroe Islands that EPA used to develop non-cancer toxicity values (reference doses) in the draft MCLG documents.

Response: As an initial matter, EPA disagrees with the commenters' characterization of the Agency's reliance on the draft MCLG documents and Interim HAs. EPA considered the peer-reviewed scientific studies underlying the toxicity assessments supporting the draft MCLG documents and the interim HAs as part of the Agency's comprehensive evaluation of available scientific information regarding the human health and environmental effects of exposure to PFOA and PFOS. To that point, as delineated in Section V, EPA considered hundreds of peer-reviewed publications in determining that exposure to PFOA or PFOS, when released into the environment, may present a substantial danger to the public health or welfare or the environment, including the 2016 EPA Health Effects Support Documents for PFOA and PFOS, the 2021 ATSDR Toxicological Profile for PFAS, and numerous peer-reviewed epidemiological and toxicological studies (*ATSDR, 2021; U.S. EPA, 2016c, 2016d*).

Secondarily, while beyond the scope of today's action, because these documents were finalized in 2024 as part of a separate, unrelated rulemaking after undergoing a robust peer-review and public comment process EPA rejects the commenter's assertion that the draft MCLG documents are inherently flawed because of issues identified by the Science Advisory Board (SAB). The Agency's final toxicity assessments reflect recommendations from both the Science Advisory Board (SAB) and the public comment process and address the SAB PFAS Review Panel's recommendations to improve the transparency of EPA's systematic review process. Additionally, EPA updated and expanded the protocols and methods based on SAB recommendations to improve the transparency of the process EPA used to derive the MCLGs for PFOA and PFOS and to improve consistency with the *ORD Staff Handbook for Developing IRIS Assessments* (*U.S. EPA, 2022*). EPA followed this transparent systematic review process to evaluate the best available peer-reviewed science to conduct the PFOA and PFOS toxicity assessments (*U.S. EPA, 2024b, 2024c, 2024d*). For information on EPA's PFAS NPDWR rule, visit EPA's website at *https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas,* or visit *www.regulations.gov,* under Docket No. EPA–HQ–OW–2022–0114.

EPA also disagrees with the commenter's claim that the Faroe Islands epidemiological studies fail to provide evidence of the impacts of PFOA and PFOS on vaccine response in children. The Faroe Islands epidemiological studies were peer-reviewed by the various scientific journals in which they were published. Additional studies, including one from a Greenland epidemiological study, provide support for associations between decreased vaccine response in children and exposure to PFOA and PFOS (*Timmermann et al., 2022; Zhang et al., 2023*). Additionally, the Science Advisory Board—in their ''Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS''—agreed with the selection of the critical study, *Grandjean et al.* (*2012*), that identified an association between exposure to PFOA and PFOS and suppression of a vaccine response in children exposed during development, as appropriate for the derivation of chronic RfDs [69] for PFOA and PFOS.

D. Effects of Designation

1. Reporting and Notification Requirements

a. Reportable Quantity (RQ) for PFOA and PFOS Should be Set Either Higher or Lower Than 1 Pound

Comment: Some commenters stated that EPA should lower the RQ to 0.1 pound while others expressed that the RQ should be higher than one pound. A few commenters stated that EPA should consider a RQ for cumulative releases, *i.e.,* X pounds per year. One commenter argued that EPA's proposed RQ would allow companies to release massive amounts of PFAS-containing waste before triggering any CERCLA requirements.

Response: Pursuant to CERCLA section 102, in this final rule the Agency is assigning a default RQ of one pound to PFOA and PFOS and their salts and structural isomers. The Agency believes that the statutory default RQ is appropriate in this instance because it will facilitate reliable reporting of substantial releases of PFOA or PFOS and allow government officials to evaluate and undertake timely response actions, if appropriate to do so. To ensure that it focuses its resources on those releases that threaten public health or welfare or the environment, EPA, may, however, consider adjusting the default RQ in the future if it receives data regarding the scope of releases of PFOA or PFOS indicating that one pound is not a suitable unit on which to base a notification requirement.

b. The Reportable Quantity (RQ) of One Pound Is Appropriate

Comment: A few commenters expressed support for a RQ of one pound.

Response: For the reasons provided in response to the prior comment (*see 1.a.),* the Agency agrees that it is appropriate to maintain a reportable quantity of one pound over a 24-hour period.

c. The Reportable Quantities (RQs) Should Be Chemical-Specific, Not Applied to PFAS as a Class

Comment: One commenter argued that EPA's decision to establish a RQ of one pound is indicative of the fact that the Agency lacks sufficient risk information for PFOA and PFOS to set a chemical-specific RQ, thereby demonstrating that the rulemaking is premature. Another commenter stated that there is precedent for tailoring reportable quantities to the unique characteristics of a given class of hazardous substances; specifically, the commenter pointed to the RQ approach the Agency has adopted with respect to radionuclides as support for their proposed methodology.

Response: This action is focused on designating PFOA and PFOS, and their salts and isomers as CERCLA hazardous substances. CERCLA 102(b) establishes a default of one pound and EPA has assigned 1 pound for each of these substances, including their salts and isomers. The Agency may revise the RQ in the future through notice and comment rulemaking after reviewing release information received pursuant to CERCLA 103.

On May 25, 1983, the Agency proposed to adjust the statutory default

[69] Reference Dose (RfD)—An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. Generally used in EPA's noncancer health assessments. Durations include acute, short-term, subchronic, and chronic. (*https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system*).

RQ of one pound for radionuclides. *See Notification Requirements; Reportable Quantity Adjustments,* 48 FR 23514, 23552 (May 25, 1983). EPA subsequently published a final rule and assigned a specific RQ for each radionuclide based on a methodology specific to those substances. *See Reportable Quantity Adjustment Radionuclides,* 54 FR 22405, 22524 (May 24, 1989). Similarly, with respect to PFOS and PFOA, the Agency may exercise its discretion at any time after designation to adjust the RQ if it determines that the circumstances warrant doing so.

d. Effluent That Violates NPDES Permit Limits

Comment: One commenter stated that effluent that violates any present or future NPDES permit covering PFAS needs to be reported under CERCLA to help attain the primary goal of this rulemaking: determining where releases of PFOA and PFOS occur and in what amount.

Response: Whether a particular release of PFOA or PFOS is exempt from CERCLA reporting requirements requires a case-by-case evaluation based on specific permit language or applicable control requirements. Generally, any release that violates a standard or limit specified in a facility's NPDES permit must be reported pursuant to CERCLA section 103 and EPCRA section 304. If the permit limit is below the RQ for these substances, those releases are not required to be reported.

d. The Reportable Quantity (RQ) Should Be Applied Over a Different Time Period Than 24 Hours

Comment: One commenter argued that EPA should require reporting of releases on a monthly basis rather than over a 24-hour period. To support this proposition, the commenter argued that the conditions of water-borne discharges do not change on a day-to-day basis and reporting can therefore be handled through other statutory reporting structures, specifically, under the terms of NPDES permits issued under the CWA. The commenter also argued that this designation would result in inconsistent reporting requirements as between TSCA and CERCLA. Here, the commenter stated that, under EPA's Chemical Data Reporting (CDR) rule, PFOA and PFOS are subject to a 2,500-pound reporting threshold at a single site. The commenter then noted that, regardless of TSCA stipulations, if the reporting quantity threshold is one pound in 24 hours, a site could spill 0.99 pounds per day for 365 days a year, or nearly 360 pounds, with no reporting required. If, however, EPA imposed a weekly or monthly RQ reporting timeframe, the commenter contended that this issue would be addressed. Finally, the commenter noted that, pursuant to Toxics Release Inventory reporting requirements, facilities in regulated industry sectors must report annually on releases and the waste management of certain listed toxic chemicals that they manufacture, process, or otherwise use above certain threshold quantities (100 pounds for PFOA and PFOS).

Response: EPA declines the commenter's request to amend the timeframe it uses to determine if a reportable release has occurred. The Agency believes that a 24-hour reporting period—which it has utilized successfully for 38 years and with which the regulated community is highly familiar—best serves the primary purpose of CERCLA's notification requirements, namely, to alert government officials to releases that may require timely and proper response action to prevent or mitigate damage to public health or welfare or the environment. To the extent facilities are aware of ongoing releases of hazardous substances below the reportable quantity, the Agency believes that regulated entities will conduct due diligence by reporting any releases that may cause substantial danger to the public health, or welfare or the environment. Finally, while the commenter identifies what it regards as inconsistencies in reporting thresholds between various regulatory programs, EPA notes that statutory and regulatory programs maintain reporting thresholds that are intended for different purposes. For example, EPCRA section 313 (Toxic Release Inventory (TRI)) requires certain facilities that manufacture, process, or otherwise use listed toxic chemicals in amounts above reporting threshold levels to report their environmental releases and other waste management quantities of such chemicals annually. TRI data can, in conjunction with other information, be used as a starting point in evaluating such exposures and the risks posed by such exposures. The purpose of the Chemical Data Reporting Rule under TSCA is to provide EPA with information on the production and use of chemicals in commerce. However, release reporting requirements under CERCLA section 103 and EPCRA section 304 create a reporting process that inform government officials of releases that require immediate evaluation to determine the need for response action.

f. The Proposal Provides Little or No Guidance on How PFAS Quantities Are To Be Specifically Determined or Calculated for the Purposes of the RQ

Comment: Several commenters argued that the designation would necessitate costly daily sampling for PFOA and PFOS; relatedly, these commenters also claimed that the designation fails to provide adequate guidance regarding the appropriate methodology for sampling of PFOA and PFOS.

Response: This final designation under CERCLA does not require any testing and EPA does not intend to require any further testing beyond that which is already required by other statutes and their implementing regulations. Testing may be required on a site-specific basis, consistent with CERCLA section 104(b).

g. Reportable Quantities of PFAS May Be Difficult or Impossible To Identify Due to Being Proprietary, Being Disclosed Incompletely in Safety Data Sheets, or Not Meeting the 1 Percent Labeling Threshold

Comment: Several commenters were concerned with the identification of reportable PFAS because in some cases, PFAS chemicals in products are listed as proprietary, not by name or Chemical Abstracts Service (CAS) number. Furthermore, because not all Safety Data Sheets (SDSs) accurately disclose PFAS constituents, these commenters argue that the designation will result in constant uncertainties regarding quantities, reporting and recordkeeping, even though EPA has taken the position that SDSs and Technical Data Sheets should be considered primary sources of information in ascertaining the presence of PFAS-containing compounds. One commenter also noted that compositions of products containing PFOS or PFOA, or other PFAS, are currently not required to be communicated on Safety Data Sheets or otherwise labeled normally below one percent, questioning how EPA proposes to make determinations on volumes if percent composition is not disclosed by manufacturers. One commenter stated that the rule should clarify expectations and requirements for PFOA and/or PFOS producers regarding the communication and/or disclosure of these substances when used as ingredients. By way of example, the commenter suggested that EPA should consider whether PFOA and PFOS producer reporting requirements should be effectuated through OSHA regulations such as the Hazard Communication Standard.

One commenter noted that EPA's current proposal would designate not just PFOA and PFOS as hazardous substances with RQ requirements, but also ''their salts and structural isomers'' which often do not even have their own names. The commenter asserted that if a constituent has not even been named yet and/or is not currently detectable with the available sampling methods, then the regulation of that constituent is not practicably enforceable and puts regulated entities in an untenable situation.

Response: According to OSHA's Hazard Communication Standard (HCS), a manufacturer, importer, or employer may claim ingredients in their product as proprietary if they meet the requirements of 29 CFR 1910.1200(i). However, if a chemical ingredient is below the thresholds (*i.e.,* 1% or 0.1%, depending on the specific health endpoint), it is required to be listed on an SDS if the chemical can cause a health hazard below the cut-offs.[70] Downstream users of mixtures or products that contain PFOA, PFOS, or their salts and isomers are encouraged to contact their distributors as well as manufacturers to obtain (SDSs), which should include concentrations of each ingredient or constituent in a mixture or product. The specific requirements for developing SDS and its contents are regulated under OSHA HCS. *See 29 CFR 1910.1200. (Note: EPA's CompTox Chemicals Dashboard (https://comptox.epa.gov/dashboard/) is a resource that can be used to identify salts and structural isomers of PFOA and PFOS. EPA periodically updates the CompTox Chemicals Dashboard to include new information on PFAS, including PFOA and PFOS.)* EPA has amended Table 302.4 of 40 CFR part 302 to designate PFOA, PFOS and their salts and structural isomers and parties that use such chemicals are responsible for knowing the makeup of their products and ingredients and ensuring compliance with the CERCLA and EPCRA reporting requirements if a release occurs. The regulations at 40 CFR 302.6 (b) provides requirements for release reporting of mixtures with known and unknown constituents or their quantities. *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-J/part-302/section-302.6.*

[70] EPA coordinated with OSHA to develop this response.

h. EPA Should Clarify That Any NPDES Permit Violation for PFOA and PFOS Would Not Constitute a ''Federally Permitted Release'' and Must Be Reported

Comment: One commenter argued that EPA should clarify that any releases of PFOA or PFOS in violation of the terms of a NPDES permit would not constitute a ''federally permitted release'' under CERCLA section 101(10)(C) and must therefore be reported in accordance with CERCLA section 103. This commenter also argued that EPA's ability to require monitoring of PFOA and PFOS through NPDES permits is limited because the Agency's April 2022 guidance—*Addressing PFAS Discharges in National Pollutant Discharge Elimination System Permits and Through the Pretreatment Program and Monitoring Programs* (Memorandum)—is directed only at federally issued NPDES permits.

Response: CERCLA requires a person in charge of a vessel or a facility to report any release (other than a federally permitted release) of a hazardous substance over a certain quantity to the National Response Center as soon as they are aware of a release. *See* 42 U.S.C. 9603(a). CERCLA section 101(10) defines the term ''federally permitted release,'' which includes NPDES permits issued under the Clean Water Act. See CERCLA 101(10)(A), (B), & (C). Whether a particular release is a ''federally permitted release'' such that it would be exempt from CERCLA section 103 reporting requirements requires a case-by-case determination based on the specific permit language or applicable control requirement. These provisions are sufficient to inform whether a release is a federally permitted release for any hazardous substance, including releases of PFOA and PFOS. EPA also notes that on December 5, 2022, it updated the Memorandum to provide guidance to States for addressing PFAS discharges when they are authorized to administer the NPDES permitting program and/or pretreatment program. *https://www.epa.gov/system/files/documents/2022-12/NPDES_PFAS_State%20Memo_December_2022.pdf.*

i. Default Reportable Quantity (RQ) of 1 Pound

Comment: One commenter noted that EPA arbitrarily set the default reporting requirement at one pound, which is not supported by scientific analysis.

Response: Although one commenter argues that EPA acted ''arbitrarily'' in setting the reportable quantity (RQ) for PFOA and PFOS at one pound, in fact, the Agency is setting the RQ by operation of law at the statutory default of one pound pursuant to CERCLA section 102(b). *See* 42 U.S.C. 9602(b) (''Unless and until superseded by regulations establishing a reportable quantity under subsection (a) of this section for any hazardous substance as defined in section 9601(14) of this title, (1) a quantity of one pound, or (2) for those hazardous substances for which reportable quantities have been established pursuant to section 1321(b)(4) of title 33, such reportable quantity, shall be deemed that quantity, the release of which requires notification . . .'').

2. Community Notification Requirement Under CERCLA Section 111(g)

Comment: One commenter requested clarification regarding the impact of the rule on the community notification requirement of section 111(g) of CERCLA.

Response: Upon finalization of this rulemaking, the owner or operator of a facility or vessel from which PFOA or PFOS have been released will be required to ''provide reasonable notice to potential injured parties by publication in local newspapers serving the affected area.'' CERCLA section 111(g). Note that the section 111(g) notification mechanism is independent of the reporting requirements of section 103(a). See Notification Requirements; Reportable Quantity Adjustments, 50 FR 13456, 13464 (Apr. 4, 1985) (''One commenter asked whether RQ notification requirements revoke section 111(g). The newspaper notification requirement established by section 111(g) of CERCLA is not affected by any of the notification requirements in today's rule.'').

E. National Priorities List (NPL) Sites—Existing and Future Contamination

Comment: A number of commenters were concerned that the designation of PFOA and PFOS would result in the addition of a significant number of new sites to the NPL, thereby preventing EPA from focusing on significantly contaminated sites. One commenter noted that designation would require EPA to prioritize the cleanup of new Superfund sites, but also claimed that the Agency has not clarified how any prioritization process would occur. Another commenter noted their specific concern that the designation will result in the implication of a significant number of agricultural operations as Superfund sites.

Several commenters also argued that designation could both extend the

remediation timeline for existing Superfund sites and slow down the rate at which sites can be deemed ''closed.'' Ongoing and unmitigated releases could result in a contaminated site having to be cleaned up multiple times. Finally, multiple commenters stated that EPA has not properly accounted for and considered the additional economic burden associated with the addition of multiple new Superfund sites, reopening of sites, and corresponding cleanup obligations.

Response: EPA does not expect the number of sites on the NPL to substantially increase after designation. EPA already has the authority to list PFOA and PFOS sites to the NPL, and the rule has no impact on that authority. Indeed, EPA has already listed sites on the NPL in part due to the presence of these substances at a site, and this practice would continue. For example, Saint-Gobain Performance Plastics, Blades Groundwater, and Galey and Lord mention PFOA, PFOS, or both PFOA and PFOS, in their listing proposal. Designation does not automatically make sites eligible for placement on the NPL because of the presence of PFOA and PFOS.

Designation does not change the Hazard Ranking System (HRS), which is EPA's primary tool for evaluating releases to determine NPL eligibility. (40 CFR part 300, Appendix A). The HRS broadly defines ''hazardous substance'' as including CERCLA hazardous substances, pollutants, and contaminants as defined in CERCLA section 101(14) and 101(33). Available scientific data demonstrate that PFOA and PFOS meet the definition of pollutant or contaminant, and therefore sites with PFOA and PFOS are evaluated in the NPL listing process, regardless of designation.

The HRS process considers several factors for the purpose of scoring a site and determining its eligibility for listing on the NPL. The HRS is designed to assesses the relative potential of sites to pose a threat to human health or the environment. Scores are based on three categories, including the likelihood that a site has released or has the potential to release hazardous substances and/or pollutants or contaminants into the environment; characteristics of the waste (toxicity and waste quantity); and people or sensitive environments (targets) affected by the release. These scores are calculated for one or more pathways including ground water migration, surface water migration, soil exposure and subsurface intrusion, and air migration. If the combined scores meet or exceed the threshold listing score of 28.5, the site is eligible for the NPL.

Even when a site is eligible for the NPL, EPA may choose to not list the site and look to other options. Alternatives to NPL listing may include the Superfund Alternative Approach, State cleanup, cleanup by other Federal agencies, EPA removal action, deferral to another EPA program, or various other enforcement mechanisms. Thus, PFOA or PFOS releases may be addressed through non-NPL mechanisms even after designation.

Between FY 2003 and FY 2022, only about four percent of all contaminated sites added to EPA's Active Site Inventory were placed on the NPL. Since 2013, EPA has, on average, added 11 non-federal sites per year to the NPL,[71] and EPA does not expect the rate at which annual additions to the NPL occur to increase as a result of this rule. Moreover, NPL listing does not trigger any immediate actions, liability, or requirements for the site.[72]

A hazardous substance designation under section 102(a) of CERCLA does not lead automatically to any response actions. Response actions, which include investigations of releases of hazardous substances and determining if removal or remedial action is necessary, are contingent, discretionary, and site-specific. 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; and cost considerations, among other important factors such as protectiveness, are part of CERCLA's site-specific cleanup approach.

EPA disagrees with the commenter that designation of PFOA and PFOS will slow the Agency's ability to remediate Superfund sites. Designation itself does not affect the length of time it may take to fully implement a remedial action. However, in some cases, there may need to be additional work to address PFOA and PFOS contamination, depending on what other contaminants of concern (COCs) are located at a site and whether the responses to those other contaminants have the co-benefit of addressing PFOA and PFOS contamination. Typically, remedial actions address a number of COCs at once. In some cases, the remedy for other COCs will also address PFOA and PFOS contamination; in other cases, additional work will be needed. For instance, if PFOA and PFOS are not part of a remedy for the site, adding them to the remedy would then have the potential to increase efforts and cost of the remedy (*e.g.,* by increasing the frequency of GAC replacement).

In all cases, EPA should evaluate whether the remedy can mitigate any unacceptable risk from PFOA or PFOS contamination or whether additional actions may need to be taken. CERCLA section 121 provides that if an action is needed to assure protectiveness as a result of findings of a five-year review, those actions can be taken. In some cases, it may be necessary to revise or expand the previous risk assessment as part of a five-year review. For example, the risk assessment may need to be revised when there is a new exposure pathway, a new potential contaminant of concern, or an unanticipated toxic byproduct of the remedy. Five-year reviews (FYR) can also recommend further investigation to determine whether an additional response action is needed. *See* CERCLA section 121(c); 40 CFR 300.430(f)(4)(ii).

Additionally, several commenters stated that without first ensuring PFOA and PFOS are no longer entering the environment, ongoing and unmitigated releases could potentially cause a site to be cleaned up multiple times. First, PFOA and PFOS contamination stems largely from historic releases. Even though there will likely be future releases, the use of PFOA and PFOS has diminished, and EPA does not expect releases at particular sites to result in additional widespread, significant contamination at or from that site, in part because the designation will allow EPA to act earlier. Second, EPA notes that (as discussed in Section III.C.), it has committed to a comprehensive and

[71] This estimate is based on data from EPA's SEMS database with respect to non-federal NPL sites. EPA determined that it was appropriate to assess the designation's impact with respect to non-federal NPL sites only, because federal sites are generally expected to address PFOA and PFOS in the absence of designation consistent with CERCLA section 104. As discussed in Chapter 2 of the RIA, federal sites are addressing PFAS in the baseline as authorized by CERCLA section 104 and corresponding Executive Orders, as required by the NDAA, and consistent with federal facilities agreements under CERCLA section 102. Therefore, EPA expects that federal sites will address PFOA and PFOS contamination in the absence of the final rule. With federal sites taking action to address PFAS in the baseline, indirect impacts of the final rule will likely be related to actions taken at non-federal sites. For additional context, since FY 2000 EPA has added 8 federal sites to the NPL.

[72] EPA considered the portion of non-federal NPL sites that may be impacted by designation depending on site-specific circumstances. Of final, proposed, or deleted non-federal NPL sites that have been tested for PFOA and/or PFOS, an estimated 33.1% of NPL sites have detectable levels of PFOA and/or PFOS. See Section 3.3 of the RIA for more details about this estimate. In evaluating the designation's impact on non-federal NPL sites, this estimate is instructive and serves as a benchmark for assessing designation's potential impact to those sites. There are currently 5 sites where either PFOA or PFOS contributed to NPL listing.

ambitious whole-of-Agency plan to address PFAS. Under this approach, EPA has identified a variety of authorities, including TSCA, SDWA, and RCRA, that it intends to use to prevent or minimize ongoing PFOA and PFOS releases into the environment. Additionally, EPA has considered the economic impacts of designation, including a consideration of potential impacts of designation on the NPL listing process. Please see chapter 5 of the RIA for this final rule.

F. Regulate PFAS as a Class

Comment: A few commenters stated that EPA should regulate PFAS as a class rather than listing chemicals one by one.

Response: PFOA and PFOS are prevalent because they have been produced and used since the 1940s, were among the most widely used of the PFAS constituents and persist in the environment for a substantial period of time. EPA considered the available scientific and technical information, and concluded each of these substances may present substantial danger to public health or welfare of the environment. EPA also evaluated the totality of the circumstances, including available scientific and technical information, and concluded that designation is warranted. The Agency also recently sought input and data regarding potential future hazardous substance designation of categories of PFAS and is still evaluating the feedback it received on this issue. See Addressing PFAS in the Environment, 88 FR 22399 (Apr. 13, 2023).

G. Phase-Out & PFOA Stewardship Program

Comment: Several commenters also argued that the production of PFOA and PFOS is being phased out, thus the value of this rulemaking is questionable.

Response: EPA disagrees with the commenter's assertion that the value of designating PFOA and PFOS is questionable since these chemicals have been phased out in many cases. First, although PFOA is not produced domestically by the companies participating in the 2010/2015 PFOA Stewardship Program, PFOA may still be produced domestically by non-participating companies. PFOS may still be produced or used domestically as well. Second, EPA has also published Significant New Use Rules (SNURs) to require notification to EPA before manufacture (including import) of certain PFAS, including PFOA and PFOS. This notification process would allow EPA the opportunity to evaluate the new use and, if necessary, take action to prohibit or limit the activity. However, these SNURs exempted certain ongoing uses, including a few specifically limited, highly technical uses. In the absence of any notices received under these SNURs, EPA has limited sources of data regarding the ongoing use of PFOA and PFOS. Currently, the CDR generally requires manufacturers (including importers) to report for PFOA and PFOS if they meet a 2,500-pound production volume threshold at a single site. TRI reporting requires facilities to report releases of PFOA and PFOS if the facility manufacture, produce, or otherwise use at or above 100 pounds per year. Recent TRI reports indicate there maybe on-going uses of these substances. While TRI reports show on-going uses, EPA is unable to definitively state the extent to which PFOA and PFOS are still in commerce in the United States.[73]

Regardless of the phase-out, designation is warranted based on the scientific and technical data available, suggesting that releases into the environment pose a hazard; are persistent and mobile (fate and transport); and prevalent in the environment. EPA has existing data that suggest that, despite the phase-out, PFOA and PFOS will continue to be detected in the environment. For example, EPA has detected PFOA and PFOS at approximately 400 NPL sites. These sites are mainly locations associated with AFFF use, textile coating operations, metal plating facilities, and landfills. As appropriate, these sites, and others like them, should be investigated, and site-specific risk assessments should be performed to assess whether further response actions, if any, are necessary to protect human health and the environment. Designation will allow EPA to address the legacy of sites that are contaminated with these substances and address future releases.

H. Managing PFOA and PFOS Contaminated Waste

Comment: Several commenters claimed that the designation of PFOA and PFOS will result in a significant increase in the generation of hazardous wastes; these commenters also argued that EPA has not provided sufficient disposal capacity or storage requirement guidance to address the ramifications of the designation. Multiple commenters also stated that the Agency may not be able to satisfy the requirements of CERCLA section 104(c)(9), which requires States to assure the availability of hazardous waste treatment or disposal facilities that have adequate capacity to manage the hazardous waste reasonably expected to be generated within the State over 20 years, prior to EPA providing funding for any remedial actions. Relatedly, some commenters noted that EPA has not disclosed whether it has entered into any agreements with States to ensure that they possess the capacity to destroy, treat, or securely dispose of material contaminated with PFOA and PFOS. Further, several commenters argued that EPA has not considered whether Subtitle C landfill capacity is available to accommodate PFOA or PFOS-contaminated hazardous waste. Some commenters also alleged that EPA has not described disposal methods for contaminated soils or other media from new Superfund sites that could be created in the wake of this rulemaking. Finally, several commenters argued that EPA must finalize its *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) and Materials Containing PFAS-Substances* (''Interim Guidance'') and estimate available waste disposal capacity before finalizing this rulemaking.

Response: Comments suggest a misunderstanding of waste disposal requirements under CERCLA. The Agency disagrees with the assumption that all waste containing PFOA and PFOS must be disposed of in Subtitle C facilities. EPA's *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances—Version 2 (2024*), acknowledges that PFAS wastes could be sent to both hazardous waste and municipal solid waste landfills. For CERCLA cleanups, section 121(d)(3) of CERCLA, as implemented by 40 CFR 300.440 (''*Offsite Rule*''), applies to any CERCLA response action involving the off-site transfer of any hazardous substance or pollutant or contaminant (*CERCLA wastes*). The Offsite Rule requires that CERCLA wastes are transferred to a facility operating in compliance with applicable Federal and State requirements for the waste at issue. As such, for CERCLA cleanups, only hazardous wastes listed or identified under RCRA section 3001 (or an authorized State program) are required to be managed at RCRA Subtitle C facilities.

EPA rejects the assertion that it has not evaluated if sufficient capacity exists for disposal and storage of PFOA

[73] The Agency expects to receive additional information about ongoing use of PFAS as part of the TSCA section 8(a)(7) PFAS reporting rule that was finalized on October 11, 2023 (88 FR 70516).

and PFOS contaminated materials. EPA also acknowledges that CERCLA section 104(c)(9) does not allow the Agency to provide any remedial action funding to a State, unless the State first enters into a Superfund State Contract or Cooperative Agreement (CA) that assures the availability of adequate capacity to manage hazardous wastes generated in the State for 20 years following the date of the response agreement. EPA is designating PFOA and PFOS as CERCLA hazardous substances. No PFAS are currently listed, or being proposed to be listed, as hazardous wastes under RCRA,[74] However, PFOA- and PFOS-containing waste is and will likely continue to consume a fraction of hazardous waste treatment and disposal capacity. Although waste containing PFOA and PFOS is not necessarily hazardous waste (unless the particular wastes are hazardous for some other reason), some waste generators, perhaps to be cautious, have been sending PFAS-containing wastes to hazardous waste facilities. To ensure hazardous waste landfill capacity is available in the future, EPA reviews and analyzes the Biennial Hazardous Waste Report and other data to develop and then publish an assessment of national capacity for hazardous waste management. The last such capacity assessment indicated that there is adequate capacity nationwide through 2044, and it would have incorporated PFOA and PFOS as wastes in the category of ''Not RCRA Federally-Defined Hazardous Wastes.'' Of these wastes, no assumption regarding a certain percentage of PFOA and PFOS was made. Anew assessment is currently underway to incorporate new information and extend the time horizon.[75] EPA will continue to work with States to monitor waste treatment and disposal capacity and report on the status.

The science on treating, destroying, and disposing of PFAS is evolving. The National Defense Authorization Act for Fiscal Year 2020 (FY 2020 NDAA) directed the Agency to publish interim guidance on the destruction and disposal of PFAS and materials containing PFAS. Subsequently, on December 18, 2020, EPA developed and issued the *Interim Guidance* (*U.S. EPA, 2020*), which outlines the current state of science on techniques and treatments that may be used to destroy or dispose of PFAS and PFAS-containing materials from non-consumer products. Consistent with the FY 2020 NDAA, EPA is also required to publish revisions to the interim guidance as appropriate, but not less frequently than once every three years. EPA recently posted *the Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances—Version 2 (2024*).

I. Comments on Economic Assessment/ Regulatory Impact Analysis

Comment: Several commenters asserted that EPA must prepare and publicly issue a full economic analysis of the rulemaking. These commenters claimed that EPA's economic assessment is insufficient for failing to provide any quantitative assessment of anticipated indirect costs, particularly those related to increased response actions. Several commenters called upon the Agency to issue a complete RIA while other commenters stated that EPA is required to prepare a regulatory cost benefit analysis consistent with Executive Order 12866. These commenters also asserted that EPA should conduct a full RIA pursuant to OMB Circular A–4 that considers the full compliance and cleanup costs, including the direct and indirect costs and benefits, associated with the designation. One commenter stated that the rulemaking cost estimates prepared by EPA do not appropriately reflect the total costs associated with the designation.

Response: With new information received during the public comment period, EPA updated its analysis of direct costs. As part of this rulemaking, EPA has expanded its economic assessment and has conducted an RIA consistent with E.O. 12866 and OMB Circular A–4 in support of designation. As required by the E.O. and Circular A–4, the RIA assesses reasonably foreseeable indirect costs, transfers, and benefits. Specifically, for costs, transfers and benefits, EPA has developed estimates under a range of scenarios based on historic information about response costs and benefits. These ranges reflect the uncertainty associated with estimating potential response costs, transfers, and benefits, as it is difficult to assess with certainty what future actions will be taken since CERCLA decisions are made on a site-specific basis. EPA also asserts that the scope of costs counted by the Agency as direct costs—including an estimated low and high range of potential notification requirement frequencies and associated costs—is consistent with the requirements of E.O. 12866 and OMB Circular A–4. Consistent with the guidance of Office of Management and Budget's (OMB's) Circular A–4, this RIA includes an assessment of potential indirect costs, benefits, and transfers to provide the public with insights related to these impacts. Please see chapters 3, 4, and 5 of the RIA for more information about EPA's methodologies and discussion of direct and indirect costs, benefits, and transfers.

1. Liability and Costs to Public Utilities

Comment: Numerous comments claim that EPA has failed to consider the potential impact of the designation on public water utilities/water systems and ratepayers with respect to potential litigation costs. These comments also argue that the designation does not account for the potential remediation costs associated with PFOA and PFOS cleanups (which the commenters assert could be passed on to local communities and public clean water utility ratepayers). These commenters also claim that local drinking water and wastewater agencies will incur substantial costs to remove PFOA and/or PFOS from water sources and propose that all such direct and indirect costs should be evaluated in a full RIA. One commenter asserted that EPA's approach to designation could potentially harm sectors and facilities that provide essential daily functions to communities, such as wastewater treatment facilities and municipal landfills (*i.e.,* facilities that do not generate or use PFAS but that may, in the regular course of business, receive waste or wastewater containing PFAS).

Response: The Agency recognizes that certain stakeholders are concerned about CERCLA liability resulting from the designation of PFOA and PFOS as hazardous substances. The most significant direct impact of this CERCLA designation is the requirement that any person in charge of a vessel or facility report a release of PFOA and/or PFOS of one pound or more within a 24-hour period. Neither a release nor a report of a release automatically triggers cleanup action under CERCLA. EPA makes CERCLA response decisions based on site-specific information, which includes evaluating the nature, extent, and risk to human health and/or the environment from the release. In

[74] EPA has proposed to amend its RCRA regulations to add multiple PFAS compounds, including PFOA and PFOS, as hazardous constituents. These PFAS would be added to the list of substances identified for consideration in RCRA facility assessments and, where necessary, further investigation and cleanup through the corrective action process at hazardous waste treatment, storage and disposal facilities. Although this is one step toward listing a hazardous waste, it is not a regulatory hazardous waste listing.

[75] Background information and links to related documents are available at *https://www.epa.gov/hwpermitting/assessment-national-capacity-hazardous-waste-management.*

addition, designation does not automatically result in CERCLA liability for any specific release. Whether an entity may be subject to litigation or held liable under CERCLA are site-specific and fact-dependent inquiries. Likewise, CERCLA affords the EPA broad discretion as to whether or how to respond to a release. For those reasons, EPA cannot assess with reasonable certainty what liability outcomes may indirectly result from this designation since those outcomes are often linked to EPA's discretionary decisions with respect to CERCLA response actions as well as site-specific and fact-dependent court rulings. Nevertheless, EPA considered these issues in its totality of the circumstances analysis. For further information regarding the interplay between the designation and potential liability concerns please see sections VI.B.2 and VI.B.3.

Efforts to address PFAS in public drinking water and wastewater treatment have already been initiated prior to this designation, and the associated costs of those efforts are attributable to those separate efforts. In the case of drinking water utilities, EPA's 2024 NPDWR mandates that certain drinking water utilities (community water systems and nontransient, noncommunity water systems) should deliver drinking water with PFOA and PFOS concentrations below the MCLs. The costs of monitoring, treatment, administration, disposal of drinking water treatment media residuals, and other costs have been considered in the associated Economic Analysis as part of that rulemaking effort. *Please see 2024 NPDWR. https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas,* or visit *www.regulations.gov,* Docket No. EPA–HQ–OW–2022–0114. For potential cleanups of private drinking water wells, EPA acknowledges it has expanded its economic assessment to estimate a subset of potential health benefits where data was available to allow quantification. This subset includes those populations who rely on private drinking water wells within one mile of sites that may have response and cleanup as a result of the final rule. Refer to RIA Chapter V.

2. Consideration of Costs for Small Entities

Comment: One commenter expressed concern that the designation may create significant costs for small entities associated with monitoring and analyzing samples for PFOA and PFOS to ensure compliance with CERCLA. The commenter recommended EPA evaluate and consider the real costs associated with the designation through an evaluation of the number and types of facilities that may release reportable quantities of PFOA or PFOS, to determine what monitoring and analysis costs these facilities may incur to ensure compliance with CERCLA. Then, the commenter suggested that if EPA determines that costs should not be considered as part of the designation, costs should be considered as a factor of complying with CERCLA.

Response: EPA disagrees with the commenter that designation of PFOA and PFOS as CERCLA hazardous substances will lead to significant cost impacts for small businesses. First, this rule does not require monitoring and analysis specifically. Second, in its RIA, EPA demonstrated that the rule would not result in a significant impact to a substantial number of small entities; in fact, consistent with long-standing EPA policy regarding the implementation of the Regulatory Flexibility Act, the RIA considered small entity impacts related to the direct cost impacts of the rule and found that they are limited to the costs associated with the reporting of PFOA/PFOS releases at or above the RQ.

3. Direct Costs for Rule Familiarization

Comment: One commenter stated that EPA failed to consider the cost of ''regulatory familiarization'' in its economic analysis of the rulemaking. The commenter described ''regulatory familiarization costs'' as accounting for the value of time and effort that every potentially affected individual or business must undertake to determine if a regulation applies to their situation or not, and how their activities must adapt to comply.

Response: Rule familiarization constitutes a negligible cost of the rule. Facilities are expected to be familiar with the baseline requirements associated with reporting releases of non-PFOA/PFOS CERCLA hazardous substances to the NRC and to the State, Tribal and local emergency planning and response agencies. While the final rule is adding PFOA and PFOS to CERCLA's list of hazardous substances, this designation does not change or add requirements to CERCLA section 103, CERCLA section 111, and EPCRA section 304 release notification requirements.

4. Costs, Benefits, and the Economic Assessment

Comment: One commenter states that the rulemaking will result in a net social cost as markets over-adjust to concerns regarding CERCLA's joint and several liability scheme. The commenter also contends that any transfer of costs from the public to polluters could occur even in the absence of the designation, thereby concluding that the rulemaking is unnecessary. Finally, the commenter states that any consistency between the designation and ongoing actions to address PFOA and PFOS contamination is irrelevant to a determination as to whether the designation meets a compelling public need.

Response: EPA disagrees with the commenter that the designation will cause the market to over-adjust in response to CERCLA's liability provisions. Market efficiency generally increases as more information becomes available. EPA is unaware of data suggesting that an over-adjustment is likely, and the commenter provided no such data. Further, once CERCLA's notification requirements and broadened enforcement authorities are applicable to PFOA and PFOS releases, the likelihood that costs will be shifted from the Federal government to polluters will increase. Specifically, reporting will facilitate increased transparency regarding releases of PFOA and PFOS, which will, in turn, both inform the Agency's understanding of the presence of these substances in the environment and allow EPA to respond to contamination in a timely manner.

EPA disagrees with the commenter that the consistency between the designation and other ongoing actions to address PFOA and PFOS contamination is irrelevant to a determination that the rule meets a compelling public need. Designation is still warranted independent of other Agency actions and is consistent with EPA's Agency-wide approach outlined in the Roadmap. As noted by the commenter, OMB Circular A–4 states that an agency ''should try to explain whether the action is intended . . . to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy.'' Greater consistency between actions will ''improve governmental processes'' by allowing for greater efficiency and effectiveness in addressing PFOA and PFOS contamination across the United States. Additionally, when EPA is able to transfer certain response costs to PRPs, this represents an improvement in societal equity.

Comment: One commenter argues that EPA has not explained how designation encourages better waste management practices or how PFOA or PFOS-contaminated materials should be disposed of. This commenter also argues that EPA has failed to support its assertion that the designation will

produce public health benefits. Here, the commenter points out that EPA identifies the regulatory requirement to report a release of one pound of PFOA or PFOS as a particular benefit of the proposed rulemaking but contends that the quantity of material that would need to be released for reporting requirements to attach would be significant. Finally, the commenter states that the designation may have the unintended consequence of increasing treatment costs in both drinking water and wastewater.

Response: EPA agrees with the commenters that reports of releases at or above the RQ represent a meaningful benefit of the rule, as reporting will allow EPA to evaluate and respond to such releases in a timely manner. EPA disagrees with the commenter that the rule will not lead to improvements in the management of PFOA and PFOS contaminated materials. A potential direct benefit that may result from the reporting requirement is better waste management and/or treatment by facilities handling PFOA or PFOS, resulting from improved efforts to further reduce potential releases. Greater transparency provided by release reporting can lead to fewer releases to the environment and thus to potential health benefits associated with avoided exposure. For additional information regarding the potential benefits of the designation, including other benefits of release reporting, see Section VI of this preamble.

In this final action, EPA has expanded its economic assessment of indirect benefits to include illustrative quantified and unquantified health benefits. EPA quantified a small subset of potential health benefits. This includes an illustrative assessment of reduced incidence of cardiovascular disease, birthweight impacts, and renal cell carcinoma under a range of scenarios. This considers potential benefits to those populations which rely on private drinking wells, where there may be response and cleanup as a result of the final rule. Additionally, EPA assessed additional unquantified health benefits. *See* RIA Chapter 5.

EPA does not agree with the commenter that the proposed rule will hinder water treatment or efforts to remove background levels of PFOA or PFOS in wastewater and drinking water. When, how, and why the water sector would remove these substances from drinking water and whether they dispose of it in a hazardous waste landfill is complex and will depend on the volume and concentration of PFAS captured, availability of disposal sites, decisions made at individual public water systems, and State and Federal regulatory actions and enforcement actions.

EPA also disagrees with the claim that designation will increase the costs associated with managing drinking water treatment residuals. As discussed in section VII.I.1, efforts to address PFAS in drinking water and wastewater treatment have already been initiated prior to this designation, and the associated costs of those efforts are attributable to those separate efforts. The NPDWR Economic Assessment Appendix H includes a sensitivity analysis that accounts for potential cost increases associated with treatment of residuals as hazardous waste. The designation of PFOA/PFOS as CERCLA hazardous substances does not require disposal or treatment of water treatment residuals as hazardous waste.

Comment: One commenter challenged whether the designation would have the benefits that EPA claims. The commenter asserts that existing tools at EPA's disposal, as well as those in development, can provide the Agency with the authority it needs to address PFOA and PFOS releases and obviate the need for designation. The commenter also states that EPA's failure to quantify the likely costs and purported benefits of this rule are especially egregious in light of the Agency's alleged failed to consider alternative actions to achieve its goals. The commenter also encouraged EPA to conduct a full RIA. Finally, the commenter claimed that there are negligible positive effects associated with the designation, and challenged EPA's assertion that substantial benefits will flow from the designation as flawed.

Response: EPA disagrees with the commenter that the rule is unlikely to lead to the benefits the Agency has identified. EPA has identified a significant body of scientific evidence demonstrating 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. Therefore, to the extent that this designation results in reduced or eliminated exposure to PFOA/PFOS, as EPA expects it will, there may be potentially significant human health benefits associated with designation. EPA further explains its reasoning regarding these benefits in Section VI.A of this preamble and in the RIA. For example, the notification requirement under the designation will facilitate earlier notification of EPA and State authorities regarding releases of PFOS and PFOA. Relatedly, designation will enable EPA to exercise its statutory authorities to address PFOA and PFOS contamination in a timely manner.

With respect to the commenter's claims that the Agency has failed to substantiate its quantification of potential costs, transfers, and benefits, the RIA accompanying the final rule has quantitatively assessed such impacts to the extent possible. Additional benefits and costs remain unquantified due to a lack of available data and highly uncertain circumstances, as further discussed in the rule and RIA. Additionally, EPA has included an analysis of potential alternative policy options associated with the reporting requirement; details of this analysis are found in the Appendix of the RIA.

a. Indirect Costs

Comment: One commenter points out that EPA's economic assessment estimates only the costs associated with reporting activity. The commenter also stated that all costs related to potential increases in response activities and increases in the speed of response activities are only qualitatively described, and that EPA refers to these costs as indirect costs. However, when EPA discusses the benefits of the proposed rule, all the reported benefits related to health protection stem from these ''indirect'' effects. The commenter also said that costs associated with conducting response activities, including the significant costs associated with complex litigation that frequently occurs under CERCLA, is a direct impact of designating substances as CERCLA hazardous substances and must be considered in a regulatory impact analysis. EPA has a wealth of information to inform the frequency at which sites are placed on the NPL; data also exist to inform the costs of final cleanup decisions, as memorialized in public Superfund decision documents. The commenter asserts that while these analyses may not be perfect, they would be far superior to simply ignoring costs which are an inevitable and direct result of the proposed rule.

A commenter asserts that EPA has not fully considered the potential cost impacts of the Proposed Designation and it is evidenced by the lack of information provided by EPA as to the magnitude and scope of those impacts. The commenter states that the limited economic analyses that EPA performed to support the proposal is flawed and its analysis about airports is particularly deficient. The commenter states that the airport analysis simply does not make sense, and seems to have been completed in a vacuum, with little or no outreach to airport operators or others with airport expertise. Another

commenter pointed out that the cost for the airport industry to transition to a new foam is not insignificant and many airports will struggle to transition absent any Federal grant funding.

Response: EPA disagrees with the commenter's assertion that potential response costs are direct; such actions are discretionary, contingent, and made on a site-by-site basis. EPA also disagrees that the Agency ignored the potential indirect costs of the proposed designation of PFOA and PFOS as CERCLA hazardous substances; the economic assessment developed for the proposed rule included a detailed qualitative assessment of these potential indirect costs. The RIA accompanying the Final Rule provides quantified estimates of potential indirect costs and cost transfers associated with response, as well as certain related indirect benefits. These estimates are in part based on the data suggested by the commenter, *e.g.,* NPL listing process, RODs, etc.

EPA does not agree with the commenter that a more detailed evaluation of direct costs is necessary. EPA provides, in the RIA, an estimated low and high range of potential reporting requirement frequencies and associated costs. Consistent with the guidance of Office of Management and Budget's (OMB's) Circular A–4, this RIA includes an assessment of potential indirect costs, benefits, and transfers to provide the public with insights related to these impacts. To better inform the public of potential indirect costs and benefits, EPA has expanded its analyses of indirect costs, cost transfers, and benefits in the final rule RIA relative to the analysis developed for the proposed rule. For many of the potential impacts that could result from the designation, EPA has developed estimates under a range of scenarios designed to reflect uncertainty in response activity.

EPA also considered quantitative and qualitative benefits and costs as part of its totality of the circumstances analysis. Please see Section VI of this preamble.

EPA appreciates the information provided by commenters on potential PFAS cleanup costs at airports regarding the costs to replace AFFF delivery systems. However, EPA disagrees that the designation would lead to a significant increase in costs of transitioning to use of PFAS-free foam for airports. Independent of EPA's CERCLA hazardous substance rulemaking, Congress has taken certain actions to address PFAS contamination, including directing the transition away from PFAS-containing AFFF, protecting fire fighters, preventing runoff from airports, and requiring DOD to prepare a remediation schedule and develop information about associated costs. The aviation industry is already in the process of transitioning away from AFFF to other types of firefighting foam that do not contain PFAS. The costs associated with this transition are unrelated to the proposed designation of PFOA and PFOS as CERCLA hazardous substances. Once this transition is complete and AFFF is no longer used at airports, EPA expects no or minimal releases from airports. In the interim, any direct costs incurred by airports as a result of a designation would be limited to the costs of reporting in the event that a PFOA/PFOS release of one pound or more occurs in a 24-hour period.

Comment: Many commenters disagree with EPA's proposition that the uncertainties are too great to conduct a robust analysis and stated that EPA should conduct a more detailed analysis of the potential direct and indirect effects of the proposed designation. Some commenters asserted that the costs of the designation would dramatically outweigh any benefits. A commenter stated that their analysis, PFOS and PFOA Private Cleanup Costs at Non-Federal Superfund Sites (referred to as the Cleanup Cost Analysis), estimates that the costs of cleanup for potentially responsible parties (PRP) could total over $17.4 billion dollars for existing non-Federal national priority sites alone, and annualized private party cleanup costs at existing non-federal sites could cost $700–$900 million annually. The commenter asserts that despite any existing uncertainties, these costs are simply too large for EPA to ignore. The commenters also pointed to DoD's ongoing remediation work which can provides example cost data that EPA could use to build estimates. EPA has acknowledged cleanup cost uncertainties in the past and has still estimated these costs.

A commenter suggested that EPA should follow OMB guidance and conduct a formal quantitative analysis of relevant uncertainties (*e.g.,* the number of sites to be remediated, the cost of available cleanup technologies, the cleanup level goals for each possible media). Regardless of whether this proposal exceeds the billion-dollar threshold for formal probabilistic uncertainty analysis, Circular A–4 does not prevent an agency from conducting such an analysis if it would inform agency decision making.

Response: EPA has conducted a more thorough and robust RIA that characterizes uncertainties to better describe potential direct and indirect costs, benefits and transfers associated with the designation.

EPA provides, in the RIA, an estimated low and high range of potential reporting requirement frequencies and associated costs. Consistent with the guidance of Office of Management and Budget's (OMB's) Circular A–4, this RIA includes an assessment of potential indirect costs, benefits, and transfers to provide the public with insights related to these impacts.

To better inform the public of potential impacts, EPA has expanded its analyses of indirect costs, benefits, and transfers in the final rule RIA relative to the analysis developed for the proposed rule. For costs, transfers, and benefits, EPA has developed estimates under a range of scenarios designed to reflect uncertainty in indirect costs, transfers, and benefits. EPA disagrees that the commenter's cost analysis provides a reasonable representation of the costs associated with the proposed designation of PFOA and PFOS as hazardous substances. The analysis is based on several unfounded or inaccurate assumptions that lead to the overestimation of costs. For example, it assumes that the proposed designation would require all existing non-Federal NPL sites to search for PFOS/PFOA contamination. The designation, however, does not by itself require any systematic re-evaluation of NPL sites. Throughout the Superfund process, from the remedial investigation through site cleanup to five-year reviews, EPA evaluates potential risks posed by actual and threatened releases of hazardous substances, pollutants or contaminants. Since PFOA and PFOS are already considered as pollutants or contaminants, this rulemaking, by itself, should not result in any change to the investigation, cleanup and review processes for sites that are currently on the NPL. Any policy decisions to address PFOA/PFOS subsequent to the hazardous substance designation would likely apply to a subset of NPL sites where potential PFOA/PFOS contamination is not already being addressed rather than systematically to all existing non-federal NPL sites. Chapter 5 of the RIA also presents cost estimates for response at non-NPL sites. As noted in the Final Rule, EPA expects that response costs to address PFOS/PFOA will fall within typical response cost ranges for actions to address other hazardous substances and recognizes that response costs will be significant in some cases.

Additionally, EPA disagrees with the commenter's suggestion for EPA to use cost data for Department of Defense

(DoD) PFAS response efforts as the basis for estimating costs likely to result from the proposed designation. Data for DoD sites (*i.e.,* military installations, facilities of the National Guard, and Formerly Used Defense Sites (FUDS) in the United States) would not be representative of costs associated with non-Federal CERCLA sites as the types, quantity, and handling of PFAS are expected to vary greatly. DoD's cost estimates represent one reference point for potential PFAS response costs with a focus specifically on applications related to national defense. EPA also expects the size and scope of, and therefore costs associated with, Federal PFOA and PFOS cleanup sites to be substantially larger than non-federal sites in part because Federal sites are generally larger in size than non-federal sites. The costs associated with addressing PFAS released by Federal agencies are not representative of non-federal facilities as the types, quantity, and handling of PFAS vary greatly. Among other factors, this may also reflect that AFFF use is disproportionately higher at military sites relative to other sites; AFFF is a major source of PFAS contamination.

J. Enforcement

Comment: Numerous commenters expressed support for the rulemaking, noting that designation facilitates CERCLA's ''polluter-pays'' principle by placing the burden of investigating, responding to, and addressing PFOA/PFOS contamination to the parties responsible for the release. These commenters also stated that designation could potentially accelerate the Superfund cleanup process. One commenter requested that EPA ensure that the costs of cleanup are borne by manufacturers and users of PFOA and PFOS, not the public.

Response: The Agency agrees that designation clearly supports the timely cleanup of contaminated sites and facilitates CERCLA's polluter-pays principle. EPA also notes that, as discussed in Section III.C of this preamble, it expects to focus on implementing the objectives of the PFAS Strategic Roadmap by holding responsible those who significantly contribute to the releases of these substances into the environment.

Comment: Numerous commenters expressed concerns that the designation will shift the costs of CERCLA cleanups of PFOA and PFOS from chemical and product manufacturers to various third parties, including water utilities, waste management utilities, airports, fire departments, State governments, farmers, and landowners. Another commenter claimed that utilities could be implicated as PRPs at both NPL and non-NPL sites—despite being potentially de minimis contributors to contamination—and, because of CERCLA's joint and several liability scheme, such parties could theoretically be held responsible for the entire cost of cleanup.

Many commenters argued that EPA's use of enforcement discretion will neither adequately address the liability concerns of certain public sector entities nor ensure that cleanups and settlements assign primary responsibility to parties that significantly contributed to contamination or otherwise profited from the conditions resulting in contamination.

Some commenters also requested that the Agency clarify how enforcement discretion would function in the context of PFOA- or PFOS-related contamination, particularly for water utilities. Finally, several commenters asked EPA to clarify that a CERCLA designation will not impact the land application of municipal biosolids in any way before finalizing this rulemaking.

Response: While EPA acknowledges that the designation has the potential to impact municipalities, EPA does not have information suggesting that designation will result in unusual liability outcomes. EPA recognizes that some parties who do not bear primary responsibility for contamination may be sued and face uncertain litigation costs. EPA believes that CERCLA's liability limitations, coupled with EPA enforcement discretion policies, should operate to minimize hardship for parties that did not significantly contribute to contamination. EPA expects that designation should not change CERCLA's liability framework and that CERCLA will continue to operate as it has for decades (with respect to the more than 800 existing hazardous substances) to resolve who should pay for the cleanup and how much.

EPA also disagrees with the commenters' position that designation will necessarily result in a shift of cleanup costs from PFOA or PFOS manufacturers, to utilities and other sectors. As the Agency describes in sections II.E.7 and VI.B., CERCLA liability does not inevitably flow from any particular release. The question of whether an entity may be subject to litigation or could be held liable under CERCLA involves both site and fact-specific analyses. Additionally, while one commenter raised the issue of incurring potential CERCLA liability despite de minimis contribution to contamination at Superfund sites, EPA notes that—as described in Section VI.B.2—the statute already includes several provisions that may limit liability or the financial impact of liability, including for de minimis parties.

EPA gave careful consideration to CERCLA's liability scheme, and the impact designation may have on CERCLA liability. EPA concluded that designation will not change CERCLA's liability framework. Designation does not automatically confer liability, nor does it alter CERCLA's statutory or regulatory framework for liability. EPA determined that existing limitations in CERCLA coupled with existing CERCLA enforcement policies are sufficient to mitigate concerns about liability that may arise after designation. No additional action is necessary to ensure that those limitations and policies continue to operate as they have for decades. Nonetheless, EPA intends to develop a policy, consistent with those limitations and policies, that explains EPA's priorities for CERCLA enforcement in the context of PFOA and PFOS releases. Please see Section VI.C. for a more detailed discussion. *See also* FY 2024–2027 National Enforcement and Compliance Initiatives.

Regarding the question about application of biosolids, please refer to section VII.A.3.

VIII. Summary of This Final Rule

The designation of PFOA and PFOS as hazardous substances would have three direct effects: (1) Reporting and notification obligations when there is a release of PFOA or PFOS, their salts or structural isomers above the reportable quantity, (2) obligations on the U.S. Government when it transfers or sells certain properties, and (3) an obligation on DOT to list and regulate CERCLA designated hazardous substances as HMTA hazardous materials.

A. Default Reportable Quantity

EPA is setting the RQ by operation of law at the statutory default of one pound pursuant to section 102(b) of CERCLA for PFOA and PFOS and their salts and structural isomers. EPA did not propose, nor is it including in this final action, a RQ adjustment for these substances. 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 Designating PFOA, PFOS, and Their Salts and Structural Isomers as Hazardous Substances

1. Release Reporting Requirements

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. As of the effective date of this action, 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, their salts or structural isomers in any 24-hour period is required to immediately notify the NRC in accordance with 40 CFR 302.6. CERCLA section 111(g) requires owners or operators of any vessel or facility to ''provide reasonable notice to potential injured parties by publication in local newspapers serving the affected area'' of a release of a hazardous substance.

In addition to these CERCLA reporting requirements, EPCRA section 304 requires owners or operators of facilities to immediately notify their SERC (or TERC) and LEPC (or TEPC) when there is a release at or above the reportable quantity of PFOA or PFOS, their salts or structural isomers in a 24-hour period. EPCRA section 304 also 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. *https://www.govinfo.gov/content/pkg/USCODE-2021-title42/pdf/USCODE-2021-title42-chap103-subchapI-sec9620.pdf.*

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

Section 306(a) of CERCLA requires substances designated as hazardous under CERCLA to be listed and regulated as hazardous materials by DOT under the Hazardous Materials Transportation Act.

IX. 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 14094: Modernizing Regulatory Review

This action is a ''significant regulatory action'', as defined under section 3(f)(1) of Executive Order 12866, as amended by Executive Order 14094. Accordingly, EPA, submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis, ''*Regulatory Impact Analysis of the Final Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as CERCLA Hazardous Substances*'', is also available in the docket and briefly summarized in *Section I, Executive Summary* of this action.

B. Paperwork Reduction Act

The information collection activities in this final rule have been submitted for approval to the OMB under the Paperwork Reduction Act. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR number 2708.02, OMB Control No. 2050–0227. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The designation of PFOA and PFOS, and their salts and structural isomers, as hazardous substances 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 and section 111 of CERCLA and section 304 of EPCRA.

Estimated number of respondents: 0 to 614 releases per year.

Frequency of response: Varies.

Total estimated burden: 6,889 hours (per year) maximum. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: Approximately $1,630,000 (per year) maximum, includes approximately $585,000 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 EPA's regulations are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this 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, including importers and importers of articles that contain these

substances, are: (1) PFOA and/or PFOS manufacturers; (2) PFOA and/or PFOS processors; (3) manufacturers of products containing PFOA and/or PFOS; (4) downstream users of PFOA and PFOS; (5) downstream users of PFOA and/or PFOS products; (6) waste management facilities; and (7) wastewater treatment facilities. (*Note: PFOA and PFOS noted here include their salts and structural isomers*). The Agency has estimated that there may be up to 614 reported releases of PFOA or PFOS in any one year and that a small percentage of the annual reports will be submitted by small entities. As further context, even if the maximum number of reports (614) were created to account for every estimated release in a given year and all 614 of these reported releases were from the smallest of the small entities (as described in the RIA, defined using SBA size standards), only 2.5 percent of the 24,836 smallest of the small businesses identified by EPA would be affected. The estimated cost of $2,658 to report a release of PFOA or PFOS is not greater than one percent of the annual revenues for the typical small entity in any impacted industry. For example, estimated annual breakeven costs per facility are lowest for Reupholstery and Furniture Repair (NAICS 811420) at $3,591 at the one percent threshold. Given the estimated notification costs per release of $2,658, EPA does not expect a small business facility's cost to cross even the one percent threshold. Additionally, EPA considered how direct reporting costs may impact small governmental jurisdictions. The $2,658 reporting cost per release associated with the final rule represents 0.001 percent of average local government revenues serving a population of 50,000 or less, which is well below one percent. Further, for a local government serving just 100 residents, the $2,658 in costs for reporting represents 0.5 percent of these revenues, also well below a one percent threshold.

Details of this analysis are presented in Section 6.2 of the *Regulatory Impact Analysis of the Final Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as CERCLA Hazardous Substances,* available in the docket.

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. The action imposes no enforceable duty on any State, local or Tribal governments that may result in expenditures, in the aggregate, or to the private sector, of $100 million or more in any one 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.

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

This action does not have Tribal implications as specified in Executive Order 13175. 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. Thus, Executive Order 13175 does not apply to this action.

Designating PFOA and PFOS, and their salts and isomers as CERCLA hazardous substances triggers release reporting requirements under EPCRA section 304 in addition to the release notification requirement under CERCLA section 103. Under EPCRA section 304, facilities are required to immediately report any releases of these substances at or above the default RQ of one pound to the State, Tribal, and local implementing agencies. The associated reporting burden of this effort on Tribes is expected to be minimal and if release were to occur, and Tribal agencies would be able to take action, if necessary, to protect their community from exposure to these substances. If Tribal agencies do not have the resources to respond to an emergency situation, they may request assistance from the State or local emergency response agencies. Executive Order 13175 does not apply to this action.

Consistent with EPA's Policy on Consultation with Tribal Nations, EPA offered government-to-government consultation to all federally recognized Tribes during the development of this action. No Tribe requested consultation. EPA hosted a national Tribal informational webinar on September 7, 2022, to explain the action and answer questions (*https://clu-in.org/conf/tio/TribesPFOAPFOS_090722/*.)

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

Executive Order 13045 directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is subject to Executive Order 13045 because it is a significant regulatory action under section 3(f)(1) of Executive Order 12866, and EPA believes that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Evidence indicates that exposure to PFOA and/or PFOS are associated with adverse health effects relevant to children, including developmental effects to fetuses during pregnancy or to breast-fed infants, cardiovascular effects and immune effects in children. Other evidence suggests that these substances are associated with endocrine and reproductive effects that impact development. Both PFOA and PFOS are known to be transmitted to the fetus via the placenta and to the newborn, infant, and child via breast milk. Further information on all health effects of PFOA and PFOS is in section V. A. PFOA and PFOS Pose a Hazard. Accordingly, we have evaluated the environmental health or safety effects of PFAS exposures on children. The protection offered by using the suite of tools CERCLA provides to address prevalent PFAS contamination may be especially important for children because childhood represents a life stage associated with increased susceptibility to PFAS-related health effects, such as developmental effects.

Furthermore, EPA's *Policy on Children's Health* also applies to this action. Information on how the Policy was applied is available under ''Children's Environmental Health'' in section V. A. PFOA and PFOS Pose a Hazard of this preamble.

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

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. This action designates PFOA and PFOS as CERCLA hazardous substances and 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 and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

Executive Order 14096 (88 FR 25,251, Apr. 26, 2023) directs Federal agencies to advance the goal of environmental justice (EJ) for all. This action builds upon and supplements the efforts of Executive Order 12898 (59 FR 7629, February 16, 1994) to address EJ concerns.

EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with EJ concerns. The demographic analysis of plastics manufacturers, facilities reporting to the TRI, and U.S. airports found that people of color and low-income populations are disproportionately represented (except near small/medium airports). In particular, these sites have a higher percentage of people of color surrounding them relative to the national average. This finding holds whether focusing on assessing all populations within one or three miles of these sites or only populations served by private wells.

EPA believes that this action is likely to reduce existing disproportionate and adverse human health or environmental effects on communities with EJ concerns. To the extent that the final rule leads to additional response actions to mitigate or eliminate exposure to PFOA/PFOS, or to actions that mitigate exposure earlier, health risks for populations communities living near sites where releases occur may decline. Based on the above analysis, the proportion of the population near these sites identified as racial or ethnic minorities with various potential communities with EJ concerns or (in some cases) people living in structures with a higher probability of containing lead paint (built before 1960) exceeds the national average. Thus, EPA expects that the final rule will at least partially mitigate the existing burden of PFOS/PFOA exposure that falls disproportionately on communities with EJ concerns.

Potential exposure across several key demographic categories were analyzed relative to facilities with known historical use, releases, and/or known contamination of PFOA and PFOS (U.S. EPA, 2024e). Due to uncertainty regarding the location of future PFOA/PFOS releases, this analysis uses these facilities as a proxy for identifying where response actions for PFOA and PFOS may occur and provides demographic information about the surrounding populations. This analysis examines the following site types as proxies for facilities that may potentially be affected:

- Sites owned/operated by plastics material and resin manufacturing firms identified as having produced PFOS and/or PFOA [76]
- Sites owned/operated by companies reporting PFOS and PFOA releases (including PFOA and PFOS salts) to EPA's Toxic Release Inventory (TRI) (U.S. EPA, 2023e) [77]
- Operating U.S. airports and airfields [78]
  - Large U.S. airports and airfields
  - All other U.S. airports and airfields (*i.e.,* medium and small)

Areas around plastics material and resin manufacturer sites and/or sites reporting releases to TRI, on average, are in areas with higher concentrations of people of color, Black/African American residents, and households with a ratio of income to poverty level of two and below compared with national average. These areas also have much higher rates of structures built before 1960 which can have lead paint and lead to higher exposures of lead. These findings suggest that releases related to manufacturing facilities could have EJ implications, such as disproportionate adverse impacts on local communities. Additionally, on average, airports across the U.S. are surrounded by populations that generally reflect national averages in relevant demographic categories. Large airports, however, are more likely to be surrounded by higher rates of people of color relative to the U.S. population. A complete discussion of the analysis behind these findings is available in Section 6.3 of the RIA 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 policy priorities outlined in Executive Orders 14096 (The White House, 2023) and 14008 (The White House, 2021), EPA expects this regulation will have a beneficial impact on disadvantaged communities as well as populations or communities with EJ concerns. While the locations that may be affected by this final rule are uncertain, to the extent that these proxy locations are representative of likely locations, this screening analysis suggests that the designation may improve conditions for 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 will determine the magnitude of effects on the surrounding human and natural environment. These details will likely become more apparent over time as EPA implements response actions and release reports are made, allowing for a more robust analysis of disproportionate and adverse outcomes experienced by populations communities with EJ concerns. This improved information would not increase risk for communities with EJ concerns and may improve the speed and design of response actions.

Further, the information supporting this Executive Order review is contained in the following sections in the preamble to this action: II.C., VI.A. and B. These sections explain that the

[76] Data acquired from: Environmental Protection Agency, ''Enforcement and Compliance History Online (ECHO)'', August 2023. Because not all plastic material and resin manufacturers use PFAS, only a fraction of the facilities reported in ECHO as plastics material and resin manufacturers were used in this analysis. To filter facilities involved in the use or manufacture of PFAS, this analysis uses proxy sites identified using sites owned/operated by companies that participated in EPA's PFOA Stewardship Program, under the assumption that the likelihood of PFOA/PFOS contamination is potentially high at these sites.

[77] TRI reporting is not currently required for isomers of PFOA and PFOS.

[78] Because the National Plan of Integrated Airport Systems (NPIAS) public facing dataset presented by the Federal Aviation Administration (FAA) does not contain geographic information, this analysis relies on data from the United Nations Office for the Coordination of Humanitarian Affairs. To assess the coverage of the UN database, this analysis cross-referenced the list of airports represented in both datasets; this exercise found that the UN data contained 98% of all airports listed in the NPIAS. Of the 2% of sites listed in the NPIAS but not in the UN database, about half were located in rural Alaska. Full citations of these datasets are presented below:

(1) United Nations Office for the Coordination of Humanitarian Affairs, ''The Humanitarian Data Exchange: Airports in the United States of America'', June 2021. Downloaded on June 18, 2021. Accessed at: *https://data.humdata.org/dataset/ourairports-usa.* The dataset categorized airports by the following size categories: small, medium, and large.

(2) Federal Aviation Administration. ''National Plan of Integrated Airport Systems (NPIAS)—Current—Airports'', October 07, 2020. Downloaded February 2022. Accessed at: *https://www.faa.gov/airports/planning_capacity/npias/current/.*

designation of PFOA and PFOS as hazardous substances 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.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and EPA will submit the rule report to each House of the Congress and to the Comptroller General of the United States. This action meets the criteria set forth in 5 U.S.C. 804(2).

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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 amends 40 CFR part 302 as follows:

PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

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

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

■ 2. Amend § 302.4:

■ a. By revising ''Note II to Table 302.4''.

■ b. In ''Table 302.4'' by adding, in alphabetical order, entries for ''Perfluorooctanesulfonic acid, salts, & structural isomers[v]'', ''Perfluorooctanesulfonic acid[v]'', Perfluorooctanoic acid, salts, & structural isomers[v]'', and ''Perfluorooctanoic acid[v]'';

■ c. In Appendix A to § 302.4 by adding in numerical order entries for ''335–67–1'' and ''1763–23–1''.

The revision and additions read as follows:

§ 302.4 Hazardous substances and reportable quantities.

* * * * *

Note II to Table 302.4

Hazardous substances are given a Statutory Code based on their statutory source. The ''Statutory Code'' column indicates the statutory source for designating each substance as a CERCLA hazardous substance. Statutory Code ''1'' indicates a Clean Water Act (CWA) Hazardous Substance [40 CFR 116.4; 33 U.S.C. 1321(b)(2)(A)]. Statutory Code ''2'' indicates a CWA Toxic Pollutant [40 CFR 401.15, 40 CFR part 423 Appendix A, and/or 40 CFR 131.36; 33 U.S.C. 1317(a)]. Statutory Code ''3'' indicates a CAA HAP [42 U.S.C. 7412(b); Pub. L. 101–549 November 15, 1990; 70 FR 75047 December 19, 2005; 69 FR 69320 November 29, 2004; 61 FR 30816 June 18, 1996; 65 FR 47342 August 2, 2000; 87 FR 393 January 5, 2022]. Statutory Code ''4'' indicates Resource Conservation and Recovery Act (RCRA) Hazardous Wastes [40 CFR part 261 Subpart D—Lists of Hazardous Wastes; 42 U.S.C. 6921]. (Note: The ''RCRA waste No.'' column provides the waste identification numbers assigned by RCRA regulations). Statutory Code ''5'' indicates a hazardous substance designated under section 102(a) of CERCLA. The ''Final RQ [pounds (kg)]'' column provides the reportable quantity for each hazardous substance in pounds and kilograms.

* * * * *

TABLE 302.4—LIST OF HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES

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

[v] The Agency may adjust the statutory RQ for this hazardous substance in a future rulemaking; until then the statutory one-pound RQ applies.

* * * * *

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

CASRN	Hazardous substance
* * * * * * *	
335–67–1	Perfluorooctanoic acid

CASRN	Hazardous substance
* * * * * * *	
1763–23–1	Perfluorooctanesulfonic acid

* * * * *

[FR Doc. 2024–08547 Filed 5–7–24; 8:45 am]

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