Response to Comments

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

February 14, 2024 – Draft

Table of Contents

1.	Gen	eral Comments	
		General Support for the Rule	
		General Disagreement with the Rule	
2.		al Considerations	
	2.A.	Legal Authority	8
		2.A.1 Substantial Danger Standard Articulated by EPA in the NPR	kM8
		2.A.2 Existing CERCLA Authority to Address PFOA/PFOS as Pollor Contaminants	13
		2.A.3 Retroactive Application of the Rule	14
		2.A.4 Authority to Create Exclusions/Exemptions	16
	2.B.	Statutory Interpretation	18
		2.B.1 Consideration of Cost and 102(a)	
		2.B.2 Major Questions Doctrine	19
		2.B.3 Nondelegation Doctrine	19
		2.B.4 Administrative Procedures Act	20
	2.C.	Statutory Authorities Available to Address PFOA/PFOS	22
		2.C.1 CERCLA	
		2.C.2 Other Statutory Authorities	26
3.]	EPA'	s Finding That PFOA And PFOS May Present Substantial Danger	27
		3.A. In Support of EPA's Proposed Finding that PFOA and PFOS M Present a Substantial Danger	
		3.B. Not in Support of EPA's Proposed Finding that PFOA and PFO Present a Substantial Danger	OS May
	3.C.	Miscellaneous	45
		3.C.1 The inclusive definition used for PFOA and PFOS and data or effects and toxicity	
		3.C.2 Differentiating between PFOA, PFOS, and different types of P	FAS46
		3.C.3 Bearing of WHO analysis on designation	46
		3.C.4 Inclusion of salts or structural isomers of PFOA and PFOS	47
		3.C.5 Disparity Between Assessments	48
		3.C.6 National Standards and Limits	51
		3.C.7 Uncertainties regarding cleanup, D&D, standardization of test	ting51
		3.C.8 Site-specific risk assessment	52

1 .	Effe	cts of Designation54
	4.A.	Reporting and Notification Requirements54
		4.A.1 The reportable quantity (RQ) of one pound is appropriate54
		4.A.2 Reportable quantity (RQ) for PFOA and PFOS should be set either higher or lower than 1 pound
		4.A.3. Continuous Release Reporting option54
		4.A.4 The reportable quantity (RQ) should be chemical-specific, not applied to PFAS as a class
		4.A.5 The reportable quantity (RQ) should be applied over a different time period than 24 hours
		4.A.6 The Proposal provides little or no guidance on how PFAS quantities are to be specifically determined or calculated for the purposes of the RQ
		4.A.7 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 threshold62
		4.A.8 EPA should clarify that any NPDES permit violation for PFOA and PFOS would not constitute a "federally permitted release" and must be reported
		4.A.9 The Preamble does not mention how the community notification requirement under CERCLA Section 111(g) will be implemented63
		4.A.10 Exemption from Reporting64
	4.B.	Requirement upon Transfer of Government Property66
		4.B.1 The Proposal would place significant and potentially costly constraints on airport sponsors' ability to manage their property66
		4.B.2 The Proposal does not explain the real value of the federal property disclosure requirement of CERCLA 120(h)67
	4.C.	Requirement of DOT to List and Regulate CERCLA Hazardous Substances
		4.C.1 More clarity is needed relating to the requirements of the Hazardous Materials Transportation Act (HMTA)67
	4.D.	Impacts on National Priorities List (NPL) Sites69
		4.D.1 The designation will result in higher Hazard Ranking System (HRS) scores (enabling the EPA to start cleanup) and strengthen cleanup requirements for existing NPL sites contaminated with PFOA and PFOS.
		4.D.2 The designation will add many sites to the NPL and lead to reopening closed sites, slowing rather than speeding up cleanups and resulting in significant costs. Consequently, there is a significant

			funding gap and insufficient staff and resources that need to be filled	70
	4.E.	Impa	cts on Managing Waste Streams and Identifying Contamination	76
			Cleanup Goals	
		4.E.2	Managing PFOA/PFOS Contaminated Waste	87
	4.F.	Poten	tial Liability and Enforcement	94
			The proposed action is beneficial because it will assign liability to polluters and shift cleanup costs away from communities	
		4.F.2	The EPA has significant enforcement discretion and multiple other tools available to ensure that polluters are held accountable, not innocent parties.	97
		4.F.3	Designation will shift cleanup costs from responsible parties to communities and public utility ratepayers and impose considerable liability on entities in a variety of sectors	99
		4.F.4	Liability can arise without a site being listed on the NPL1	13
		4.F.5	The Agency needs to clarify how enforcement discretion would work, particularly for water utilities1	14
		4.F.6	Enforcement discretion is not sufficient to protect public sectors that do not create PFAS—such as water utilities and municipal landfills—from liability1	16
		4.F.7	The EPA should exempt from liability and reporting requirements various public organizations, including public water utilities, solid waste utilities, local governments, airports, firefighters, landowners affected by offsite sources, agricultural producers; specific activities such as land application of biosolids and paper mill sludge or and specific wastes.	20
	4.G	Impa	cts on Specific Sectors1	
		_	POTW/Water Treatment Sector1	
			Biosolids-Related (including Pulp and Paper)1	
		4.G.3	Airports/Aviation/Transportation/Firefighting Sector1	51
		4.G.4	Agriculture Sector (Excluding Biosolids and Pulp and Paper)1	66
		4.G.5	Other Sectors1	69
		4.G.6	State, Tribal, and Local Governments1	75
5.	Stati	us of E	PA, Federal, State, and International Actions1	80
	5.A	Other	Actions Being Taken by EPA1	80
		5.A.1	Support for EPA to address PFAS under the Roadmap and need for EPA program offices to work together1	80

		5.A.2 The PFOA/PFOS hazardous substance designation does not confer a hazardous waste designation under RCRA	181
		5.A.3 Agreement with EPA's source control measures under TSCA	182
		5.A.4 The CERCLA designation must consider the impact of the Office of Water's SDWA proposal	183
		5.A.5 The proposed rule impact on the Leaking Underground Storage Tank (LUST) Trust Fund	183
		5.A.6 The rule could jeopardize No Further Action designations under the Risk Based Corrective Action (RBCA) and trigger PFOA and PFOS to become subject to ASTM Due Diligence site assessment standards	184
	5.B	Actions Being Taken by Other Federal Agencies	184
		5.B.1 Commenters pointed to pre-existing federal actions and a necessary cradle to grave and fate and transport regulatory approach	
		5.B.2 The Department of Defense must be held accountable under the CERCLA designation.	185
	5. C	Actions Being Taken by States or Municipalities	
		5.C.1 States and municipalities have already taken a number of actions to address PFOA and PFOS, and the Agency should coordinate with them	
6.	COS	ST AND ECONOMIC ASSESSMENT	
•		General Comments Associated with the Economic Analysis	
		6.A.1 EPA's economic assessment with the proposed rule was insufficient, the EPA must prepare and publicly report a full economic and regulatory impact analysis that meets the requirements of EO 12866 and 13563 and Circular A-4	
		6.A.2 EPA needs to consider the actual costs associated with the Proposed Rule	196
		6.A.3 EPA should conduct a Regulatory Impact Analysis (RIA) that considers the impact on landfill operation, drinking water and wastewater utilities, and cost to the public. EPA needs to ensure that the "polluter pays" principal will not be replaced with the "public pays" principal.	208
		6.A.4 EPA must consider the impacts of the rule on local governments (e.g., public works operations).	215
		6.A.5 Economic analysis fails to take into account agency actions related to environmental justice and disproportionally impacted communities	217
		6.A.6 Economic Analysis fails to consider remediation costs, and, in the absence of standards, requirements, and criteria, EPA should	

	to municipalities to m	219
	6.A.7 EPA should follow the proper procedures as outlined in the Administrative Procedure Act, including the Federalism Consultation process.	221
	6.A.8 The EPA should use publicly available information to estimate the number reportable releases and associated costs	222
	6.A.9 The EPA's economic assessment for this rule should focus on the potential direct costs associated with this designation	223
	6.A.10 The EPA has not identified a compelling public need for the proposed action.	224
6.B	Direct Costs	226
	6.B.1 EPA's hazardous substance designation will create minimal direct costs.	226
	6.B.2 EPA's claim that the Proposal will have only limited direct economic impact is not consistent with OMB's designation	228
	6.B.3 The EPA should revise the Proposed Rule to clarify reporting obligations and direct costs to be incurred by regulated entities, including drinking water and wastewater utilities.	229
	6.B.4 The EPA should conduct a more thorough evaluation of the potential impacts of the proposed designation on transportation of PFOA and PFOS, including the requirement for DOT to list PFOA and PFOS under HMTA.	230
	6.B.5 The EPA should consider additional direct and indirect costs not previously considered in the EA.	231
	6.B.6 The proposal should reference CERCLA Section 120(h) requiring notification of contamination upon property transfer	233
	6.B.7 EPA should conduct a more detailed evaluation of the costs associated with RQ compliance.	233
	6.B.8 The Proposal may increase direct costs for fire departments	234
6.C	Indirect Costs	235
	6.C.1 The indirect costs of the Proposal are ignored but potential indirect benefits are promoted.	235
	6.C.2 There is a need for planning for funding cleanup and liability	237
	6.C.3 The Economic Assessment does not provide any quantitative assessment of anticipated indirect costs, particularly those related to increased litigation and site assessment and remediation	238
	6.C.4 Ecological and surface water restoration costs should be considered, and benefits and costs should be incorporated into the designation decision by incorporating a risk-based approach to clean-up	240

	municipalities, public utilities, small entities, and special districts	243
	6.C.6 The EPA fails to consider the costs and adverse economic impacts to airports related to the proposed designation. In particular, EPA's proposed rule would impact ongoing airport infrastructure development and delay safety-critical projects.	252
	6.C.7 The EPA needs to consider indirect costs to local fire departments as the Proposal may increase these.	260
	6.C.8 The EPA's Rulemaking will have significant implications and liabilities for businesses, consumers, and governments	264
	6.C.9 The EPA needs to address and prepare for cost implications for state programs.	269
6.D	Direct and Indirect Benefits	270
	6.D.1 The designation of PFOA and PFOA as hazardous substances will accelerate the cleanup of contaminated sites	270
	6.D.2 The hazardous substance designation will provide public benefits and cost savings.	271
	6.D.3 It is premature to comment on R&D-related benefits	271
	6.D.4 The proposal makes the unsupported assertion that the designation will encourage better management of chemicals and will produce public health benefits but does not explain those benefits	272
	6.D.5 The Proposed Rule will not have the benefits that the EPA claims	
6.E	Uncertainties Regarding Indirect Impacts on Response Activities	277
	6.E.1 Information and comment exist that may allow EPA to estimate incremental costs associated with this rule	277
	6.E.2 Commenters noted uncertainties regarding the potential sites affected by the proposed rule.	278
	6.E.3 Commenters noted significant uncertainties regarding the development of standards and technologies for the cleanup, handling, and disposal and/or destruction of PFOA and PFOS	283
	6.E.4 Commenters disagree with EPA's proposition that the uncertainties are too great to conduct a robust analysis.	286
	6.E.5 EPA needs to not only account for benefits of the proposed rule but also must account for impacts in addition to reporting.	289

7.	Statutory and Executive Order Review		292
	7.A	Executive Order 12866: Regulatory Planning and Review	292
	7.B	Regulatory Flexibility Act	294
	7. C	Unfunded Mandates Reform Act	297
	7.D	Executive Order 13132: Federalism Analysis	298
	7. E	Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use	299
	7. F	Executive Order 12898: Impacts on Minority and Low-Income Populations	299
8.	Miscellaneous Comments		303
	8.A	Need for Stakeholder Engagement	303
	8.B	Regulate PFAS as a Class	304
	8. C	Need for Advances in Science and Technology and More Research	305
	8.D	Call for Source Control	307
	8.E	Extension of Comments Period	309

1. General Comments

1.A. General Support for the Rule

Many commenters expressed support for the proposed designation because they believe it will provide significant public health, environmental, and economic benefits nationwide by reducing exposure to PFOA and PFOS. Numerous commenters encouraged EPA to promptly finalize the rule. Multiple commenters pointed to the proposed designation as the first step in holding polluters accountable and in both cleaning up existing contamination and discouraging future contamination. Several commenters detailed the negative impacts of PFOA and PFOS on subsistence fishers, tribes, recreational fishers, and farmers. Another commenter underscored the significance of cleanup to the redevelopment and reuse of contaminated properties. Some commenters cited specific corporations that they argued must be held accountable for PFOA and PFOS contamination.

Other commenters stressed that exposure to PFAS is particularly jeopardizing the health of communities of color and low-income communities. Several commenters noted their concerns regarding the extent of PFOA and PFOS-related contamination of groundwater and tap water across the United States. A few commenters stated that the proposed designation could help communities combat the health hazards associated with exposure to PFOA and PFOS. Several commenters discussed the disease burden resulting from PFAS exposure and subsequent costs, which they estimated to range from \$5.52 billion up to \$62.6 billion. Some commenters addressed how occupational exposure—e.g., firefighting—can increase exposure to PFAS relative to the general population.

A number of commenters stated that the proposed designation will support the ability of states to address PFOA/PFOS contamination. One commenter expressed support for the proposed designation which it regarded as essential to the ability of certain parties to pursue natural resource damage claims under CERCLA. Another commenter argued that the designation of PFOA and PFOS as hazardous substances will free up federal funds for affected communities and cleanup/remediation efforts of other hazardous substances. One commenter specifically noted that the proposed designation will help address PFAS contamination in Kansas because it will incentivize responsible parties' investigating and remediating PFAS to cooperate with the state's environmental enforcement efforts. One commenter encouraged EPA to issue new guidance to state permitting authorities to address PFAS in National Pollutant Discharge Elimination System (NPDES) permits.

A few commenters specifically addressed how the designation would impact U.S. Department of Defense (DoD) facilities located near their communities. Some commenters identified what they described as "unusual" clusters of serious health effects in communities with heavily PFAS-contaminated water located near DoD facilities. One commenter noted that at least 10 current or former military installations in Massachusetts have contributed significant PFAS contamination to drinking water supplies. Another commenter claimed that the cleanup of military installations contaminated with PFAS has been delayed by the DoD. Several commenters argued that the designation will help promote cleanup sites currently or formerly owned or operated by DOD that have are known or are suspected to be contaminated by PFAS.

Several commenters asserted that technologies to address PFOA and PFOS contamination are too expensive. Other commenters were concerned that several consumer products (i.e., carpets, cookware, food packaging) continue to contain PFOA and PFOS. One commenter stated that with the designation, PFOA and PFOS will need to be addressed to complete an American Society for Testing and Materials (ASTM) compliant Phase I Environmental Site Assessment (ESA). A few commenters also shared their concerns about other "forever chemicals" and expressed the opinion that the proposed designation could set the precedent for future designations of other "forever chemicals."

Response

EPA agrees with the commenters that the designation will substantially benefit both the public and the environment. The Agency believes that the designation will allow it to deploy the full suite of CERCLA tools necessary to identify, characterize, and clean up the most contaminated sites expeditiously. The designation will also allow EPA to ensure that those parties responsible for significant 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. The Agency also believes that this action is likely to reduce existing disproportionate and adverse effects on people of color, low-income populations, and/or indigenous communities with EJ concerns. EPA also agrees that cleaning up sites also promotes economic benefits, such as improved property values and making land available for reuse. See the Preamble to the Final Rule Sections VI.A. (Advantages of Designation) and VI.A.2.d. (Environmental Justice (EJ) Considerations for Designation).

EPA also agrees with commenters that designation will allow EPA to hold accountable those polluters accountable for contamination they caused. Designation serves CERCLA's express purpose of ensuring that the "Polluter Pays" for cleanup. *See* the Preamble to the Final Rule Section I.A. (*Executive Summary*) and *infra* RTC 4.F.

EPA 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. The Agency also discussed some of the hazards associated with occupational exposure to PFOA and PFOS in the final designation. See the Preamble to the Final Rule Sections V.A. (PFOA and PFOS Pose a Hazard) and VI.A.2.c. (Cost Estimates of Burden of PFAS-Related Disease).

The Agency agrees that designation may be supportive of complementary state efforts. For example, CERCLA and EPCRA 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 agrees that this designation will lead to more total resources available for cleanups. See the Preamble to the Final Rule Section VI.A.1.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).

Comments regarding the impact of the proposed designation on specific cleanup activities, such as comments pertaining to activities occurring in Kansas, are outside the scope of this rulemaking and require no response.

EPA agrees the designation may promote the restoration of natural resources and makes available CERCLA authorities to recover natural resource damages (NRD) and NRD assessment costs. 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. *See* CERCLA section 107(a)(4)(A)-(D).

EPA will continue to consider the need for additional guidance concerning PFAS and NPDES permits. On December 5, 2022, EPA updated its memorandum, *Addressing PFAS Discharges in National Pollutant Discharge Elimination System Permits and Through the Pretreatment Program and Monitoring Programs*, to provide guidance to states for addressing PFAS discharges when they are authorized to administer the NPDES permitting program and/or pretreatment program. Additional information is also available on EPA's website at https://www.epa.gov/cwa-methods/frequent-questions-about-pfas-methods-npdes-permits. *See also* the Preamble to the Final Rule Section VII.D.1.h.

The commenters' concerns regarding the DoD are outside the scope of this rulemaking and no response is required.

EPA recognizes that the science on treating, destroying, and disposing of PFAS continues to evolve. *See* response to comment ("RTC") in Section 4.E.1-5. The Agency also acknowledges that 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. *See Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances*, 87 Fed. Reg. 54415, 54417 (proposed Sept. 6, 2022) (providing a brief history of PFOA and PFOS production and use). EPA is pursuing a comprehensive approach to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment. For further discussion of this effort, see the PFAS Strategic Roadmap, available online at the Agency's website at: https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.

The Agency agrees that for a Phase I ESA to be All Appropriate Inquiries Rule-compliant, due diligence requires screening for CERCLA hazardous substances. *See* RTC 4.G.5.

The commenters' concerns regarding the potential regulation of other so-called "forever chemicals" are outside the scope of this rulemaking and require no response.

1.B. General Disagreement with the Rule

Many commenters expressed opposition to the proposed designation and/or stated that the proposed designation is unnecessary. Multiple commenters argued that EPA failed to issue a full Regulatory Impact Analysis (RIA) and therefore had not properly assessed the economic, legal, operational, and practical consequences of the proposed designation. One commenter stated that the proposed designation violated the Administrative Procedure Act (APA) because EPA failed to consider the economic costs imposed by the rule and weigh those costs against the theoretical

benefits. Another commenter challenged EPA's conclusion that that the proposed designation will result in increased transparency about releases of PFOA and PFOS. Specifically, the commenter claimed that the Agency overestimated the number of releases that are likely to occur. Several commenters claimed that the production of PFOA and PFOS is being phased out, thus questioning the value of the proposed designation.

One commenter claimed that—given the ubiquitous nature of PFOA and PFOS—the proposed designation would result in a "regulatory burden" upon consumers, manufacturers, product distributors, waste management and water treatment facilities. Other commenters urged EPA to utilize other statutory authorities to address the risks posed by PFOA and PFOS contamination. Similarly, several commenters urged EPA not to proceed with the designation prior to examining all other available regulatory options.

Some commenters specifically expressed concerns regarding the impact of the proposed designation on businesses, landowners, and water utilities considering the broad scope of CERCLA's cost recovery and strict liability scheme. Additionally, several commenters asserted that the proposed designation could potentially result in utilities assuming responsibility for the cost of cleaning up PFAS-related contamination that public water and wastewater agencies did not produce. These commenters opposed moving forward with the proposed designation without an EPA-created exclusion from liability.

One commenter argued that the proposed designation relied on a flawed and skewed analysis of relevant science and failed to properly establish and follow criteria for designation under CERCLA section 102. Here, the commenter stated that EPA selectively focused on questionable endpoints and studies, while the Agency dismissed credible, relevant studies which would result in the conclusion that PFOA and PFOS do not present a substantial danger to the public health, welfare, or the environment that warrants the proposed designation. Regarding criteria, the commenter stated that EPA did not establish how it would assign weight to the various criteria introduced or how it would determine whether the criteria was against or in favor of a hazardous substance designation. The commenter underscored how the criteria differed drastically from similar listing determinations made by EPA under other environmental statutes and claimed that the criteria used by the Agency to assess a substance's relative substantial danger are vague. Another commenter also opposed the proposed designation due to the need to complete risk assessments to ground future regulatory actions in sound science.

A few commenters argued that EPA should not proceed with the designation in the absence of specific guidelines and standards for cleanup and established treatment and disposal methods.

Response

EPA disagrees with the commenters' conclusion that the proposed designation is not appropriate, lacks a sound factual and scientific basis, or is otherwise unnecessary. Today's designation of PFOA and PFOS as CERCLA hazardous substances is legally, factually, and scientifically supported. See the Preamble to the Final Rule Sections IV. (Legal Authority), V. (PFOA and PFOS may present a substantial danger to the public health or welfare or the environment when released into the environment) and VI. (The totality of the circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted).

EPA disagrees with the claims that it relied on flawed data and that the Agency selectively focused on certain scientific information to support the designation. EPA confirmed its finding

that exposure to PFOA and PFOS may pose a substantial danger after evaluating the available scientific and technical information as well as public comments. See the Preamble to the Final Rule Section V. (PFOA and PFOS may present a substantial danger to the public health or welfare or the environment when released into the environment) and infra RTC 3.B. The Agency further disagrees both with the contention that the criteria it considered in the proposed rule were vague or undefined or inconsistent with other statutory methodologies historically used to identify CERCLA hazardous substances. See the Preamble to the Final Rule Section IV.B. (Consistency with other methodologies for identifying CERCLA hazardous substances); and infra RTC 2.A.1-2 and 2.A.1-3.

EPA also disagrees with the commenters' position that the Agency failed to properly assess at proposal the direct and indirect impacts, including costs and benefits, of the designation. *See infra* RTC 6.A-5. Further, the Agency disagrees with the commenter's assertion that designation will not result in increased transparency regarding release of PFOA and PFOS. Notification requirements that result from designation will better inform state, federal, and tribal decisionmakers about releases of these substances in the environment and allow for a more timely response if necessary. For further discussion of the EPA's estimation of the upper bound of reporting regarding PFOA and PFOS releases, *see infra* RTC 6.A-9. EPA also 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. *See* the Preamble to the Final Rule Sections I. (*Executive Summary*), VI. (*Totality of the Circumstances Analysis*) and VII.G. (*Phase-out & PFOA Stewardship Program*).

EPA disagrees that the proposed designation will create a regulatory burden on consumers, manufacturers, product distributors, waste management and water treatment facilities. Designation does not require facilities to take any specific response actions, such as sampling, treatment, or disposal. CERCLA is not a traditional "command and control" statute that prospectively limits pollution. Instead, CERCLA is a remedial statute. It addresses contamination already released into the environment on a site-specific basis to ensure that communities and ecosystems do not face unacceptable levels of risk. Designation does not require any response action by a private party and does not determine liability for hazardous substance release response costs. Response actions are contingent, discretionary, and site-specific decisions made after a hazardous substance release or threatened release. They are contingent upon a series of separate discretionary actions and meeting certain statutory and regulatory requirements. Cost considerations (such as those associated with sampling, treatment, or disposal) are evaluated on a site-specific basis.

The only direct requirements for private entities that result from designation are certain reporting and notification requirements, as described in the Preamble to the Final Rule Section VIII.B. (Direct Effects of Designating PFOA, PFOS, and their Salts and Structural Isomers as Hazardous Substances). See also the Preamble to the Final Rule Section VII.D.1.a-c. (Reporting and Notification Requirements) for further detail regarding the associated reporting and notification impacts of the designation.

EPA also disagrees with the commenters' suggestions to utilize other statutory authorities or to further evaluate other regulatory options to address the risks posed by PFOA and PFOS. EPA considered which of EPA's statutory authorities could most effectively address highly

contaminated sites and concluded that CERCLA is best suited to address the problem posed by legacy PFOA and PFOS contamination. For further explanation of how EPA is evaluating the use of its various statutory authorities to address the hazards posed by PFOA and PFOS contamination, see the Preamble to the Final Rule Sections III.C. (EPA's PFAS Strategic Roadmap) and VI. (Totality of the Circumstances Analysis); see also infra RTC 2.C.1-2.

The Agency recognizes that certain stakeholders are concerned about CERCLA liability resulting from the designation of PFOA and PFOS as hazardous substances. 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 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. CERCLA is also designed to ensure that highly contaminated sites are prioritized relative to other sites. The site-specific and discretionary nature of CERCLA safeguards against cleanups that are not necessary to protect human health and the environment and safeguards against excessive liability outcomes.

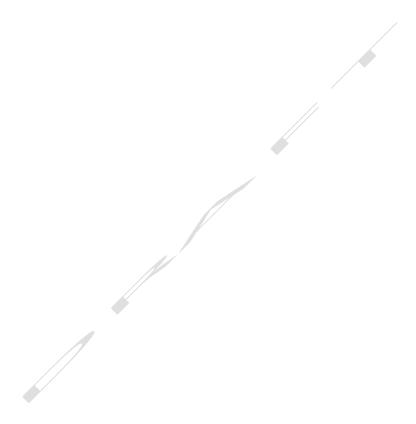
EPA is focused on holding responsible those who have manufactured and released significant amounts of PFOA and PFOS into the environment. As EPA states in the FY 2024-2027 National Enforcement and Compliance Initiates (NECI), the Agency expects to "focus on implementing EPA's PFAS Strategic Roadmap and holding responsible those who significantly contribute to the release of PFAS into the environment" The NECI also clarifies that "OECA 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 OECA exercises CERCLA enforcement discretion in other areas."

As explained in the Preamble to the Final Rule Section VI.B.2. (*Potential hardship for parties that did not contribute significantly to contamination*), EPA expects CERCLA to continue to function normally after the designation of PFOA and PFOS as it has for over forty years for the over 800 hazardous substances already designated under CERCLA.

Designation does not alter CERCLA's liability framework. Designation does not expand the definition of "potentially responsible parties," nor does it amend, change, or curtail existing statutory limitations on liability. Liability determinations are site-specific, and designation does not determine liability. EPA expects to continue to operate as it has for decades to equitably resolve who should pay. See the Preamble to the Final Rule Sections VI.B.2. (Potential hardship for parties that did not contribute significantly to contamination), and VII.J. (Summary of the Public Comments and Responses – Enforcement), VII.I.1. (Liability and Costs to Public Utilities) and infra RTC 4.F and 4.G. The Agency also declines to create exceptions for certain uses of PFOA and/or PFOS in this rulemaking. See RTC 2.A.4. and the Preamble to the Final Rule Section VII.B.1. (Authority to Create Exclusions from the Designation).

The Agency disagrees with the commenter's stance that EPA should not proceed with the designation in the purported absence of specific guidelines and standards for cleanup and established treatment and disposal methods. Although 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. *See* the Preamble to the Final Rule Section

VII.B.1. (Comments suggesting that other authorities are better suited to address PFAS contamination) and RTC 2.C.1.and 4.E.1-5.



2. Legal Considerations

2.A. Legal Authority

2.A.1 Substantial Danger Standard Articulated by EPA in the NPRM Support

A number of commenters stated that EPA has met the criteria for designating PFOA/PFOS, including their salts and structural isomers, as hazardous substances under CERCLA section 102(a). These commenters stated that PFOA and PFOS are toxic, causing a range of serious adverse effects including developmental and reproductive toxicity, liver toxicity, cancer, and other adverse health effects. Additionally, the commenters explained that these chemicals warrant designation as CERCLA hazardous substances given the long time they remain in humans, their well-documented persistence and mobility in the environment, their widespread contamination of environmental media, and their impact on welfare—from drinking water contamination to the contamination of farmland. [0810/EDF, 0414/Attorneys General, 0519/WV Rivers, 0458/Earthjustice, 0823-Katusha, 0784/Citizen, 0552/EWG, 0365/EPN]

Some commenters also agreed with EPA's proposed interpretation that the "may present" statutory language in CERCLA section 102(a) indicates Congress did not require certainty that a substance presents a substantial danger or require proof of actual harm for designation. One commenter explained that a plain meaning analysis of section 102(a) shows that EPA merely needs to provide evidence to indicate a possibility or probability of substantial danger based on scientific risk assessments; neither certainty of danger nor proof of actual harm, however, is required for designation. This commenter further stated that this conclusion is supported by case law on the degree of certainty required for protective actions based on endangerment findings of comparable provisions of other environmental statutes. [0552/EWG, 0365/EPN, 0572-Citizen, 0458/Earthjustice, 0494/S.O.H2O]

- First, the commenter pointed to judicial decisions applying the endangerment standard of Section 107 of the Resource Conservation and Recovery Act (RCRA) to show that "may" denotes the potential for harm—not the certainty of harm. [0494/S.O.H2O]
- Second, the commenter noted that when Congress overhauled the Toxic Substances Control Act (TSCA) in 2016, it expanded EPA's authority to act when a chemical substance "may present an unreasonable risk to human health or the environment." The commenter also noted that courts have found the "may present" language in TSCA "empowers the EPA to act at a lower threshold of certainty than that required for regulation." *Chemical Mfrs. Ass'n v. U.S. EPA*, 859 F.2d 977, 985 (D.C. Cir. 1988). [0552/EWG]
- Finally, the commenter noted that statutory requirements in other sections of CERCLA use the same language as section 102(a), including CERCLA section 104, which authorizes a federal response action "whenever there is a release or substantial threat of release into the environment of any pollutant or contaminant which may present an imminent and substantial danger to the public health or welfare," and CERCLA section 106, which allows the federal government to seek judicial enforcement when "there may be an imminent and substantial endangerment to public health or welfare or to the

environment because of an actual or threatened release of a hazardous substance from a facility." The commenter explained that these sections have never required certainty that a substance presents a substantial danger and concluded that CERCLA section 102(a) should be interpreted similarly. [0365/EPN]

Response

EPA agrees with the commenters that the scientific and technical data relied upon in finding that PFOA and PFOS "may present substantial danger" is sufficient to designate these substances, and their salts and isomers, as hazardous substances under CERCLA section 102(a). See the Preamble to the Final Rule Section V (PFOA and PFOS may present a substantial danger to the public health or welfare or the environment, when released into the environment) and infra RTC 3.A. EPA agrees with the commenters that "may present" does not require certainty, consistent with the plain meaning of "may" and case law. The Agency 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. See the Preamble to the Final Rule Sections IV.A. (CERCLA section 102(a) Designation Considerations), VII.A.2. (Interpretation of the phrase "may present substantial danger").

Oppose

Multiple commenters argued that EPA's standard for evaluating whether a substance poses a "substantial danger" under CERCLA section 102(a) is not well defined and that the Agency's criteria for evaluating PFOS and PFOA are too vague. These commenters argued that EPA failed to explain what characteristics a substance must exhibit to meet the Agency's criteria for evaluating substantial danger, did not establish methods to evaluate whether a substance exhibits those characteristics, has not explained why it chose the criteria it selected, and has not coherently applied the criteria to PFOA and PFOS to determine whether the criteria are fulfilled. [0419-API et al.; 0543-AWWA; 0345-3M Company; 0569-U.S. Chamber of Commerce et al]

Several commenters argued that the proposed designation failed to identify the threshold for the level of evidence required to designate a substance as hazardous under CERCLA section 102(a). One commenter noted that rather than articulating precise criteria for listing PFOA and PFOS under CERCLA section 102(a), EPA proposed to consider a set of general information about the substances (i.e., hazard, fate and transfer) and weigh this information to determine whether the substances may present a "substantial danger." The commenter asserted that EPA's interpretation provided little guidance on when this general information rises to the level that a particular substance can be determined to present a substantial danger. The commenter also claimed that EPA provided no specific criteria that would allow the Agency to make consistent and non-arbitrary decisions in its use of the CERCLA section 102(a) authority going forward, and the Agency has interpreted its authority as to allow it to designate almost any substance without criteria or scientific support. [0543-AWWA, 0421-ACC, 0569-A1 U.S. Chamber of Commerce et al, 0242-API and AFPM]

Another commenter noted that the proposed designation references a number of studies on PFOA and PFOS to support the Agency's finding that PFOA and PFOS may present a significant danger. The commenter, however, claimed that EPA has not defined what level of evidence is needed to support its finding. The commenter argued that if EPA intends to provide the public with a meaningful opportunity to comment on the proposed designation, then the

Agency must clearly document the threshold for the level of evidence necessary to substantiate a substantial danger finding. [0543-AWWA]

One commenter stated that EPA failed to apply its proposed criteria to PFOS and PFOA in the proposed designation and instead discusses "chemical/physical characteristics," "toxicity and toxicokinetics," and "environmental prevalence" as the evidence for designation of PFOA and PFOS as hazardous substances. The commenter claimed that EPA made no effort to explain the link between the information it considered and the criteria it proposed to guide its decision. [0345-3M Company, 0421-ACC, 0522-WMC, 0391/SSP, 0543-AWWA, 0551/CCIG, 0569- U.S. Chamber of Commerce et al.]

Multiple commenters stated that vague criteria for evaluating a substance's substantial danger under CERCLA section 102(a) could result in the designation of a wide range of compounds. One commenter argued that under EPA's standard, the mere presence of a substance in the environment for an extended period constitutes "substantial danger" and stated that if EPA were allowed to set such a precedent, the Agency could theoretically list hundreds of other substances under CERCLA section 102(a). Another commenter opined that without considering costs and the likelihood of exposure to levels that have health effects, EPA's proposed designation lays out a path forward that could support a wide range of substances, including substances such as sodium, under CERCLA. Similarly, one commenter claimed that under EPA's proposed parameters, the Agency could choose to designate any substance it wants, and its rationale could be used to expand the list of hazardous substances without adequate justification and scientific support. Another commenter noted that the vague and broad nature of EPA's rationale would allow EPA to list a wide range of chemicals, including many persistent and bioaccumulative substances, as hazardous substances, even though many of these same substances would never meet a reasonable definition of substantial danger. [0569-US Chamber of Commerce Coalition, 0543-AWWA, 0391/SSP, 0569-U.S. Chamber of Commerce et al]

One commenter noted that the proposed designation has the potential to open and reopen numerous Superfund sites based on the presence of PFOA and PFOS on site. Since EPA can use its authority under CERCLA to compel site cleanup (or cost recovery for site cleanup), the commenter argued that EPA must explain why PFOA and PFOS may present a substantial danger to public health and the environment from contaminated sites. The commenter, however, argued that EPA cannot demonstrate that PFOA and PFOS may present a substantial danger if it cannot quantify how many sites are contaminated with PFOA and PFOS, the extent to which those substances are present, which sites will require cleanup, and how much human or environmental exposure there is to these substances from these sites. [0569-U.S. Chamber of Commerce et al]

A commenter noted that stakeholders currently have a level of predictability because the current hazardous substance definition under CERCLA incorporates lists of chemicals from other statutes that either adopt lists designated by statute or have more specific criteria for the types of hazards or risk that is contemplated. This commenter posited that EPA must provide a similar level of predictability for future designations of hazardous substances by clearly defining the criteria in CERCLA section 102(a), recognizing where it differs from the other statutory mechanisms that are imported by CERCLA. Several commenters noted that EPA makes determinations about the potential risks of certain substances under a number of environmental statutes—RCRA, the CWA, TSCA, and the CAA—all of which can trigger hazardous substance designations under CERCLA. One commenter recommended that EPA develop a similar

approach for the proposed designation and propose criteria specific to CERCLA section 102(a) that will be used for the proposed designation and any future hazardous substance designations. Another commenter noted that the Agency has indicated that it has yet to evaluate the existing data for PFOA or PFOS or establish a record to support a proposal to identify them as hazardous constituents under RCRA. [0569-U.S. Chamber of Commerce et al]

Several commenters noted that no substance has previously been listed under the designation process provided in CERCLA section 102(a) and therefore extensive analysis by stakeholders is required to accurately assess the potential impacts of the proposed designation, including an estimation of indirect costs that were not measured in the proposed rule as well as a review of a regulatory impact analysis and risk assessment information. [0543-AWWA, 0421-ACC, 0569-A1 U.S. Chamber of Commerce et al, 0242-API and AFPM]

A few commenters recommended that EPA promulgate regulations setting forth a clear standard for designating a substance a CERCLA hazardous substance and then, if PFOA and/or PFOS meet that standard, propose designation of those substances. The commenters argued that this standard should be set forth in regulation subject to notice and comment and should consider cost. One commenter further noted that separately promulgating a standard would be appropriate on policy grounds as well as consistent with the goal of administrative law to ensure treatment in accordance with the law, providing all stakeholders a reasonable opportunity to comment on the standard before it is applied to a specific substance. [0391/SSP] [0345-3M Company]

Another commenter claimed that EPA's interpretation of its authority under CERCLA section 102(a) authority varies significantly from the interpretation articulated in a draft Advanced Notice of Proposed Rulemaking issued in January 2021. The commentor further noted the 2021 ANPRM indicated a deep analysis was required to support a hazardous substance designation. While the draft 2021 ANPRM did not include the necessary detailed criteria, the commenter claimed it elaborated on the statutory language in a way that offered some guidance and consistency in how the EPA would make decisions under CERCLA section 102(a). The commenter then claimed that EPA's interpretation of its authority in the proposed designation provides no such guidance and will lead to inconsistent and unsupported use of the Agency's authority under CERCLA section 102(a). [0419-The American Petroleum Institute (API), et al.]

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. See the Preamble to the Final Rule Section VII.A.2. (Interpretation of the phrase "may present substantial danger"). Relatedly, while several commenters argue that EPA's test for substantial danger opens the door to designation of almost any benign or ubiquitous substance, this claim misapprehends the standard adopted by the Agency and the level of evidence supporting this rulemaking. See the Preamble to the Final Rule Sections IV. (Legal Authority), V. (PFOA and PFOS may present a substantial danger to the public health or welfare or the environment when released into the environment) and VI. (PFOA and PFOS may present a substantial danger to the public health or welfare or the environment when released into the environment); see also infra RTC 3.A.

EPA also disagrees with the commenters position that the proposed designation failed to provide sufficient detail regarding its interpretation of CERCLA section 102(a) and what criteria EPA

considered in evaluating the substantial danger posed by PFOA and PFOS. The proposed designation provided sufficient information concerning the basis for EPA's conclusion that PFOA and PFOS may present a substantial danger when released for the public to meaningfully comment. EPA has responded to comments concerning our evaluation and concluded that its approach is reasonable given the statutory context of CERCLA section 102(a) and the consistency of the Agency's analysis with other statutory methodologies historically used to identify CERCLA hazardous substances.

EPA also disagrees with the commenter's position that CERCLA section 102(a) requires the Agency to promulgate a standard for designating hazardous substances in advance of this rulemaking. 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). Further, EPA reaffirms its conclusion that PFOA and PFOS may present a substantial danger to public health and the environment is clearly supported by the weight of scientific evidence, and it notes that the factors it considered in the context of CERCLA section 102(a)—hazard, and fate and transport—are historically consistent with other statutory methodologies used to identify CERCLA hazardous substances. For further discussion of these issues, see the Preamble to the Final Rule Sections IV.B. (Consistency with other methodologies for identifying CERCLA hazardous substances), V. (PFOA and PFOS may present a substantial danger to the public health or welfare or the environment, when released into the environment), and VII.A.2. (Interpretation of the phrase "may present substantial danger"); see also infra RTC 3.A.

The Agency disagrees with the commenter's claim that it lacked a meaningful opportunity to comment on the proposed designation. The 60-day comment period provided an ample opportunity for interested parties to submit more than 60,000 comments offering a broad array of perspectives on the Agency's action and the number and comprehensiveness of the comments received disprove commenters' claim that the comment period was insufficient. After reviewing the comments and the requests for additional time, EPA does not believe that extending the comment period is or was necessary for the public to receive sufficient notice of, and opportunity to comment on, the proposed designation.

The Agency's actions with respect to regulation of PFOA and PFOS under RCRA are outside the scope of this rulemaking, and no response is required.

EPA disagrees that EPA did not adequately consider indirect costs or other cost information included in the proposed economic assessment. See infra RTC 6.A and the Preamble to the Final Rule Sections VI. (The totality of the circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted) and VII.I. (Comments on Economic Assessment/Regulatory Impact Analysis).

EPA also disagrees that EPA must conduct risk assessments and evaluate those assessments prior to designating PFOA and PFOS. CERCLA is designed to assess risk on a site-specific basis. CERCLA, the NCP, and related guidance provide the framework for evaluating risk for specific releases and allow for EPA to take a response action as necessary. *See infra* RTC 4.F.3. for more information regarding CERCLA's parameters for evaluating risk; *see also* the Preamble to the Final Rule Section II.E. (*What are CERCLA's primary objectives, and how does it operate to protect human health and the environment?*).

The Agency also disagrees that CERCLA section 102(a) requires that a release of a substance in fact presents a substantial danger in any given location it is found. See the Preamble to the Final Rule Section IV.A.2. (CERCLA section 102(a) Designation Considerations), and VII.A.2. (Interpretation of the phrase "may present substantial danger").

EPA disagrees with the commenters' stance that its interpretation of "substantial danger" is inconsistent with its past interpretation of this phrase or EPA's interpretation of similar phrases. See the Preamble to the Final Rule Section VII.A.2. (Interpretation of the phrase "may present substantial danger").

For further information regarding EPA's reasoning on the above issues, see the Preamble to the Final Rule Sections IV. (*Legal Authority*), VI. (*Totality of the Circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted*), VIII. (*Summary of this Final Rule*), VII.A.2. (*Interpretation of the phrase "may present substantial danger"*), and VII.C.1. (*Data Supporting Designation*).

For comments regarding reopening Superfund sites based on the presence of PFOA and PFOS, see RTC 4.D.2.

2.A.2 Existing CERCLA Authority to Address PFOA/PFOS as Pollutants or Contaminants

One commenter argued that PFOA and PFOS should be designated as pollutants or contaminants under CERCLA section 101(33) before they are designated as hazardous substances under CERCLA section 102(a). Specifically, the commenter claimed that CERCLA establishes a hierarchy of substances, with the pinnacle representing a substantial danger posed by releases or threatened releases of hazardous substances. The commenter then argued that CERCLA's structure reveals that a hazardous substance must present more of a danger than CERCLA pollutants or contaminants. Next, the commenter claimed that EPA's justification for the proposed designation declares PFOA and PFOS to be pollutants and contaminants "because of their release into the environment and their resistance to degradation," which, the commenter claimed, does not specifically address the elements required under the statute. The commenter stated that EPA should make the showing required to establish PFOA and PFOS as CERCLA "pollutants or contaminants." Specifically, the commenter argued that EPA must demonstrate that PFOA and PFOS "cause or are reasonably expected to cause death, disease, physiological malfunctions, or any other conditions in the definition of 'pollutant or contaminant'" in CERCLA section 101(33). The commenter also claimed that EPA must explain how the standard proposed in the designation distinguishes the lower standard for "pollutants and contaminants" from the standard for "hazardous substances," which carries the maximum level of liability under CERCLA. [0569-Chamber of Commerce]

Other commenters asserted that EPA should use its existing authority to address PFOA and PFOS as pollutants and contaminants rather than moving forward with the proposed designation. These commenters stated that EPA has asserted that CERCLA already provides significant authority to federal agencies to address PFOA and PFOS releases because these two chemicals are pollutants and contaminants. The commenters also noted that EPA has used its existing authority to require the cleanup of PFOA and PFOS as pollutants and contaminants without relying on the designation of these substance as hazardous. Accordingly, the commenters concluded that the pollutants and contaminants threshold is not difficult to meet and has not

inhibited EPA's ability to take prompt action throughout the history of CERCLA. Therefore, before declaring PFOA and PFOS to be hazardous substances pursuant to CERCLA section 102(a), the commenters argued that EPA should utilize the ample tools available in the statute to address them as such, including, for example, CERCLA removal authority. Two commenters further stated that in fact, EPA has on occasion identified PFOA and PFOS as "pollutants and contaminants" at specific Superfund sites. [0341-AFBF, 0485-MI Farm Bureau, 0391-SSP, 0569–U.S. Chamber of Commerce, 0454-IFB, 0472–NYFB]

Response

EPA disagrees with the commenters' position that it should refrain from designating PFOA and PFOS as CERCLA hazardous substances and should instead rely solely on its existing authority to address PFOA and PFOS as CERCLA pollutants or contaminants. EPA also rejects the argument that PFOA and PFOS must be specifically designated as pollutants or contaminants before they are designated as hazardous substances; CERCLA requires no such prerequisite, nor does it include designation authority for pollutants and contaminants. Further, the evidence presented demonstrates that PFOA and PFOS qualify as pollutants or contaminants under section 101(33) of CERCLA. EPA also notes that it has used its CERCLA authority to address PFOA and PFOS as pollutants and contaminants in circumstances where releases may present an "imminent and substantial endangerment." EPA disagrees with the commenter's claim that PFOA and PFOS could be better addressed utilizing other statutory authorities. Finally, EPA concurs that it has previously identified and treated PFOA and PFOS as pollutants and contaminants at several Superfund sites. For further discussion of these issues, see the Preamble to the Final Rule Sections I. (Executive Summary), VI.A. (Advantages of Designation), VII.B.1. (Comments suggesting that other authorities are better suited to address PFAS contamination.), and VII.B.2. (Addressing PFOA/PFOS as "pollutants or contaminants").

2.A.3 Retroactive Application of the Rule

Several commenters argue that EPA lacks the authority to imbue its designation of PFOA and PFOS under section 102(a) of CERCLA with any retroactive effect. Additionally, one commenter suggests that the Supreme Court's decision in *Bowen v. Georgetown University Hospital*, 488 U.S. 204 (1988), supports its argument that the Agency does not possess the authority to "create retroactive liability" under section 102(a) in the absence of a clear expression of legislative intent to apply the statute retroactively. The same commenter also contends that the Administrative Procedure Act authorizes only the "prospective" application of rulemakings issued under section 102(a) of CERCLA. [0569-US Chamber of Commerce Coalition, 0565-USWAG, 0495-PFAS Regulatory Coalition, 0394-OSEE/ODEQ, 0372-NEW Water, 0391–SSP]]

Some commenters also argued that the retroactive application of CERCLA liability will harm certain facilities, including airports and wastewater treatment plants, that had no previous knowledge of issues with PFOA and PFOS. The commenters added that facilities that have historically used or disposed of PFOA/PFOS, even in small amounts, may become involved in costly and lengthy litigation regarding cost-recovery that will delay, not accelerate, cleanup of contaminated sites. In addition, the commenters claimed that the retroactive liability caused by the proposed designation will have direct impacts beyond reporting for facilities, including a massive number of new sites subject to CERCLA and reopening of cleanup decisions for old Superfund sites. [0424- Airports Council International – North America (ACI-NA), 0369-Hillsborough County Aviation Authority (HCAA) Tampa International Airport, 0398-

Pennsylvania Department of Environmental Protection, 0523-Western States Petroleum Association (WSPA), 0538-NACWA, 0398-Pennsylvania Department of Environmental Protection

Response

EPA disagrees with commenters that it is promulgating a retroactive rule. EPA also disagrees that EPA's action runs counter to the Supreme Court's decision in *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204 (1988).

EPA is not promulgating a retroactive rule. Today's action does nothing more than add PFOA and PFOS, and their salts and isomers, to CERCLA's list of hazardous substances. At the time that the rule goes into effect, it will expand the definition of hazardous substances in section 101(14) of CERCLA. This action does not automatically "create retroactive liability," as commenters suggest, nor does it require the EPA or any private party to take any response actions.

EPA understands that the commenters' concern is related more generally to the retroactive application of CERCLA, but as one commenter explicitly acknowledges, even after *Bowen* courts have regularly upheld the constitutionality of retroactive application of the statute. *See Franklin Co. Convention Facilities Authority v. Am. Premier Underwriters*, 240 F.3d 534, 551 (Sixth Cir. 2001) (noting that "Congress intended CERCLA to function retroactively."); *U.S. v. Olin Corp.*, 107 F.3d 1506, 1513-1514 (11th Cir. 1997) ("An analysis of CERCLA's purpose, as evinced by the statute's structure and legislative history, also supports the view that Congress intended the statute to impose retroactive liability for cleanup.").

Bowen does not run counter to this conclusion. In Bowen, the Court stated that, "[c]ongressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result." Bowen, at 471. In that case, the Court considered the "structure and language" of the statute at issue, and so EPA finds it appropriate to do so here, particularly section 107 of CERCLA, from which retroactive liability flows—and which EPA understands to be the primary concern of commenters.

Section 107(a), which establishes the scope of CERCLA liability, manifests an intent to impose that liability retroactively on responsible persons. Sections 107(a)(1) and (2), for example, impose liability not only on the current "owner and operator of a vessel or facility" where there is a release or threat of release of hazardous substances, but also on "any person who at the time of disposal of any hazardous substances owned or operated any facility. . . " 42 U.S.C. § 9607(a)(1) & (2) (emphasis added). The phrase "at the time of disposal" is clear on its face, is not time-limited, and means exactly what it says. See U.S. v. Northeastern Pharmaceutical, 810 F.2d 726, 733 (8th Cir. 1986) ("Although CERCLA does not expressly provide for retroactivity, it is manifestly clear that Congress intended CERCLA to have retroactive effect. The language used in the key liability provision, [section 107 of] CERCLA . . . refers to actions and conditions in the past tense. . . "). Similarly, section 107(a)(3) imposes liability on "any person who . . . arranged for disposal or treatment, or arranged with a transporter for transport for disposal or treatment, of hazardous substances owned or possessed by such person. . . " 42 U.S. C. § 9607(a)(3). Finally, section 107(a)(4) imposes liability on "any person who accepts or accepted any hazardous substances for transport" under certain specified conditions. 42 U.S.C. § 9607(a)(4). Congress' use of the past tense, consistent with its imposition of liability under

section 107(a)(2) on persons who owned a facility at the time of disposal, is clearly indicative of its intent to establish retroactive liability. Fundamentally, it is the structure and language of the statute itself that requires retroactive application, not the action to designate PFOA and PFOS as CERCLA hazardous substances. This outcome is also wholly consistent with congressional intent to ensure not only the "timely cleanup of hazardous waste sites," but to ensure that "the costs of such cleanup efforts were borne by those responsible for the contamination." *Burlington Northern and Santa Fe Ry. Co. v. U.S.*, 556 U.S. 599, 602 (2009).

EPA also disagrees with the commenter's argument that its designation of PFOA and PFOS under section 102(a) of CERCLA creates an issue of first impression. There were no CERCLA "hazardous substances" before CERCLA was enacted in 1980. Once CERCLA was enacted, all of the substances listed in the statute's definition of "hazardous substance," which includes substances listed under other laws, retroactively subjected the potentially responsibility parties who disposed of them to CERCLA liability, regardless of when the disposals happened. When new substances are added to the set of CERCLA "hazardous substances," potentially responsible parties may then be retroactively liable for any disposals of those newly designated materials as well. That is how Congress intended CERCLA to work and this is how CERCLA has functioned for over 40 years. See H.R. Rep. No 1016, 96th Cong., 2d Sess. 17 (1980) (noting that EPA will have authority to recover costs "with respect to [inactive hazardous waste] sites," in other words, sites at which there are no ongoing activities); see also S. Rep. No. 848, 96th Cong., 2d Sess. 13 (1980) (stating that the overall goal of the liability scheme is to "assur[e] that those who caused chemical harm bear the costs of that harm . . .").

In sum, EPA disagrees with the position that a designation initiated under section 102(a) "creates" retroactive liability. Liability determinations are made by the courts, not as a result of designation. *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.").

EPA believes that designation will not disrupt the normal operation of CERCLA, including its liability framework. As EPA explains in the final designation, existing limitations in CERCLA coupled with existing CERCLA enforcement policies are sufficient to mitigate concerns about liability that may arise after designation. Indeed, CERCLA 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. See the Preamble to the Final Rule Section IV.B.2. (Potential hardship for parties that did not contribute significantly to contamination). CERCLA itself provides for a "risk-based approach" to addressing releases of hazardous substances and pollutants or contaminants. EPA determines whether to take a response action, and if so, what measures to take, on based on an assessment of site-specific risk. See the Preamble to the Final Rule Section VII.A.3. (Authority to Create Exclusions from the Designation) for additional explanation as to how CERCLA's process operates to prioritize response to releases that pose actionable risk. See the Preamble to the Final Rule Section VII.E. (National Priorities List (NPL) Sites – Existing and Future Contamination) for information regarding designation and the NPL listing process.

2.A.4 Authority to Create Exclusions/Exemptions

One commenter argued that EPA lacks the authority to grant exemptions from the proposed designation. This commenter pointed out that Congress has already clearly delineated a set of

exemptions in various aspects of the statute; accordingly, it is unlikely that Congress intended to provide the EPA with additional discretion to exempt additional industries in other statutory contexts. By way of example, the commenter noted that CERCLA provides some exemptions from the definition of what it considers a release, including exposures that take place solely within the workplace, exhaust pipe emissions from motor vehicles, releases of nuclear materials regulated under the Atomic Energy Act of 1954, and the normal application of fertilizers. The commenter also noted that Congress exempted some entities from CERCLA's definition of "owner and operator" including certain innocent landowners and bona fide purchasers; government when property is acquired through seizure or otherwise in connection with enforcement activity or through bankruptcy, tax delinquency, or abandonment; and certain Alaska native villages; and some lenders. Finally, the commenter pointed to the D.C. Circuit's decision in *Waterkeeper Alliance v. EPA*, 853 F.3d 527, 534-35 (D.C. Cir. 2017), to make the point that courts have found that in the absence of delegation language, CERCLA does not grant the EPA authority to exempt entities from CERCLA's reporting requirements, aside from those expressly identified in the statute.

Other commenters argued that while EPA's authority to grant exemptions is not clearly defined, the Agency is not limited to designating specific compounds as hazardous substances. Instead, the commenters posited that EPA possesses the clearly defined authority to craft a rule that accounts for differences in toxicity at different levels and the risk of exposure to the substance. The commenter recommended EPA adopt its proposed approach, claiming that it would ensure that liability for historical and ongoing releases of PFOA and PFOS are limited to those facilities that EPA has identified as significant sources to the environment with releases posing a substantial threat, as opposed to broadly designating PFOA and PFOS and introducing liability for entities involved in *de minimis* releases. In considering this alternative regulatory approach, the commenters encouraged EPA to leverage forthcoming data to be collected pursuant to the TSCA Data Reporting and Recordkeeping Rule, data collection studies under the CWA program, and the extensive research that is available on sources of PFAS in the environment historically. [0544-American Water Works Association]

Alternatively, several commenters contended that EPA has the authority to create exclusions from the designation. These commenters clarified that they were not asking EPA to issue a liability exemption rule under CERCLA section 107. Instead, the commenters asked EPA to exclude from the regulatory listing of PFOA and PFOS in Table 302.4 of the CERCLA regulations, PFOA and PFOS under certain circumstances, e.g., when they are contained in paper mill residuals that are beneficially land applied as a fertilizer or soil conditioner. The commenters claimed that section 102(a), which provides EPA with the authority to "... promulgate and revise as may be appropriate, regulations designating as hazardous substances" gives the Agency the clear authority to exclude PFOA and PFOS from a listing regulation when they are contained in paper mill residuals that are beneficially land applied. The commenters also pointed to CERCLA's definition of "hazardous substance," in section 101(14), to argue that Congress envisioned that hazardous substance listings – including those promulgated by EPA under Section 102(a) - can have exclusions. The commenters further noted that CERCLA section 102(a) authorizes EPA to designate hazardous substances "as may be appropriate." Here, the commenters claim that Congress's choice of words gives EPA broad discretion to determine the scope and conditions of any CERCLA section 102(a) listing. Finally, the commenters stated that creating exclusions not included in the proposed designation would not violate the case law rule that a final rule must be a "logical outgrowth" of a proposed designation because interested

persons could reasonably anticipate that affected entities would ask EPA to implement those exclusions in the final rule. [0423-American Forest & Paper Association; 0520-Wisconsin Paper Council]

Response

EPA declines to create exceptions for certain uses of PFOA and/or PFOS in this rulemaking. See the Preamble to the Final Rule Section VII.A.3. (Authority to Create Exclusions from the Designation).

2.B. Statutory Interpretation

2.B.1 Consideration of Cost and 102(a)

Several commenters asserted that EPA must consider costs when designating a hazardous substance pursuant to CERCLA section 102(a). These commenters disagreed with EPA's 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 support this interpretation by: (1) asserting that there is no textual basis to preclude cost considerations through analogy to 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. [0494-Save Our Water (S.O.H2O), 0749-Anonymous, 0414-Attorneys General of the States of New York, et al, 0428-Citizens Against Ruining the Environment (CARE), 0458-Earthjustice et al, 0365-Environmental Protection Network (EPN), 0552-Environmental Working Group (EWG), 0463-Little Hocking Water Association, 0273-Lowry Landfill Superfund Site Citizens Advisory Group (LLSF Site CAG), 0374-Minnesota Pollution Control Agency (MPCA), 0468-National Ground Water Association (NGWA), 0566-Natural Resource Use & Management Clinic at the University of Arizona, 0393-New Mexico Environment Department (NMED), 0560-*Publi*– *Health* - *Seattle* and *King County (PHSKC)*]

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 EPA's interpretation that CERCLA section 102(a) precludes the consideration of cost. As one commenter stated, EPA's interpretation "accords with CERCLA's unambiguous text, statutory structure, and judicial interpretations of comparable provisions of other environmental laws." The commenter noted 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 stated 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 contrasted 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 suggested that CERCLA section 102(a) is akin to other "health-focused provisions of other environmental laws" that courts have interpreted to exclude cost considerations. [0410-Wyoming Department of Environmental Quality (WDEQ)]

Response

In taking final action, EPA decided it need not determine whether section 102(a) precludes consideration of costs and benefits. See the Preamble to the Final Rule Sections IV.A. (CERCLA section 102(a) Designation Considerations), IV.C. (CERCLA Section 102(a) and Cost Considerations), and VII.A.1. (Consideration of Cost and Section 102(a)).

2.B.2 Major Questions Doctrine

Several commenters contended 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 argued that the designation will have a substantial "economic, social, and legal impact" and pointed to the fact that EPA is utilizing section 102(a) of CERCLA for the first time to make the point that today's action represents a novel and transformative expansion of the Agency's regulatory authority. [0569-US Chamber of Commerce Coalition; 0523-Western States Petroleum Association]

Response

EPA disagrees with the commenters' position that this rulemaking raises a major question as defined in *West Virginia v. EPA*, 142 S. Ct. 2587 (2022). *See* the Preamble to the Final Rule Section VII.A.4. (*Designating PFOA and PFOS as "Hazardous Substances" Under CERCLA section 102(a) does not present a "Major Question."*).

2.B.3 Nondelegation Doctrine

One commenter stated that EPA's use of CERCLA Section 102(a) to designate PFOA and PFOS as CERCLA hazardous substances raises questions as to the constitutionality of the proposed designation under the non-delegation doctrine. To delegate authority to executive agencies, the commenter argued that Congress must supply an "intelligible principle" for the agency to apply, so that the agency's discretion is bounded. Here, the commenter claimed that Congress failed to supply EPA with that "intelligible principle" in CERCLA section 102(a) when it delegated the authority to decide whether it is "appropriate" to "designat[e] as hazardous substances ...

substances which, when released into the environment may present substantial danger to the public health or welfare." Then, the commenter claimed that saying "may present a substantial danger to the public health or welfare" does not provide an intelligible principle for the Agency to act upon. Ultimately, the commenter concluded that EPA cannot fix Congress' failure by adopting criteria that limit its authority. [0345-3M Company]

Response

EPA 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. See the Preamble to the Final Rule Section VII.A.2. (Interpretation of the phrase "may present substantial danger").

2.B.4 Administrative Procedures Act

Several commenters stated that the EPA's approach to this rulemaking violates the APA's prohibition against arbitrary and capricious rulemaking in various ways:

- One noted EPA's use of CERCLA authority arbitrarily makes parties in various sectors liable under CERCLA for contamination they have no responsibility for. [0392-NAWC]
- Other commenters noted that the designation of PFOA and PFOS as hazardous substances is arbitrary and capricious for two reasons. First, the commenters argued that EPA determined in 2021 that it did not have enough data to determine the appropriateness of a listing under CERCLA and whether PFAS posed a substantial danger. The commenters claim that EPA points to no new science since its 2021 determination to justify a change and conclude that using the same scientific data that leads to the opposite conclusion of an earlier agency decision is arbitrary and capricious. Second, the commenters assert that OMB Circular A-4 and the Government Accountability Office require EPA to perform an analysis of why and how a substance is hazardous and how the hazardous substance will be dealt with including the likely standards and costs of the testing, equipment, and cleanup required to properly address the substance. Instead, the commenters claim that EPA described why it would not be complying with the requirements. The commenters also stated that EPA's lack of analysis and the absence of a complete record for public review and comment is arbitrary and capricious as defined by the APA. [0523-Western States Petroleum Association, 0493-POWER!
- One commenter noted that EPA arbitrarily set the default reporting requirement at one pound, which is not supported by scientific analysis. [0523-Western States Petroleum Association]

A few commenters noted that EPA asserted that it is not required to conduct a cost analysis for the proposed designation and argued that taking such a significant action without fully considering its impacts is arbitrary and capricious. The commenters stated that the proposed designation invokes a broad and forceful environmental regulatory scheme and provides private and state rights of action that will have broad impacts on public water and wastewater agencies and their ratepayers across the country. The commenters noted the EPA should produce an RIA and release it for public review and comment before proceeding further. The commenters also argued that the existing economic analysis issued in conjunction with the proposed designation

violates the APA because EPA failed to provide a reasonable explanation for its decision, failed to consider important parts of the problem, and provided an explanation that runs counter to the evidence before it. Specifically, the commenters claimed that the EA failed to account for costs associated with liability and waste management and by failing to properly account for these costs, EPA created a one-sided analysis that fails to consider important parts of the problem and prevents the public from meaningfully understanding and commenting on the potential impacts of the proposed designation. [0493-POWER!, 0543-American Water Works Association]

Response

EPA disagrees with the commenters that the designation is arbitrary or capricious because EPA failed to fully consider potential impacts of designation, such as liability and costs pertaining to liability. Designation does not alter CERCLA's liability framework. Designation does not expand the definition of "potentially responsible parties," nor does it amend, change, or curtail existing statutory limitations on liability. Liability determinations are site-specific and designation does not determine liability. EPA expects to continue to operate as it has for decades to equitably resolve who should pay. *See* the Preamble to the Final Rule Section VI.B. (*Potential Disadvantages of Designation*) and Section VII.J. (Enforcement) and *infra* RTC 4.F and 4.G.

With respect to the 2021 ANPRM, EPA disagrees that it is changing its position on the sufficiency of data available to designate PFOA and PFOS pursuant to CERCLA section 102(a). See the Preamble to the Final Rule Section VII.A.2. (Interpretation of the phrase "may present substantial danger"). EPA also believes that a robust body of epidemiological and toxicological studies, including information released since 2021, support the Agency's conclusion that exposure to PFOA and/or PFOS above certain levels may result in serious and wide-ranging adverse health effects. See the Preamble to the Final Rule Sections I. (Executive Summary) and V, (PFOA and PFOS may present a substantial danger to the public health or welfare or the environment, when released into the environment); see also RTC 3.A. EPA disagrees with the commenters to the extent they argue that the EA was insufficient. See RTC 6.A.2. EPA complied with OMB Circular A-4 and conducted an analysis of costs. In the proposed designation, EPA included an analysis of direct costs in its proposed Economic Analysis, as required by OMB Circular A-4, including an estimated low and high range of potential direct costs associated with reporting requirement. See RIA Chapters 4 and 5 for more information about EPA's methodologies and discussion of direct and indirect costs, benefits, and transfers; see also the Preamble to the Final Rule Section VII.I. (Comments on Economic Assessment/Regulatory Impact Analysis). EPA also requested comment on costs and benefits (e.g., whether indirect costs and benefits should be considered for the final rule). See Proposed Rule, Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances, 87 Fed. Reg. 54415, 54423 (Sept. 6, 2022). EPA received a number of comments relevant to direct and indirect costs and benefits and, among other things, asserted that EPA must consider costs and benefits in designation decisions pursuant to CERCLA section 102(a). In the final rule, EPA exercised its discretion to conduct an additional totality of the circumstances analysis. As part of that analysis, 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 Analysis¹ accompanying this final rule. Based on that "totality of the circumstances" analysis, EPA concluded that designation is warranted because the advantages of designation outweigh the disadvantages *See* the Preamble to the Final Rule Section VI.C. (*Results of Totality of the Circumstances Analysis*).

EPA disagrees with the commenter's argument that it acted "arbitrarily" in setting the reportable quantity (RQ) for PFOA and PFOS at one pound. *See* the Preamble to the Final Rule Section VII.D.1.f. (*Default Reportable Quantity (RQ) of 1 pound*).

2.C. Statutory Authorities Available to Address PFOA/PFOS

2.C.1 CERCLA

One commenter expressed strong support for the designation, arguing that because CERCLA is the nation's primary cleanup law, the designation will substantially strengthen EPA's authority and accelerate cleanups, thereby helping to address the PFAS contamination crisis. [0552 – Environmental Working Group]

Other commenters challenged EPA's position that CERCLA is the appropriate tool to address PFOA and PFOS in the environment. Many commenters stated that CERCLA is not a traditional regulatory statute that prospectively regulates behavior. Instead, the commenters argued that CERCLA is remedial in nature, designed to address contamination on a site-specific basis, where there is an identifiable source, such as a plume impacting groundwater. Accordingly, the commenters concluded that CERCLA is not the appropriate tool for dealing with PFOA and PFOS given their ubiquitous nature in the environment. Instead, the commenters asserted that control and reduction of PFAS should be addressed via federal laws and regulations that prevent their manufacture and use in commerce and subsequent release into the environment. These commenters also stated that manufacturers of PFOA and PFOS should face full responsibility for the costs of clean up and treatment of PFAS already released to the environment. One commenter underscored that without first ensuring that PFOA and PFOS are no longer entering the environment, ongoing and unmitigated releases could result in a contaminated site having to be cleaned up multiple times. [0325-ORNL; 0339-ASDWA, 0351-City of St Charles, 0369-HCAA, 0407-WCA PFAS,0538-NACWA, 0372-NEW Water, 0542-CLA, 0390-NMPF, 0387-PA Chamber of Business & Industry et al, 0808-NASF, 0354-City of Roseville, 0392-NAWC, 0460-*ILTA*, 0569-U.S. Chamber of Commerce et al, 0527-Metro

Multiple commenters argued that the proposed designation is premature given the current data and science, and lack of appropriate cleanup thresholds, standards, and treatments for PFOA and PFOS.

• Numerous commenters stated that substances previously designated as hazardous substances under CERCLA had an existing regulatory framework in place via other environmental statutes such as RCRA, CAA, CWA, and SDWA. The commenters asserted that, generally, CERCLA site cleanup standards and responsibilities are

¹The 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 in its presentation of net benefits. This analysis is silent on whether designation is warranted and is a neutral analysis of benefits and costs that may result from designation.

informed by other statutes' regulatory frameworks to ensure consistency and full compliance across statutes. However, the commenters argued that as EPA has not yet regulated PFOA and PFOS under other statutes, there is a limited regulatory framework in place to provide direction to stakeholders on how to address contamination. [0413–ACWA; 0421-ACC, 0341-AFBF, 0409-SCVWD, 0522-WMC, 0350-City of Henderson, 0548-NAM, 0468-NGWA, 0481-NM Farm Bureau, 0496-NEORSD, 0565-USWAG, 0493-POWER!]

- Other commenters argued that proceeding with regulation under CERCLA is premature due to the persistence of PFOA and PFOS, which they noted will continue to wash off, wear off, disperse in air, and otherwise be released from household and industrial products and processes into the environment for the foreseeable future. These commenters also stated that the solubility, persistence, and multiple environmental release mechanisms from countless disparate sources make PFAS contamination a unique problem not well-suited to CERCLA's discrete cleanup actions. [0413–ACWA; 0421–ACC, 0341-AFBF, 0409-SCVWD, 0522-WMC, 0350-City of Henderson, 0548-NAM, 0468-NGWA, 0481-NM Farm Bureau, 0496-NEORSD, 0565-USWAG, 0493-POWER!]
- One commenter stated that EPA asserted, incorrectly, in the proposed designation that "many states, including California, Michigan, and Vermont, have drinking water standards for PFOA and PFOS." The commenter, however, claimed that California does not yet have such drinking water standards. [0413; ACWA, 0512–Stericycle, 0496-NEORSD]
- Another commenter stated that implementation of the proposed designation before establishment of remedial endpoints for PFOA and PFOS would contradict one of the purported objectives of the NCP under CERCLA section 105(a)(8). [0512–Stericycle]
- Multiple commenters claimed that no cost-effective disposal and treatment technologies for PFOA and PFOS currently exist and pointed to EPA's interim guidance on the destruction and disposal of PFAS as acknowledging the uncertain efficacy of current technologies.
- A few commenters acknowledged that PFAS affect the environment and human health and are ubiquitous, but nevertheless argued that the designation is premature because there is not yet a complete enough understanding of the overall risk the chemicals present, sources of the chemicals, what standards adequately protect the environment and human health, and what is required to effectively remediate them. [0342 – AEA, 0322 – Environmental Compliance Manager]
- One commenter noted that the fact that EPA admits it lacks sufficient risk information for PFOA and PFOS to set a chemical-specific RQ demonstrates that this rulemaking itself is premature. [0419-American Petroleum Institute (API) et al]

Other commenters argued that the designation is ill-timed as many facilities are still in the process of assessing their compliance with interim updated lifetime drinking water health advisories issued by the Agency for certain PFAS in June 2022. The commenters claimed that response actions may be questioned or may need to be repeated once the science regarding PFAS has further evolved. One commenter stated that facilities serving some of the most vulnerable populations are just receiving long needed assistance to address noncompliance with existing

regulations and remediation efforts could be significantly delayed as these water systems await clarity from EPA before proceeding with improvements. [0313-American Public Works Association (APWA)]

Another commenter stated that the development of a legally binding water standard is critical to provide clarity and assure that PFAS is addressed uniformly throughout the country rather than having to rely upon state-specific policies, and then trying to discern how those rules will be impacted by the CERCLA designation of PFOA and PFOS. [0536-Aclarity]

Another commenter specifically suggested a certain five-year incremental step-down approach to the concentration of PFOA and PFOS in drinking water to allow industry, testing and remediation technologies to adapt over time to EPA's National Primary Drinking Water Regulation. [0559-RuttenKern LLC]

Response

EPA believes that CERCLA is the best tool to address the challenges posed by PFOA and PFOS contamination. See the Preamble to the Final Rule Section VI (The Totality of the Circumstances confirms that designation of PFOA and PFOS has Hazardous Substances is Warranted) and VII.B.1. (Comments suggesting that other authorities are better suited to address PFAS contamination). The Agency disagrees with the claim that its designation of PFOA and PFOS is premature. Considering the significant, and growing, body of evidence that PFOA and PFOS, when released in the environment, may present substantial danger, designation is warranted. And, although one commenter argues that the Agency lacks a complete understanding of the sources of PFOA and PFOS contamination, in fact, EPA looked at scientific and technical data regarding toxicity and toxicokinetics, chemical and physical characteristics, and the environmental prevalence of PFOA and PFOS and has concluded that the evidence related to the chemical and physical characteristics of these substances indicates that they are persistent in the environment and that they bioaccumulate in both humans and wildlife. See the Preamble to the Final Rule Section V.A. (PFOA and PFOS Pose a Hazard). V.C. (Other Information Considered); see also infra RTC 3.A.

The Agency does not concur with the position that, at present, there is no regulatory framework in place that allows EPA respond effectively to PFOA and PFOS releases. EPA also disagrees with the commenter's stance that the designation contravenes CERCLA section 105(a)(8). Relatedly, EPA disputes the commenters' assertion that designation under CERCLA is inappropriate in the purported absence of pre-existing regulatory standards for PFOA and PFOS. For further discussion of these issues, see the Preamble to the Final Rule Section V. (PFOA and PFOS may present a substantial danger to the public health or welfare or the environment, when released into the environment), and VII.B.1. (Comments suggesting that other authorities are better suited to address PFAS contamination); see also infra RTC 3.B.

EPA acknowledges the commenter's statement that California does not yet have enforceable drinking water standards for PFOA or PFOS. However, while there are no enforceable maximum contaminant levels for PFOA and PFOS in California, there have been recent updates to notification levels and response levels for publicly supplied drinking water.

EPA also disagrees with the commenters to the extent they suggest the Agency should not designate because there are insufficient methods to treat, destroy, and dispose of PFOA and PFOA. As noted in RTC 4.E.1& E.2, there are currently methods available to address PFOA and

PFOS contamination and the Agency and other parties continue to work to improve those methods.

The Agency disagrees with the commenter's argument that designation of PFOA and PFOS will result in sites being cleaned up multiple times. *See* the Preamble to the Final Rule Section VII.E. (National Priorities List (NPL) Sites – Existing and Future Contamination). For additional questions regarding reopening Superfund sites based on the presence of PFOA and PFOS, see RTC 4.D.2.

EPA challenges the assertion that it lacks sufficient information to establish a PFOA or PFOS-specific 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, their salts and isomers. Accordingly, the designation will require that any person in charge of a vessel or facility report releases of PFOA and PFOS of one pound or more within a 24-hour period. Reporting of releases at this level will give the Agency, State, Tribal, and local governments, and the public a better understanding of where releases occur, and the quantities involved. For further discussion regarding the risk information necessary to establish a reportable quantity, see the Preamble to the Final Rule Section VI.D.1.c. (The reportable quantities (RQs) should be chemical-specific, not applied to PFAS as a class); see also infra RTC 4.A.4.

EPA disagrees with the commenters' claim that the designation will impede the ability of certain water systems to assess their compliance with the Agency's interim updated lifetime drinking water health advisories for certain PFAS. The Agency also disagrees with the commenter's specific claim that the designation will impact the rate at which water systems conduct remedial efforts to address noncompliance with existing regulations. The commenters provide no evidence to support either of these assertions and with the exception of certain release reporting and notification requirements, the designation does not impose any regulatory requirements on any specific facilities.

The Agency disagrees with the commenter's position that designation of PFOA and PFOS as CERCLA hazardous substances is inappropriate because response actions may be questioned or may need to be repeated once the science regarding PFAS has further evolved. 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. See the Preamble to the Final Rule Section VII.B.1. (Comments suggesting that other authorities are better suited to address PFAS contamination); see also infra RTC 4.E.1-5.

EPA acknowledges the commenter's statement with respect to its National Primary Drinking Water Regulation. For further information about this regulatory action, please visit the Agency's website at https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas, or www.regulations.gov under docket id EPA-HQ-OW-2022-0114. The commenter's request for a specific approach to the concentration of PFOA and PFOS in drinking water is outside the scope of this rulemaking and no response is required.

For comments on the control and reduction of PFAS, see the Preamble to the Final Rule Section III.C. (*EPA's PFAS Strategic Roadmap*).

2.C.2 Other Statutory Authorities

Many commenters argued that EPA should regulate PFOA and PFOS under other statutory regimes instead of CERCLA.

- Some commenters asserted that EPA should use TSCA to focus on controlling the introduction of PFAS substances into the environment by industrial and domestic sources. The commenters claimed that the use of TSCA would help to prevent the introduction of PFOA/PFOS into the environment and is preferable to holding public utilities liable after using EPA-approved chemicals. [0348-BGMU, 0415-AMCA, 0798-Citizen, 0430-Elyria, 0370-Oregon ACWA, 0485-MI Farm Bureau, 0396-MWEA, 0473-MESERB, 0464-JEA, 0538-NACWA, 0455-IEUA, 0372-NEW Water, 0496-NEORSD, 0415-AMCA, 0539-NCWQA, 0554-DC Water]
- Other commenters stated that EPA should use the Safe Drinking Water Act (SDWA) in lieu of designation of PFOA and PFOS as CERCLA hazardous substances. These commenters argued that EPA has previously used SDWA to abate potential threats to public health from PFOA/PFOS contamination of drinking water and that SDWA represents a better way to regulate PFOA/PFOS than the proposed designation. The commenters pointed to SDWA section 1431, which gives EPA the authority to take appropriate enforcement action if an imminent and substantial endangerment for a public water system or underground source of drinking water, to argue that the Agency may issue administrative orders and/or file a civil action to compel responsible parties to conduct remedial actions to protect the public from exposure to PFOA or PFOS. Several commenters also noted that EPA had announced its intent to establish drinking water standards for PFOA and PFOS under SDWA by the end of 2023. These commenters stated that the SDWA standards will determine the cleanup target for remediation at National Priorities List (NPL) and other sites. [0391-Superfund Settlements Project, 0421-American Chemistry Council (ACC), 0341-American Farm Bureau Federation, 0419-American Petroleum Institute, 0549-California Farm Bureau, 0565-USWAG, 0558-SD Farm Bureau, 0418-AGC, 0569-A1 U.S. Chamber of Commerce Coalition of Companies and Trade Associations, 0495-PFAS Regulatory Coalition, 0484-NACD]
- A number of commenters stated that EPA should use the Resource Conservation and Recovery Act (RCRA) to regulate PFOA/PFOS instead of the proposed designation. These commenters claimed that under RCRA, the Agency could focus its regulatory efforts on the presence of PFOA and PFOS in certain sources (e.g., manufacturers) as well as from certain activities (e.g., the use of AFFF) and only regulate the chemicals that are above a certain concentration threshold. A few commenters also noted that RCRA gives EPA the authority to address substances that qualify as solid waste even if those substances have not been designated as hazardous if the substance presents a substantial endangerment to health or the environment under RCRA section 7003. Several commenters stated that EPA has initiated the process to add four PFAS, including PFOA and PFOS, to RCRA's list of hazardous constituents which would trigger cleanup authority under the RCRA corrective action program and constitute a step towards listing targeted substances as RCRA hazardous wastes that would become CERCLA hazardous substances. [0391-Superfund Settlements Project, 0421-American Chemistry Council

(ACC), 0341-American Farm Bureau Federation, 0543-AWWA, 0565-USWAG, 0418-AGC, 0569-A1 U.S. Chamber of Commerce Coalition of Companies and Trade Associations, 0495-PFAS Regulatory Coalition, 0392-NAWC]

• Some commenters claimed that EPA could use the Clean Water Act (CWA) to set Effluent Guidelines and other rules for managing environmental and human risk from PFOA/PFOS without the need to resort to CERCLA's "broad regulatory powers." These commenters also argued that the Agency has the authority under the CWA to develop ambient water quality criteria that could be incorporated into National Pollutant Discharge and Elimination System permits to manage discharges of PFOS and PFOA. [0348-BGMU, 0744-Young, 0419-API, 0341-American Farm Bureau Federation, 0419-American Petroleum Institute, 0455-IEUA, 0538-NACWA, 0391-Superfund Settlements Project (SSP), 0543-AWWA, 0569-U.S. Chamber of Commerce et al., 0449-City of Weatherford, TX, 0430-City of Elyria]

Response

EPA does not agree with the commenters that the Agency should rely on TSCA, SDWA, RCRA, or the CWA in lieu of designation of PFOA and PFOS under CERCLA section 102(a). Although these statutes each represent important tools in addressing the hazards posed by PFOA and PFOS, CERCLA is the right tool for addressing wide-spread, existing PFOA and PFOS contamination, which is a nationwide concern. See the Preamble to the Final Rule Sections III.C. (EPA's PFAS Strategic Roadmap) and VII.B.1. (Comments suggesting that other authorities are better suited to address PFAS contamination).

EPA acknowledges the commenter's statement with respect to its National Primary Drinking Water Regulation. For further information about this regulatory action, please visit the Agency's website at https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas, or www.regulations.gov under docket id EPA-HQ-OW-2022-0114.

Comments regarding the Agency's action to list specific PFAS as RCRA hazardous constituents under 40 CFR Part 261 Appendix VIII are outside the scope of the final rule and no response is required.

3. EPA's Finding That PFOA And PFOS May Present Substantial Danger

3.A. In Support of EPA's Proposed Finding that PFOA and PFOS May Present a Substantial Danger

A number of commenters supported EPA's conclusion that the scientific and technical information concerning PFOA and PFOS support a finding that those substances present a substantial danger to human health, welfare and the information when released into the environment.

Some commentors noted that EPA has met the criteria for designating PFOA/PFOS, including their salts and structural isomers, as CERCLA Section 102(a) hazardous substances. These

chemicals are toxic, causing a range of serious adverse effects including developmental and reproductive toxicity, liver toxicity, cancer, and other adverse health effects. [ATSDR. (2021). Toxicological Profile for Perfluoroalkyls.

https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237] In addition to their toxicity, these chemicals warrant designation as CERCLA section 102(a) hazardous substances given the long time they remain in humans [ATSDR. (2021). Toxicological Profile for Perfluoroalkyls. https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237], their well-documented persistence and mobility in the environment, their widespread contamination of environmental media, and their impact on welfare—from drinking water contamination to the contamination of farmland. Commenters also noted that the inclusion of structural salts and isomers is appropriate: PFOA/PFOS have been manufactured in various salt forms. When added to water, the salts break down into their component ions, which includes their anionic acid forms typically found in environmental media. Additionally, structural isomers of PFOA/PFOS have different arrangements of their carbon atoms in the fluorinated carbon chain, but they maintain PFOA/PFOS's distinctive carboxylic acid and sulfonic acid functional groups. See 87 Fed. Reg. 54,418. For these reasons, the designation appropriately includes PFOA/PFOS salts and structural isomers. [0810/EDF, 0414/Attorneys General, 0519/WV Rivers, 0458/Earthjustice, 0823-Katusha, 0784/Citizen, 0552/EWG, 0365/EPN]

One commenter noted that exposure of over 30 years of PFOA through industry-contaminated surface water sources used for drinking water (https://www.hpcbd.com/wp-content/uploads/migrations/2061991/dupont/Amended-Complaint.PDF) has resulted in communities near Parkersburg, WV suffering from severe long-term health effects, including higher rates of thyroid disease, autoimmune disease, testicular and kidney cancer, and pregnancy-induced hypertension. (hpcbd.com/wp-content/uploads/migrations/2061991/dupont/Probable-Link-cancer-april-15.pdf) 61766). [0519/WV Rivers]

One commenter recommended that EPA include a citation in the final rule for the July 28, 2022, consensus report from the National Academy of Science, Engineering, and Medicine. This report concludes there is sufficient evidence for an association between exposure to PFOA, PFOS, and five other PFAS chemicals and increased risk of lowered antibody response in adults and children, decreased infant and fetal growth, and kidney cancer in adults. (https://nap.nationalacademies.org/catalog/26156/guidance-on-pfas-exposure-testing-and-clinical-follow-up). [0365/EPN]

Another commenter indicated that inclusion of newer studies on the adverse effects of PFOA and PFOS would further add to the weight of the evidence. The commentor provided additional studies in the Appendix to their comments and requested that EPA include them in the record for this rulemaking. [0810/EDF]

A commenter stated that PFOA and PFOS are well recognized for their ability to bioaccumulate in animals and humans, in addition to their environmental persistence and toxicity. This commenter also stated that over 98% of Americans have PFAS in their blood that could remain in the body for years. Additionally, prenatal PFAS exposure could affect fetal growth and subsequent risk of childhood obesity. [0452 – Defend Our Health]

A commenter noted the adverse health effects reported including cancer, decreased vaccine response in children, liver and kidney disruption, increased cholesterol, increased risk of high blood pressure or pre-eclampsia in pregnant women, and reproductive and developmental disorders. This commenter noted how resistant 'forever chemicals' are to degradation, and therefore, how the chemicals continue to persist in the environment and human body. [0567 – WE ACT]

Similar to the previous commenter, this one stated that the CDC's National Health and Nutrition Examination Survey (NHANES) reported that 97% of Americans had PFAS in their blood. Furthermore, the commenter stated that Black individuals are up to 53% more likely to live near particular matter-emitted facilities. Therefore, Black individuals who live close to those facilities suffer the most health implications. Additionally, a study showed that Black women in Southeast Michigan and Boston had higher concentrations of total PFOS compared to white women. [0530 – International Association of Fire Chiefs]

Another commenter specifically focused on the health effects among the occupational group of firefighters. This commenter stated that the nation's firefighters have a higher prevalence of cancer than the general population and that research has shown there are significant increases in the risks of cancers in the bladder, colon, kidney, lung, prostate, and other organs in firefighters; for certain types of cancer, the risk relative to the general population can be 229% higher. Specifically, the commenter noted how the relationships between kidney and testicular cancer and PFOA and thyroid cancer with PFOS reported in the 'General Information' section of the proposed ruling are driven by the higher rate of those types of cancers in the fire service than the general population.

A commenter sought to supplement the Rulemaking's record with two systematic studies estimating the total disease burden and related economic costs of human exposure to PFOA and PFOS. This commenter underscored the difficulty in quantifying indirect social costs such as increased anxiety, depression, and stress; lost wages; lost years of life; reduced quality of life; and subsequent impacts on communities and families. The commenter also underscored that the designation would help to correct decades of industry cost externalization onto overburdened communities. [0428 – CARE] The two systematic studies are summarized below:

- Taking a highly conservative and systematic approach that accounted for risk of bias in studies, earlier this year, a group of New York University public health experts identified five statistically significant disease outcomes associated with exposure to PFOA based on published meta-analyses of epidemiological studies—(1) low birth weight due to prenatal exposure, (2) childhood obesity due to prenatal exposure, (3) kidney cancer due to lifetime exposure, (4) testicular cancer due to lifetime exposure, and (5) hypothyroidism in females due to lifetime exposure. Not even accounting for PFOS exposure, the experts determined that at least \$5.52 billion in annual disease burden and associated social costs is attributable to PFOA exposure. Based on additional disease outcomes identified in systematic or scoping reviews, and alternate PFOA and PFOS exposure estimates, the study's sensitivity analysis revealed as much as \$62.6 billion in annual costs.
- In 2019, the Nordic Council of Ministers published a study estimating PFAS' socioeconomic costs resulting from impacts on human health and the environment. Finding indicate annual health-related costs of 2.8 4.6 billion EUR for the Nordic

countries and 52 - 84 billion EUR for all European Economic Area countries. Accounting for population size and exchange rate differences, equivalent health-related costs for the United States would be \$37–59 billion annually.

One commenter noted the pollution from the Dupont Chemical Corporation and its effects on cows' health, individuals' health, and the water supply. One commenter noted the pollution from 3M whose downstream pollution has contaminated fish for decades where individuals are cautioned not to eat the fish.

Several commenters expressed strong support for the designation because it is in line with the scientific evidence that the chemicals can accumulate in the human body, act as endocrine disruptors, and result in adverse health effects in the environment and humans (including cancer, reproductive difficulties, and thyroid disruption among humans). One of these commenters specifically noted the health effects experienced by communities of color and low-income communities. Many of the commenters cited that PFAS has polluted the tap water for at least 16 million individuals across 33 states and Puerto Rico; additionally, PFAS has polluted the groundwater across at least 38 states. Other commenters cited the contamination in West Virginia specifically, where a statewide study of source water reported that 67 water systems were contaminated by at least one PFAS and among those 37 were contaminated by PFOA and PFOS at levels above the EPA guidance for human health. Others also noted the contamination in Ohio. One commenter stated that their community was informed that their water was contaminated with PFAS, and therefore, the city shut down the most contaminated wells and mixed water from other wells to provide the cleanest drinking water possible. Other commenters also noted their concern over PFAS contamination in their drinking water and how technologies, like reverse osmosis, are too expensive. The Michigan Department of Environment, Great Lakes, and Energy (EGLE) has reported that more than 1.5 million Michigan residents have drinking water contaminated with PFAS, along with 11,300 potential sites where PFAS have been used. If this proposal becomes a rule, it can help Michigan residents combat the health concerns that they might face due to the stopped exposure. Subsistence fishers, tribes and recreational fishers have been impacted by fish advisories driven by tissue concentrations of these compounds. Additionally, farmers have also seen the effects in their crops and livestock. Given that most Americans have one or more specific PFAS in their blood and the health effects of PFOA and PFOS (i.e., cancer and developmental effects, thyroid disease, etc.), it is crucial for EPA to proceed with the ruling so the public can proceed with healthier lives. One commenter noted that the International Agency for Research on Cancer (IARC) classified PFOA as "possibly carcinogenic to humans" (Group 2B) based on limited evidence in humans that PFOA can cause kidney and testicular cancer and limited evidence that PFOA can cause cancer in lab animals. Additionally, commenters highlighted how the PFAS crisis is particularly jeopardizing the health of communities of color and low-income communities. The PFAS crisis is perceived as an environmental justice issue nationwide. [0264 - Endocrine Society, 0467 - NCHR, 0365 -*EPN*, 0273 – *LLSF* Site CAG

Comments on Contamination/Prevalence

Another commenter stated that for over 50 years, releases from the manufacturing and testing of aqueous film forming foam from facilities owned by Johnson Controls International/Tyco Fire Products have caused extensive harm to health and property within the Town of Peshtigo. In

2013, the facilities reported PFAS contamination at their fire training facility that exceeded 400,000 parts per trillion. Later in 2017, PFAS was reported in the private drinking wells in the Town of Peshtigo. The commenter also noted the cases of cancers, delayed development, low birth weight, thyroid disease, and ulcerative colitis throughout the town. [0308 – Town of Peshtigo]

A commenter specifically called out the benefit to the Lowry Landfill Superfund Site and three-mile-long off-site plume of toxic chemicals that has yet to be tested for PFAS. [0273 – LLSF Site CAG]

The designation will benefit the Marinette and Peshtigo area, which is affected by the releases of firefighting foams from Johnson Controls/Tyco Fire Products' (JC/Tyco) manufacturing and testing operations. A commenter stated that the drinking water of the areas is contaminated with PFAS, which was confirmed by the Wisconsin Department of Natural Resource; 330 out of 415 drinking water wells tested had detectable levels of PFOA and/or PFOS with the highest concentration of 2,100 parts per trillion. [0494 – S.O.H2O]

A commenter expressed strong support for the designation, especially given its potential impact on Michigan and other Great Lake states. The Department of Great Lakes, Energy and the Environment (EGLE) identified 228 contaminated PFAS sites in Michigan alone with as many as 11,000 sites estimated. Among those sites, commenter specifically noted the sites neighboring communities and the responsibility of the Department of Defense. For instance, commenter stated that in Oscoda, Michigan, PFAS were released from aqueous film forming foam (AFFF) at the former Wurtsmith Air Force Base. These substances, including PFOA and PFOS, contaminated the groundwater and surface water for decades. However, the Department of Defense has yet to clean up the contaminated site. Additionally, commenter stated that Wolverine Worldwide dumped PFAS chemicals at the House Street Disposal Area in Belmont and their former tannery site in Rockford for years, contaminating groundwater with very high PFAS levels in both communities. Finally, the commenter discussed how it was estimated that Michigan taxpayers and ratepayers have paid over \$202 million to identify, mitigate, and remediate PFAS contamination. Particular concern was expressed for communities that face disproportionate exposure to PFAS and low-income communities. [0301 – GLPAN] A commenter stated that PFOA and PFOS contamination have been significant environmental and public health concerns for communities across Alaska. The Alaska Department of Environmental Conservation (ADEC) reported that several communities in the Bristol Bay region experienced exposure to PFOA, PFOS, and other PFAS from contaminated drinking water with the likely source being aqueous film forming foams (AFFFs) during firefighting equipment testing. PFAS were detected in at least 58 wells in the Bristol Bay region to date including wells that were used as public drinking water sources for years. [0319 – BBNA] A commenter discussed the PFAS contamination faced by the Will County communities. Will County communities with extremely high concentrations of PFOA and PFOS in their drinking water have consistently been in the top quartile (and in many cases the top 5th percentile) of the Environmental Justice Index (EJI) launched by the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry. The commenter underscored how the designation will be the first step in addressing Will County communities and other

environmental justice communities disproportionately overburdened by cumulative chemical and non-chemical stressors for decades. [0428 - CARE]

The commenter expressed that the communities should not have to shoulder the capital and maintenance costs to ensure safe drinking water; therefore, the designation would rightfully shift those costs to the industries using PFOA and PFOS. Additionally, commenter noted how the Government Accounting Office urged EPA to conduct a nationwide analysis of data regarding the presence of PFAS in drinking water in environmental justice communities, and the National Environmental Justice Advisory Council also urged EPA to revise the PFAS Roadmap to focus on environmental justice issues, including suggesting emergency response plans that offer immediate relief through bottled water or air filters in underserved communities.

Response

EPA strongly agrees that the scientific and technical data in the proposed rule support EPA's conclusion that PFOA and PFOS "may present substantial danger" to human health, welfare and the environment when released, and the Agency is taking final action to designate PFOA and PFOS and their salts and isomers. Further, EPA acknowledges that PFAS science continues to evolve and studies of the hazards of PFOA and PFOS, as well as other PFAS, continue to be published in the peer-reviewed literature. EPA agrees that newer studies showing the adverse effects of PFOA and PFOS further add to the weight of the evidence supporting the designation of PFOA and PFOS as hazardous substances. EPA also strongly agrees that there is evidence of widespread contamination of drinking water wells by PFOA and PFOS and that significantly elevated concentrations of these substance have been detected in private drinking water wells in communities in proximity to facilities that manufacture PFOA, PFOS, or formulate mixtures of these substances.

As discussed in the preamble to the final rule, there is sufficient information to designate PFOA and PFOS as hazardous substances now. EPA agrees that final designation of PFOA and PFOS will provide a considerable advantage to EPA, states, and the public in addressing the hazards associated with releases of PFOA and PFOS. For its part, EPA intends to focus its enforcement efforts on holding responsible those parties who manufactured PFOA/PFOS and/or used PFOA/PFOS in the manufacturing process, federal agencies that released PFOA/PFOS, and other industrial parties who significantly contributed to the release of PFAS contamination in the environment. EPA may also take Fund-lead response actions when it cannot identify a viable PRP.

See Preamble to the Final Rule: Section V ("PFOA and PFOS may present a substantial danger to the public health or welfare or the environment, when released into the environment") and Section VII.C. (Toxicity, Human Health Effects/Mobility, Persistence, Prevalence/Release into the environment).

Section VIII.B. (Direct Effects of Designating PFOA, PFOS, and their Salts and Structural Isomers as Hazardous Substances).

Section IX.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).

Section III.C. (EPA's PFAS Strategic Roadmap).

3.B. Not in Support of EPA's Proposed Finding that PFOA and PFOS May Present a Substantial Danger

A number of commenters questioned EPA's proposed conclusion that the scientific and technical information concerning PFOA and PFOS support a finding that those substances may present a substantial danger to human health, welfare or the environment when released into the environment.

The Proposed Rule because it relies on a flawed and skewed analysis of relevant science, fails to properly establish and follow criteria for designation under Section 102, and fails to consider the full economic impacts of its proposed designation. Regarding the analysis of relevant science, the commenter stated that EPA selectively focused on questionable endpoints and studies, while EPA dismissed credible, relevant studies which would result in the conclusion that PFOA and PFOS do not present a substantial danger to the public health, welfare, or the environment that warrants the proposed designation. Regarding criteria, the commenter stated that EPA did not establish how it would assign weight to the various criteria introduced or how it would determine whether the criteria was against or in favor of a hazardous substance designation. The commenter underscored how the criteria differed drastically from similar listing determinations made by EPA under other environmental statutes and how the criteria was vague. A few commenters opposed the Proposed Rule because it was not based on established guidelines for scientific implementation, established guidelines and standards for cleanup, and established treatment and disposal methods. Without adequate technology and appropriate standards, the commenters needed more time to fully assess consequences of the designation. [0298 - SD] DANR, 0345 – 3M, 0493 – POWER!

Another commenter also opposed the designation due to the need for completed risk assessments to ground future actions in sound science. Additionally, two commenters underscored that the designation potentially holds utilities responsible for PFAS chemicals that public water and wastewater agencies did not produce; the utilities only serve as passive receivers of PFOA and PFOS. Those commenters opposed the Proposed Rule unless it includes the specific clarifications and exclusions necessary for clean water communities; otherwise, there will be significant adverse consequences. [0447 – Coalition of Recyclers of Residual Organics by Practitioners of Sustainability CRROPS, 0386 – Renewable Water Resources]

A few commentors noted that the evidence presented to demonstrate that PFOA and PFOS meet the hazardous substance designation under CERCLA Section 102(a) may be overstated. [0390-National Milk Producers Federation (NMPF), 0345-A1-3M Company]

One commenter described several human health effects associated with PFAS exposure presented in the May 2021, Agency for Toxic Substances and Disease Registry (ATSDR). The commenter noted the key takeaway from the ATSDR document is that while there may be some

association with PFAS and human health effects, no cause-and-effect relationships have been established. [0390-NMPF]

Another commenter noted that although the EPA claims to rely only on the support documents for the 2016 Health Advisories for PFOA and PFOS to support its Proposed Rule, the Proposed Rule itself is clear that EPA also relies on the 2021 "Draft Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal" documents ("draft MCLG documents"). The body of available science does not show that PFOA and PFOS "may present a substantial danger" to human health or the environment, rendering EPA's conclusion otherwise arbitrary. [0345-3M Company]

One commenter indicated that the EPA should clearly identify whether the agency has relied on any science, scientific process, or scientific findings for which the Science Advisory Board (SAB) has previously provided a review and recommendations, and that the agency should also address those comments, concerns, and recommendations provided by the SAB in a final rule. The commenter further indicated that it is unclear as to extent EPA relied on the five documents the SAB reviewed in issuing its final report titled "Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS," issued August 22, 2022, in determining that PFOA and PFOS "may present substantial danger . . . to the public health or welfare or the environment." The EPA should be transparent about the use of this information in making a "substantial danger" finding or provide an explanation about why that type of transparent analysis is not necessary. [0407-Water Coalition Against PFAS] One commenter indicated the evidence for potential adverse health effects is drawn from the 2016 LHAs [Lifetime Health Advisories] developed by the Office of Water which, although subject to peer review, are non-enforceable and were not subject to regulatory notice and comment. The proposal also references the draft updated health effects analyses developed by the Water Office to support the development of National Primary Drinking Water Regulations that have not yet been proposed. Further, those documents were subject to criticism by the SAB. Rather than depend on the ongoing Safe Drinking Water Act evaluation, the OLEM should conduct its own evaluation of the available data under the established mechanisms outlined in CERCLA. [0421-American Chemistry Council]

A few commenters urged EPA to perform a science-based risk assessment of PFOA and PFOS that is publicly available. [0304 – Water & Health Advisory, 0449 – Weatherford]

Other commenters stated that EPA's assessments of the potential health risks from exposure to PFOA and PFOS are flawed, and therefore, should not be used as a basis for regulation. The assessments are deficient and cannot reliably support the proposed designation; commenter noted that the Scientific Advisory Board's recent review of the draft maximum contaminant level goal documents identified substantial concerns related to EPA's review processed and, ultimately, concluded that EPA was not consistent in its evaluation of studies and inadequately justified its exclusion of relevant studies. One of these commenters also stated that the National Academies of Sciences, Engineering, and Medicine rejected EPA's recently issued lifetime health advisory levels relied on health outcome associations. Among the several issues highlighted by the Academies was EPA's largely unsupportable reliance on the suppression of vaccine response in children as an appropriate health endpoint given the facts surrounding the subject study. EPA's

Science Advisory Board ("SAB") expressed these same concerns, among others, in connection with its SDWA review. [0345 – 3M, 0808 – National Association of Surface Finishing (NASF), 0421 – ACC, 0565 – Utility Solid Waste Activities Group (USWAG), 0391 – Superfund Settlements Projects (SSP)]

More scientific analysis is necessary before EPA can propose a hazardous substance designation. The commenter further stated that EPA's proposal does not meet the threshold of evidence of substantial danger that EPA initially determined should be met for such designation. Instead, EPA's proposal appears to set a very low threshold for evidence. [0523-Western States Petroleum Association (WSPA)]

Since EPA can use its authority under CERCLA to compel site cleanup (or cost recovery for site cleanup), EPA must explain why PFOA and PFOS may present a substantial danger to public health and the environment from contaminated sites. EPA acknowledges in the proposed rule that there are numerous uncertainties in how many sites could be impacted. EPA claims that it cannot know how many sites could have PFOA and PFOS contamination, and therefore, it cannot know to what extent the substances are present, which sites will require cleanup, and how much human or environmental exposure there is to these substances from these sites. Without answering these questions (including using quantification techniques as appropriate), EPA cannot demonstrate that PFOA and PFOS "may present a substantial danger" to public health or the environment under CERCLA. EPA must attempt to evaluate existing data sources on known PFOA and PFOS exposures, including, as appropriate, the use of modeling efforts that are available to EPA to assess these questions, as the commenter did for non-federal Superfund sites. [0569-U.S. Chamber of Commerce et al]

A few commentors state that the Proposed Rule does not contain a thorough substantiation of why PFOA and PFOS "may present substantial danger to the public health or welfare or the environment," as required by the plain language of CERCLA Section 102. [0398-PA DEP, 0512-Stericycle]

One commenter stated that without this substantiation, neither the anticipated benefits of the Proposed Rule nor the overall costs associated with it may be properly contextualized. [0512-Stericycle]

Furthermore, while EPA claimed that PFOA and PFOS exposure is associated with numerous health effects (i.e., high cholesterol, preeclampsia, thyroid disorders, etc.), a commenter stated that the science shows, at most, inconsistent associations with PFOA and PFOS exposures. For several of the endpoints, EPA conflates changes in biomarkers with increased risk of adverse disease outcomes in human when no causality between PFOA and PFOS and actual clinical disease has been scientifically established.

One commenter stated that ATSDR (2021) does not include thyroid effects in its list of health outcomes possibly associated with exposure to PFOA and PFOS, reflecting the lack of consensus on the relevance of PFOA and PFOS exposure to thyroid disorders and that ATSDR (2021) also noted "no studies found increases in the risk of low-birth-weight infants" associated with maternal serum PFOS levels. Therefore, decreased birthweight is not established as a substantial danger of PFOA or PFOS exposure." [0345-3M]

Several commenters addressed specific analyses on the epidemiology data regarding vaccine response and carcinogenicity. [0341-American Farm Bureau Federation (AFBF), 0569- US Chamber of Commerce Coalition, 0415-Association of Missouri Cleanwater Agencies (AMCA), 0421 – ACC, 0512-Stericycle, 0387-A1 Pennsylvania Chamber of Business and Industry et al, 0386-Renewable Water Resources (ReWa), 0518-Wet Weather Partnership (WWP), 0393-New Mexico Environment Department (NMED)]

The finding of reduced vaccine response is based on a unique population of children; in the Faroe Island study, researchers observed an association between maternal serum concentrations and antibodies in only one of two cohorts. The evidence for an increase in infection rates among children is conflicting and minimal. The assessment of potential carcinogenicity of PFOA was based on a study with a relatively small number of cancer cases that does not show a clear doseresponse. The data also conflicted with several other epidemiology and toxicology studies. [0421-ACC]

A commenter specifically underscored the need for a risk-based assessment rather than a hazard-based assessment; establishing that PFOA and PFOS are hazardous is beside the point because it does not inform the public about the actual concentration that would affect public health, just that the possibility, if mismanaged, exits. [0525 – Consumer Choice Center]

Some commenters urged EPA to focus on further understanding the risks from PFAS to the environment and human health to ensure policies and standards are being driven by science. These commenters recommended EPA rely on the best available science, complete and defensible toxicological evaluations, and appropriate risk assessment tools in establishing any human health and ecological toxicity values, regulatory standards, threshold levels, sampling methods, or cleanup actions for PFAS, while another commenter noted that science and technology have not advanced to the point at which PFAS standards are necessary to protect the environment and human health; additional research is needed to better inform standards set under the Clean Water Act and other environmental statutes. [0547 – ME DACF, 0298 – SD DANR, 0473 – MESERB]

Many commenters stated that EPA has not revised the December 2019 groundwater memorandum but issued revised HALs in June 2022 of 0.004 ppt (PFOS) and 0.02 ppt (PFOA) that is more than 17,500 and 3,500 times less than the prior HAL of 70 ppt that applied to both PFOS and PFOS individually and to a combination of those two PFAS chemicals. The new HAL is well below the value that laboratory methods can accurately quantify. Stated differently, drinking water analyzed at present time as not having detectable concentrations of PFOA and PFOS may in fact have concentrations well above the current HAL. One of these commenters stated that designating these chemicals as CERCLA hazardous substances before EPA has sufficient knowledge to even set a drinking water standard is unreasonable. [0341-American Farm Bureau Federation (AFBF), 0415-Association of Missouri Cleanwater Agencies (AMCA), 0340-Association of State and Territorial Solid Waste Management Officials, 0556-Institute of Scrap Recycling Industries (ISRI), 0375-Metropolitan St. Louis Sewer District (MSD), 0492-SC Water Quality Association (SCWQA), 0539-NC Water Quality Association (NCWQA), 0313-American Public works Association (APWA), 0512-Stericycle, 0569- US Chamber of Commerce

Coalition, 0303-Clermont County Water Resources Department, 0477-Louisiana Chemical Association (LCA)]

One commenter stated that it is also worth noting that a number of states and the Department of Defense have conducted a considerable number of evaluations of drinking water sources. This data provides strong evidence that at the prior HAL of 70 ppt there are a finite number of groundwater sources used for drinking water to address. Another commenter stated that the revised health advisories have been challenged in rulemaking litigation in separate petitions by the American Chemistry Council and Chemours alleging that the unachievable standards were established in circumvention of the SDWA and APA. [0341-American Farm Bureau Federation (AFBF), 0569- US Chamber of Commerce Coalition, 0415-Association of Missouri Cleanwater Agencies (AMCA), 0512-Stericycle, 0387-A1 Pennsylvania Chamber of Business and Industry et al, 0386-Renewable Water Resources (ReWa), 0518-Wet Weather Partnership (WWP), 0393-New Mexico Environment Department (NMED), 0415-Association of Missouri Cleanwater Agencies (AMCA)]

A few commenters stated that while per the proposed designation, "[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. [0556-ISRI, 0303-Clermont County Water Resources Department]

Several commenters stated that the inability to determine whether drinking water meets the current HAL or the soon to be proposed MCL creates additional unnecessary uncertainty about the potential impact of costs associated with the proposed CERCLA PFOA and PFOS designation. If EPA delayed this proposal until there was a final MCL, it would be possible to make some projections not possible at present about the costs and time needed to address drinking water contamination under CERCLA's remedial authority. [0341-American Farm Bureau Federation (AFBF), 0415-Association of Missouri Cleanwater Agencies (AMCA)]

A commenter stated that, although EPA indicates at 87 FR 54426 that it is not relying on the 2021 interim HAs, EPA cites to the interim HAs as support for the proposed CERCLA designations in no less than four passages in this Federal Register (FR) notice (see 87 FR at 54417, 54426, 54430 and 54431). Thus, clearly EPA has included the interim HAs as support for this proposed designation, and if not corrected, will almost certainly use them as support for future drinking water standards, effluent limitation guidelines, clean-up standards, etc. Importantly, not only are the underlying toxicity assessments behind the interim HAs flawed, but the toxicity values underlying the interim HAs have not been finalized by the Agency. EPA released the toxicity assessments in November 2021 for Science Advisory Board (SAB) review as part of their draft approach for deriving Maximum Contaminant Level Goals for PFOA and PFOS. [0815-DAIKIN, 0391-Superfund Settlements Project (SSP), 0543-American Water Works Association (AWWA), 0512-Stericycle, 0569-US Chamber of Commerce Coalition]

A few commenters stated that SAB in connection with its SDWA review issued their final review report to EPA in August of 2022, requesting that the Agency address several methodological flaws and concerns including but not limited to concerns about the consistent

application of inclusion and exclusion criteria for epidemiology data and animal studies and "concerns about the study evaluation and evidence synthesis process used by EPA." but that EPA has not yet responded to the SAB nor provided a revised toxicity assessment. Until EPA fully addresses the SAB's identified flaws and concerns, as well as those identified below, the EPA should not be relying on, in whole or in part, the interim HAs for this rulemaking. Another commenter stated that the National Academies of Sciences, Engineering, and Medicine questioned the use of many studies that EPA has endorsed and pointed to the raised issue of EPA's largely unsupportable reliance on the suppression of vaccine response in children as an appropriate health endpoint given the facts surrounding the subject study. This commenter also stated that the WHO's September 2022 draft provisional drinking water guideline values for PFOA and PFOS dismissed hundreds of the animal and human studies used by EPA and certain states in setting drinking water advisory levels and standards. [0815-DAIKIN, 0569-US Chamber of Commerce Coalition, 0391-Superfund Settlements Project (SSP)]

A few commenters stated that the PFOA and PFOS lifetime HAs are based on novel use of human data from the Faroe Islands published in 2012, with additional analysis published in 2017 and 2018, that show a decrease in vaccine antibody levels associated with increasing serum PFOA and PFOS levels in children. These commenters stated that these studies are controversial and have not been used by other agencies. One of these commenters stated that, since the initial release of the 2012 Faroe Island data, over a dozen U.S. and international agencies, including the U.S. Agency for Toxic Substances and Disease Registry (ATSDR), Health Canada, Germany, the Netherlands, the World Health Organization, Australian National University, Food Standards Australia New Zealand, California Office of Health Hazards Assessment, New Jersey Drinking Water Quality Institute, Minnesota Department of Health, and Michigan's Science Advisory Board, have rejected the use of these data as a critical effect endpoint for derivation of health-based regulatory values. [0815-DAIKIN, 0543-AWWA]

One commenter stated that EPA's evaluation of health effects includes significant reliance on human epidemiology studies. Human epidemiology studies have significant limitations, including an ability to establish causation. This is particularly problematic for cross-sectional studies; positive associations are scientifically simply not the same as proving a causal relationship. Whether an association is causal must be evaluated in light of possible alternative explanations, including bias, confounding, and chance. While many EPA assessments of other chemicals have conducted this type of evaluation, it is notable that, in the proposed rule, EPA is only able to discuss health effects that are associated with PFOA and PFOS, as causal relationships have not been established. The commenter also stated that in 2014 EPA proposed to rely on liver weight changes as the adverse effect but subsequent to peer reviews pivoted to a different endpoint. Peer reviewers also questioned whether the persistence of PFOA might lead to the induction of enzymes that could be beneficial to removing toxins from the body. One commenter stated that EPA should transparently discuss other health effects since it is currently unclear if cardiovascular disease, carcinogenicity, or developmental effects may be relevant at levels above the interim health advisory. [0569-US Chamber of Commerce Coalition, 0815-DAIKIN, 0543-American Water Works Association (AWWA)]

A commenter provided several problems with the use of the Faroe Islands epidemiological study including the study population, their diet, other contaminants to which they may be exposed, the measured outcome, and model used. [0815-DAIKIN, 0543-AWWA]

Another commenter [0815-DAIKIN] provided the details below:

Faroe Island studies: First, there is no unexposed control group in the cohort studies, which prohibits a determination of statistical association related specifically to PFAS exposure. Second, potential confounders were not fully examined by the study authors or EPA (Drew & Hagen, 2016). For example, the Faroe Island study population was also exposed to elevated levels of other contaminants that are also linked to immune system effects, including PCBs and methylmercury. Grandjean's statistical analysis did not adequately examine the potential for confounding effects. Grandjean et al. (2012) state, "Results adjusted for PCBs in milk and 5-year serum as predictors of PCB immunotoxicity were not materially different," however, the rationale for selection of this specific exposure period only was not well described and is inconsistent with EPA's dose metric and statistically significant time periods used for the PFOA and PFOS dose-response analysis. The potential confounding of methylmercury was also not addressed by Grandjean, nor EPA, despite Grandjean's own work demonstrating that the levels of PFOS concentrations correlated with the concentrations of mercury in Faroese whale meat consumers (Weihe et al., 2008). A third aspect of the Faroe Island studies that calls into question the reliability of the results is the fact that not all of the observed associations between PFOA and PFOS and antibody levels were statistically significant. EPA states: "No biological rationale has been identified as to whether one time period for exposure or outcome measures is more predictive of an overall immune response." (USEPA, 2021) p. 151). EPA then further suggests that "The variability in the [immunosuppression] results, including null and positive associations, could be related to differences in sample sizes, individual variation, vaccine type, and differences in timing of the boosters, as well as differences in timing of antibody measurements in relation to the last booster. However, these factors cannot be explored further with currently available evidence." It is also quite possible that the negative associations (i.e., the increase of PFOA/PFOS exposure related to a decrease in antibody level) could also be by chance or confounding that was not adequately addressed by EPA. As noted in a review of the immunotoxicity of PFOA and PFOS for Food Standards Australia New Zealand (FSANZ, 2017): "It is therefore possible that variables other than PFOS or PFOA may have contributed to lower vaccine antibody titer in the Faroe Island study, particularly if there is a common exposure pathway such as dietary fish or whale meat. Indeed, for the Faroe Island cohort, a number of environmental pollutants in the blood of mothers or children (PCBs, mercury as well as various PFASs) have been associated with altered levels of various antibodies in children... Some of the associations are much stronger than for the PFASs."

Use of these data as a critical effect endpoint: This commenter stated that the association between PFOA and PFOS and reduced vaccine antibodies is inconsistent across available studies and that EPA is unjustified for use of this novel endpoint as the critical effect for PFOA and PFOS.

In general, epidemiology studies on associations of PFOA/PFAS are plagued with inconsistent results and small effect sizes. In their 2021 review in support of draft toxicity criteria, California's Office of Environmental Health Hazards Assessment (OEHHA) determined that only approximately one third of the studies (4 out of 13 for anti-tetanus and 5 out of 13 for anti-diphtheria) that evaluated associations between PFOA and vaccine antibodies report a

statistically significant inverse association. An even smaller percentage of studies with PFOS found inverse associations (8% for anti-tetanus and 31% for anti-diphtheria). In addition, only the two studies selected by the EPA (out of thirteen studies available) showed PFOA or PFOS associations with antibody titers falling below protective levels

Results from the Faroe Islands cohort are inconsistent with data from other cohorts; overall there are not clear patterns or consistent findings between PFOA and PFOS exposure and vaccine responses from these or other datasets, and most results are not statistically significant. EPA has not provided a hypothesis to explain these inconsistent results, and therefore is unjustified in selecting this novel endpoint as the critical effect for deriving human toxicity values. Reductions in vaccine-induced antibody titers: Changes in vaccine antibody titers is not an informative metric of immunotoxicity. Vaccine antibodies are not solely responsible for immune function and protection against infection. A recent analysis concluded that the relevance of reduced vaccine antibody titers for human health risk assessment is questionable in the absence of an increase in clinical infections associated with PFAS serum levels, and an association cannot be concluded due to the small number of studies, heterogeneity of study methodologies, and small effect sizes (Antoniou et al., 2022). Epidemiology studies have reported inconsistent associations between both PFOA and PFOS and common infections or symptoms (see discussion in (ATSDR, 2021; Steenland et al., 2020)) and the National Toxicology Program scored both compounds as "low confidence" for association with infection disease outcomes (NTP, 2016). The evaluation of vaccine antibody titers may be a useful screening tool, as it provides preliminary information on potential immunotoxicity. However, there are natural fluctuations and wide variability of antibody levels observed in populations, due to a variety of factors, such as overall health of the individual, recent/previous infections, presence of other diseases, vaccine type, number of vaccine doses, current medications, etc. Therefore, it is incorrect to rely on vaccine antibody titers as a marker of immunotoxicity without additional measurements of immune function (Drew & Hagen, 2016). In many of the available studies that looked at PFAS associations with vaccine antibody titers, other common measurements of reduced immune function were not included. Both the United Kingdom Committee on the Toxicology of Chemicals in Food, Consumer Products and the Environment (UK-COT, 2021) and the European Medicines Agency (EMA, 2018) caution against the sole use of a reduced antibody titer as relevant endpoint to indicate an effect on vaccination efficacy. As mentioned above, the initial Faroe Island data have been available since 2012, and EPA's own 2016 evaluation and numerous other regulatory agencies have rejected the immunosuppression endpoint as the critical effect for various reasons (for example, see USEPA 2016a, 2016b, Health Canada 2018, Minnesota Department of Health, New Jersey Drinking Water Quality Institute, ATSDR 2021, FSANZ 2021.)

Although many suggest that the animal data corroborate the human immunotoxicity data, the immunologic animal data are largely from one strain of mice, exposed to several thousand times higher doses of PFOA or PFOS, and use a different immune endpoint that is not the same as human vaccine response. For example, Zodrow et al., (2022), demonstrates that serum levels of the no-observed effect levels associated with decreased antibody response to antigens in mice corresponded to internal doses of 675 to 2,360 ng/mL for PFOS and 21,400 ng/mL for PFOA, which is within or above the serum levels reported for exposed workers. Combined, there is no evidence that exposure to PFOA or PFOS, particularly at low environmentally relevant levels, results in immunotoxicity. The commenter stated that EPA's selection of vaccine antibody titers

as the critical effect for PFOA and PFOS toxicity values is unsupported by the available data and inconsistent with best practices for toxicity assessments.

Overly conservative benchmark response level (BMR) of 5%: The commenter stated that EPA relied upon dose-response analysis of the original Faroe Island data published by the study authors in 2018 (Budtz-Jørgensen & Grandjean, 2018) instead of conducting their own independent evaluation of the data. EPA's SAB requested that the Agency conduct their own analysis and transparently present and justify the results consistent with EPA's guidance (USEPA Science Advisory Board, 2022). EPA has not yet produced this analysis or presented and justified its results for public review.

Budtz-Jorgensen and Grandjean (2018) developed benchmark-dose models for maternal serum PFOA and PFOS and antibodies to tetanus and diphtheria vaccines at age 5 years (pre-booster), and for serum PFOA and PFOS at age 5 and antibodies to tetanus and diphtheria vaccines at age 7. EPA then selected the lowest benchmark doses, corresponding to the serum PFOA at age 5 and tetanus antibody response at age 5, and serum PFOS at age 5 and diphtheria antibody response at age 7, as the key critical effects and points of departure for their PFOA and PFOS toxicity values. EPA claims that their technical guidance instructs them to use a lower benchmark response (BMR) "when severe or frank effects are modeled" (PFOA document p. 320). As such, the rationale for the BMR 5% for immune effects are based on the assumption that the effects are "severe". For PFOA, EPA states: "Diphtheria and tetanus are serious infectious diseases that can lead to medical conditions that range in severity and including the most severe, fatality. Anti-tetanus and anti-diphtheria antibody concentrations can protect against and prevent these diseases. For an endpoint of mortality, a BMR of 1% is recommended. For a developmental effect, a BMR of 5% is recommended. Given the range of health outcomes includes fatality and the effect on children, a BMR of 5% is a reasonable and appropriate choice."

This EPA rationale for selection of a 5% BMR grossly overstates the findings of the Grandjean studies. In the Grandjean studies, none of the antibody levels were associated with any known increase in infectious diseases in the Faroese children. In fact, the antibody variation noted within the Grandjean studies likely falls within the natural wide variability of antibody levels. Therefore, the reduced antibody levels should not be interpreted as "severe" even if the disease for which the vaccines are designed against are considered "severe." Instead, consistent with EPA's Benchmark Dose Technical Guidance, it should have used a BMR of 10% (USEPA, 2012).

Use of the epidemiology immune data to derive toxicity values for PFOA or PFOS is inconsistent with other authoritative agency reviews of the same data worldwide: The commenter stated that key questions remain on the suitability of the human data to support inference of causal effects of PFAS exposure on immune system function and what the dysregulation mechanism(s) of PFAS-mediated immunotoxicity may be.

Health Canada's 2018 review of the available data led them to conclude that "...the [immune] dataset remains relatively small with only 5 studies, which were all observational, and the risk of residual confounding, bias and chance cannot be discounted. Although all studies investigated the effects on the immune system, the outcomes were not specific (measured different effects), no clear dose-response was observed, and most associations were weak. Conflicting results were common in the dataset, with variations observed between genders, specific microbial immunoglobulins, PFASs, infections, mother vs. child exposure, and child years, amongst other

characteristics. These flaws impede concluding on a causative mechanism, and the nature of the association remains unclear." (Health Canada, 2018)

Food Standards Australia New Zealand (FSANZ) recently reviewed the available epidemiology literature pertaining to PFAS and immunotoxicity and concluded that "...the data are insufficient to establish causal relationships and it cannot be ruled out with reasonable confidence that the observed statistical associations may have been due to confounding, bias or chance. On the basis of the uncertainties and limitations in the evidence base, immunomodulation is not currently considered suitable as a critical endpoint for quantitative risk assessment of PFAS." (FSANZ, 2021).

Regarding the immune endpoint, the World Health Organization recently concluded: "In summary, it is suggested that decreased antibody response to vaccination may lead to reduced immune system functionality. However, studies report inconsistencies in the relationship between PFAS exposure and infection propensity in early life (Antoniou et al., 2022; ATSDR, 2021; EFSA, 2020; Steenland et al., 2020; US EPA, 2021a; 2021b) and therefore, the clinical relevance of these findings is unclear. More studies, particularly with more objective measures of infections, are needed (EFSA, 2020)." (WHO, 2022)

Cancer risk evaluation: The commenter stated that although noncancer effects drive the humanhealth based regulatory values for drinking water, EPA's PFOA and PFOS cancer evaluation is relevant for CERCLA because noncancer and cancer risks are evaluated separately at contaminated sites. EPA's documentation also suggests there is cancer risk associated with exposure to PFOA and/or PFOS. The section of carcinogenicity classification of PFOA/PFOS list some epidemiology studies and the results of animal studies with the endpoint carcinogenicity. However, a detailed evaluation of the studies is not provided, and conclusions made by other organizations are mainly used and uncertainties in the evaluations are not given. In the Agency's 2021 toxicity assessment, EPA developed multiple draft cancer slope factors (CSFs) for PFOA based on animal studies and human epidemiological studies. EPA derived the most conservative CSFs for PFOA based on the Shearer et al., (2021) epidemiological study for incidences of renal cell carcinoma. However, this study is not appropriate to derive a CSF due to numerous limitations. Steenland and Winquist, (2021) pointed out that serum PFAS concentration contrasts in Shearer et al. study were relatively small, as they reflected general population levels (the lowest PFOA concentration quartile was <4 ng/ml, while the uppermost was >7.3–27.2 ng/ml). This raises a question regarding the defensibility of the risk ratios for the dose-response. In addition, the study utilized a serum level measured at one point in time as the baseline, which does not account for cumulative exposure and likely mis-represents changes in exposure levels over time. Therefore, attributing cancer incidences based on a single serum baseline measurement will overestimate the cancer potency and result in overly stringent cancerbased screening levels for CERCLA risk assessments.

Steenland et al., (2020) concludes regarding PFOA that "Overall, the epidemiologic evidence remains limited "and "the epidemiologic evidence remains supportive but not definitive for kidney and testicular cancers." For PFOA, EPA acknowledges that the results in epidemiology studies are mixed without a clear conclusion possible and lists the limited animal studies available as supporting evidence. However, human relevance of the observed tumors in animals and modes of action are not discussed. EPA's mechanistic evaluation is generally superficial for all endpoints. EPA's own cancer guidelines call for an evaluation of carcinogenic mode of action and analysis across multiple lines of evidence (USEPA, 2005).

Response

EPA disagrees that the scientific evidence is insufficient to support the determination that PFOA and PFOA may present a substantial danger when released into the environment. As explained in the preamble to the Final Rule, the scientific evidence supports EPA's conclusion that PFOA and PFOS may pose a substantial danger to human health, welfare and the environment when released based on a large number of studies on the potential adverse impacts associated with exposure to those substance and other characteristics of those substances (e.g., bioaccumulative, persistent, and mobile). See Section V of the Preamble to the Final Rule. Along with concluding that PFOA and PFOS "may present a substantial danger," EPA also exercised its discretion to conduct an additional "totality of the circumstances" analysis. 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 provides the necessary tools to protect human health, welfare, and the environment from exposure to both existing and new releases of PFOA and PFOS and ensure that those responsible for the contamination are required to pay to clean it up. See Section VI of the Preamble to the Final Rule. Many of the comments above are addressed in the preamble to the Final Rule and to the extent they are not we address them below.

EPA relied on an extensive body of final, peer reviewed science in concluding that PFOA and PFOS may present a substantial danger when released into the environment, and the Agency considered the same factors in evaluating PFOA and PFOS under CERCLA section 102(a) as are considered when substances are designated hazardous under other environmental statutes. See Section IV.B. of the Preamble to the Final Rule. Thus, the commenter's assertion that the designation establishes a minimal threshold for evidence necessary to establish substantial danger is misplaced. See Preamble to the Final Rule Section IV.A (CERCLA section 102(a) Designation Considerations).

As explained in Section V of the preamble to the Final Rule, the scientific studies support a conclusion that exposure to PFOA and PFOA can result in a wide range of adverse human health effects and that it can negatively impact animals and many of the comments concerning the hazards posed by PFOA and PFOS are addressed therein and in the portion of the preamble responding to significant comments.

Regarding the commenter's claim that EPA's evidence for potential adverse health effects is drawn from Lifetime Health Advisories (LHAs) developed by the Office of Water in 2016, EPA believes the commenter is conflating the LHAs with the scientific Health Effects Support Documents (HESDs) supporting the LHAs. The HESDs supporting the 2016 LHAs were peer reviewed, final toxicity assessments suitable for helping to inform EPA's designation decision. 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 2022 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 support the finding that they "may present substantial danger to the public health or welfare or the

environment" when released into the environment." While beyond the scope of this action, EPA rejects the commenter's assertion that the draft MCLG documents are inherently flawed because of issues identified by the 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. 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 RfDs² for PFOA and PFOS. See preamble Section VII.C. (Toxicity, Human Health Effects/ Mobility, Persistence, Prevalence/ Release into the environment).

EPA also strongly disagrees with the claim that designation of PFOA and PFOS is premature. EPA has evaluated many studies of PFOA and PFOS and has determined that exposure to these substances can result in adverse effects to human health and ecosystems. And, although one commenter argues that the Agency lacks a complete understanding of the sources of PFOA and PFOS contamination, in fact, the data demonstrate the environmental prevalence of these substances and the Agency finds that the most contaminated sites are likely those where PFOA and PFOS were manufactured and or used in the manufacture of products. See Preamble to the Final Rule Section V.A. (PFOA and PFOS Pose a Hazard) and V.C. (Other Information Considered). In addition, EPA notes that the available information supports a conclusion that many communities and ecosystems may be at risk of exposure to dangerous levels of PFOA and PFOS because these substances have been in use since the 1940s and because they are persistent and mobile once released into the environment.

EPA does not agree that the ongoing efforts by EPA and other interested parties to evaluate the hazards posed by PFOA and PFOS, to improve methods to test for and address PFOA and PFOS contamination, or to establish standards for the regulation of PFOA and PFOS change the fact that PFOA and PFOS present hazards today that must be addressed in order to protect communities and ecosystems from unacceptable levels of risk. EPA further notes that there are methods available to address PFOA and PFOS contamination that also address other CERCLA hazardous substances and that we expect methods to improve as we address the hazards posed by

² 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)

PFOA and PFOS. In fact, EPA has already started addressing PFOA and PFOS contamination at NPL sites as pollutants or contaminants, so we know there are ways to protect disproportionately impacted communities from exposure due to their location close to highly contaminated sites.

EPA also notes that there is no prerequisite that drinking water standards or health advisories be available before designating a hazardous substance under CERCLA. With respect to drinking water standards, less than 100 of the over 800 currently listed CERLA hazardous substances have drinking water standards (https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulation-table) so it is clear that a drinking water standard is not a prerequisite to designation. Moreover, EPA HAs primarily serve as information to drinking water systems and officials responsible for protecting public health when emergency spills or other contamination situations occur. They are non-enforceable, but they can help inform setting CERCLA cleanup levels.

In any case, 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 MCLGs as relevant and appropriate cleanup standards 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.

In addition, EPA has set Regional Screening Levels (RSLs) and Regional Removal Management Levels (RMLs) for PFOA and PFOS (https://www.epa.gov/risk/regional-screening-levels-rsls). Although these are not cleanup standards, these levels support site risk assessments that help EPA determine if investigation and/or response (removal or remedial) activities may be needed. For further information regarding EPA's reasoning on the above issues, see the Preamble to the Final Rule Section IV. (Legal Authority), Section VI. (Totality of the Circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted), Section VIII. (Summary of this Final Rule), Section VII.A.2. (Interpretation of the phrase "may present substantial danger").

See also Preamble to the Final Rule, Section VII.C. (Toxicity, Human Health Effects/Mobility, Persistence, Prevalence/Release into the environment); RTC Section 2.A.2-3 and 3.C.2 (responding to comments on the science underlying the rule); Section V of the final preamble and RTC Section 2.A.1. (responding to comments on the standard for designating PFOA and PFOS as hazardous substances under CERCLA section 102(a)); RTC Section 4F (responding to comments on liability and enforcement); and RTC Section 6 (responding to comments on costs and economic assessment).

3.C. Miscellaneous

3.C.1 The inclusive definition used for PFOA and PFOS and data on health effects and toxicity.

A commenter expressed support for the inclusive definition for PFOA and PFOS, which included salts and structural isomers – linear and branched. The commenter noted the inclusive definition

is necessary to ensure the substances imported and manufactured are covered by the designation, in addition to the substances formed by precursor compounds and remaining from legacy production. Another commenter also stated their support for amending Part 302 of the CERCLA regulations to add PFOA and PFOS including their salts and structural isomers. [0365 – Environmental Protection Network (EPN), 0567 – WE ACT for Environmental Justice]

Response

EPA agrees that the available scientific and technical information about PFOA and PFOS, and their salts and isomers, support designation. For additional discussion refer to the Preamble to the Final Rule, Section VIII.B (Direct Effects of Designating PFOA, PFOS, and their Salts and Structural Isomers as Hazardous Substances). For additional discussion on toxicity and health effects refer to the preamble to the Final Rule, Section V, and VII, C. (Toxicity, Human Health Effects/Mobility, Persistence, Prevalence/Release into the environment).

3.C.2 Differentiating between PFOA, PFOS, and different types of PFAS

A commenter expressed concern that the proposed rulemaking often references the general category of "PFAS," notwithstanding that the rulemaking itself is limited to the CERCLA designation of only two substances. EPA refers to "PFAS" throughout the rulemaking and, in many instances, attributes information specific to PFOA and/or PFOS (or potentially, other nonpolymeric PFAS) to the broad category of PFAS. For example, EPA states that "the potential dangers posed by PFOA and PFOS specifically, and more generally by PFAS, have been recognized by numerous Federal, state and international government entities..." However, the PFAS category of substances includes thousands of substances with different and distinct chemical, physical, and toxicological properties. Furthermore, commenter noted that other administrations and agencies have acknowledged that not all PFAS are the same and may present different levels of potential risk to human health, including the U.S. EPA's Office of Chemical Safety and Pollution Prevention, which set forth a regulatory approach that rejects treating all PFAS as the same and instead intends to group them based on their toxicity and other factors. Overall, the commenter supported efforts to categorize and make regulatory decisions by PFAS groups prioritized by hazard and risk but requests that EPA clearly and consistently differentiate among the different types of PFAS, both in any listing determination of PFOA and PFOS, as well as any subsequent considerations. [0408 – W.L. Gore and Associates]

Response

EPA agrees that the rule should differentiate between the terms "PFOA," "PFOS," and "PFAS" and the Agency has attempted to make the necessary differentiation in the final rule. For additional discussion refer to the preamble to the final rule, Section VIII.B (*Direct Effects of Designating PFOA, PFOS, and their Salts and Structural Isomers as Hazardous Substances*). For additional discussion on toxicity and health effects refer to preamble to the final rule, Section V, and VII. C (*Toxicity, Human Health Effects/Mobility, Persistence, Prevalence/Release into the environment*).

3.C.3 Bearing of WHO analysis on designation

A commenter countered statements by other commenters that used the recent World Health Organization analysis of PFOA and PFOS to cast doubt on the well-established science that PFOA and PFOS are toxic at low-levels. The commenter stated that the recent WHO analysis was deeply flawed and unauthoritative; the draft report stated that it was not intended to be a comprehensive summary of the primary literature, and therefore, not all studies were cited. The commenter stated that the report should have no bearing on the EPA's decision because it applies discredited toxicokinetics data, dismisses cholesterol and immune impacts, and excludes new studies showing PFOA and PFOS toxicity at low levels. Additionally, other commenters stated that causality between PFOA and PFOS and adverse health effects in humans has not been established, especially for immune effects (e.g., WHO 2022).

On the other hand, a number of commenters stated that the World Health Organization (WHO) recently proposed drinking water standards of 100 ppt for each of PFOA and PFOS and 500 ppt for combined PFAS which that are more firmly grounded in science. This would be comparable to the prior 2016 HAL of 70 ppt and may be more in line with what EPA may propose for drinking water limits. These commenters stated that EPA needs to address this disparity in health-based levels for these chemicals by the world's two leading public health agencies before EPA takes any further regulatory action. [0341-American Farm Bureau Federation (AFBF), 0569-US Chamber of Commerce Coalition]

Response

EPA considered all the available peer reviewed studies concerning PFOA and PFOS and also considered other information, including the WHO proposed Guidelines for Drinking-water Ouality, when determining that those substances may present a substantial danger and concluded that the evidence supports a conclusion that exposure to them can lead to a broad range of adverse health effects. See Section V of the Preamble to the Final Rule. However, EPA does not agree that the Agency should refrain from designating PFOA and PFOS under CERCLA section 102(a) because of the WHO draft Guidelines. The WHO provisional guideline value of 100 ng/L is not a health-based value because WHO takes into account practical issues such as monitoring feasibility and analytical methods. Therefore, the WHO provisional guidelines cannot be directly compared to EPA's lifetime HALs or MCLGs, which are only based on health effects information. Furthermore, the WHO states in their response to comments on the Background document for the development of their provisional guideline values that: "The provisional guideline value of 100 ng/L for PFOA and PFOS proposed in the draft background document is not a health-based value and the draft background document does not suggest this is a safe level of exposure. Therefore, the WHO's proposed provisional guideline value should not be compared to health-based values established by other agencies."(https://cdn.who.int/media/docs/default-source/wash-documents/wash-chemicals/pfosand-pfoa-in-dw-comments-responses-21.11.23.pdf?sfvrsn=71261026 1)

For these reasons, EPA does not agree that the proposed WHO drinking water standard should be the main or even a primary consideration in the Agency's determination that PFOA and PFOS may present a substantial danger. See Preamble to the Final Rule Section V (discussing the scientific and technical information considered in determining that PFOA and PFOS may present a substantial danger).

3.C.4 Inclusion of salts or structural isomers of PFOA and PFOS

A few commenters stated that the inclusion of isomers in the definition of PFOA and PFOS is not justified as EPA presented virtually no scientific information on the isomers and their

environmental and human health effects, and therefore, did not demonstrate that each of the isomers and salts "may present a substantial danger to the public health and welfare or the environment." A commenter noted that EPA did not identify or least list what substances are included in "all salts and structural isomers" at the time of proposal. EPA only cited the CAS registry numbers that apply to n-perfluorooctanoic acid and n-perfluorosulfonic acid. Furthermore, current analysis for PFAS by any EPA method does not mention chromatographic resolution of the structural isomer peaks and quantitative reference standards are not available for most branched isomers. Overall, the commenter stated that EPA must justify the listing of each compound that will be designated as a hazardous substance. [0419 – API et al., 0569 – Chamber of Commerce, 0495 – PFAS Regulatory Coalition]

Response

EPA disagrees with the comment and concludes that the scientific and technical information about PFOA and PFOS salts and isomers supports including them in the designation. PFOA and PFOS salts and isomers) can occur in acid forms (e.g., perfluorooctanoic acid) and salt forms (e.g., ammonium perfluorooctanoate). Salts are deemed to have the same toxicity as the commonly referenced acid versions because, once put in water (and likewise when in 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. (2004) used the ammonium salt of PFOA. The potassium salt of PFOS was generally used in animal toxicity studies such as Ankley et al. (2004). These studies note that PFOA or PFOS were dissolved in water to prepare the test solutions. The potassium perfluorooctanesulfonate has a water solubility of 0.5 g/l, and ammonium perfluorooctanoate and sodium perfluorooctanoate have water solubility of 374 and 169 g/l, respectively (Jenson et al. 2008). For additional discussion refer to the final rule section VIII subsection B. Direct Effects of Designating PFOA, PFOS, and their Salts and Structural Isomers as Hazardous Substances. For additional discussion on toxicity and health effects refer to the final rule section V., and VII., subsection C. Toxicity, Human Health Effects/Mobility, Persistence, Prevalence/Release into the environment.

In the rule section of the Final Rule, EPA is including the list of all known salts and isomers of PFOA and PFOS in Appendix C and D.

3.C.5 Disparity Between Assessments

A commenter asserted that the EPA assessment approach is at odds with another government body, the Food and Drug Administration (FDA). The commenter stated that EPA should attempt to reconcile the disparity between assessments used between the two regulatory bodies because FDA has stated that whatever PFAS exposure exists with the drugs and devices, they are safe to the point where the benefits far outweigh the risks. Overall, the commenter was concerned that if EPA approaches PFAS production too strictly, costs will be inflated and reliance will be shifted to other countries to provide the U.S. with PFAS.

For regulatory policy to be sensible and evidence-based, regulators need to differentiate between hazard- and risk-based assessments. The arguments that have led to criticism of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) are based on hazard-based assessments. In its own words, the EPA writes "CERCLA authorizes the Administrator to promulgate regulations designating as hazardous substances such elements, compounds, mixtures, solutions, and substances which, when released into the environment, may present

substantial danger to the public health or welfare or the environment." The inherent difference between hazard- and risk-based assessments is that hazard is something that could potentially cause harm, while risk analyses the likelihood that it will.

Many household cleaning items used by consumers on a daily basis could be viewed as highly hazardous, and they are. From a risk management perspective, they represent no acute public health danger because consumers are well-aware that drinking their window cleaner solution is detrimental to their health.

Thus establishing that PFOA and PFOS are hazardous is beside the point – it does not inform the public about the actual concentration that would affect public health, just that the possibility, if mismanaged, exists. If the standard of "if released into the environment" and "present substantial danger to public health or welfare or the environment" were to be applied across the board, then a wide array of consumer goods or building materials would never be approved for use. Regulators should make the distinction between intended use, and leakage or dumping for which companies and individuals ought to be made responsible.

To that end the EPA needs to provide the following information:

- To what extent has the presupposition of "if released into the environment" been based on leakage and illicit dumping? Have there been instances in which substantial danger to public health, or welfare, or the environment, were determined within the realm of intended use of PFOA and PFOS?

Additionally, there appears to be a significant divide between government agencies regarding PFAS exposure more generally. The EPA's approach to PFAS is at odds with another government body, the Food and Drug Administration (FDA). The FDA, the regulatory body responsible for ensuring that pharmaceuticals and medical devices work, and that their health benefits outweigh their known risks, has continuously approved both drugs and devices that contain PFAS. Most don't know that the medical community is heavily reliant on PFAS products. Take for example medical implants like vascular grafts, stent grafts, surgical meshes, catheter tubes/wire and heart patches. It is estimated that 8-10 per cent of Americans have implantable medical devices, many of which rely on PFAS, and are approved by the FDA. In fact, the implantable medical devices market, valued at \$72.2 billion, is expected to grow significantly as the American population continues to get older.

Drugs containing PFAS, again approved by the FDA, include but are not limited to to Tachyarrhythmias (Flecainide), antidepressants (fluoextine), non-steroidal anti inflammatories (celecoxib), antibiotics (levofloxacin), rheumatoid arthritis therapeutics (leflunomide), cholesterol lowering agents (atorvastin), and even Covid19 antivirals such as Paxlovid.

For all of those drugs and devices, the notoriously over-cautious FDA has clearly stated that whatever PFAS exposure exists with these products, they are safe to the point where the benefits far outweigh the risks. Simply put, the presence of PFAS for these drugs and devices pass a safety check and a cost benefit analysis.

What we have here is two government agencies taking drastically different approaches to the

issue of PFAS. The EPA should take into consideration the FDA's approval process for pharmaceuticals and medical equipment and attempt to reconcile the disparity between the two regulatory bodies.

Lastly, there is a long list of troubling consequences if the EPA approaches PFAS production too strictly. Those include but are not limited to:

- 1) Significantly increasing the costs of responsible production, which will inflate costs for products that use PFAS in the production process. This would add to existing inflationary pressures and worsen the inflation crisis.
- 2) Shifting reliance on PFAS to China, which puts America at a strategic disadvantage and runs the risk of significantly disrupting supply chains should conflict arise in Taiwan. It is also worth nothing that by shifting reliance into China, the US is thus encouraging production in a jurisdiction where the level of environmental stewardship is significantly lower. [0525 Consumer Choice Center]

Response

EPA disagrees that there is a disparity between EPA and FDA assessments. The commenter is correct that FDA has approved drugs and medical devices that contain PFAS or are PFAS. However, this rulemaking is specific to PFOA and PFOS, and the FDA has not approved drugs or devices that contain PFOA and PFOS. EPA also disagrees that designation of PFOA and PFOS will impact production of PFAS generally and, as discussed in the preamble to the Final Rule, PFOA and PFOS production and use have been largely phased out in the US in response to studies indicating the hazards posed by those substances. Furthermore, consistent with this Final Rule, in 2016, the FDA revoked the regulations authorizing the remaining uses of these longchain PFAS in food packaging (see 81 FR 5, January 4, 2016 and 81 FR 83672, November 22, 2016). As of November 2016, long-chain PFAS are no longer used in food contact applications sold in the United States. Even if PFOA and PFOS were authorized for use in some critical medical implants (e.g., stents and vascular grafts), that would not undermine EPA's designation under CERCLA because many medical implants are necessary to sustain life in the short term so risk of potential long term adverse effects from PFOA and PFOS exposure would be of much less concern than the risk of forgoing a life-saving device needed today. EPA believes there is a significant difference between a person that accepts a risk knowingly, as in the case of an implant recipient, and a person that is exposed to an unacceptable level of risk because of another person's release of a harmful substance into the environment.

EPA agrees that there is a difference between a hazard and a risk. Hazardous substances are those that have the potential to cause serious reversible and irreversible adverse human health and environmental impacts at relatively low doses. As discussed in the preamble to the Final Rule, the many studies of PFOA and PFOS support a conclusion that exposure to PFOA and PFOS can cause a wide range of adverse human health effects. Risk, as the commenter indicates, can only be determined based on potential exposure. With respect to PFOA and PFOS, the available information supports EPA's conclusion that many communities are potentially at risk of repeated exposure to high levels of PFOA and PFOS in large part due to the widespread use of PFOA and PFOS in many industrial sectors since the 1940's. Thus, PFOA and PFOS pose a hazard and there is a risk of exposure to high levels of PFOA and PFOS. Furthermore, after

designation of PFOA and PFOS, CERCLA and its implementing regulations require the level of risk be considered before establishing a remedy and that requirement ensures that the costs of addressing PFOA and PFOS releases are limited to those costs necessary to address unacceptable risks from the releases. See Section XX of the Preamble to the Final Rule (explaining how risk is considered when determining the appropriate remedy under CERCLA).

3.C.6 National Standards and Limits

Additionally, while there are regions that face high PFOA and PFOS concentrations that require immediate action and response, setting a national standard must be based on accurate and current national occurrence and toxicity data before a single approach, requiring significant funding and staffing is required of all water systems.

A commenter recommended that EPA identify industrial users who produce PFAS and promulgate limits that can be enforced, inspected, and sampled. [0322 – Environmental Compliance Manager]

Response

Comments appear to be commenting on EPA's proposed drinking water standard for PFOA and PFOS and several other PFAS and suggesting EPA issue effluent standards for PFOA and PFOS, and, for this reason, the comments are outside the scope of the final rule. A hazardous substance designation under CERCLA does not set standards nor produce limits that can be enforced, inspected and sampled.

3.C.7 Uncertainties regarding cleanup, D&D, standardization of testing

[0366 – EHP, 0565 – USWAG, 0391 - SSP] A few commenters noted that the Proposal is not appropriate given the significant uncertainties regarding the presence and extent of PFOA and PFOS use and contamination, and associated assessment, cleanup criteria, remediation, destruction, and disposal technologies and methodologies. Strict guidelines on what testing would look like as a part of the Proposed Rule should be included. While there is some information available regarding PFAS testing strategy (i.e., National PFAS Testing Strategy Report released in 2021), the current Proposed Rule does not address a standardization of testing for PFOA and PFOS that is crucial for businesses and facilities. One of these commenters underscored the discrepancies in reporting based on differences in the accuracy and sensitivity of the testing method.

A commenter stated that overall, the Proposed Ruling is ahead of the science and technology, and therefore, inappropriate at this time. Another commenter stated that while PFOA and PFOS do pose threats to the environment and human health, there has to be 100% certainty regarding the health outcomes following PFOA and PFOS exposure.

Response

EPA does not agree with the comments that the rule is not appropriate given what commenters stated are significant uncertainties.

Regarding the extent of PFOA and PFOS releases and associated assessments, EPA has evaluated studies of PFOA and PFOS and has determined that exposure to these substances can result in adverse effects on public health. EPA has clearly delineated the environmental prevalence of these substances. In addition, the Agency intends to focus its attention on those sites

where PFOA and PFOA were manufactured or used in the manufacture of products after designation. 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. See Preamble to the Final Rule Section VII.B.1 (Comments suggesting that other authorities are better suited to address PFAS contamination), Preamble to the Final Rule Section V.A. (PFOA and PFOS Pose a Hazard). V.C. (Other Information Considered) and RTC 2C-1 (Statutory Authorities Available to Address PFOA/PFOS, CERCLA)

Regarding testing, this final designation under CERCLA does not require any testing. Regarding the availability of analytical methods, EPA recognizes that robust, reliable and accurate sampling and analytical methods are essential for detecting and measuring PFAS contamination in air, land, and water, evaluating exposure risks, and determining the effectiveness of destruction and removal technologies. To address this need, EPA has validated and published several standardized analytical methods that are suitable for quantitative analysis of PFOS, PFOA and other PFAS analytes in drinking water and other relevant environmental media. EPA scientists continue to collaborate with other federal and state agencies, commercial testing laboratories and academia to develop and validate additional PFAS sampling and analysis methods, and as these methods are published and made publicly available, EPA and the public will have additional tools with which to generate the data they need to make risk management decisions from PFOS and PFOA contamination in the most efficient and cost-effective manner possible. For information about cleanup requirements and regulatory standards, *see RTC 4.E.1(Clean Up Goals)*.

For information about remediation, destruction and disposal technologies, *see RTC 4.E.1(Clean Up Goals) & 4.E.2 (Managing PFOA/PFOS Contaminated Waste)*. There are currently methods available to address PFOA and PFOS contamination and the Agency and other parties continue to work to improve those methods.

Finally, EPA does not agree that absolute certainty is required before designation is warranted. See Section IV. Legal Authority, A. CERCLA section 102(a) Designation Considerations of the Preamble to the Final Rule (explaining that the CERCLA section 102(a) does not require certainty as to the scope and extent of the hazard before designation).

3.C.8 Site-specific risk assessment

[0391 - SSP]

A commenter noted it is difficult to accurately identify protective threshold concentrations, such as the no-observable-effects concentrations. Robust studies are needed to identify such concentrations. The commenter highlighted a multigenerational study of the effects of PFOS on the zebrafish completed by the U.S. Army Corps of Engineers in collaboration with EPA. The zebrafish study may be an extreme example, but until sufficient studies are done to identify accurate and confident threshold concentrations, hyper-conservative regulatory criteria will remain in play and will drive remedial goals (concentrations) that are multiple orders of magnitude more conservative than necessary to be protective.

Commenter Note: 121 Gust, K. A., Mylroie, E., Kimble, A.N., Wilbanks, M. S., Catherine, J., Cox, S., Chapman, K.A., Kennedy, A. J., Jensen, K., Erickson, R., Ankley, G., Conder, J., Vinas,

N. G. Moore, D. M. In preparation. Survival, Growth, and Reproduction Responses in a Three-Generation Exposure of the Zebrafish (Danio rerio) to Perfluorooctane Sulfonate (PFOS). Excerpt ID(s): 62882, 62813

Response

EPA strongly disagrees that the scientific evidence is insufficient to support the development of accurate protective threshold concentrations for-PFOA and PFOS. For example, EPA released draft PFOA and PFOS Water Quality Criteria for the Protection of Aquatic Life in 2022³, ⁴. These documents evaluated available acute and chronic PFOA and PFOS toxicity data and specifically identified protective toxicity thresholds based on the scientific evidence available at the time these draft documents were released. EPA intends to finalize the PFOA and PFOS Aquatic Life Criteria in the near future. Moreover, the preamble to the Final Rule explains that the scientific evidence supports EPA's conclusion that PFOA and PFOS pose a danger to human health and welfare as well as the environment. The preamble to the Final Rule drew these conclusions from a large number of studies on the potential adverse impact associated with exposure to those substance and other characteristics of those substances (e.g., bioaccumulative, persistent, and mobile). See Section V of the Preamble to the Final Rule. Along with concluding that PFOA and PFOS "may present a substantial danger," EPA also exercised its discretion to conduct an additional "totality of the circumstances" analysis. 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 provides the necessary tools to protect human health, welfare, and the environment from exposure to both existing and new releases of PFOA and PFOS and ensure that those responsible for the contamination are required to pay to clean it up. Further, Superfund remedial sites are evaluated with a site-specific risk assessment to determine if cleanup is needed and what the cleanup levels should be. The Superfund program does not set general cleanup levels that would be applicable to all sites, and designation of PFOA and PFOS as hazardous substances would not set regulatory criteria for cleaunup.

³ https://www.epa.gov/wqc/aquatic-life-criteria-perfluorooctane-sulfonate-pfos

 $^{^4\,\}underline{\text{https://www.epa.gov/wqc/aquatic-life-criteria-perfluorooctanoic-acid-pfoa}$

4. Effects of Designation

4.A. Reporting and Notification Requirements

4.A.1 The reportable quantity (RQ) of one pound is appropriate.

The commenter supported reporting of a release of 1 lb. or greater of PFOA/PFAS within a 24-hour period. [0273-Lowry Landfill Superfund Site Citizens Advisory Group (LLSF Site CAG)]

Response

EPA agrees that, at this time, a reportable quantity of one pound for PFOA and PFOS is appropriate. EPA has the authority to revise the RQ level in the future and the Agency may consider doing so after the final rule is effective, and the Agency begins receiving release information on PFOA and PFOS substances based on the default one-pound statutory RQ.

4.A.2 Reportable quantity (RQ) for PFOA and PFOS should be set either higher or lower than 1 pound.

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. [0503-The National PFAS Contamination Coalition (NPCC), 0519-West Virginia Rivers Coalition, 0426-California Department of Toxic Substances Control (DTSC), 0810-Environmental Defense Fund (EDF), 0355-City of Los Angeles Sanitation and Environment (LASAN), 0458-Earthjustice et al, 0564-U.S. PIRG Education Fund & Environment America, 0552-Environmental Working Group (EWG), 0374-Minnesota Pollution Control Agency (MPCA), 0452-Defend Our Health, 0452-Defend Our Health, [0551-Cross-Cutting Issues Group (CCIG), 0552-Environmental Working Group (EWG)]

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. See RTC 4.A.1.

4.A.3. Continuous Release Reporting option

A commenter stated that recent studies have shown elevated levels of PFAS in some reclaimed water sources used for industrial purposes which would disincentivize facilities from using PFAS containing reclaimed water because it would complicate their compliance with underground injection control (UIC) regulations, opting instead for fresh water that does not contain any PFAS, because the plants cannot operate without cooling water. Cooling water towers also emit large amounts of water vapor originating from the use of reclaimed water into the air in the form of drift droplets. The commenter asserted that the Proposed Rule could trigger continuous release reporting requirements under CERCLA Section 103(f)—and, because of the low RQ, could potentially affect all facilities using reclaimed water that contains even trace amounts of PFOA or PFOS. [0551-Cross-Cutting Issues Group (CCIG)]

Response

Any entity may use the continuous release reporting option instead of reporting every time an RQ is met or exceeded every 24 hours, if certain criteria described in the regulations at 40 CFR 302.8 are met.

4.A.4 The reportable quantity (RQ) should be chemical-specific, not applied to PFAS as a class.

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 expressed that EPA should assign a separate RQ for each of these substances similar to the RQs assigned to radionuclides based on their intrinsic hazard. [0419-American Petroleum Institute (API) et al, 0428-Citizens Against Ruining the Environment (CARE)]

Response

EPA disagrees with the commenter that the RQ for PFOA and PFOS, their salts and isomers is not chemical specific. Each of these substances are assigned a default RQ of 1 pound pursuant to CERCLA section 102. 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 RQ of one pound for radionuclides. *See Notification Requirements; Reportable Quantity Adjustments*, 48 Fed. Reg. 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 Fed. Reg. 22405, 22524 (May 24, 1989).

4.A.5 The reportable quantity (RQ) should be applied over a different time period than 24 hours.

A commenter preferred a monthly reporting scheme, rather than daily reporting, and with no follow-up reporting requirement because the conditions of the discharge would not change day to day and therefore could be handled in monthly operating reports that are submitted electronically to Ohio EPA under the commenter's NPDES permit. [0430-City of Elyria, Ohio Wastewater Pollution Control Plant and Municipal Separate Storm Sewer System (MS4)]

Another commenter stated that according to the EPA Chemical Data Reporting (CDR) rule under TSCA PFOA and PFOS would be subject to a 2,500-pound reporting threshold at a single site. This commenter stated that regardless of TSCA stipulations, if the spill reporting quantity threshold is 1 lb in 24 hours (one 24-hr day), a site could spill 0.99 lbs per day for 365 days a year, or nearly 360 lbs, apparently with no reporting required. However, if weekly or monthly maximums were in place and repeated spillage was addressed, this would not be allowed. The commenter also noted that pursuant to Toxics Release Inventory (TRI) reporting requirements, facilities in regulated industry sectors must report annually on releases and other waste management of certain listed toxic chemicals that they manufacture, process, or otherwise use above certain threshold quantities (100 pounds for PFOA and PFOS). The rulemaking should speak to inconsistencies between the various reporting thresholds. [0326-National Tribal Water Council (NTWC)]

Another commenter asserted that it is unlikely that landfill leachate concentrations and flow volume over a 24-hour period will be sufficient to trigger the proposed Reportable Quantity for PFOA and PFOS, however landfill leachate can be quite variable day-to-day, and assuring accurate measurement will make an ongoing testing regimen unavoidable resulting in cost that were not considered in the cost analysis. [0399-Local Government Coalition for Renewable Energy]

Response

EPA declines the commenter's request to amend the timeframe it uses to determine if a reportable release has occurred. And, although one 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. See the Preamble to the Final Rule Section VII.D.1.e. (*The reportable quantity (RQ) should be applied over a different time period than 24 hours*). Finally, EPA disagrees with the commenter's position regarding testing; this final designation under CERCLA does not require any testing.

4.A.6 The Proposal provides little or no guidance on how PFAS quantities are to be specifically determined or calculated for the purposes of the RQ.

A few commenters stated that sampling on a daily basis would be extremely costly and that the Proposal provides little or no guidance on how PFAS quantities are to be specifically determined or calculated and requested clarification and poses compliance and enforcement issues and would result in additional costs. Two commenters noted that the Proposal lists a 24-hour default Reportable Quantity of one (1) pound per twenty-four (24) hour period, based on the highest levels found in the recent analytical results from the California State Water Board's 2021 Investigative Order for Publicly Owned Treatment Works (POTWs)]. [0490-Pennsylvania Municipal Authorities Association (PMAA), 0398-Pennsylvania Department of Environmental Protection, 0325-Oak Ridge National Laboratory (ORNL), 0511-WateReuse, 0428-Citizens Against Ruining the Environment (CARE), ; 0568-Water and Wastewater Equipment Manufacturers Association (WWEMA), 0510-Water Environment Association of Texas (WEAT) and Texas Association of Clean Water Agencies (TACWA), 0447-Coalition of Recyclers of Residual Organics by Practitioners of Sustainability (CRROPS), 0347-Brevard Co, FL. Board of County Commissioners, 0428-Citizens Against Ruining the Environment (CARE), 0555-American Association of Airport Executives (AAAE), 0538-National Association of Clean Water Agencies (NACWA), 0399-Local Government Coalition for Renewable Energy, 0340-Association of State and Territorial Solid Waste Management Officials (ASTSWMO), 0547-Maine Department of Agriculture, Conservation and Forestry (DACF), 0485-Michigan Farm Bureau, 0348-Bowling Green Municipal Utilities (BGMU), 0426-California Department of Toxic Substances Control (DTSC), 0355-City of Los Angeles Sanitation and Environment (LASAN), 0352-Clark County Water Reclamation District, 0468-National Ground Water Association (NGWA), 0318-Madison Metropolitan Sewerage District (MMSD), 0372-NEW Water]:

Response

Neither CERCLA section 103 nor EPCRA 304 require facilities to conduct any testing or monitoring to determine if a RQ of a hazardous substance is released. Facilities may use their professional judgement to report a release as soon as they have knowledge of a release of a hazardous substance that meets or exceeds the RQ.

Comments on specific sector exemptions

These commenters also requested clarification for various sectors, practices, or wastes:

Wastewater Treatment Plants (WWTPs) - Clarify the reporting structure and how PFAS quantities are to be determined. How would a public clean water agency measure simultaneous releases from a number of different points in its treatment plants and across collection systems that might span miles? Should these releases be combined or should each release point be considered separately? Will monitoring and testing be required for every discharge, or can quantities be estimated on previous, representative samples? The CERCLA default RQ is not designed to be a metric monitored or tracked by water utilities, and utilizing it fails to consider how water utilities can monitor effluent and biosolids concentrations to determine an RQ without validated test methods and sufficient lab capacities. Will consistent discharges over time, such as the effluent discharge at a treatment plant, be considered differently compared to one-time discharges, such as sanitary sewer overflows (SSOs)? Will PFAS measurements or estimates from each biosolids land application site be added to the overall effluent measurement to determine a plants Reportable Quantity (RQ)? Will PFOA and PFOS point source discharges in excess of the NPDES permit have to be reported under CERCLA?

Response

Upon designation of PFOA and PFOS, their salts and isomers as CERCLA hazardous substances, all facilities are required to report releases of these substances that meet or exceed the RQ of one pound in any 24-hour period. If WWTPs have a NPDES permit under an EPA approved state program or under Section 402 of the Federal Water Pollution Control Act, it may have specific standards and/or limits, as well as monitoring and testing requirement for PFOA and PFOS as well as other hazardous substances listed in 40 CFR 302. If the discharge exceeds the permit limits and it is at or above the RQ, the facility is responsible for reporting those releases under CERCLA 103 and EPCRA 304. Such releases should be reported to the NRC, SERC or TERC, and LEPC or TEPC as required under CERCLA section 103 and EPCRA section 304. EPA also encourages entities to report releases using the best available information or studies to assist in determining if an RQ is met or exceeded for any CERCLA hazardous substance. See National Oil and Hazardous Substances Contingency Plan, 55 Fed. Reg. 8439-8896 (Mar. 8, 1990); Notification Requirements; Reportable Quantity Adjustments, 48 Fed. Reg. 23555 (May 25, 1983 As discussed in the preamble to these Federal Register notices, EPA encourages entities to report release(s) using the best available information or studies to assist you in determining if an RQ is met or exceeded for any CERCLA hazardous substances. Additionally, facilities may utilize the continuous release reporting requirements rather than reporting per occurrence provided that the criteria in the regulations in 40 CFR 302.8 are met.

For discharges that occur from various points at a facility, the quantity of the hazardous substance released from each point can be added together to determine if the total amount of the hazardous substance released in any 24-hour period is at or above the RQ. As mentioned above, if WWTP has a permit with standard or limits for any hazardous substance, the facility is only required to report if the quantity released is above the permit limits. WWTPs are not required to report hazardous substances discharged into the plant from industries or other sources.

Accidental or intentional releases of hazardous substances that occurs from a facility in any 24-hour period that meet or exceed the RQ of the substance would be subject to CERCLA 103 and EPCRA 304 reporting requirements. However, any releases that are routine, anticipated, and

intermittent and incidental to normal operations may qualify for continuous release reporting. See continuous release reporting regulations at 40 CFR 302.8.

Municipal Separate Storm Sewer Systems (MS4) – Would the trigger of a one pound "release" per 24-hour period apply to each individual discharge point within an MS4 or to the MS4 as a whole?

Response

The Agency clarified the definition of *facility* to mean that concurrent releases (releases occurring within the same 24-hour period) of the same hazardous substance from one contiguous plant or installation need not be reported individually but should be reported in a single notification. (50 FR 13456, April 4, 1985).

Landfills – Requests clarification on how the release reporting limit of one pound or more in a 24-hour period is to be interpreted and applied by wastewater or a waste disposal facility (landfill). If less than one pound per day disposed in daily trash of a business or home is combined with other collected trash, a landfill leachate from collected trash producing an unacceptable result may occur. Also, please clarify any reporting issue requirement associated with storm sewer overflows which may occur during extreme weather events.

Response

The amount of PFOA and PFOS released from landfills is a function of the concentration of the chemicals in the leachate and the volume of leachate produced. Published papers on the quantity of PFAS (including PFOA and PFOS) in U.S. landfill leachate show that it is unlikely that any landfills will exceed the RQ. The annual total of 70 PFAS released by U.S. landfills through their leachate was estimated to be approximately 600 kg distributed across 1540 landfills (*Johnsie R. Lang, B. McKay Allred, Jennifer A. Field, James W. Levis, and Morton A. Barlaz, Environmental Science & Technology* 2017 51 (4), 2197-2205).

Landfills must address other conditions for release of leachate. Under the Clean Water Act, a landfill discharging leachate to waters of the U.S. or to a wastewater treatment plant (POTW), in accordance with any the pretreatment program regulations and requirements, under the conditions established in a NPDES permit, would have to follow the conditions established in the permit. If a permit or standard establishes any limitations, monitoring or reporting requirements for PFOA or PFOS then the permittee (landfill) would need to comply with it.

In regard to storm sewer overflows, research studies show that PFAS stormwater runoff levels are generally in the low part per trillion level (e.g., *Codling, G., Yuan, H., Jones, P.D. et al. Metals and PFAS in stormwater and surface runoff in a semi-arid Canadian city subject to large variations in temperature among seasons. Environ Sci Pollut Res 27, 18232–18241 (2020)*). Thus, it is not anticipated that the amount of PFOA or PFOS released via typical stormwater overflow events would reach the level of a reportable quantity in a 24-hour period.

Land application - Are land applications reportable as continuous releases under Section 103(f)(2) of CERCLA, or reportable under Section 103(a)? Will each biosolids land application site be monitored and calculated separately or together? How often and with what tools? How

would EPA quantify PFAS-contaminated manure with levels in the parts per billion, and would any utilization of manure or other soil amendments require extensive testing for a specific salt or isomer? A commenter noted an example where biosolids containing more than 2,000 ppb of PFOS were land applied, a land application at standard rates could release a pound of PFOS from only 50 acres of application if the right circumstances applied such as runoff from significant precipitation or surface drainage occurred. Farms are not required to nor could they conceivably monitor all stormwater releases from their fields, so whether an actual release occurs and whether it releases a pound of PFOS in a 24-hour period is completely unknown. Another commenter asked if application of PFAS-containing fertilizer (i.e., byproducts) pursuant to nutrient management activities on a farm constitute a "release" under CERCLA; and another if a spill that occurred while transporting the untreated waste to a treatment and/or disposal facility would be considered a release or potential release of a hazardous substance from a known or unspecified source. [0485-Michigan Farm Bureau, 0547-ME DACF, 0398-PA DEP]

Response

Land application of biosolids may qualify for continuous release reporting (CRR) if certain criteria established in the regulations, 40 CFR 302.8, are met. The owner or operator of the facility may use their professional judgment to estimate releases of CERCLA hazardous substances when filing continuous release reports. The definition of "facility" is provided in the regulations at 40 CFR 302.3, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-J/part-302/section-302.3

Release reporting regulations in CERCLA 103 do not require facility owner or operator to conduct any testing to estimate the releases, unless the limits are specified under EPA approved state permit program or federally issued permits.

Spills of untreated waste containing PFOA-PFOS, or their salts or structural isomers while in transportation is required to be reported in accordance with CERCLA section 103(a) (40 CFR 302.6).

If the site(s) where biosolids applied are co-located and are owned/operated by the same person, the amount of hazardous substance can be added together to determine if the RQ is met or exceeded in any 24-hour period.

For response to the question if application of biosolids is considered a release under CERCLA, see Section VII.A.3 of Preamble to the Final Rule.

Airports – EPA's analysis notes airports "...as known sites with past use of PFOA and PFOS and a broad geographic distribution. It is not clear what, if any, reporting obligations may be required by airports as a result of this rule." Airports are unaware exactly what quantities of phased-out or modern short-chain PFOA may or may not be included in AFFF, making it extremely difficult, if not impossible, for an airport to know whether the reportable quantity has been exceeded in the event an airport is forced to discharge AFFF. Clarification is needed.

Response

The hazard communication standard (HCS) under the Occupational Safety and Health Act (OSHA) requires manufacturers and importers to prepare Safety Data Sheets (SDS) (formerly known as Material Safety Data Sheets (MSDS)) for downstream users of their chemicals. The

airports should receive SDS/MSDS from their distributors of AFFF, which should include the percentage/concentration of PFOA or PFOS in the AFFF which would then allow the facility to determine the amount of these chemicals based on the amount of AFFF used.

RQ Amount clarification - It is not clear whether this refers to one pound of PFOA molecules, one pound of PFOS molecules, one pound of PFOA and PFOS molecules, or one pound of a substance containing PFOA and/or PFOS (e.g., AFFF concentrate or AFFF solution) or of a mixture of PFOA and/or PFOS. Are salts of PFOA and PFOS counted separately? What quantity of a substance or mixture is required to account for the amount?

Response

The reportable quantity for each hazardous substance, except for radionuclides, listed in the regulations at 40 CFR 302.4 is in pounds or in kilograms. For reporting releases of PFOA and PFOS, and their salts and structural isomers, EPA established the default RQ of one pound to each substance. To determine the quantity of PFOA and PFOS in a mixture, the facility may use the "mixture rule" that EPA adopted from the CWA rule. (50 FR 13456, April 4, 1985). Additionally, refer to the regulations at 40 CFR 302.6 (b), Notification Requirements. https://www.ecfr.gov/current/title-40/chapter-I/subchapter-J/part-302/section-302.6

Definition of Release: "Release" is not defined in the Proposed Rule but is defined at 40 CFR 302.3 which is problematically applied to PFOA and PFOS. How would commercial products containing minuscule amounts of PFOA and/or PFOS be considered under the 40 CFR 302.3 definition if they were "pour[ed], emitt[ed], empt[ied], or discharg[ed]"? The preamble did not give enough information to understand the measurement of PFOA and PFOS in resulting mixtures and affected products to enable evaluation of the effects of this proposed regulation on commercial operation and function.

Response

The hazard communication standard (HCS) under the Occupational Safety and Health Act (OSHA) requires manufacturers and importers to prepare Safety Data Sheets (SDS) (formerly known as Material Safety Data Sheets (MSDS)) for downstream users of their chemicals. The SDS/MSDS of a hazardous chemical is required to include the components and concentration of PFOA or PFOS. Facilities may use the "mixture rule" that was adopted from CWA program to CERCLA release reporting requirements. See regulations at 40 CFR 302.6(b). https://www.ecfr.gov/current/title-40/chapter-I/subchapter-J/part-302/section-302.6

Deliberate vs Negligent or Inadvertent Release: Also, deliberate application of a PFAS-containing material (e.g., AFFF) for its intended application (e.g., to save life and property) should be differentiated from negligent or inadvertent discharges.

Response

The definition of "release" in CERCLA section 101(22) does not distinguish releases based on negligence or inadvertent releases. EPA declines to create exemptions for certain releases or uses

as part of this final action. In regard to comment on intended application and exclusions from such activities, see Preamble to the Final Rule, Section VII.A. (*Legal Authority*).

The implementing regulations (40 CFR 302.6) for CERCLA 103 requires facilities to immediately report releases of any hazardous substance at or above its reportable quantity within a 24-hour period. CERCLA does not require any testing. If releases qualify for continuous release reporting, based on the criteria established in the regulations at 40 CFR 302.8, facilities may report their on-going releases rather than per occurrence. In regard to comment on intended application and exclusions from such activities, see Preamble to the Final Rule, Section VII.A. (*Legal Authority*).

One-time Release vs. Ongoing Release: Does the RQ refer to one-time releases or ongoing releases? Will 24-7 real-time monitoring be required? Are there systems already in place to do this type of real-time monitoring?

Response

The implementing regulations (40 CFR 302.6) for CERCLA 103 requires facilities to immediately report releases of any hazardous substance at or above its reportable quantity within a 24-hour period. CERCLA does not require any testing. On-going releases may qualify for continuous release reporting, if certain criteria established in the regulations at 40 CFR 302.8 are met. https://www.ecfr.gov/current/title-40/chapter-I/subchapter-J/part-302#302.8

Laboratory Methods and Capacity - There is a lack of EPA approved sampling and test methods for affected media/sources, as well as insufficient capacity of certified labs for the increase in sampling/analysis demand the listing will create. Because of the delay in receiving analytical results necessary to determine whether an RQ release has occurred, EPA must also acknowledge that timely reporting of a PFAS-containing release under CERCLA may be separated in time from the actual release triggering the report.

Response

CERCLA does not itself impose any testing requirements for the purposes of release notifications, *see* "Notification Requirements; Reportable Quantity Adjustments," 50 FR 13456, at 13463 (April 4, 1985), and EPA is not establishing any testing requirements as part of this final rule. However, there may be resting requirements under other statutes and their implementing regulations. EPA recommends that facilities and vessels that may have releases of any CERCLA hazardous substances should follow standards and permits issued by state or local agencies, which may include testing as part of the permits.

Regarding the comment on timely reporting and actual release information, EPA recommends that as soon as the facility has knowledge of the release, NRC, state, tribal, and local agencies should be notified immediately as provided in CERCLA 103 and EPCRA 304. If the facility receives accurate information through analytical results or by other methods on the actual quantity released, the facility may correct the previously reported information by contacting NRC, state, tribal and local agencies.

4.A.7 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.

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, not all Safety Data Sheets (SDSs) accurately disclose PFAS constituents it 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 PFAScontaining compounds. Another commenter 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 1 percent questioning how EPA proposes to make determinizations on volumes if percent composition is not disclosed by manufacturers. Another commenter stated that the rule should clarify expectations and requirements for PFOA and/or PFOS producers to communicate and/or disclose PFOA and PFOS as ingredients. (For example, EPA should consider whether producer reporting requirements should be effectuated through OSHA regulations like the Hazard Communication Standard.) [0563-Union Tank Car (UTLX), 0565-Utility Solid Waste Activities Group (USWAG), 0551-Cross-Cutting Issues Group (CCIG), 0362-GATX Corp, 0468-National Ground Water Association (NGWA), 0565-Utility Solid Waste Activities Group (USWAG)]

A 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. [0551-Cross-Cutting Issues Group (CCIG)]

Response

According to the OSHA Hazardous Communication Standard (HCS), a facility 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%), it is required to be listed on an SDS if the chemical can cause a health hazard below the cut-offs. Downstream users of these substances are encouraged to contact their distributors as well as manufacturers of these substances to obtain SDS, which should include concentrations of each constituent in a mixture. The specific requirements for developing SDS and its contents are regulated under OSHA HCS. *See 29 CFR 1910.1200*.

EPA has amended Table 302.4 of 40 CFR part 302 to designate PFOA, PFOS and their salts and structural isomers known to the Agency at this time and parties that use such chemicals are responsible for knowing the makeup of their products and ingredients and ensuring compliance with the CERCLA reporting requirements if a release occurs.

Regarding salts and isomers of PFOA and PFOS that have not been identified, EPA has amended 40 CFR 302.4 by listing all salts and isomers known to the Agency in Appendix C and D. The Agency may revise the list as new information is received. *See the Preamble to the Final Rule*

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⁵ EPA coordinated with OSHA to develop this response.

Section VII.D.1.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).

4.A.8 EPA should clarify that any NPDES permit violation for PFOA and PFOS would not constitute a "federally permitted release" and must be reported.

A commenter noted that per the EPA, it will use the NPDES program to restrict PFAS discharges to water bodies for federally-issued permits and use the data gathered to inform the development of Effluent Limitation Guidelines. Section 107(j) limits CERCLA liability for "federally permitted releases." 42 U.S.C. § 9607(j). In addition, per Section 103(a), a "federally permitted release" need not be reported. 42 U.S.C. § 9603(a). This includes discharges made pursuant to a NPDES permit. 42 U.S.C. § 9601(10)(C) (defining "federally permitted release" as, inter alia, a "continuous or anticipated intermittent discharges from a point source, identified in a permit or permit application under section 402 of the Federal Water Pollution Control Act, which are caused by events occurring within the scope of relevant operating or treatment systems. . . . "). The commenter stated that it would not serve public health or the goal of determining where PFOA and PFOS releases occur and in what amount if releases that violate a NPDES permit do not have to be reported under CERCLA. Therefore, EPA should clarify that any violation of a NPDES permit covering PFOA and PFOS would not constitute a "federally permitted release" and must be reported. The commenter pointed out that the U.S. EPA's April 2022 guidance is only directed at federally issued NPDES permits. April 2022 U.S. EPA NPDES Memo at 1 ("for federally-issued permits, EPA will include requirements to monitor for PFAS"). NPDES permits in only three states (Massachusetts, New Hampshire and New Mexico) are federally-issued, further limiting the reach of addressing PFAS in NPDES permits pursuant to the April 2022 U.S. EPA guidance. The commenter pointed to a letter House lawmakers sent to EPA on October 11, 2022, urging the U.S. EPA to issue guidance for state-issued permits with regards to PFAS, have known or suspected sources disclose PFAS pollution as part of their existing NPDES permit and not delay disclosure until the next permit cycle, and "to clarify that [publicly-owned treatment works] must evaluate the introduction of PFAS into their systems and use existing authority to ensure Industrial Users are pretreating consistent with the prohibition on pass-through or interference." [0428-Citizens Against Ruining the Environment (CARE)]

Response

EPA declines to adopt the commenter's position with respect to "federally permitted releases." Whether a particular release is a "federally permitted release" such that it would be exempt from relevant reporting requirements requires a case-by-case determination based on a number of factual issues, including the specific permit language or applicable control requirement. See Preamble to the Final Rule Section VII.D.1.h (responding to comments that EPA should clarify that any NPDES permit violation for PFOA and PFOS would not constitute a "federally permitted release" and must be reported).

4.A.9 The Preamble does not mention how the community notification requirement under CERCLA Section 111(g) will be implemented.

A commenter requested clarification on how the notification requirements of CERCLA section 111(g) will be implemented should PFOA and PFOS be designated as hazardous substances. This section requires the owner/operator of a facility which has released a hazardous substance to

provide reasonable notice to potential injured persons by publication in local newspapers serving the affected area. The preamble of the proposed rule mentions notifications under CERCLA section 103 and Emergency Planning and Community Right-to-Know Act section 304 but does not mention the community notification requirement under CERCLA section 111(g). [0365-Environmental Protection Network (EPN)]

Response

Upon finalization of the 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." 42 U.S.C. § 9611(g) (CERCLA Section 111(g)). See the Preamble to the Final Rule Section VII.D.2 (Community notification requirement under CERCLA Section 111(g).

4.A.10 Exemption from Reporting

4.A.10-1 Waste management infrastructure should be exempt from release reporting

Some commenters stated that it is unlikely that most public wastewater facilities will meet the one-pound/24-hour period reportable quantity (RQ) that trigger the reporting requirements in the rule. However, water and wastewater utilities (including municipal separate storm sewer systems, MS4s) should be exempted from the proposed CERCLA regulations regarding the requirements to report releases of 1 pound or more of PFOA and PFOS within a 24-hour period. Water and wastewater utilities have no ability to control the amount of these chemicals received at their treatment facilities, which imparts an unfair burden on water and wastewater utilities to have to remove these chemicals from waste streams that are discharged. [0276-DCWS/City of Vancouver; 0303-Claremont County; 0316-MeWEA; 0422-AWWI; 0517-Wessler; 0535-MRWA; 0561-WUWC]

A commenter stated that EPA should exempt waste management infrastructure (landfills, wastewater treatment plants and WTE facilities) from the proposed Reportable Quantity requirement. Such action by EPA will eliminate a costly and unnecessary monitoring and reporting obligation and at the same time serve as a signal to state regulators that targeting public service infrastructure as a means for addressing PFOA-PFOS contaminants will not meaningfully enhance environmental protection. The commenter also noted that EPA refers to the possible use of an RQ adjustment for PFOA and PFOS (87 FR 54429) in the proposed designation. Similar to an RQ adjustment, an RQ exclusion would be particularly well justified. The commenter also noted that states have adopted PFOA and PFOS exemption regulations, as EPA discusses in its rulemaking proposal. Any similar federal action should be adopted in conjunction with the above-described RQ exclusion for public service infrastructure. (0399-Coalition for Renewable Energy)

Response

EPA declines to create exclusions for certain uses of PFOA and/or PFOS in this rulemaking. See Preamble to the Final Rule, Section VII.A.3. (Authority to Create Exclusions from Designation), RTC Section 4.A.6. (The Proposal provides little or no guidance on how PFAS quantities are to be specifically determined or calculated for the purposes of the RQ Comments on specific sector exemptions.)

EPA encourages entities to report release(s) using the best available information or studies to assist in determining if an RQ is met or exceeded for any CERCLA hazardous substances. Additionally, facilities may utilize the continuous release reporting requirements rather than reporting per occurrence provided that the criteria in the regulations in 40 CFR 302.8 are met.

As stated in the proposed rule, EPA has the authority to revise the RQ level in the future and the Agency may consider doing so after the final rule is effective, and the Agency begins receiving release information on PFOA and PFOS substances based on the default one-pound statutory RQ.

4.A.10-2 Wastewater and biosolids should NOT be exempt from CERCLA.

One commenter stated that PFOA and PFOS, concentrated into effluent and biosolids, cannot continue to be released into the environment. The proposed designations will signal that these practices have to change, which will prompt the development of new treatment technologies and industries. According to data presented by EPA at a 2020 U.S. EPA Biosolids PFOA & PFOS Problem Formulation Meeting, https://www.epa.gov/sites/default/files/2021-02/documents/biosolids-pfoa-pfosmeeting-summary-nov-2020.pdf, concentrations of PFOS in biosolids have not significantly diminished since 2001, even after its use has been curtailed in United States. Application of biosolids containing PFAS onto agricultural land could result in PFAS contaminated food. Studies have found a direct correlation between PFAS concentrations in soil and bioaccumulation in plants, with variability depending on the type of plant and the length of the chain of the PFAS (Ghisi, R., et al. 2019. Accumulation of perfluorinated alkyl substances (PFAS) in agricultural plants: A review. *Environ Res* 169:326-41 doi: 10.1016/j.envres.2018.10.023; Wang, W., et al. 2020. Uptake and accumulation of per- and polyfluoroalkyl substances in plants. Chemosphere 261, doi: 10.1016/j.chemosphere.2020.127584).

This commenter welcomed EPA's plan to "[f]inali[ze] a risk assessment for PFOA and PFOS in biosolids, which will serve as the basis for determining whether regulation of PFOA and PFOS in biosolids is appropriate." (87 FR 54431). However, this process will take years and will result in hundreds of additional pounds of PFAS being land applied. Considering that PFOA and PFOS appear to have been largely phased out, most concentrations of these substances will fall into the hands of wastewater treatment plants, and thereafter significant amounts placed on farmland as biosolids.

This commenter also noted that biosolids are federally regulated under 33 USC § 1345 (Section 405(d) of the Clean Water Act). CERCLA's detailed definition of "federally permitted release" [42 USC § 9601(10)] does not mention Section 405 of the Clean Water Act. However, Section 101(22) of CERCLA exempts "the normal application of fertilizer" from the definition of "release," a phrase not defined in the statute [42 USC. §9601(22)(D)]. Legally speaking, it is unclear whether the application of biosolids containing hazardous PFAS to farmland is a "normal application of fertilizer," based on cases construing that term. Compare, e.g., Sheridan v. D&D Grading, Inc., No. 16-CV-5085(JS)(ARL), 2019 U.S. Dist. LEXIS 54340, at *13 (E.D.N.Y. Mar. 29, 2019) ("applying topsoil that contains numerous CERCLA hazardous substances is not 'the normal application of fertilizer' within the meaning of the statute, and the exception does not apply") and Fallowfield Dev. Corp. v. Strunk, Nos. 89-8644 and 90-4431, 1994 U.S. Dist.

LEXIS 12758, at *70 (E.D. Pa. Sep. 2, 1994) ("uncontradicted evidence support a finding that the sludge applied by the Strunk's was not 'normal' because it was contaminated. Accordingly, the exemption for normal application of fertilizer is inapplicable") with City of Tulsa v. Tyson Foods, Inc., 258 F. Supp. 2d 1263, 1287-88 (N.D. Okla. 2003) (after noting that exceptions to CERCLA liability are narrowly construed, construing "normal" according to its plain meaning as 'conforming with, adhering to, or constituting a norm, standard, pattern, level or type' and denying summary judgment since "it is the 'norm' which is in dispute").

The commenter also expressed concern about EPA's recent pronouncements pledging to preserve land application and incineration of biosolids by wastewater treatment facilities (https://insideepa.com/daily-news/epa-pledges-preserve-biosolids-disposal-options-face-pfas-fears; Oct. 11, 2022). Given that exposure through food as well as PFAS-containing sludges running off to surface water and leaching into groundwater are just a few of the many PFAS exposure pathways for environmental justice communities already burdened by cumulative stressors, these practices cannot continue. Increased attention around PFAS is already driving promising research into treatment techniques, which will only be hastened by the proposed designations. [0428-CARE]

Response

In this final action, EPA is not creating exclusions for any specific entities or releases of PFOA and PFOS. See preamble to the Final Rule Section VII.A.3 (Authority to Create Exclusions from the Designation).

EPA is working diligently to complete its biosolids risk assessment for PFOA and PFOS and expects to complete the assessment by December 2024. More information, please visit: https://www.epa.gov/biosolids/risk-assessment-pollutants-biosolids#pfas

4.B. Requirement upon Transfer of Government Property

4.B.1 The Proposal would place significant and potentially costly constraints on airport sponsors' ability to manage their property.

A commenter was concerned that the Proposal would place significant and potentially costly constraints on airport sponsors' ability to manage their property. The CERCLA designation could limit airports' ability to secure releases of federal obligations on land parcels acquired with federal assistance (e.g., AIP grants) or conveyed to the airport by the federal government in the past. The Proposed Designation may also affect airport sponsors' ability to enter into leasing arrangements with prospective tenants, whether for aeronautical or non-aeronautical uses. These constraints will directly impact airports' ability to be financially self-sustaining and increase costs on airport users, including the traveling public. [0424-Airports Council International -North America (ACI-NA)]

Response

EPA does not believe that the designation of PFOA and PFOS as hazardous substances will impose significant and costly restraints on airport property management. Regarding "the ability to secure releases of federal obligations," EPA notes that a federal entity's clean up obligations regarding property transfers are statutorily mandated. EPA believes that for transfers of federal

property to non-federal transferees, designating PFOA/PFOS as hazardous substances is unlikely to slow property transfers, particularly as CERCLA section 120(h) provides that federal property can be transferred before (or after) cleanup, subject to certain conditions.

4.B.2 The Proposal does not explain the real value of the federal property disclosure requirement of CERCLA 120(h).

A commenter stated that the proposal does not explain whether there is any real value to the CERCLA federal property disclosure provision in CERCLA Section 120(h) that would be triggered by the designation of PFOA and PFOS as CERCLA hazardous substances. The commenter asserts that this kind of disclosure in the context of a sale of federal property and further cleanup commitment could be implemented by Executive Order directed to all federal agencies and by adoption of individual agency policies. [0341/American Farm Bureau Federation (AFBF)]

Response

EPA disagrees with the commenter's position that EPA should further explain the value of CERCLA section 120(h) with respect to PFOA and PFOS releases. Moreover, EPA disagrees with the implication that the application of CERCLA section 120(h) to situations involving PFOA or PFOS-related contamination lacks value CERCLA requires Federal agencies to provide a covenant warranting that "all remedial action necessary to protect human health and the environment with respect to any [PFOA or PFOS] 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." 42 U.S.C. § 120(h)(3). These provisions help assure that federal properties are remediated as necessary to protect human health and the environment, as well as protect purchasers and help communities benefit from faster reuse and redevelopment of property impacted by PFOA/PFOS contamination.

EPA also disagrees with the commenter's assertion that the Agency should refrain from designating PFOA and PFOS as hazardous substances because the impacts of CERCLA section 120(h) can be achieved through alternative mechanisms. The commenter provides no indication why an Executive Order and/or adoption of individual agency policies represents a superior approach to designation. In fact, this designation immediately obviates the need for other types of federal action to put the requirements of section 120(h) in place. Moreover, Executive Orders are generally not enforceable which means that a purchaser of federal property would likely have no means of legal redress if the requirements of CERCLA 120(h) were not met.

4.C. Requirement of DOT to List and Regulate CERCLA Hazardous Substances

4.C.1 More clarity is needed relating to the requirements of the Hazardous Materials Transportation Act (HMTA)

A few commenters were concerned with the impacts of the designation as CERCLA hazardous substances on PFOS and PFOA containing shipments. One of these commenters noted that EPA determined that the effects of the designation would be limited to reporting obligations for PFOA or PFOS releases above the reportable quantity, obligations on the United States when it transfers properties, and an obligation on the DOT to list and regulate CERCLA designated hazardous substances as hazardous materials. While these impacts are fewer than the

requirements for proper handling pursuant to RCRA, the impacted universe is larger for the CERCLA designation than those entities covered by a RCRA listing because this applies to any person in charge of a vessel or facility pursuant to CERCLA Section 103. Still, the agencies also note that listing PFOA and PFOS under RCRA would necessarily result in the same CERCLA reporting requirements contemplated by this rulemaking pursuant to Section 101(14). Other commenters pointed to a lack of clarity relating to the requirements of the Hazardous Materials Transportation Act (HMTA) and how the designation might apply (or not) to materials containing trace amounts of PFOA or PFOS such as biosolids, which are commonly transported via truck to distant management sites. These commenters asked whether HMTA requirements could be triggered for biosolids, other materials and water transport and if they would need to be transported as hazardous materials or whether HMTA requirements are intended solely for the chemical compounds themselves, not materials containing dilute concentrations of them. If HMTA requirements did apply, this would be extremely costly and may impact disadvantaged and underserved communities and the commenters believed EPA should analyze whether there would even be sufficient hauling services available to fulfill the new levels of demand, since presumably far more than biosolids would be similarly affected. Additional associated questions include whether biosolids destined for land application would be eligible for the agricultural materials exemption. [0462-Los Angeles County Sanitation Districts, 0393-New Mexico Environment Department (NMED), 0551-Cross-Cutting Issues Group (CCIG), 0468-National *Ground Water Association (NGWA)*]

A commenter stated that the designation would create new labeling, packing, tracking and reporting requirements. The commenter noted that these new requirements will ensure that if shipping does happen, it happens safely and that any incidents are addressed immediately. [0552-Environmental Working Group (EWG)]

Response

Section 306(a) of CERCLA requires the Secretary of the U.S. Department of Transportation to regulate hazardous substances listed or designated under section 101(14) of CERCLA as hazardous materials under the Hazardous Materials Transportation Act (HMTA). See 42 U.S.C. § 9656(a) ("Each hazardous substance which is listed or designated as provided in section 9601(14) of this title shall . . . at the time of such listing or designation, whichever is later, be listed and regulated as a hazardous material under chapter 51 of title 49."). The Pipeline and Hazardous Materials Safety Administration (PHMSA) carries out the rulemaking responsibilities of the Secretary of Transportation under the HMTA. With the final designation, PHMSA will assume responsibility for amending its Hazardous Materials Regulations (HMR) to incorporate the regulation of PFOA and PFOS as hazardous materials. See 49 CFR parts 171-180.

The Agency agrees that DOT's HMR require that when regulated materials are shipped in quantities equal to or greater than their RQs, and are present in a single package, above certain concentration thresholds, they must be identified as such on shipping papers and by package markings.

EPA refers the commenters seeking clarification regarding whether biosolids destined for land application would be exempt from CERCLA's definition of "release," to the Preamble of the Final Rule Section VII.A.3.

4.D. Impacts on National Priorities List (NPL) Sites

4.D.1 The designation will result in higher Hazard Ranking System (HRS) scores (enabling the EPA to start cleanup) and strengthen cleanup requirements for existing NPL sites contaminated with PFOA and PFOS.

A commenter stated that sites contaminated with PFOA and PFOS will be prioritized under the designation because a higher hazard ranking score can be assigned to sites with hazardous substances. The higher hazard ranking score will enable EPA to start cleanup. [0552-EWG]

Another commenter shared how current response is slow with 1,329 Superfund sites, 43 additional proposed sites, and only 452 sites cleaned and removed. However, commenter expressed that the proposed designation would strengthen cleanup requirements and remove barriers that marginalized communities experience when seeking to clean up contaminated sites. The commenter underscored the need for the proposed rule to not further exacerbate cleanup costs in overburdened communities; the proposed rule should ensure that PFAS waste is not transferred to incinerators, landfills, wastewater treatment facilities, etc. located near low-income communities. [0567-WE ACT]

Response

EPA agrees that designation of PFOA and PFOS as CERCLA hazardous substances will allow EPA to utilize the full suite of CERCLA authorities, which will enable EPA to address more sites, allow for earlier action, and expedite eventual cleanup. However, EPA disagrees that designating PFOA and PFOS as hazardous substances will result in higher HRS scores or change the approach EPA uses to prioritize sites for cleanup. Designation does not change the Hazard Ranking System (HRS), which is EPA's primary tool for evaluating releases to determine NPL eligibility. 40 C.F.R. Part 300 Appx. A. EPA already evaluates releases of PFOA and PFOS as part of its HRS scoring process, and indeed, EPA has already listed sites on the NPL, in part, due to the presence of these substances at a site. The HRS is a numerically based screening tool used to identify sites that may impact human health and the environment. Once a site meets or exceeds the 28.5 HRS threshold score, it is eligible for placement on the NPL. See preamble to the Final Rule Section VII.E (National Priorities List (NPL) Sites – Existing and Future Contamination) for more information about NPL site prioritization.

A higher score does not influence EPA's process for evaluating and selecting, if appropriate, a remedy for the site or portions of the site. The remedial process is distinct and separate from the HRS scoring process. The designation does not change cleanup requirements for CERCLA remedies, which at a minimum must be protective of human health and the environment and comply with ARARs, unless a specific ARAR is waived. *See* CERCLA section 121(a)-(d); 40 CFR 300.430(f)(1)(i)(A).

EPA evaluates environmental justice as part of its process to identify and respond to releases pursuant to CERCLA. A key EPA objective is to ensure everyone experiences the same degree of protection from environmental health hazards. About 73 million people live within 3 miles of a Superfund site. Many of the communities within this range have a higher number of low-income people, people of color, or indigenous people. They are also more burdened by other environmental stressors (e.g., poor air quality, lead paint) when compared to the general population. EPA is prioritizing environmental justice throughout the cleanup process, including when engaging communities, making cleanup decisions and supporting Superfund site reuse. A

cornerstone of environmental justice is to advocate for and strengthen early and meaningful community participation during Superfund cleanups to ensure communities have a voice throughout the decision-making process. The community engagement approach selected for each site draws on a robust set of tools and resources developed over the past several decades to specifically to address environmental justice through outreach, translation, needs assessments, technical assistance and capacity building. (Superfund Environmental Justice Best Practices, August 2023).

EPA agrees that designation best protects environmental justice communities and that swift action to address harmful releases can reduce the need for more expensive, more expansive cleanup in the future. As explained in the final Preamble Section VI.A.2.d (*Environmental Justice (EJ) Considerations for Designation*) and Section IX.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*), and Section VII.G (*Managing PFOA and PFOS Contaminated Waste*), EPA believes that this action is likely to reduce existing disproportionate and adverse effects on people of color, low-income populations, and/or indigenous peoples. To the extent that the final rule leads to additional response actions to mitigate or reduce exposure to PFOA/PFOS, or to actions that mitigate exposure earlier, health risks for populations living near sites where releases occur may decline. Also, CERCLA response actions involving the off-site transfer of any hazardous substance, pollutant or contaminant, must comply with the off-site rule, i.e., transferred to a facility operating in compliance with applicable Federal and State requirements for the waste at issue.

4.D.2 The designation will add many sites to the NPL and lead to re-opening closed sites, slowing rather than speeding up cleanups and resulting in significant costs. Consequently, there is a significant funding gap and insufficient staff and resources that need to be filled.

Some commenters stated that the designation would add new sites to the National Priorities List that would not have otherwise been considered and/or eligible. Two commenters underscored the ubiquity of PFAS in the environment that would contribute to new sites. They noted that there will be significant costs associated with new NPL sites. This has the potential to bog down progress at NPL sites with PFOA and PFOS. One of these commenters stated that EPA has not properly accounted for and considered the additional economic burden associated with additional sites, reopening of sites, and the corresponding cleanup obligations. Ultimately, the designation could result in cleanup delays due to all the potential litigation. Another commenter also noted that sites not meeting the scoring criteria to be listed on the National Priorities List may be abandoned due to the liability created by designating PFOA and PFOS as hazardous substances. One commenter noted that the proposal has the potential to open and reopen numerous Superfund sites based on the presence of PFOA and PFOS on the property. [0565-USWAG, 0495-PFAS Regulatory Coalition, 0394-OSEE/ODEQ, 0372-NEW Water, 0391-SSP, 0569-U.S. Chamber of Commerce et al]

Some commenters were concerned that many new sites would be added to that National Priorities List because of the designation, preventing the EPA from focusing on the most significant sites. They noted that a recent publication by Salvatore et al. in Environmental Science and Technology Letters estimated that more than 57,000 sites may be contaminated with

PFOA and PFOS. Additionally, thousands of these sites may be implicated unnecessarily due to CERCLA's joint liability scheme, which would prolong cleanup of PFOA and PFOS contamination at significant sites. Prioritization of new sites will be essential, but the EPA has not clarified how that will occur. One of the commenters was specifically concerned that thousands of agricultural operations would be implicated as Superfund sites. A commenter also noted that 2,143 agricultural operations were notified of potential PFAS contamination due to military activity adjacent to those lands; the report was published in March 2021 by the U.S. Military. [0569-Chamber of Commerce Coalition, 0327 – Citizen, 0808-NASF, 0390–NMPF, 0512–Stericycle, 0522-WMC, 0523-WSPA]

In addition to the number of potential new NPL sites, commenters noted that remediating Superfund sites is a multi-year to multi-decade process involving several assessments, decisions, and studies. In cases where potentially responsible parties do not agree to comply, the process is further lengthened by litigation. A commenter cited that approximately 75% of the sites on the NPL have been on the NPL for more than 20 years. Additionally, the presence of PFOA and PFOS contamination during the Five-Year Reviews of sites where remediation was previously completed would slow down the rates of sites deemed "closed" and remediated. This could slow clean up rather than speed it up.

A commenter also noted that limitations in remedial technologies will further complicate and slow cleanup for future sites. EPA needs new data and information on the effectiveness of different technologies and approaches for removing PFAS from the environment and managing PFAS and PFAS-containing materials to inform decisions on drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and end-of-life materials management. This information is also needed to better ensure that particular treatment and waste management technologies and approaches do not themselves lead to additional PFAS exposures, particularly in overburdened communities where treatment and waste management facilities are often located." [0512 - Stericycle]

Another commenter noted the significant EPA funding gap required to assess and remediate sites already included under CERCLA. The commenter specifically called out insufficient staff and resources to undertake the full remediation process. Without appropriate funding, the designation will likely be ineffective. [0339 - ASDWA]

A number of commenters stated that designating PFOA and PFOS as CERCLA hazardous substances could result in the reopening of potentially every closed Superfund site, even those that were clean closed and deleted NPL sites, as EPA has proposed no grandfathering or "effective date" to make the listing prospective only. Even for long-since remediated sites, any property past the Record of Decision (ROD) stage is subject to statutory Five-Year Review (FYR) requirements, which entails an assessment of any new contaminants of concern (COC) and any newly applicable or relevant and appropriate requirements (ARARs) for the site, that were unknown at the time of the ROD. PFOA and PFOS will now be part of the FYR process if EPA's rule is finalized, prompting new assessment and potentially remediation even though cleanup standards and accepted remedial alternatives are not identified. • Every post-ROD NPL site with "possible" PFAS contamination will now have to sample for PFOA and PFOS before the next FYR. When detected, "background" (upgradient, offsite, or other representative) PFOA and PFOS may (or may not) be required to be sampled as well, to determine if a "release" has occurred consistent with Hazard Ranking System scoring and to aid in interpretation of what is undeniably a widespread issue. Given the high cost of PFAS sampling and laboratory analyses

and related disposal costs, sampling alone could result in over \$100,000 per site depending on the number of "suspected" media and the amount of investigation derived waste that now would require separate handling and disposal due to the CERCLA designation. All sites where a remedy was not designed for PFOA or PFOS removal, or where PFOA or PFOS presence was unknown, could be critiqued as "not protective" if concentrations exceed ARARs or EPA regional removal management levels, or if cumulative risks now trigger an "unprotective" mathematical determination. In many cases, the "cumulative risk" cannot be known without updating the remedial investigation-phase human health risk assessment (HHRA) and reconfirming compliance with the ROD limits. This could lead to another \$100,000-\$150,000 per site due to the many changes in HHRA guidance in the last 30 years of CERCLA's implementation. The potential for increased environmental response costs could also affect the status of existing settlement agreements and consent decrees pursuant to which PRPs have resolved their liabilities with EPA and state environmental regulatory agencies. Such settlements often include reopeners based on CERCLA Section 122(f)(6)(A), which provides: "A covenant not to sue a person concerning future liability to the United States shall include an exception to the covenant that allows the President to sue such person concerning future liability resulting from the release or threatened release that is the subject of the covenant where such liability arises out of conditions which are unknown at the time the President certifies ... that remedial action has been completed at the facility concerned."

The reopeners based on this statutory provision stand to be triggered by the discovery of previously unidentified CERCLA hazardous substances at a site. This could occur both at active Superfund sites, where settlements with nonperforming parties have been reached, and at sites that have been entirely "closed out," because regulators historically have not prioritized sampling for PFAS. Such reopening may result in significant unforeseen liabilities, triggering a new wave of CERCLA litigation not only between site owners and EPA, but among public and private potentially responsible parties (PRP) attempting to allocate costs for cleanup. Re-opening previously closed sites on a broad scale would likely lead to a stalled and disrupted federal site cleanup process, potentially increasing risks to public health, welfare, and the environment. One commenter suggested that the EPA should develop a protocol to identify and eliminate evaluation of PFOA and PFOS at sites where there is no evidence of PFOA or PFOS manufacture, use, disposal or release, and require assessment of PFOA and PFOS at closed sites and sites undergoing a five-year review only if EPA can make an endangerment finding. [0393 - NMED, 0340 - ASTSWMO, 0398 - PA DEP, 0542-CLA; 0563-UTLX; 0391-SSP; 0512-Stericycle; 0419-API

A commenter suggested that EPA should clarify that its proposed listing will be applicable prospectively only – solely for any new releases or disposal of PFOA/PFOS. [0419-API]

Response

EPA disagrees that designation will change its process for listing and/or deleting NPL sites or evaluating remedies' protectiveness through five-year reviews, and it will not require PFOA and PFOS sampling at all current sites. Response actions, including those that may be warranted based on findings in a five-year review, such as starting a new investigation, are contingent, discretionary, and site-specific decisions. They are contingent upon a series of separate discretionary actions and meeting certain statutory and regulatory requirements.

EPA does not expect the number of sites on the NPL to substantially increase after designation. EPA already has the authority to list sites with PFOA and PFOS on 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 PFOA and PFOS.

Designation will not change the HRS process, nor does EPA believe that the rule will change EPA's approach to assigning resources and staffing. Additionally, EPA disagrees with commenters reference to the Salvatore et. al. report indicating that all sites identified as having historical PFAS use would potentially need to be added to the NPL. EPA has addressed this comment about the possible expansion of sites and how EPA selects sites for the NPL in the Preamble to the Final Rule Section VII.E.5 (*National Priorities List (NPL) Sites – Existing and Future Contamination*).

Designation enables earlier and more EPA response work by diversifying EPA's options—response work can now be conducted by EPA or a PRP, which should help alleviate EPA resource constraints if it could only conduct response work with its own resources.

EPA disagrees that designation will delay eventual cleanup, nor will it change EPA's approach to assigning resources and staffing. As stated in the Preamble to the Rule, Section VII. E, 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. Moreover, designation is expected to accelerate the time it would take to respond to PFOA and PFOS releases, absent designation. For example, 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. See Preamble to the Final Rule Section VI.A.

EPA disagrees with the commenters that indicate this designation will directly result in sites investigating PFOA and PFOS as part of the five-year review process and that any site past the ROD stage is statutorily required to perform a five-year review.

First, in general, five-year reviews are required whenever a remedial action results in hazardous substances, pollutants, or contaminants remaining on site after completion. EPA conducts five-year reviews, as required by CERCLA section 121(c), when remaining on-site hazardous substances, pollutants, or contaminants are above levels that allow for "unlimited use and unrestricted exposure." See 40 CFR 300.430(f)(4)(ii). Five-year reviews should be conducted either to meet the statutory mandate under CERCLA section 121(c) or to meet EPA policy requirements.

Second, EPA does not need to develop a protocol to identify and eliminate the need for an evaluation of PFOA and PFOS at certain NPL sites. EPA has existing procedures to assess the effects of newly emerging contaminants and does not believe a PFAS-specific procedure is required. The site investigation and the five-year review process will operate as it has for decades. There are no blanket requirements for any further investigation or sampling. The five-

year review is based on site-specific facts and a case-by-case process that integrates information contained in historical documents, site decision documents, operational and performance data for a remedy, and the experiences of those responsible for and affected by actions at the site. The site manager uses the information to assess the remedy's performance, and ultimately, to determine the protectiveness of the remedy.

CERCLA section 121 provides that if action is appropriate to assure protectiveness, as a result of findings of a five-year review, those actions can be taken. As stated in the Preamble to the Rule, VII. E, 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. The risk assessment may also need to be updated to follow current guidance and policy, including addressing cumulative risk, as appropriate. Five-year reviews can also recommend further investigation to determine whether an additional response action is needed. Generally, decisions on whether further investigation or sampling is conducted are based on site history and the potential for contaminants to be related to the release. Also, as stated in the rule: In all cases, EPA should evaluate whether the remedy can mitigate any unacceptable risk or whether additional actions may need to be taken. FYR Requirements can be found in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR 300.430(f)(4)(ii) and CERCLA section 121(c). See Preamble Section VII.E (National Priorities List (NPL) Sites – Existing and Future Contamination) for more information about NPL site prioritization.

In some cases, there may need to be additional work to address a new contaminant of concern (such as PFOA and PFOS), 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 the new COC. 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 addressing contaminated drinking water).

If sampling is necessary for additional COCs, EPA acknowledges that there are additional costs and that this will depend on site specific circumstances. Generally, sampling and analysis costs will depend on the number of COCs, data quality objectives included in a project management plan, and potentially other factors. Based on EPA's experience to date, the cost of collecting and testing samples at PFAS contaminated sites is likely to be more than the average cost for other classes of chemicals, however, EPA doesn't expect those costs to be dramatically different. The cost of sample testing for PFOA and PFOS may be on the order of \$300-500 per sample. The cost of sample collection may also be slightly higher than for other classes of chemicals due to care and precautions needed to minimize background contamination, but otherwise sample collection costs should be on par with other classes of chemicals. These costs could decrease over time as techniques, lab capabilities, and lab capacities improve.

Designation does not alter the remedial process and will not impact EPA's process for evaluating and selecting, if necessary, remedies at current and future NPL sites or the five-year review process. While it is true that PFOA and PFOS regulations, environmental standards, and remediation technologies are evolving, EPA believes this is not a hinderance to designation. For

more information, see preamble to the Final Rule, Section VII.B.1 (*Operation of CERCLA*) and for management of wastes, see the preamble to the Final Rule Section VII.H (*Managing PFOA and PFOS Contaminated Waste*).

EPA disagrees that designating PFOA and PFOS as hazardous substances could result in the reopening of many deleted Superfund sites. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion from the NPL does not preclude further remedial action, although additional response actions are not frequently performed at deleted sites. EPA may take a response action at a deleted site, as appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system. See the preamble to the Final Rule Section VII.E (National Priorities List (NPL) Sites – Existing and Future Contamination) for more information about reopening sites. EPA disagrees with commenters that potential liability and litigation will result in cleanup delays or interfere with addressing priority releases. Such claims are speculative and not supported by evidence in the record. After a careful analysis, EPA expects that designation should not disrupt CERCLA's liability framework and that CERCLA will continue to operate as it has for decades. For more information about CERCLA and "polluter pays" see preamble to the Final Rule Section VI.C (Results of Totality of the Circumstances Analysis), and preamble to the Final Rule Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way).

EPA disagrees that the designation will trigger a "new wave of CERCLA litigation" based on the reopener language in CERCLA Section 122(f)(6)(A) as this provision only applies to site-wide consent decrees that provide covenants for "future liability." Many CERCLA agreements only apply to a discrete cleanup or cost recovery actions and thus do not include the reopener language in CERCLA Section 122(f)(6)(A). For site-wide consent decrees, EPA's model settlement agreement includes a reservation for unknown conditions, stating that "the United States reserves the right to issue an administrative order or to institute proceedings in this action or in a new action seeking to compel Settling Defendants to perform further response actions relating to the Site, to pay the United States for additional costs of response, or any combination thereof. The United States may exercise this reservation only if, at any time, conditions at the Site previously unknown to EPA are discovered, or information previously unknown to EPA is received, and EPA determines, based in whole or in part on these previously unknown conditions or information, that the Remedial Action is not protective of human health or the environment." Whether the United States exercises that right is at its discretion and that decision would be made on a site-by-site basis informed by site-specific circumstances. Based on those limitations, EPA does not expect a significant increase in litigation based on the reopener language in CERCLA Section 122(f)(6)(A).

EPA disagrees that agriculture operations notified pursuant to the 2021 National Defense Authorization Act (NDAA) will be implicated at Superfund sites. Designation alone does not require any person to take a response action, require an NPL listing, or determine liability for hazardous substance release response costs. CERCLA and the NCP prescribe a detailed process of identifying sites eligible for the NPL, and any response actions that may be appropriate for a

release are based on unacceptable risk to human health and the environment. Notification under the NDAA is separate and distinct from EPA's process for identifying potential NPL sites and what response actions, if any, may be appropriate for a given release. The 2021 NDAA requires DoD to notify agricultural operations located within one-mile down gradient of a Military Installation or National Guard facility where PFOA or PFOS (1) has been detected in groundwater on base; (2) has been hydrologically linked to a local agricultural or drinking water source; and (3) is known or suspected to be the result of a PFAS release at a Military Installation or National Guard facility located in the United States. In those cases, the presumption from the statutory language is that DoD caused the release and is responsible for the contamination.

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. For more information, see the Preamble to the Final Rule, Section VI.A.1 (Designation enables earlier, broader, and more effective cleanups of contaminated sites.).

For many of the potential impacts that could result from the designation, EPA has developed estimates under a range of scenarios. See preamble to the Final Rule, Section VII.I (*Comments on Economic Assessment/Regulatory Impact Analysis*), Section VI. A, and RIA Ch. 4 and 5 for more information about direct and indirect economic impacts.

EPA provides, in the RIA, an estimated low and high range of potential associated costs. See Preamble to the Final Rule, Section VII.I (*Comments on Economic Assessment/Regulatory Impact Analysis*) and the RIA for more information about economic impacts.

See Preamble Section VI.A.1 (Designation enables earlier, broader, and more effective cleanups of contaminated sites) and Preamble Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way) for information on clean-up of contaminated sites and liability and enforcement.

For information regarding CERCLA and its retroactive effect, please see RTC 2.A.3.

4.E. Impacts on Managing Waste Streams and Identifying Contamination

4.E.1 Cleanup Goals

4.E.1-1 Pretreatment standards should be left to individual POTWs.

Several commenters stated that instead of one-size-fits-all, pretreatment standards, managing these standards is best left to POTWs serving domestic and non-domestic users in delegated states. A few of these commenters stated that for example, POTWs that discharge to coastal marine waters will not impose any PFAS-related loadings on downstream water plants. Thus, the only concern for those facilities would be solids reuse/disposal issues. That circumstance might allow a different approach to nondomestic users than one where a POTW discharges proximately

upstream to a water intake. Even where a POTW discharges upstream of a water intake, it is most likely that PFAS barrier technology at the downstream water plant is more appropriate than piecemeal upstream controls (including on non-domestic users of the POTW systems). [0342-Association of Environmental Authorities (AEA), 0539-North Carolina Water Quality Association (NCWQA), 0492-South Carolina Water Quality Association (SCWQA), 0518-Wet Weather Partnership (WWP)]

Response

CERCLA does not provide authority for establishing pretreatment standards for POTWs nor does designation affect treatment standards for POTWs. These issues are outside the scope of this rulemaking.

EPA also refers the commenter(s) to the Agency's December 5, 2022, Memorandum "Addressing PFAS Discharges in NPDES Permits and Through the Pretreatment Program and Monitoring Programs." EPA expects the NPDES actions described in this memo to significantly reduce PFAS in wastewater treatment plant influent, which will reduce PFAS in wastewater treatment sludge.

https://www.epa.gov/pfas/key-epa-actions-address-pfas

4.E.1-2 The EPA should establish pretreatment standards and effluent limitation guidelines for PFOA and PFOS.

Numerous commenters encouraged EPA to develop effluent limitations guidelines (ELGs) and pretreatment requirements and standards so that POTWs and states can leverage their CWA industrial pretreatment programs for targeted reductions in industrial loading to their systems and, ultimately, municipal biosolids. At least one commenter stated that EPA should promote adoption of PFAS limits in the National Pollutant Discharge Elimination System (NPDES) permits of wastewater treatment plants to mitigate potential future liability. CERCLA Section 107(j) limits liability from federally permitted releases, including releases subject to NPDES permits under the CWA.

A few other commenters stated that EPA establish a list of categorical industrial users and develop appropriate pretreatment standards for PFOS and PFOA, and other PFAS substances as necessary. One of these commenters stated that pretreatment controls can only address concentrated and known industrial or commercial sources but not PFAS from homes and many businesses and therefore industrial controls alone (combined with extremely low or below detection levels) cannot eliminate PFAS entering water systems. [0480-National Waste & Recycling Association (NWRA) and Solid Waste Association of North America (SWANA), 0269-Hispanic Leadership Fund (HLF), 0569-U.S. Chamber of Commerce Coalition of Companies and Trade Associations, 0430-City of Elyria, Ohio Wastewater Pollution Control Plant and Municipal Separate Storm Sewer System (MS4), 0415-Association of Missouri Cleanwater Agencies (AMCA), 0518-Wet Weather Partnership (WWP), 0360-Great Lakes Water Authority (GLWA)]

Several other commenters stated that EPA's premise that industry could simply treat leachate to eliminate any PFAS prior to discharging to wastewater treatment plants in order to reduce potential CERCLA liability is flawed. Implementing treatment methods does not address potential liabilities for contributions from prior POTW discharges; technologies for PFAS

removal from landfill leachate at scale are still developing and require a multi-step process that includes (1) pretreatment of leachate to address non-PFAS constituents, (2) subsequent PFAS treatment using one or more removal technologies (which creates PFAS-containing residuals), and (3) PFAS residuals treatment/management. Landfill leachate pre-treatment will add significantly to the costs of landfill operation. The estimated capital cost to implement leachate pretreatment and PFAS treatment at a moderate-sized landfill (i.e., biological treatment of 30,000-40,000 gallons per day of leachate) necessary to minimize PFAS in leachate ranges from \$2-\$12 million or more. These commenters further noted that technologies for PFAS residuals management have not been evaluated at full-scale to determine costs and operational effectiveness. Per technology developers and estimates/extrapolations from small-scale studies residuals management could increase the costs of treating landfill leachate by approximately \$0.06 - \$0.39 (potentially even higher) per gallon of raw leachate processed (i.e., a cost increase of at least 400% to 800%) increasing costs associated with PFAS management to total approximately \$966 million to \$8.187 billion per year for municipal solid waste landfills alone, creating huge pressure on local governments, taxpayers, small businesses and disproportionately low-income households.

Response

CERCLA does not provide authority to establish Effluent Limitations Guidelines (ELGs) and pretreatment standards for POTWs or landfills nor does designation effect those limitations or standards. These issues are outside the scope of this rule. EPA also notes that there is no prerequisite to have ELGs and pretreatment requirements and standards in place for the Agency to designate a substance as a hazardous substance under CERCLA. To designate PFOA and PFOS as hazardous substances, CERCLA section 102(a) requires EPA to find that PFOA and PFOS "may present substantial danger to the public health or welfare or the environment" when released into the environment." 42 U.S.C. 9602(a). See Preamble to the Final Rule, Section III. C. (EPA's PFAS Strategy Roadmap).

EPA also disagrees with commenters that designation will require any specific obligations pertaining to treatment, disposal, or storage of PFOA and PFOS contaminated wastes. Designation does not require facilities to take any specific response actions, such as sampling, treatment, or disposal. CERCLA is not a traditional "command and control" statute that prospectively limits pollution. Instead, CERCLA is a remedial statute that addresses contamination already released into the environment on a site-specific basis to ensure that communities and ecosystems do not face unacceptable levels of risk. See RTC Section 4.E.1-2 (Designation does not automatically confer liability, nor does it alter CERCLA's statutory or regulatory framework for liability) and RTC 4.F.4. (CERCLA is designed to target and prioritize sites that present unreasonable risk). See RTC 4.E.1-5 for information on treatment technologies.

4.E.1-3 RSLs, RMLs, and the PRG should be more closely aligned with the toxicity findings in the new interim lifetime health advisories.

A few commenters stated that current RSLs, RMLs, and PRGs are outdated and do not reflect the latest science and should be updated and aligned more closely with the toxicity findings in the new interim lifetime health advisories and ensure that the cleanup responses are safe and effective. Another commenter stated that comprehensive, science-based approaches to safe

PFAS management and destruction are vital. Another commenter stated that clean up and remediation of contaminated sites will be difficult or unattainable at the proposed concentration levels and will present a significant burden to states (PFOA: 0.004 parts per trillion, PFOS: 0.02 parts per trillion). [0552-Environmental Working Group (EWG), 0567-WE ACT for Environmental Justice (WE ACT), 0538-National Association of Clean Water Agencies (NACWA), 0474-Mississippi Farm Bureau Federation (MFBF), 0369-Hillsborough County Aviation Authority (HCAA)]

A few commenters stated that EPA should provide states and PRPs with complete and defensible toxicological evaluations, and appropriate risk assessment tools in establishing any regulatory standards, threshold levels, sampling methods, or clean up actions for PFOA/PFOS. [0328-Florida Water Environment Association (FWEA), 0565- Utility Solid Waste Activities Group (USWAG)]

Another commenter stated that according to EPA's Interim Recommendations to Address Groundwater Contaminated with PFOA and PFOS, if both PFOS and PFOA are detected in tap water, PFOS regional screening level (RSL) = 6 parts per trillion (ppt). If they are the only contaminant detected in tap water, PFOA RSL = 60 ppt and PFOS RSL= 40 ppt. The commenter requested an explanation as to why varying screening levels for PFOA and PFOS are recommended in tap water dependent on other contaminants present. [0398-Pennsylvania Department of Environmental Protection]

Response

EPA has established Regional Screening Levels (RSLs) and Regional Removal Management Levels (RMLs) for PFOA and PFOS (https://www.epa.gov/risk/regional-screening-levels-rsls). The RSLs and RMLs are updated every six months, and the PFOA and PFOS RSLs and RMLs will be evaluated and updated as appropriate as new final toxicity values become available due to the evolving science.

RSLs and Regional RMLs help inform response actions based on risk to human health. RSLs are used to determine if a site warrants further investigation, and RMLs are a factor to consider among others to undertake a removal action. Preliminary remediation goals are initial cleanup goals and comply with ARARs. They are based on updated science and Superfund guidance, including EPA's Risk Assessment Guidance for Superfund. Superfund guidance provides that draft toxicity values are not appropriate for use in Superfund risk assessment. See U.S. Envt'l Prot. Agnc'y, Human Health Toxicity Values in Superfund Risk Assessments, p. 3 (Dec. 5, 2003).

Per this guidance, generally sites are screened for further evaluation if the Hazard Index is above 1. The Hazard Index is the sum of the Hazard Quotient for the different contaminants found at a site. Thus, if multiple contaminants are found at a site, a lower Hazard Quotient is used to screen the various contaminants to determine if the Hazard Index is above one and thus further investigation is needed.

PFOA and PFOS are often found together at sites along with other PFAS and non-PFAS contaminants, so it is appropriate to use a lower screening level based on a lower Hazard Quotient to determine if further investigation is needed. Finally, health advisories, interim or final, are informative at Superfund sites, but do not constitute ARARs.

For Superfund and the NCP, RSLs and RMLs and existing guidances are available for states and PRPs to use to investigate and respond to PFOA and PFOS. They are already in use.

CERCLA authority provides EPA with tools to address immediate and long-term needs for mitigating and reducing PFOA and PFOS exposures that present unacceptable risk. See the Preamble to the Final Rule VII.C. (Results of Totality of Circumstances Analysis).

See RTC 4E 1-5 for information on tools for PFAS management and destruction and RTC 4.E.2 for information on managing waste.

4.E.1-4 EPA should provide guidance on potential cleanup standards for remedies, including identifying potential Applicable or Relevant and Appropriate Requirements (ARAR) and To Be Considered (TBCs) that may be applicable to PFOA and PFOS.

Some commenters stated that cleanup goals under CERCLA consider all applicable or relevant and appropriate requirements (ARARs) and found that the CERCLA requirement that a response action meet ARARs and To Be Considered ("TBC") is troublesome because EPA's revised HALs, which are below detection limits, the subject of litigation, and conflicting with other governing bodies conclusions, would be TBCs. In the past, when addressing drinking water cleanup, maximum contaminant levels (MCLs) for the contaminant have been used. One of these commenters stated that the recommended levels of 0.004 parts per trillion (ppt) for PFOA and 0.02 ppt for PFOS are below levels that current technology can detect. ARARs have typically been a single substance with only one MCL being used. In the case of PFOA and PFOS, EPA may set two different MCLs. Another of these commenters stated that EPA should provide additional clarity as to how the Agency's SDWA process will impact the setting of cleanup goals. [0339-Association of State Drinking Water Administrators (ASDWA), 0462-Los Angeles County Sanitation Districts, 0493-Protecting Our Water, Environment, and Ratepayers Coalition (POWER!), 0391- Superfund Settlements Project (SSP), 0418-AGC; 0538-National Association of Clean Water Agencies (NACWA)]

Another commenter stated that it appears ARARs do not yet exist and urges EPA to delay this rulemaking until such standards are developed. Another requested that EPA develop guidance that a) will require PFOA and PFOS site-specific cleanup criteria be based on site-specific realistic exposure scenarios together with a requirement that the cleanup criteria do not exceed background concentrations and b) implement a blanket ARAR waiver for PFOA and PFOS until the science is more fully defensible and to result in nationwide consistency. Another commenter also noted that without an assessment of potential removal and remediation costs, it is impossible for the regulated community to determine the scope of its potential legal liabilities stemming from the proposed designations. [0462- LA Sanitation Districts, 0391- Superfund Settlements Project (SSP), 0538-National Association of Clean Water Agencies (NACWA)]

A commenter stated that the lack of a regulatory cleanup standard is particularly troubling under CERCLA section 102(a) because this section does not have an established process for identifying clean-up standards whereas designation in reference to other statutes (Clean Water Act, Resource Conservation and Recovery Act) provide regulatory processes for classifying hazards (e.g., concentration-based limits) and, thereby, provide guidance through an Applicable or Relevant and Appropriate Requirement ("ARAR"). [0477-Louisiana Chemical Association (LCA)]

Finally, a commenter stated that the burden or responsibility of cleanup is of particular concern without clear standards for apply to PFOA and PFOS cleanup. Ultimately, CERCLA would trigger extreme liability for remediation without a mechanism to limit liability for non-responsible parties. [0418- Associated General Contractors of America]

Response

The Agency disagrees with commenters' assertion that designation under CERCLA is premature. EPA also disagrees that, at present, there is no regulatory framework in place that allows EPA to respond effectively to PFOA and PFOS releases. See the Preamble to the Final Rule, Section VII.B.1. (Comments suggesting that other authorities are better suited to address PFAS contamination).

Additionally, as the commenter(s) mentioned, cleanup requirements can vary widely from site to site, as CERCLA response actions are determined on a site-specific basis based on site-specific information. EPA cannot predetermine the scope of a response action, and the potential cost of a response, until it fully evaluates the releases at issue consistent with CERCLA and the NCP. See supra Section 6A and RIA.

Relatedly, ARARs or TBCs that may be identified as relevant to a site-specific remedy are determined on a site-specific basis, as are any relevant ARAR waivers. This is true in the context of PFOA and PFOS as well as the other 800 hazardous substances subject to CERCLA. Removals must comply with ARARs to the maximum extent practicable.

Existing CERCLA guidance relevant to establishing protective cleanup levels is equally applicable to sites that include PFOA and PFOS releases, and no additional guidance is necessary at this time. EPA's guidance, Role of Background Guidance (US EPA, 2002b), presents a discussion on how background may be factored into risk management decisions. Generally, under CERCLA, cleanup levels are not set at concentrations below natural background levels. Similarly, for anthropogenic contaminant concentrations, the CERCLA program normally does not set cleanup levels below anthropogenic background concentrations (US EPA, 1996; US EPA, 1997b; US EPA, 2000c).

Commenters suggest that EPA establish a nationwide ARAR waiver for PFOA and PFOS but provide no legal support for such a policy.

For Superfund and the NCP, RSLs and RMLs and existing guidances are available for states and PRPs to use to investigate and respond to PFOA and PFOS. They are already in use.

Finally, EPA disagrees that designation will lead to "extreme liability." Designation does not alter CERCLA's liability framework. Designation does not expand the definition of "potentially responsible parties," nor does it amend, change, or curtail existing statutory limitations on liability. Liability determinations are site-specific, and designation does not determine liability. EPA expects CERCLA to continue to operate as it has for decades to equitably resolve who should pay. See the Preamble to the Final Rule, Section VI.B and Section VII.J

4.E.1-5 Acceptable remedial tools and remedial and removal technologies for PFOA and/or PFOS are lacking.

Numerous commenters pointed out that effective and cost-effective remediation and removal technology with sufficient capacity are currently not known or acceptable to remediate PFAS insitu or can pose significant challenges such as excavating and thermally treating or disposing impacted soils offsite, jeopardizing compliance. One of these commenters stated that they are not aware of any definitive wastewater treatment that EPA has identified as workable at scale 3 and that treatment associated with drinking water compliance obligations (such as carbon and ion exchange) may not transfer to the management of wastewater effluent, which is typically chemically more complex. Therefore, the commenter asked EPA to hold off on the PFOA and PFOS designation. [0565- Utility Solid Waste Activities Group, 0342-Association of Environmental Authorities (AEA), 0325-Oak Ridge National Laboratory (ORNL), 0355-City of Los Angeles Sanitation and Environment (LASAN), 0432-City of Columbus OH, Department of Public Utilities (CDPU), 0350-City of Henderson, NV, 0328-Florida Water Environment Association (FWEA) Utility Council et al, 0496-Northeast Ohio Regional Sewer District (NEORSD), 0314-Maine Water Utilities Association (MWUA), 0298-South Dakota Department of Agriculture and Natural Resources] [0543-American Water Works Association (AWWA)]

A commenter stated that research has shown that PFAS can be removed, although ineffectively, by conventional treatment (coagulation, flocculation, and sedimentation) as well as other processes like lime softening (Xiao, 2012; Belkouteb, 2020; Zhang, 2021; Cornelson, 2021). The commenter stated that the potential for PFAS to be present in conventional treatment residuals increases with the use of powder activated carbon prior to sedimentation and pointed to some vendors that are also working to develop coagulants that aid in the removal of PFAS, such as PerfluorAd (TRS Group, 2020). The commenter asserted that given that CERCLA liability is strict, even minimal levels of PFAS present in these residual streams will cause changes in waste management by drinking water systems. One commenter stated that estimates for installing and operating new granulated activated carbon treatment systems at their three drinking water plants are \$100-200 million in capital investment and \$8-10 million annually for operating costs, not even accounting for the hazardous waste materials disposal created by the process. [see also Appendix A, Legal Appendix, Comment 0544-A1, for supporting legal arguments]; [See Comment 0543-A1, PDF pp.19-23 for complete citations]. [0432-City of Columbus OH, Department of Public Utilities (CDPU)]

A commenter urged the Administration to provide a pathway for alternative technologies to seek approval from the EPA as a viable PFAS destruction technology once they have been able to demonstrate the viability of their technology as EPA has done for methane emissions (EPA's Methane Proposal for the Oil and Gas Sector – A Strong Foundation to Reduce Methane Emissions and Regulatory Path for More. The commenter listed companies with advanced destruction technologies currently in the field today, including: Aclarity, Aquagga, 374Water, AECOM, Batelle. Purafide, Enspired Solutions, OnVector, Axine, Xyvant, and Claros Technologies. [0536-Aclarity Inc.]

A commenter stated that per the CERCLA section 107(a) remediation process, parties must perform a Remedial Investigation ("RI") followed by a Feasibility Study to evaluate alternative remediation options and select remedies to be implemented, but that the regulated community currently lacks the tools and information necessary to perform these required investigative steps,

making compliance infeasible if not impossible should the Proposal go into effect. [0565- Utility Solid Waste Activities Group (USWAG)]

[0428-Citizens Against Ruining the Environment (CARE)] The commenter provided some emerging treatment/destruction techniques to supplement this rulemaking's records:

- A new study exists that showcases a novel method of breaking down carboxylic PFAS molecules. This method does not work on sulfate-based PFAS molecules like PFOS. The scientists found that, in a low-temperature setting of 120 degrees Celsius, mixing the carboxylic PFAS (e.g., PFOA) with a solution of DMSO and NaOH (lye) resulted in the acidic head, which is also the active portion of PFAS molecules, being removed from the molecular structure, resulting in an inert carbon-fluorine chain. The study produced a finding that for PFOA specifically, there was a 90.1% fluorine recovery—with a +/- 5.8% recovery rate. This high fluorine recovery means PFOA is being destroyed and there is limited fluorine ions being released into the solution. Furthermore, there were minimal amounts of side-products formed from this chemical reaction. Lastly, DMSO and NaOH are inexpensive to procure. Considering this, coupled with the low temperature needed to perform the reaction, shows that this process is a promising and feasible way to destroy the PFAS that will be concentrated in the hands of wastewater and drinking water treatment plants. This study showcases that breaking down carboxylic PFAS, such as PFOA, can be relatively easy to destroy and render inert.
- A separate study from 2013 shows a potentially effective way of destroying PFAS molecules with an active sulfate group, such as PFOS. This method utilized KOH, a similar molecule to NaOH that was utilized in the previous study, but instead of adding heat or DMSO, the researchers used mechanochemical destruction. Mechanochemical destruction is the utilization of mechanical forces to initiate a chemical reaction, in this case, a reaction that breaks down PFAS, including PFOS. The byproducts of this reaction include potassium sulfide (K2SO4), potassium carbonate (C2CO3), and potassium fluoride (KF). KF is known to be toxic to humans and K2SO4 is known to be an irritant to humans. Despite the byproducts that this reaction forms, over an eight-hour period, over 90% of PFOS was destroy through the mechanochemical reaction.
- Pyrolysis, a thermal process, was found to destroy PFAS in biosolids, leaving a biochar with no detectable PFAS. However, the study concludes that additional research "is warranted to understand all potential PFAS transformation emission routes and optimal air pollution emissions control strategies for this technology class"

Response

There are currently methods available to remediate, destroy and dispose of PFOA and PFOS contamination and new methodologies are being evaluated. EPA does not agree that it is necessary to identify specific control and cleanup technologies in order to designate PFOA and PFOS as hazardous substances under CERCLA nor to provide grant funding for related infrastructure; the only criteria needed is that EPA finds that PFOA and PFOS "may present substantial danger to the public health or welfare or the environment" when released into the environment.

To address comments regarding waste capacity, see Preamble to the Final Rule Section VII.H (Managing PFOA and PFOS Contaminated Waste) and RTC 4.E.2.

The science on treating, destroying and disposing of PFAS is evolving. EPA published its Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) and Materials Containing PFAS-Substances -Version 2 (2024). (https://www.epa.gov/pfas/interim-guidance-destroying-and-disposing-certain-pfas-and-pfas-containing-materials-are-not). For additional information: https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf.

The document 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 Fiscal Year 2020 National Defense Authorization Act, EPA is required to publish an interim guidance on PFAS Destruction and Disposal and will publish revisions to the PFAS Destruction and Disposal interim guidance as appropriate, but not less frequently than once every three years. In the foreseeable future, EPA will not be finalizing the guidance, but rather will be updating it to reflect new science.

This is the first update to this guidance and includes new science and testing, including EPA's PFAS Innovative Treatment Team (PITT) and other research results. EPA is incorporating new EPA test methods, along with screening methods to assess vulnerable populations near destruction and disposal sites. While the 2024 update includes up-to-date information on potential releases during PFAS destruction and disposal, key data gaps and uncertainties will need to be resolved before EPA can issue more definitive recommendations. This version also contains revisions based on public comments received. Following publication, EPA will again accept public comments on the interim guidance.

Read about related research efforts by the Department of Defense's Strategic Environmental Research and Development Program (SERDP) and the Environmental Security Technology Certification Program (ESTCP) to evaluate treatment technologies: https://serdp-estcp.org/focusareas/9a62d079-00d0-4482-a2a2-d2d8157abec9/management-of-pfas-in-the-environment.

EPA has been able to successfully implement CERCLA and clean up various types of sites even where some technical challenges existed. For instance, similar to PFOA and PFOS, chlorinated solvents, such as PCE, TCE, and Vinyl Chloride, are other hazardous substances that have been addressed at sites since the late 1970s. Technical challenges remain in addressing these traditional contaminants; cleanups have moved forward despite these challenges. Research programs and experience gained from full-scale applications have resulted in technological and remedial strategy improvements over time.

The comment requesting that EPA seek approval for alternative technologies is also outside the scope of the rule. However, although there is not currently a formal technology evaluation program, on a site-specific basis, EPA can, and has, conducted pilot-scale deployments of innovative treatment technologies to support remedy selection and implementation. In addition, the DOD SERDP/ESTCP program and individual services have a variety of pilot-scale treatment technology deployment programs. It is worth noting that, historically, neither EPA nor DOD programs have resulted in a formal 'approval' per se. Rather the technologies are evaluated against a pre-established set of performance objectives.

Please reference the Preamble to the Final Rule, Section III.C (EPA's Strategic Roadmap) and RTC Section 4E1-1 and 4E1-2 2 for responses on pretreatment requirements and standards.

EPA disagrees with one commentors assertion that EPA should delay designation until definitive wastewater treatment has been identified. Agency efforts, and related costs, under non-CERCLA authorities are not within the scope of this rule, such as drinking water regulations. However, though beyond the scope of the rule, as discussed in EPA's National Primary Drinking Water Regulation (EPA-HQ-OW-2022-0114, March 29, 2023), there are multiple treatment technologies that are available to remove PFAS including activated carbon and anion exchange. Should PFOA and PFOS be present in a utility's source water, there are a variety of factors they would consider in deciding how to reduce these contaminants in their finished water, including costs of treatment and disposal. For estimating costs to drinking water utilities as part of the national primary drinking water regulation, the EPA uses a data-driven model system approach based on a peer reviewed work break down methodology; individual systems may have higher or lower costs than national level estimates. Capital investment and annual operating and maintenance costs are influenced by numerous factors, including volume of water treated, quality of source water (including the concentration of PFAS and Total Organic Carbon), size of the drinking water plant, topography, geographic location, and disposal, among other factors. For more information about cost estimates, please see EPA's National Primary Drinking Water Regulation (EPA-HQ-OW-2022-0114, March 29, 2023) Economic Analysis.

With respect to transferability of treatment technology, "wastewater effluent" is very diverse due to the diversity of sectors which may be generating the wastewater. Consequently, identifying "any definitive wastewater treatment" when referring to broad categories is difficult.

Facilities do not need to take any action to "comply" with the designation or to "comply" generally with CERCLA (barring any specific administrative order, consent decree, or settlement agreement relevant to site-specific activities, which commenters did not identify). EPA understands that facilities may take steps to mitigate ongoing or future releases of PFOA and PFOS as a means to mitigate potential liability. Such management practices are not a requirement of CERCLA or the designation but are generally considered an advantage, and costs are outside the scope of the rule and require no response.

EPA would like to clarify that CERCLA section 107(a) is the cost recovery authority and does not include any remedial requirements, such as an RI/FS. EPA believes the commenters intended to refer to CERCLA section 121 and the NCP (40 CFR 300.430), which provide the parameters for assessing remedial alternatives and selecting remedies. EPA disagrees with the comment that the regulated community lacks the tools to perform investigations. The tools and process to conduct remedial investigations have not changed, and PFOA and PFOS are the two PFAS for which the most information is widely available.

4.E.1-6 EPA should evaluate whether there is sufficient sample collection and laboratory analysis capacity to support the proposed rule.

A commenter stated that the EPA should consider whether there is sufficient capacity for PFOA and PFOS sample collection and laboratory analysis to support the proposed designation. Although sampling and analytical methods for PFOA and PFOS have improved considerably, there remain significant limitations on both the costs and logistics associated with PFOS and PFOA monitoring. As such, the commenter recommends EPA evaluate whether there is

sufficient capacity to support the potential monitoring required under CERCLA. [0401-Wyoming Department of Environmental Quality (WDEQ)]

Response

EPA does not agree that it is necessary to evaluate sampling and laboratory analysis capacity to designate PFOA and PFOS as hazardous substances under CERCLA if the Agency finds that PFOA and PFOS "may present substantial danger to the public health or welfare or the environment" when released into the environment. However, the Agency notes that there are methodologies for sampling and analysis for PFOA and PFOS, and EPA, and other entities are working to improve our capabilities in this area.

EPA would also like to clarify that neither the designation, nor CERCLA, require any prospective monitoring for release reporting.

4.E.1-7 The Proposed Designation needs to revise language pertaining to "cleanups" and "meaningful public health benefits."

A commenter stated that the use of "cleanup" and "cleanups" throughout the text is technically incorrect. In the case of PFOA and PFOS, there would not be a "cleanup" or as required by CERCLA section 121(b), the permanent reduction of the volume, toxicity, or mobility of PFOA and PFOS. Also, the referenced legal requirements would not be met in a reasonable timeframe for an Applicable or Relevant and Appropriate Requirement (ARAR) compliance as the latest "cleanup" technologies' predictive modeling indicate that the best option is PFOA/PFOS plume containment and separation with concentrations reaching a groundwater standard years or decades into the future. With these timeframes, and the impossibility of accessing contaminated groundwater for potable purposes while cleanup is underway, the word "cleanup" needs to be put in the proper context. The commenter stated that it would be better to state that "...the Federal government is authorized to address the risk from exposure to PFOA/PFOS contamination when these substances present an imminent threat." Additionally, with the use of "meaningful public health benefits," the EPA does not address the actual risk of exposure that would provide more meaningful and tangible public health protection. [0369 – Hillsborough County Aviation Authority (HCAA) Tampa International Airport (HCAA)]

Response

Commenter does not clarify which instances of the use of the word "cleanup" or "cleanups" in the proposed rule that it believes EPA used incorrectly. Nonetheless, EPA acknowledges that the technical terms for CERCLA actions that include, but are not limited, to cleanup are "response," "remedial," and "removal." CERCLA section 101(22-25). Remedial actions include those actions described in CERCLA section 121(b).

EPA disagrees with the commenter's claim that the Agency cannot comply with CERCLA section 121(b). CERCLA section 121(b) identifies a preference for treatment that "permanently and significantly reduces the volume, toxicity or mobility" of hazardous substances, pollutants, and contaminants. It also provides nine criteria in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) that EPA must consider in selecting a remedy. The remedy selected shall be "protective of human health and the environment," be "cost effective," and utilize "permanent solutions and alternative treatment technologies or resource recovery

technologies to the maximum extent practicable." If and when EPA selects a remedy to address PFOA or PFOS contamination, it must comply with CERCLA section 121(b).

The process for identifying, selecting, and implementing a remedy can take many years, and EPA acknowledges that the comprehensive cleanup of sites with extensive PFOA and PFOS contamination could be many years in the future. However, designation provides EPA with the full suite of CERCLA tools necessary to begin the lengthy remedial process sooner rather than later and best promotes eventual cleanup of PFOA and PFOS. It also allows EPA to compel PRPs to take action, which is expected to enable EPA to address more sites than it could absent designation. Importantly, EPA may also utilize its removal authority to address PFOA and PFOS releases that require more immediate action. The tools collectively promote "cleanup," and are an advantage of designation. For further discussion of how designation promotes cleanup, please see the Preamble to the Final Rule Section VI.A.1. (*Designation enables earlier, faster, broader, and more effective cleanups of contaminated sites*).

EPA also disagrees with the commenter's assertion that the designation of PFOA and PFOS as CERCLA hazardous substances will not result in meaningful public health benefits. Designation is critical to EPA's ability to address the public health threats posed by PFOA and PFOS in the environment. For further discussion of health benefits please see the Preamble to the Final Rule Section VI.A.2. (*Designation Brings Broad Health Benefits*).

4.E.2 Managing PFOA/PFOS Contaminated Waste

Commenters raised concerns about the transport, storage, and disposal of PFOA and PFOS, which would be significantly increased by the designation. They claim that EPA has not met the CERCLA mandate of identifying sufficient disposal and 20-year storage sites. They also say that meeting this challenge will be complicated by the need to transport PFOA-contaminated sludge long distances to suitable landfills (RCRA Subtitle C facilities). Additional concerns include (1) the treatment of PFAS in nonhazardous landfills that result from residential and commercial product waste and (2) the possibility that landfilling, underground injections, and thermal treatment may not be allowed by EPA.

Many commenters asserted that the proposal will significantly increase the amount of PFAS waste that needs to be managed but that EPA has not identified waste management impacts. EPA has not established that sufficient capacity exists for disposal and storage of PFOA and PFOS wastes (e.g., biosolids, landfill leachate, contaminated soil and associated treatment media, spent granular activated carbon and filters and bags) should PFOA and PFOS be designated as hazardous. Other commenters stated that EPA's 2019 assessment of available capacity of 1.4 million tons through 2044 represents only 20% of potential waste generation by water systems and that "through 2044" means that EPA may not be able to satisfy CERCLA's mandatory 20year period of sufficient capacity for hazardous wastes beginning in 2025. A few commenters stated that additional remediation activities triggered by the designation will increase the need for disposal of PFOA and PFOS contaminated waste for which there may not be enough capacity or a limited number of facilities willing to accept the waste. This in turn will increase environmental and cost impacts from hazardous waste transportation. For example, moving and disposing of soils from infrastructure projects and reluctance of municipal solid waste landfill operators to accept sludge with PFOS and PFOA combined with a lack of treatment options, will result in PFOS- and PFOA-contaminated materials being sent to a limited number of RCRA

Subtitle C landfills and disposal facilities; an increase of this demand will then increase costs associated with hazardous waste transportation. EPA has not considered the availability of Subtitle C landfill capacity that can accommodate the 8 million tons of "hazardous" (by virtue of PFOS and PFOA being detected) sludge as well as the impact on other national policies to reduce greenhouse gas emissions released from the transport of sludge. Similarly, long-term onsite storage for example at airports will result in costly management and reporting obligations. Other commenters stated that EPA should also factor in PFAS in general into waste calculations due to nonhazardous landfills' concerns about liability, specifically with regards to waste containing PFAS that was not generated from environmental investigation sites, such as residential and commercial product waste (i.e., fluorinated ski wax, old formulations of 3M's Scotchgard, other PFOS and PFOA containing consumer products). [0468-National Ground Water Association (NGWA), 0808-National Association for Surface Finishing, 0421-American Chemistry Council (ACC), 0543-American Water Works Association (AWWA), 0418-Associated General Contractors of America (AGC), 0419-The American Petroleum Institute (API), the American Fuel & Petrochemical Manufacturers (AFPM), the Alaska Oil and Gas Association (AOGA), the Louisiana MidContinent Oil and Gas Association (LMOGA), the New Mexico Oil and Gas Association (NMOGA), The Petroleum Alliance of Oklahoma (PAO), the Petroleum Association of Wyoming (PAW), and the Utah Petroleum Association (UPA) (collectively, "the Associations"), 0394-Oklahoma Secretary of Energy and Environment and Oklahoma Department of Environmental Quality, 0569-U.S. Chamber of Commerce Coalition of Companies and Trade Associations, 0522-Wisconsin Manufacturers & Commerce (WMC), 0342- Association of Environmental Authorities (AEA), 0391- Superfund Settlements Project (SSP), 0453-Illinois Association of Wastewater Agencies (IAWA); 0269- Hispanic Leadership Fund (HLF), 0536-Aclarity, 0411-Airlines for America (A4A), 0342-Association of Environmental Authorities (AEA), 0424- Airports Council International - North America (ACI-NA), 0506-U.S. Conference of Mayors et al.]

Commenters also stated that CERCLA section 104(c)(9) mandates that EPA take steps to ensure adequate disposal capacity exists to handle CERCLA remediation wastes. Under this provision, before EPA provides funding for any remedial action, a state must demonstrate the availability and adequate capacity of hazardous waste treatment or disposal facilities to manage wastes over the subsequent 20-year period. These commenters asserted that EPA is arbitrarily ignoring or failing to address this statutory mandate and determine whether states have adequate capacity to destroy, treat, or securely dispose of all the materials contaminated with PFOA and PFOS in the next 20 years and beyond. At least one commenter stated that because that Assessment did not consider how the volume of hazardous wastes will increase dramatically by the PFOA and PFOS designation, EPA cannot guarantee it can satisfy CERCLA's mandatory 20-year period of sufficient capacity for hazardous wastes. EPA has acknowledged that it has required PFOA and PFOS cleanup at sites already by asserting that they are CERCLA pollutants or contaminants but has not described disposal methods for contaminated soils or other media from the new sites that would be created if this rule is finalized. Additionally, EPA has not disclosed any agreement with any state to ensure that the state has adequate capacity to destroy, treat, or securely dispose of all the materials contaminated with PFOA and PFOS in any period in the future. The commenter also pointed to current incineration capacity challenges that would be exacerbated. Potentially PFOA and PFOS containing biosolids alone are generated nationally at a rate of

approximately 4.5-6 million metric short tons annually and may necessitate specialized disposal solutions in some cases.

Certain waste streams with elevated levels of PFOA and PFOS require management at a RCRA Subtitle C hazardous waste facility which indicates that existing capacity would prove decidedly inadequate in short order and that waste streams from DoD facilities alone might be close to or even exceed capacity, with only a small amount remaining for any private requirements.

A commenter stated that the proposed designation which they considered insufficient to provide necessary information may result in landfilling and underground injections being precluded. Per EPA thermal treatment requires more research, which would not leave any viable waste management options. Per the commenter, farms, forest lands and landfills could also begin refusing to accept biosolids, paper mill residuals and/or other low level PFOA and PFOS containing materials. [0419-The Associations, 0569-U.S. Chamber of Commerce Coalition of Companies and Trade Associations]

Another commenter noted that free liquids cannot be landfilled without sufficient assurances and, present unique challenges for underground injection control wells due to the viscosity and other properties of AFFF and cannot be thermally or chemically destroyed in present quantities with any level of certainty.

One commenter stated that research projects produce a variety of PFAS containing wastes such as solvents that are either used in energy recovery or solidified and then landfilled in a Subtitle D landfill (water wastes). The commenter was concerned that companies may be unwilling to manage PFAS research wastes in the future due to fear of liability. The commenter stated that due to the designation of low-level research wastes as hazardous waste, for example, water PFAS waste disposal cost would increase 12-fold from \$30,000/year to \$350,000. [0411-Airlines for America (A4A), 0487 Purdue University]

A commenter cautioned that regulation of PFOA and PFOS under CERCLA could inadvertently undercut the Administration's broader environmental goals because increased costs associated with the Rule could incentivize bad actors to seek alternative means of disposal of PFAS-contaminated media and remediation wastes that are less protective of public health and the environment. [0480-NWRA/SWANA]

A few commenters stated that EPA's action could lead to decreased composting services nationwide because potentially contaminated food waste compost from contact with PFAS-lined packaging materials could cause communities to divert food waste from organics recycling programs, hindering federal, state, and local climate and waste reduction goals. One of the commenters pointed out that in addition to transforming waste materials into beneficial soil amendments that build soil health, the diversion of the food waste and biosolids in the U.S. from landfills to composting avoids approximately 2.7 million metric tons of CO2-equivalent emissions to the atmosphere annually. [0480-NWRA/SWANA, 0361-Hazardous Waste Management Program, 0805-U.S. Composting Council, 0565-USWAG]

A commenter stated that unavailability of viable disposal options will result in extended storage of waste materials which will be at odds with EPA's plans to designate PFOA and PFOS as RCRA hazardous constituents because of limited on-site accumulation timeline (90, 180 or 270 days) requirements for hazardous wastes under RCRA. This would require facilities that cannot comply to secure a RCRA permit associated potential facility upgrades and reporting

requirements. A commenter stated that because the rule may result in spent media disposal cost and very limited disposal options, EPA should consider the environmental impacts from trucking water treatment residuals across state lines for disposal of spent treatment media. [0339-ASDWA, 0495-PFAS Regulatory Coalition]

A commenter stated that CERCLA regulation will impel landfills to restrict inbound wastes and/or increase disposal costs for media with elevated levels of PFAS, including filters, biosolids, and impacted soils at Department of Defense facilities. The mere prospect of regulation in this area is already disrupting the interdependence of the drinking water, wastewater, and solid waste sectors and increased cost would impact low-income households disproportionately. A commenter stated that regulation of certain types of PFAS including PFOA and PFOS under CERCLA may disrupt the role that Municipal Solid Waste (MSW) landfills play in managing and limiting PFAS in the environment. Water and wastewater treatment facilities may be particularly impacted as they rely on the services of MSW landfills in the management of biosolids. [0361-Hazardous Waste Management Program, 0394-OSEE/ODEQ]

Many commenters stated that EPA's December 2020 Destruction and Disposal guidance document still needs to be finalized, does not provide any or clear guidance and does not provide guidance in the sense of recommending treatment methods and treatment limits but only summarized the current state of different technologies resulting in heavy reliance on Resource Conservation and Recovery Act (RCRA) Subtitle D landfills to manage PFAS waste. [0438-Bowling Green Municipal Utilities (BGMU), 0310-New England Water Works Association (NEWWA), 0394-Oklahoma Secretary of Energy and Environment and Oklahoma Department of Environmental Quality, 0311-Massachusetts Water Works Association (MWWA), 0396-Michigan Water Environment Association (MWEA), 0493-Protecting Our Water, Environment, and Ratepayers Coalition (POWER!), 0537-Association of Metropolitan Water Agencies (AMWA), 048-City of Aurora] [0341-American Farm Bureau Federation (AFBF), 0339-Association of State Drinking Water Administrators (ASDWA), 0512-Stericycle] [0419-The American Petroleum Institute (API), the American Fuel & Petrochemical Manufacturers (AFPM), the Alaska Oil and Gas Association (AOGA), the Louisiana MidContinent Oil and Gas Association (LMOGA), the New Mexico Oil and Gas Association (NMOGA), The Petroleum Alliance of Oklahoma (PAO), the Petroleum Association of Wyoming (PAW), and the Utah Petroleum Association (UPA) (collectively, "the Associations"), 0511-WateReuse Association, 0421-American Chemistry Council (ACC), 0522-Wisconsin Manufacturers & Commerce (WMC), 0430-City of Elyria Ohio Wastewater Pollution Control Plant and Municipal Separate Storm Sewer System (MS4), 0269-Hispanic Leadership Fund (HLF), 0394-Oklahoma Secretary of Energy and Environment and Oklahoma Department of Environmental Quality]

Commenters stated that this creates confusion about what disposal methods the Agency will find to be acceptable for PFOA or PFOS containing waste materials. Under CERCLA, remedies are site-specific as are the appropriate disposal/treatment methods for the remedy. In addition, OLEM has indicated that it does not plan to update the draft interim guidance until late 2023 – about the same time that EPA has indicated it will finalize the CERCLA designation for PFOA and PFOS. This leaves a substantial gap in the ability to properly dispose of waste that may be identified as part of the proposed designation. The commenters also pointed to the ongoing shortfall in incineration capacity for hazardous waste until additional capacity is expected to come online in 2024-2025. [0421-American Chemistry Council (ACC), 0522-Wisconsin Manufacturers & Commerce (WMC)]

Several commenters stated that detailed guidance for treatment media regeneration and disposal options is needed. These commenters stated that the federal government needs to invest in conducting science-based research for PFAS control, appropriate and consistent nationwide disposal options and destruction technologies to provide utilities with clear guidance moving forward and asserted that the CERCLA designation passes liabilities and cost down to local governments, and ultimately, ratepayers/taxpayers. [0339-Association of State Drinking Water Administrators (ASDWA), 0388-Suffolk County Water Authority (SCWA), 0424- Airports Council International - North America (ACI-NA), 0511-WateReuse Association, 0493-Protecting Our Water, Environment, and Ratepayers Coalition (POWER!), Tennessee Department of Environment and Conservation (TDEC), 0426-California Department of Toxic Substances Control (DTSC)]

Further, these commenters urged EPA to provide Agency-approved, safe, implementable, effective, and affordable PFAS treatment, disposal, and destruction technologies prior to a CERCLA designation of PFOA and PFOS and provide grant funding for related infrastructure.

A commenter stated that there is still ambiguity regarding the proper incineration temperature to effectively destroy PFAS compounds redistributing them back into the atmosphere. [0394-Oklahoma Secretary of Energy and Environment and Oklahoma Department of Environmental Quality]

A commenter noted that the guidance should consider a national ban on incineration or provide guidance to alternatives. For example, the Department of Defense placed a moratorium on incineration and, in June, the state of Illinois became the first in the nation to prohibit the incineration of PFAS. [0536-Aclarity]

Another commenter also referred to the DoD moratorium and bans on incineration in several states eliminating a clear pathway to dispose of PFAS in the near-term. This commenter stated that therefore end-users need clear guidance regarding to scale disposal alternatives 66, how to dispose of their existing stocks of firefighting foams, including timing, method, and which party has responsibility for the safe disposal; how to clean out apparatuses and equipment, all to avoid contamination and future Superfund liability. [0460-International Liquid Terminals Association]

Another commenter noted that the FY22 National Defense Authorization Act contained a provision instituting a moratorium on the incineration of PFAS, which the DOD implemented on April 26, 2022 (20) in response to incomplete combustion during the incineration of DOD stockpiles of PFAS-containing aqueous film-forming foam at incinerators in Cohoes, New York and Liverpool, Ohio which allegedly impacted surrounding neighborhoods. The commenter asserted that similarly the Proposed Rule could create a second tier of uncertainty and significant costs associated with not only liabilities for the primary sites that they remediate, but also for liabilities at third-party disposal sites. [0512-Stericycle]

Response

EPA disagrees with comments asserting that the agency has not evaluated impacts related to waste management, that the volume of hazardous waste is going to dramatically increase, and that EPA has not evaluated if sufficient capacity exists for disposal and storage of PFOA and PFOS wastes. EPA also disagrees that it must finalize the PFAS Destruction and Disposal

Guidance in advance of finalizing the designation and that additional guidance is necessary before EPA can designate PFOA and PFOS as hazardous substances. See RTC comment 4.E.1-5.

Designation has no impact on RCRA's list of "hazardous wastes." PFAS, including PFOA and PFOS, are not currently listed, nor being proposed to be listed, as RCRA hazardous wastes, and designation of PFOA and PFOS as CERCLA hazardous substances does not automatically require that PFOA- and/or PFOS-contaminated waste be treated or disposed of at RCRA Subtitle C facilities. The CERCLA designation does not result in any specific RCRA requirements nor does designation impose additional costs for waste management facilities. Designation does not impose any specific landfill operation or management requirements. Designation is not at odds with EPA's efforts to address PFAS, including PFOA and PFOS as RCRA hazardous constituents RCRA hazardous waste accumulation timeframes (90, 180, or 270 days) apply to generators of hazardous waste only, and not to hazardous constituents. And again, designation under CERCLA does not make PFOA and PFOS RCRA hazardous wastes. Another commenter provided no support for a statement that waste streams from DoD facilities could result in exceeding capacity to dispose of PFOA and PFOS.

It is possible that designating PFOA and PFOS as hazardous substances may have the potential to incrementally increase the amount of material being sent to hazardous waste landfills or hazardous waste treatment and disposal facility, but any potential increase is expected to be small. Waste generated at a CERCLA site that is shipped off-site for disposal must be disposed of at a facility operating in compliance with applicable federal or state requirements. CERCLA section 121(d)(3); 40 CFR 300.440. As such, only hazardous waste listed or identified under RCRA section 3001 is required to be managed at RCRA Subtitle C facilities. Additionally, hazardous waste accumulation timeframes apply to generators of hazardous waste only and not to hazardous constituents. Therefore, waste from a CERCLA site that is not categorized as a RCRA "hazardous waste" (which may include waste containing PFOA and PFOS) is not required to be disposed of at a RCRA Subtitle C facility. However, some waste containing PFOA and PFOS may be required to be disposed of at a RCRA Subtitle C facility because it is commingled with RCRA hazardous wastes.

Designation does not change how that waste must be handled. As noted in the RCRA hazardous waste manifests available via RCRAInfo.epa.gov, PFOA- and PFOS-containing wastes are already being sent to RCRA hazardous waste facilities and the designation is only expected to incrementally increase wastes from CERCLA actions.

CERCLA also allows for remedies that dispose or treat waste on site. In those circumstances, off-site disposal capacity is not at issue. PFAS-containing materials may remain on-site. Such materials are typically contained within a specially constructed containment cell to prevent the mobilization and transport of hazardous substances, pollutants or contaminants to uncontaminated soil, water, or air. EPA's PFAS Destruction and Disposal Guidance referred to in RTC 4.E 1-5 provides information for this type of disposal. The disposition of the material in question will be determined by the site-specific remedy decision document. A remedy could also include a combination of on-site containment/disposal and off-site disposal. In those circumstances, only a portion of the waste would be transported off-site, consistent with the Off-Site Rule.

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. Cost considerations (such as those associated with sampling, treatment, or disposal) are evaluated on a site-specific basis.

EPA rejects the assertion that it has not evaluated if sufficient capacity exists for disposal and storage of PFOA and PFOS contaminated materials. EPA also acknowledges that CERCLA section 104(c)(9) does not allow the Agency to initiate a remedial action, unless the state first enters into a state 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. Today's action, however, does not impose any capacity concerns that require further action under section 104(c)(9). 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.

EPA disagrees with commenters assertions that the volume of hazardous wastes will increase dramatically by the PFOA and PFOS designation, and that EPA cannot guarantee it can satisfy CERCLA's mandatory 20-year period of sufficient capacity for hazardous wastes. Furthermore, the commenters provide no data or analysis demonstrating that there is insufficient capacity for PFOA and PFOS waste nor do commenters provide information to support their assertions that designation will create a disposal capacity problem. Also, as PFOA and PFOS production and use have largely been phased out, disposal of products and wastes not associated with environmental cleanups is decreasing and thus these PFOA and PFOS waste loadings to waste facilities are also anticipated to be decreasing.

EPA disagrees that the Agency should not designate because the commenter believes there are insufficient methods to treat, destroy, and dispose of PFOA and PFOA. There are currently methods available to address PFOA and PFOS contamination, and the Agency and other parties continue to work to improve those methods. EPA's PFAS Destruction and Disposal guidance describes commercially available methods. EPA does not preclude the use of emerging technologies, which may also be appropriate, depending on the materials.

Providing grant funding for such technologies is outside the scope of this response. However, see response RTC 4E1-5 for information on pilot-scale deployments of treatment technologies. In addition, in February 2023, EPA announced the availability \$2 billion in Bipartisan Infrastructure Law funding to address emerging contaminants, including PFAS, in drinking water. https://www.epa.gov/infrastructure.

Designation is not expected to lead to many immediate response actions given the time it takes to evaluate releases, particularly legacy releases. Immediate/near term response actions are generally likely to be limited to those posing an imminent and substantial endangerment. As experience evaluating PFOA and PFOS legacy releases and the hazards they pose increases, methods to treat and destroy PFOA and PFOS are expected to improve. EPA believes that industry/the regulated community will also have an incentive to engage in these efforts and as experience has shown, may be able to achieve necessary results for less than EPA estimates.

EPA disagrees with commenters assertions that the Final Rule would preclude certain disposal and destruction methods. The designation of PFOA and PFOS as hazardous substances does not include or preclude any specific treatment or disposal methods for PFOA or PFOS. Commenters provided no information to support their statement that designation would preclude the use of

specific treatment and disposal techniques such as landfilling, underground injection control (UIC), and incineration. EPA's PFAS Destruction and Disposal Guidance describes the state of the science for these technologies and does not preclude the use of others. The comment requesting EPA consider a national ban on incineration or provide guidance to alternatives is outside the scope of this rule. These are addressed in EPA's Interim Guidance on the Destruction and Disposal of PFAS. In July 2023, DOD released its updated implementing guidance, lifting their PFAS incineration ban. For additional discussion regarding the concern for guidance on disposal and treatment of certain PFAS, please refer to the Preamble to the Rule, Section 4H; RTC Section 4.E 1-5 on EPA's Interim Guidance on the Destruction and Disposal of PFAS.

Regarding the concern expressed about liability from research projects that produce PFAS-containing waste, EPA has developed effective enforcement options that have given EPA flexibility to offer liability protections, such as de minimus or de micromis parties (parties who, based on the total amount of waste at a site, are responsible for a very small percentage of water or costs).

Commenters do not provide additional information explaining why or how designation will lead to alternative means of disposal that are less protective, decreased composting services, or transporting long distances. However, comments regarding waste disposal, transportation or composting services are outside the scope of the rulemaking and require no response. In addition, these potential issues may be occurring in the absence of the rule, given existing PFOA and PFOS contamination.

See Preamble to the Final Rule Section VI.A.1 and VII.I for information regarding CERCLA liability and enforcement. See also the Preamble to the rule VII.H. on managing PFOA and PFOS contaminated waste.

4.F. Potential Liability and Enforcement

4.F.1 The proposed action is beneficial because it will assign liability to polluters and shift cleanup costs away from communities.

Numerous commenters expressed that the designation would ultimately aid in holding polluters accountable and potentially accelerating the cleanup process; while contaminated sites have seen incremental cleanup progress, the designation would wield important Superfund authority and tools for cleaning up PFOA and PFOS contamination. Several commenters also discussed the benefit of the designation in that instead of taxpayers and ratepayers shouldering the financial burden of PFAS contamination, the costs would be shifted to the responsible parties. [0414-Attorneys General, 0374-MPCA, 0567-WE ACT, 0398-PA DEP; 0503-NPCC; 0494 – S.O.H2O, 0301 – GLPAN, 0264 – Endocrine Society, 0467 – NCHR, 0365 – EPN, 0319 – BBNA; 0273 – LLSF Site CAG; 0339-ASDWA; 0426/CA DTSC; 0501/Vermont PFAS/Military Poisons Coalition; 0519/WV Rivers; 0316-MeWEA]

Commenters stated the proposed rule would enable CERCLA's "polluter-pays" framework to shift the burden of investigating, responding to, and remediating PFOA/PFOS contamination—currently borne by governments and their taxpayers—to the parties responsible for the contamination. Accordingly, the rule would provide governments with powerful tools to clean up PFOA/PFOS contaminated sites by increasing transparency and accountability around PFOA/PFOS releases and expanding government's ability to respond to PFOA/PFOS contamination promptly and efficiently under federal and state law. It could also potentially

result in voluntary reductions in the use of the chemicals to avoid costly releases. This will provide EPA and delegated agencies with expanded CERCLA authority to respond promptly to a release or threatened release of PFOA/PFOS without the need for a determination that the release or threatened release poses "an imminent and substantial danger to the public health or welfare," and will allow EPA to compel parties to abate releases or threatened releases of PFOA/PFOS that pose imminent and substantial danger to human health or the environment. The proposed action allows viable paths for recovering the cost of cleaning up PFOA/PFOS contamination.

Several commenters support the EPA's Proposal ensuring that the costs of cleanup are borne by the responsible parties and not the public. One commenter stated that PFAS producers, not the public, should bear the cost of cleaning up contaminated sites. Another commenter expressed appreciation of the EPA's work to address PFAS across all the Agency's regulatory programs through the PFAS Strategic Roadmap. The commenter asserted that the Agency's approaches to "get upstream of the problem" and "hold polluters accountable" is critical for the long-term protection of both surface and ground water sources of drinking water. The commenter supports the general intent of this designation, as such a designation opens pathways to hold polluters accountable for the release of these chemicals. PFAS contamination has been found from a wide variety of manufacturers and users. The commenter states that the EPA must ensure that the costs of cleanup are borne by the responsible manufacturers and users of PFOA and PFOS, not the public through mechanisms such as increased water rates to cover the costs of PFAS treatment in drinking water. The commenter noted that due to several cross-media consequences, they are currently taking a neutral position on this designation.

Another commenter commends the EPA for proposing these per- and poly-fluoroalkyl substances (PFAS) compounds as hazardous substances. The commenter states that such a designation would further reinforce authority to require PRPs to address PFOA or PFOS releases, and to require PRPs, rather than taxpayers, pay for the cleanups. Another commenter stated that designation of PFOA and PFAS as hazardous substances will allow EPA to use its CERCLA enforcement authorities to recover PFOA and PFOS cleanup costs from responsible parties, transferring the cost-burden of response activities from the taxpayers to the polluters. The commenter pointed out that these actions will help protect vulnerable communities from PFOA and PFOS exposure and ensure that the parties responsible for the contamination bear the cost, actions long overdue. [0414-Attorneys General, 0374-MPCA, 0567-WE ACT, 0398-PA DEP; 0503-NPCC; 0494 – S.O.H2O, 0301 – GLPAN, 0264 – Endocrine Society, 0467 – NCHR, 0365 – EPN, 0319 – BBNA; 0273 – LLSF Site CAG; 0339-ASDWA; 0426/CA DTSC; 0501/Vermont PFAS/Military Poisons Coalition; 0519/WV Rivers; 0316-MeWEA]

A commenter specifically called out the benefit to the Lowry Landfill Superfund Site and three-mile-long off-site plume of toxic chemicals that has yet to be tested for PFAS. $[0273 - LLSF\ Site\ CAG]$

The designation will benefit the Marinette and Peshtigo area, which is affected by the releases of firefighting foams from Johnson Controls/Tyco Fire Products' (JC/Tyco) manufacturing and testing operations. A commenter stated that the drinking water of the areas is contaminated with PFAS, which was confirmed by the Wisconsin Department of Natural Resource; 330 out of 415 drinking water wells tested had detectable levels of PFOA and/or PFOS with the highest concentration of 2,100 parts per trillion. [0494 - S.O.H2O]

A commenter expressed strong support for the designation, especially given its potential impact on Michigan and other Great Lake states. The Department of Great Lakes, Energy and the Environment (EGLE) identified 228 contaminated PFAS sites in Michigan alone with as many as 11,000 sites estimated. Among those sites, commenter specifically noted the sites neighboring communities and the responsibility of the Department of Defense. For instance, commenter stated that in Oscoda, Michigan, PFAS were released from aqueous film forming foam (AFFF) at the former Wurtsmith Air Force Base. These substances, including PFOA and PFOS, contaminated the groundwater and surface water for decades. However, the Department of Defense has yet to clean up the contaminated site. Additionally, commenter stated that Wolverine Worldwide dumped PFAS chemicals at the House Street Disposal Area in Belmont and their former tannery site in Rockford for years, contaminating groundwater with very high PFAS levels in both communities. Finally, the commenter discussed how it was estimated that Michigan taxpayers and ratepayers have paid over \$202 million to identify, mitigate, and remediate PFAS contamination. Particular concern was expressed for communities that face disproportionate exposure to PFAS and low-income communities. [0301 – GLPAN]

A commenter stated that PFOA and PFOS contamination have been significant environmental and public health concerns for communities across Alaska. The Alaska Department of Environmental Conservation (ADEC) reported that several communities in the Bristol Bay region experienced exposure to PFOA, PFOS, and other PFAS from contaminated drinking water with the likely source being aqueous film forming foams (AFFFs) during firefighting equipment testing. PFAS were detected in at least 58 wells in the Bristol Bay region to date including wells that were used as public drinking water sources for years. [0319 – BBNA]

A commenter discussed the PFAS contamination faced by the Will County communities. Will County communities with extremely high concentrations of PFOA and PFOS in their drinking water have consistently been in the top quartile (and in many cases the top 5th percentile) of the Environmental Justice Index (EJI) launched by the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry. The commenter expressed that the communities should not have to shoulder the capital and maintenance costs to ensure safe drinking water; therefore, the designation would rightfully shift those costs to the industries using PFOA and PFOS. Additionally, commenter noted how the Government Accounting Office urged EPA to conduct a nationwide analysis of data regarding the presence of PFAS in drinking water in environmental justice communities, and the National Environmental Justice Advisory Council also urged EPA to revise the PFAS Roadmap to focus on environmental justice issues, including suggesting emergency response plans that offer immediate relief through bottled water or air filters in underserved communities. The commenter underscored how the designation will be the first step in addressing Will County communities and other environmental justice communities disproportionately overburdened by cumulative chemical and non-chemical stressors for decades. [0428 – CARE]

Response

EPA agrees that designation supports CERCLA's primary objectives to clean up contaminated sites and ensure the "Polluter Pays." EPA's ability to require PRPs to pay for PFOA and PFOS response costs means that more money will be available to address a multitude of priorities, particularly at NPL sites where there is no viable PRP. It also allows EPA to address more releases than it otherwise could absent designation. For more information, see Preamble to the

Final Rule Section VI (The totality of the circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted.).

EPA also intends to develop an enforcement discretion policy consistent with CERCLA's "Polluter Pays" principle. 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" The NECI also clarifies that "OECA 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 OECA exercises CERCLA enforcement discretion in other areas."

EPA has a proven track record of developing and applying enforcement discretion policies that are effective, well-received, and upheld by courts. In several instances, Congress has subsequently codified EPA's enforcement discretion policies as statutory exemptions or protections, once the effectiveness of the policies was established through practice. These statutory protections and enforcement discretion policies historically have given EPA the needed flexibility to offer liability protections when circumstances warrant. See Preamble to the Final Rule Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way.).

EPA agrees that designation will support EPA's ability to address existing PFOA and PFOS releases at highly contaminated sites, such as those identified by commenters. CERCLA ensures that the most significant releases that pose the most risks to human health and the environment are prioritized. EPA also believes that this action is likely to reduce existing disproportionate and adverse effects on people of color, low-income populations, and/or indigenous peoples. See Preamble to the Final Rule Section II.E (What are CERCLA's primary objectives, and how does it operate to protect human health and the environment?); VI.A.2.d (Environmental Justice (EJ) Considerations for Designation) and Section IX.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).

4.F.2 The EPA has significant enforcement discretion and multiple other tools available to ensure that polluters are held accountable, not innocent parties.

Some commenters stated that enforcement discretion under CERCLA section 122 (42 U.S.C. § 9622) would be sufficient to address concerns about liability for water utilities and to ensure equitable cleanups and settlements that assign primary responsibility to parties that actively contributed to the contamination or otherwise profited from the conditions resulting in contamination. The EPA has a successful record of using enforcement discretion to address similar concerns associated with hazardous substances in the past, and the commenters supported the use of enforcement discretion when appropriate to avoid unfair impacts of the designation on these facilities. In addition to enforcement discretion, the EPA can also develop and distribute policy documents and guidance to articulate how it plans to use its discretion and provide predictability to potentially affected parties. The EPA can also use settlements to equitably distribute liability. Other aspects of enforcement discretion available to the EPA include "de minimis" and "ability to pay" settlements. A settlement with the EPA creates a contribution

shield protecting that party from additional CERCLA liability and removing them from the case. Other PRPs at that site are then barred from seeking financial contribution from those parties that have already settled with the EPA. The EPA also has discretion to allow delayed payments, payment schedules, and in-kind contributions from municipal parties in settlement agreements. In addition, CERCLA has liability limits for certain parties, like innocent landowners, contiguous property owners, and bona fide prospective purchasers. These provisions are designed to protect parties who unknowingly purchased contaminated property, are victims of contamination from a neighboring property, or who plan to purchase a contaminated property and commit to allowing any ongoing removal or remedial actions. CERCLA also includes provisions specifically directed at limiting municipal liability. Municipalities are not liable for costs or damages in response to costs related to emergencies created by the release of hazardous substances, [42 U.S.C. § 9607(d)(2)] and EPA can reimburse municipalities for temporary emergency measures. [42 U.S.C. § 9623] Municipalities and other government entities like utilities can also be exempted from liability if they are conducting a cleanup in compliance with a state cleanup program. [42 U.S.C. § 9628(b)] Finally, the EPA can help publicly owned treatment works and other dischargers limit liability by developing water quality criteria and effluent limitation guidelines and incorporating discharge limits for PFOA and PFOS into National Pollutant Discharge Elimination System, or NPDES, permits. Section 107(j) of CERCLA limits liability from "federally permitted releases," including releases subject to NPDES permits. [42 U.S.C. § 9607(j)] Establishing these effluent and pretreatment requirements would also reduce the amount of PFAS going to utilities, reducing their treatment burden. The EPA should work quickly to develop these limits and provide guidance to permit writers, as promised in the National PFAS Strategic Roadmap. [0365-EPN; 0398-PA DEP; 0414-Attorneys General; 0552-EWG; 0547-DACF; 0805-US Composting Council; 0552-EWG]

A commenter stated that EPA should promptly finalize the proposed designation. Because the proposed action could result in indirect costs to states, the commenter recommended expanding federal funding to help state and local governments and other public service providers (such as publicly owned treatment works, public drinking water providers, and municipal landfills) pay for site investigation, emergency response and cleanup, and necessary drinking water and wastewater infrastructure improvements. The commenter also urged the EPA to exercise appropriate enforcement discretion under CERCLA § 122, 42 U.S.C. § 9622, to ensure equitable cleanups and settlements that assign primary responsibility to parties that actively contributed to the contamination or otherwise profited from the conditions resulting in contamination. [0414-Attorney Generals of the States of NY, and 17 others]

Response

EPA agrees with commenters that existing liability 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 to equitably resolve who should pay and how much. As more fully described in the Preamble to Final Rule Section VI, EPA concluded that designation will not disrupt CERCLA's liability framework. Although EPA understands that designation will result in new litigation regarding PFOA and PFOS releases, forty years of CERCLA experience suggests that designation should not result in unusual CERCLA liability or litigation outcomes as a result of this designation and, therefore, the potential for litigation should not be a barrier to designation. Designation does not automatically confer liability nor

does it alter CERCLA's statutory or regulatory framework for liability. Although no additional action is necessary to ensure that statutory limitations and existing enforcement policies continue to operate as they have for decades, EPA intends to develop a policy that explains EPA's priorities for enforcement in the context of PFOA and PFOS releases. See Preamble to the Final Rule Section II.E.7 (What enforcement discretion is available when exercising CERCLA authority), Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way); Section VII.J (Enforcement); and FY 2024-2027 National Enforcement and Compliance Initiatives.

Regarding the comment expanding federal funding to help state and local governments and other local service providers, this comment is outside the scope of the designation. EPA's October 2021 Strategic Roadmap included provisions to restrict PFAS industrial wastewater discharges and leveraging NPDES permitting to reduce PFAS discharges at the source. In February 2023, EPA announced the availability \$2 billion in Bipartisan Infrastructure Law funding to address emerging contaminants, including PFAS, in drinking water.

Regarding releases subject to NPDES permits, see EPA's December 5, 2022, Memorandum "Addressing PFAS Discharges in NPDES Permits and Through the Pretreatment Program and Monitoring Programs," EPA expects the NPDES actions described in this memo to significantly reduce PFAS in wastewater treatment plant influent, which will reduce PFAS in wastewater treatment sludge.

4.F.3 Designation will shift cleanup costs from responsible parties to communities and public utility ratepayers and impose considerable liability on entities in a variety of sectors.

Many commenters expressed concern about liability and resulting cleanup costs as a result of the designation. The commenters noted that the goals of CERCLA are to provide for cleanup if a hazardous substance is released into the environment and to hold responsible parties liable for the costs of those cleanups. CERCLA's liability scheme assigns strict, retroactive, joint and several liability "without regard to fault, without regard to the fact that the disposal activity now giving rise to such liability occurred decades ago, and without regard to the fact that such past practices were not only lawful but also often directed, permitted, or at least known by state officials" [Gray, Peter L., The Superfund Manual: A Practitioner's Guide to CERCLA Litigation (2019), pg. xii]. Under the definitions of "disposal" and "release," local communities, including water utilities, waste management utilities, and various other sectors (airports, fire departments, state governments, farmers, other landowners) could be held responsible for PFAS cleanups, while chemical and product manufacturers escape any liability for cleanups under CERCLA. Ultimately, CERCLA's liability scheme and the ubiquitous nature of PFOA and PFOS will result in a significant number of parties becoming subject to potential legal liability, including local clean water utilities, which are funded by public ratepayers; cleanup costs will likely fall disproportionately on local communities served by clean water utilities rather than those producing and selling the products containing PFOA and PFOS. The EPA does not have clear authority to ensure that costs are only sourced from polluters and other potentially responsible parties. Given the joint and strict liability of CERCLA, shifting cleanup costs to polluters from taxpayers is most effectively achieved through the prevention of contamination with waste management rules.

Commenters from various sectors raised specific issues related to liability:

Water Utilities: The proposed designation would create potential liability for public utilities and cause years and millions of dollars of litigation and legal costs for publicly owned treatment works ("POTW"), water supply agencies and stormwater management agencies. CERCLA was designed to create liability for cleanup, and this liability and the inevitable contribution suits from manufacturers under Section 113, have the potential to impose massive costs public agencies, despite the fact that water and wastewater agencies did not produce or intentionally use the PFOS and PFOA, but are passive receivers. Moreover, due to the ubiquity of PFAS in consumer products, much of this inflow may come not from industry but from residential consumers of PFAS-containing products. POTWs cannot impose pretreatment standards on these domestic or commercial sources. Further, MS4 operators likewise cannot control the amount or frequency of pollutants that enter their systems. Thus, utilities may be placed in a position of not being able to limit PFOA, PFOS, and other PFAS substances from entering the collection systems through private use of commercial products, while at the same time being the only major entity ultimately liable for cleanups necessitated by those substances.

Water/Waste Management Utilities: Local governments that own (or own and operate) solid waste management facilities have only narrow, limited ability to control the composition of the wastes that commercial and residential sources deliver to their WTE facilities and landfills resulting in the inability to prevent delivery of wastes in which PFOA-PFOS (or any of the other chemicals within the broader PFAS category) may be present.

A number of commenters stated that solid waste landfills would be impacted by this proposed rule as well. Since these facilities do not handle waste designated as hazardous, the designation of PFOA/PFOS as hazardous materials would introduce new liability for them as PFAS compounds have undoubtedly made their way into landfills.

Small amounts of PFAS are expected in the landfill and associated leachate that is sent to wastewater treatment facilities. Already the uncertainty of future legal risks is creating disruptions with rising costs and wastewater treatment plants rejecting leachate from landfills over contamination fears and landfills refusing to accept waste from water facilities for the same concerns. If PFAS compounds are made CERCLA hazardous substances, the liability associated with any environmental damage they cause could find its way back to landfill owners and operators. Other private companies that handle waste material (such as medical sterilizers) would also be impacted if the material they handle suddenly becomes categorized as hazardous. Congress should provide landfills and other passive receivers with a narrow exemption from liability if certain PFAS are designated as hazardous substances under CERCLA targeting only the discharge of leachate performed in compliance with Federal or State law and all applicable permits. Doing so would keep liability on producers who have profited from PFAS and not taxpayers. [0550-DSWA, 0361-Haz Waste Program, 0466-TxSWANA, 0480-NWRA-SWANA, 0557-SWACO, 0512-Stericycle, 0565-USWAG, 0313-APWA]

A commenter asserts that CERCLA was created to ensure polluters were responsible and paid for the cleanup of their contamination of the environment and their risk to public health; however, in the context of water and wastewater utilities, EPA's actions are potentially shifting that burden to water and wastewater ratepayers. The commenter further asserts that EPA's action will likely impose costs on individuals and communities that are least able to bear an increased cost for basic services and will therefore inhibit the Agency's stated goal of advancing environmental

justice. The commenter notes that EPA's proposed rule states that it wants to ensure taxpayers do not carry the brunt of the costs for polluters. Specifically, the proposed rule states "EPA and delegated agencies could recover PFOA and PFOS cleanup costs from potentially responsible parties, to facilitate having polluters and other potentially responsible parties, rather than taxpayers, pay for these cleanups" (Proposed Rule at 54418). EPA also states that this proposed rule would "allow costs to be shifted from the taxpayer to parties responsible for pollution under CERCLA" (Propose Rule at 54422). The commenter also notes that while the EPA's understanding would be the case if manufacturing and industry were the only parties threatened with being designated as PRPs, it fails to consider the real possibility of local government being designated as a PRP. The budgets of municipalities are based on the makeup of their taxpayerbase including instances where municipalities provide water and wastewater services to their constituencies. Additionally, public water districts and wastewater districts across the country are created by state law as a specialized form of local government. The budgets for these agencies are dependent on their ratepayer base – the same people EPA identifies as taxpayers. Therefore, the possible designation of local governments as PRPs will have the very impact that the EPA seeks to avoid under CERCLA. The commenter states that by not addressing the full regulatory scheme and having no mechanisms in place to provide protections for the public entities, EPA is not only directly imposing a financial liability on ratepayers across the country, but it is also providing polluters a potential pass on paying their full share for cleanups. The commenter further asserts that by not implementing a full regulatory scheme and ensuring that water agencies, wastewater agencies, and municipalities are protected from liability for simply providing essential public services, EPA is contradicting its goal of protecting taxpayers. EPA's action will invite litigation attempting to shift those costs to ratepayers. The resulting costs will inhibit efforts to advance environmental justice.

Another commenter states, contrary to EPA's intent to shift costs "from the taxpayer to parties responsible for pollution under CERCLA," (87 Fed. Reg. at 54422) the financial impact of litigation and paying for cleaning up PFOA and PFOS would actually be imposed on water utilities and their ratepayers. The commenter references the Chamber Study and notes that private sector cleanup costs at Superfund sites alone resulting from the proposed hazardous substance designation of PFOA and PFOS are estimated to cost between \$700 million and \$800 million in annualized costs (\$11.1 billion and \$22 billion present value costs) (Chamber Study at p. 3). The commenter states that the report further notes that municipalities responsible for community water systems, landfills, and publicly owned treatment works would incur significant additional costs for cleanup. The manufacturers and distributors of PFOA and PFOS should assume these costs (not water and wastewater utilities, and the communities they serve), and state/federal funding should be made available to water and wastewater utilities to mitigate PFAS contamination. The commenter asserts that currently there is insufficient federal funding available for water and wastewater utilities to pay for the cost of cleanup.

One commenter asks, does the proposed CERCLA hazardous substance designation threaten to shift the burden of significant cleanup costs and liability onto citizens and ratepayers instead of the polluters? If so, can and should this be avoided by exempting the water, wastewater, and solid waste sectors from any CERCLA designation and instead relying on the Clean Water Act (CWA) and Safe Drinking Water Act (SDWA) which are designed to address the unique demands of our sectors?

The commenter asserts that the EPA's planned listing of PFOS and PFOA as "hazardous substances" under CERCLA could have widespread and severe unintended consequences for local government providers of landfills, drinking water, wastewater, stormwater, and water reuse services. The commenter notes, given that PFAS compounds enter the waste stream through various means and are not removed through the normal wastewater treatment process, PFAS can persist in biosolids, reuse water, and treated effluent. Even with trace amounts of PFAS, under CERCLA, a party may be held responsible for contamination. Therefore, water utilities could face unwarranted liability, legal defense costs, and significant expenses to respond to the proposed PFAS regulation. The commenter subsequently asks the following: What action is needed to protect passive receivers of PFAS who provide necessary public services to the community? Will EPA's enforcement discretion or settlement authority really protect local governments, who have played no role in producing, using, or profiting from PFAS and aren't the true cause of PFAS contamination? [0347-Brevard Co; 0372-NEW Water; 0309/SESD]

Another commenter offers an illuminating example of the potential impacts CERCLA actions can have on clean water utilities and points to the Passaic River (NJ) CERCLA cleanup. That case, which has been ongoing for years and will likely result in billions of dollars in cleanup costs, involves dioxins – chemicals that, like PFAS, public clean water utilities do not use or profit from, but are downstream passive receivers which has brought multiple downstream public wastewater treatment plants into a CERCLA lawsuit as PRPs, seeking to make them pay for part of the cleanup. Despite EPA's attempts to limit their exposure, the utilities have already had to spend hundreds of thousands of public dollars each year on litigation costs alone and may well still have to foot part of the CERCLA cleanup bill. In fact, the case led to the state legislature writing a sewage exclusion into the New Jersey Spill Act to stop utilities from being exposed to this kind of liability under state law in the future. The commenter asserts that the U.S. Congress should take note.

The commenter further points out that even where courts do not hold utilities responsible for cleanup costs, the transactional costs alone of having to engage in such complex technical and legal proceedings can be staggering. Just proving that they caused de minimis contributions can cost local utilities hundreds of thousands of dollars, as was the case in the Fox River (WI) PCB cleanup, in which local utilities were implicated despite their lack of culpability for the pollution.

The commenter states that if the PFOA and PFOS designations are finalized as proposed, almost every publicly owned treatment works and municipal stormwater system in the country could have some level of exposure to such cost recovery or contribution actions by other PRPs because, as discussed below, PFAS substances are everywhere. The money that public utilities will be forced to spend simply defending themselves in such litigation could – and should – be used for other projects benefiting the communities they serve. In the context of PFAS substances in particular, CERCLA's failure to focus the imposition of costs on culpable parties could cause significant harm to local communities. As an example, the commenter references their comprehensive facilities plan for its collection and treatment systems that has identified \$470 million (in 2021 dollars) of needed capital improvements over the next 20 years. The commenter notes working in the watershed with agricultural producers and landowners to reduce phosphorus and suspended solids from being discharged to area waterways at a cost of \$40 million (in 2021 dollars) over the next 20 years. The commenter asserts that utilities do not have the financial capacity to incur a potentially extremely expensive PFOA and PFOS remediation program while making these needed improvements.

Another commenter pointed out their disagreement with the extent of cost analysis conducted for this rulemaking and the lack of considering the unintended consequences this listing will have on the public rate payers. The commenter states that they have already been impacted and anticipate residuals disposal costs will be increasing appreciably as a result of PFAS concerns. The commenter noted that if the residuals disposal prices more than double over the next five years (17% increase a year), that will have an annual impact of \$4,200,000 to the commenter's 190,000 ratepayers served, or almost \$100 per year per family. Now multiply that by the population of the United States and the number is in the billions each year.

Many commenters stated that water treatment systems will have increased liability for PFAS due to the proposed designation. Water systems with PFAS in their influent are likely to produce residuals with PFAS that may be subject to the CERCLA liability. Public clean water agencies have never produced or profited from PFAS chemicals. Under the Proposal, each of these waste streams is at risk of being the target for future lawsuits and subsequent cleanup liability, regardless of the relative contribution of PFOA and PFOS to the site, or whether they abide by industry best practices for treatment and disposal. Not only would reporting obligations (e.g., in light of the default RQ) be widespread and difficult to implement, potentially responsible parties (PRPs) brought into CERCLA litigation by the EPA or citizen suits could target water systems for these waste streams regardless of the levels of PFOA and PFOS present. Even with enforcement discretion framed up in the proposal by the EPA, examples of water systems and municipalities historically being sued by PRPs has demonstrated that water systems may expend significant funds in litigation costs and that the EPA is incapable of shielding these systems. Thus, costs associated with PFAS liability would be borne by taxpayers and customers of municipal water systems, not the polluters. [0543-AWWA, 0344-APWA, 0537-AMWA, 0348-BGMU, 0347-Brevard Co., 0346-CASA, 0350-City of Henderson, 0355-LASAN, 0354-City of Roseville, 0352-Clark County, 0447-CRROPS, 0531-EBMUD, 0307-EVMWD, 0367-ECDSM, 0360-GLWA, 0453-IAWA, 0455-IEUA, 0464-JEA, 0465-JCW, 0381-DNRP, 0463-Little Hocking, 0471-Loudoun, 0318-MMSD, 0395-MWRA, 0527-Metro, 0375-MSD, 0395-MWEA, 0473-MESERB, 0483-Monterey, 0470-MEG Wastewater, 0538-NACWA, 0528-NSDC, 0480-NWRA-SWANA, 0372-NEW Water, 0496-NEORSD, 0394-OSEE, ODEO, 0491-OCWD, 0386-ReWa, 0492-SCWQA, 0804-SPR, 0562-NBC, 0389-Town of Ledgeview, 0524-Worcester, 0506-Conference of Mayors, 0401-Village of Ashwaubenon, 0505-VAMWA, 0568-WWEMA, 0516-WRD, 0561-WUWC, 0490-PMAA, 0436-Manhattan, KS, 0447-CRROPS, 0495-PFAS Regulatory Coalition]

A few commenters stated when drinking water or water reuse agencies remove PFAS from source water via filtration media, they are responsible for the disposal of these potentially PFAS-laden filter media. The media will typically be recycled or disposed of in accordance with applicable law. Should that disposal location ever become a "facility" where there is a release or threatened release of hazardous substances, the water agency could be held liable under CERCLA and/or analogous state law as a PRP due to its lawful disposal of this necessary byproduct of a vital public health service. This outcome would force local ratepayers to cover the cleanup costs after they already paid to remove the PFAS from their source water. Furthermore, most states have their own state hazardous substance cleanup laws which are modeled after CERCLA. In California, a "hazardous substance" under the state's Superfund law is defined to include any CERCLA hazardous substance. [See, e.g., Cal. Health & Safety Code § 25316(b)] State hazardous substance cleanup laws also often incorporate many other CERCLA standards and definitions, resulting in similar standards for liability. [See, e.g., Cal. Health & Safety Code

§§ 25310, 25323, 25363(c)] Thus, designating PFOA and PFOS as CERCLA hazardous substances will result in: (1) many states regulating PFOA and PFOS as state hazardous substances; and (2) imposing strict, joint and several, and retroactive liability on drinking water and wastewater agencies who become PRPs under state law simply because PFOA and PFOS end up in their water supply from third party sources outside of their control. [0413-ACQA, 0385-NYSAWWA/NYWEA/NYRWA]

One commenter notes that EPA has not acknowledged that designating PFOA and PFOS as hazardous substances under CERCLA will have any direct impacts other than basic reporting requirements. The commenter asserts that the proposed designation would create potential liability for public utilities and cause years and millions of dollars of litigation and legal costs for publicly owned treatment works ("POTW"), water supply agencies and stormwater management agencies. The commenter also asserts that CERCLA was designed to create liability for cleanup, an approach that is well described in the Congressional record and has played out over the decades since the law was enacted. The commenter also notes that this liability, and the inevitable contribution suits from manufacturers under Section 113, have the potential to impose massive costs public agencies, despite the fact that water and wastewater agencies did not produce or intentionally use the PFOS and PFOA. The commenter further notes that cleanup liability is the heart of the CERCLA statute. Additionally, the commenter asserts that whether EPA wants to label these statutory impacts and costs as direct or indirect, EPA has not fully considered or acknowledged them for public agencies or the ratepayers and taxpayers they serve.

A few commenters asked EPA to provide guidance that spells out the potential obligations that municipal water utilities will face to address PFOA and PFOS, and how responsible parties, or the federal government, will bear the costs of cleanup. In particular, EPA should clarify the scope of responsible parties. Given the ubiquitous nature of PFAS in the environment, including in solid waste and wastewater, the number and nature of responsible parties could be significant depending on implementation of the CERCLA designation. Wastewater treatment plants may receive wastewater that contains PFOA, PFOS, or their precursors from various sources, and those sources are untraceable. Depending on the final rule provisions and EPA implementation plan, the designation of PFAS as a CERCLA hazardous substance may shift the clean-up and liability costs to municipalities and away from the chemical and manufacturing companies who profited by placing PFAS chemicals into commerce. EPA should use this rulemaking to hold polluters accountable for the release of these chemicals, and not the public through mechanisms such as increased water rates to cover the costs of PFAS treatment for drinking water. [0339-ASDWA; 0374-MPCA]

A few commenters were concerned with liability risks posed to public safety agencies and local governments and asked EPA to consider this concern in the further development of PFAS regulation. Local governments that own (or own and operate) solid waste management facilities have only narrow, limited ability to control the composition of the wastes that commercial and residential sources deliver to their WTE facilities and landfills resulting in the inability to prevent delivery of wastes in which PFOA-PFOS (or any of the other chemicals within the broader PFAS category) may be present. As a result, facilities could be forced to consider restricting access for waste generators that may be determined are sources of PFAS compounds. [0528-National Special Districts Coalition (NSDC), 0399-Local Government Coalition for Renewable Energy, 0550-Delaware Solid Waste Authority (DSWA)]

Farmers and Other Landowners: Agricultural and other private lands may have PFAS contamination through no fault of the landowner. The use of AFFF on adjacent lands poses a threat to landowners. Many wildfires occurring in the west are in the higher elevations and on federal lands which means that PFAS can migrate from federal lands onto the private lands or be present in the water that livestock drink. Many agricultural areas are adjacent to industrial facilities that also use PFAS that could migrate off-site. Agriculture should not be faced with CERCLA enforcement when they were a victim of PFAS contamination from outside sources.

[0538-NACWA; 0523-WSPA; 0543-AWWA 0432-Columbus; 0490-PMAA; 0493-POWER! fully supported by 0521 (WMWD); 04240ACI-NA; 0482-MWDSC; 0347-Brevard Co; 0372-NEW Water; 0309/SESD; 0543-AWWA, 0344-APWA, 0537-AMWA, 0348-BGMU, 0347-Brevard Co., 0346-CASA, 0350-City of Henderson, 0355-LASAN, 0354-City of Roseville, 0352-Clark County, 0447-CRROPS, 0531-EBMUD, 0307-EVMWD, 0367-ECDSM, 0360-GLWA, 0453-IAWA, 0455-IEUA, 0464-JEA, 0465-JCW, 0381-DNRP, 0463-Little Hocking, 0471-Loudoun, 0318-MMSD, 0395-MWRA, 0527-Metro, 0375-MSD, 0395-MWEA, 0473-MESERB, 0483-Monterey, 0470-MEG Wastewater, 0538-NACWA, 0528-NSDC, 0480-NWRA-SWANA, 0372-NEW Water, 0496-NEORSD, 0394-OSEE, ODEQ, 0491-OCWD, 0386-ReWa, 0492-SCWOA, 0804-SPR. 0562-NBC, 0389-Town of Ledgeview, 0524-Worcester, 0506-Conference of Mayors, 0401-Village of Ashwaubenon, 0505-VAMWA, 0568-WWEMA, 0516-WRD, 0561-WÚWC, 0490-PMAA, 0436-Manhattan, KS, 0447-CRROPS, 0495-PFAS Regulatory Coalition; 0413-ACQA, 0385-NYSAWWA/NYWEA/NYRWA: 0550-DSWA, 0361-Haz Waste Program, 0466-TxSWANA, 0480-NWRA-SWANA, 0557-SWACO, 0512-Stericycle, 0565-USWAG, 0313-APWA; 0493- Protecting Our Water, Environment, and Ratepayers Coalition (POWER!); fully supported by 0521 (WMWD); 0339-ASDWA; 0374-MPCA; 0528-National Special Districts Coalition (NSDC), 0399-Local Government Coalition for Renewable Energy, 0550-Delaware Solid Waste Authority (DSWA); 0369/HCAA; 0555-AAAE, 0417-Aircraft Rescue & Fire Fighting Working Group Inc., 0424-ACI-NA, 0553-NATA; 0341-AFBF, 0402-WyFB, FL Farm Bureau, 0358-GFB, 0485-MI Farm Bureau, 0481-NM Farm Bureau, 0540-PA Farm Bureau, 0558-SDFBF; 0402-WyFB, 0444-DPNM, 0460-ILTA, 0559-RuttenKern; 0546-AZ Farm Bureau, 0549-CA Farm Bureau, 0445-CFB, 0474-MFBF, 0469-NCFB; 0426-CA DTSA, 0556-ISRI, 0460-ILTA, 0479-NACS, NATSO, SIGMA, 0566-University of Arizona, 0562-UTLX; 0322-Environmental Compliance Manager; 0355-LASAN]

Biosolids Applications

A few commenters were concerned with liability risks posed to public safety agencies and local governments and asked EPA to consider this concern in the further development of PFAS regulation. Local governments that own (or own and operate) solid waste management facilities have only narrow, limited ability to control the composition of the wastes that commercial and residential sources deliver to their WTE facilities and landfills resulting in the inability to prevent delivery of wastes in which PFOA-PFOS (or any of the other chemicals within the broader PFAS category) may be present. As a result, facilities could be forced to consider restricting access for waste generators that may be determined are sources of PFAS compounds. [0528-National Special Districts Coalition (NSDC), 0399-Local Government Coalition for Renewable Energy, 0550-Delaware Solid Waste Authority (DSWA)]

Landfills

A number of commenters stated that solid waste landfills would be impacted by this proposed rule as well. Since these facilities do not handle waste designated as hazardous, the designation of PFOA/PFOS as hazardous materials would introduce new liability for them as PFAS compounds have undoubtedly made their way into landfills. Small amounts of PFAS are expected in the landfill and associated leachate that is sent to wastewater treatment facilities. Already the uncertainty of future legal risks is creating disruptions with rising costs and wastewater treatment plants rejecting leachate from landfills over contamination fears and landfills refusing to accept waste from water facilities for the same concerns. If PFAS compounds are made CERCLA hazardous substances, the liability associated with any environmental damage they cause could find its way back to landfill owners and operators. Other private companies that handle waste material (such as medical sterilizers) would also be impacted if the material they handle suddenly becomes categorized as hazardous. Congress should provide landfills and other passive receivers with a narrow exemption from liability if certain PFAS are designated as hazardous substances under CERCLA targeting only the discharge of leachate performed in compliance with Federal or State law and all applicable permits. Doing so would keep liability on producers who have profited from PFAS and not taxpayers. [0550-DSWA, 0361-Haz Waste Program, 0466-TxSWANA, 0480-NWRA-SWANA, 0557-SWACO, 0512-Stericycle, 0565-USWAG, 0313-APWA]

General Comments

A commenter stated that the proposed CERCLA designation shifts the financial burden of environmental clean-up from private businesses to the public. In the proposed rule, EPA states that CERCLA was "designed to address contamination on a site-specific basis" with the purpose of transferring clean-up costs "from the public to polluters." The commenter asserts that the actual result of this CERCLA designation as currently written will be the opposite noted that residents will be paying for litigation and remediation for pollution that they did not cause. The hazardous substance designation (as currently written) would shift the financial and technical responsibility from the manufacturers that create and use PFAS in their processes to downstream utilities. Residents will also pay for the environmental costs and public health consequences of pollution caused by manufacturers. The commenter states that the burden will be borne by ratepayers, in direct contradiction of EPA's intention in issuing the rule. [0432-Columbus]

A few commenters state that the Proposal does not follow the "polluter pays" principle of CERCLA as it shifts the burden to public entities by potentially imposing liability and significant costs on to water, wastewater, solid waste and stormwater authorities, which costs will unfairly burden these entities and consequently be passed on to the ratepayer. [0490-PMAA; 0493-POWER; 0521 (WMWD); 04240ACI-NA; 0482-MWDSC]

A commenter states that in the Proposed Rule, EPA identified only three direct impacts: (1) Reporting and Notification Requirements for CERCLA Hazardous Substances; (2) Requirements Upon Transfer of Government Property; and (3) Requirements for DOT to List and Regulate CERCLA Hazardous Substances. These three consequences, while direct impacts, do not convey the full list of direct impacts of this proposed rule.

A commenter asserts that EPA has not considered the full range of implications that will flow from the proposed rule. The legislation establishes a multi-step process that would ultimately allow for cleanup of a polluted site. This includes designating an area a "hazardous site," or "Superfund site;" engaging in a site assessment and cleanup; and providing EPA, citizen groups,

and other potentially responsible parties ("PRPs") the opportunity to pursue cleanup costs and recover costs from additional PRPs. Thus, the designation of a hazardous substance is just the first step in the entire CERCLA Process. Once designated, the entire force of CERCLA is available to be pursued.

A commenter notes that the direct effect of the proposed rule will be to not only require reporting of a known release of the reporting requirement of a hazardous substance, but will also create the ability for Superfund sites to be designated solely on the basis of PFOA or PFOS contamination, and will open up PRPs to liability – even if they are a passive receiver – and can leave a passive receiver solely responsible for the cleanup and environmental mitigation. The direct impact will also require the development and installation of new or modified equipment and testing procedures.

A commenter respectfully requests that EPA review and consider all direct and foreseeable indirect impacts of the proposed designation to ensure unintended consequences are properly addressed before they occur.

Other commenters noted that plumes of PFOA/PFOS may be found in locations without identifiable sources, even in miniscule quantities or concentrations. Tackling these sites with no identifiable, viable responsible party, with potentially large areas of contamination will necessitate additional regulatory resources to adequately address these sites. It is possible that even retail stores that have sold legal PFAS-containing products for decades may be involved in litigation due to this designation. The environmental burden on disadvantaged communities and small businesses disproportionately impacted by contamination, must be accounted for in the strategies for prioritizing and addressing this contamination. The use of "Gore factors" by the courts to determine cleanup responsibility may leave certain parties with unfair costs associated with this proposed ruling designation. [0426-CA DTSA, 0556-ISRI, 0460-ILTA, 0479-NACS, NATSO, SIGMA, 0566-University of Arizona, 0562-UTLX]

Due to ubiquity and historical use, there are issues with determining sources and designating PRPs under CERCLA. A commenter noted the unprecedented ubiquity – PFAS substances are literally found everywhere. The commenter asks the following: How then does EPA determine where exactly the sources of these chemicals came from historically, or where they are currently coming from since they have been used since the 1940s, do not biodegrade in the environment, and are still used in every-day American household products? Doesn't this open liability to everyone in the current CERCLA potentially responsible parties (PRP) designation? Absent an express mandate from Congress, EPA cannot be legally precluded from considering whether its actions will turn every individual running a nonstick pan or waterproof jacket through the wash into a CERCLA PRP? The commenter also referenced legacy contamination verses new contamination and stated that these chemicals have been used in the United States and in countries all over the world since the 1940's and are not easily broken down in the environment. The comment then asks the following: How does EPA plan to separate out the "legacy" contamination of these chemicals with the "new" introduction of them into the environment? Have baseline contaminant levels for all media (water, soil, air, etc.) been determined? How does EPA plan to designate PRPs under CERCLA without being able to differentiate this difference? [0325/ORNL]

Response

The Agency recognizes that certain stakeholders are concerned about CERCLA liability resulting from the designation of PFOA and PFOS as hazardous substances. EPA 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 materials or are passive receivers of environmental media contaminated with PFOA or/ PFOS. EPA acknowledges though that some parties that do not bear primary responsibility for litigation may be sued, and face litigation costs as a consequence. These costs cannot be known at this juncture with reasonable certainty.

After analyzing CERCLA's existing liability limitations, EPA's existing enforcement discretion policies, as well as CERCLA's settlement tool, EPA expects that designation will not result in significant unintended consequences. See Preamble to the Final Rule Section VI (The Totality of the Circumstances Confirms that Designation of PFOA and PFOS as CERCLA Hazardous Substances is Warranted). Neither a release nor a report of a release automatically triggers cleanup action under CERCLA. 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. Decisions are made on a site-specific basis based on site-specific information. The only direct requirements for private entities that result from designation are certain reporting and notification requirements, as described in the Preamble to the Final Rule Section VIII.B. (Direct Effects of Designating PFOA, PFOS, and their Salts and Structural Isomers as Hazardous Substances). See preamble to the Final Rule Section VII.D.1.a-c (Reporting and Notification Requirements) for further explanation.

CERCLA is designed to ensure that highly contaminated sites are prioritized relative to other sites. The site-specific and discretionary nature of CERCLA safeguards against cleanups that are not necessary to protect human health and the environment and safeguards against excessive liability outcomes.

EPA is focused on holding responsible those who have manufactured and released significant amounts of PFOA and PFOS into the environment. As EPA states in the FY 2024-2027 National Enforcement and Compliance Initiates (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" The NECI also clarifies that "OECA 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 OECA exercises CERCLA enforcement discretion in other areas."

As explained in the preamble to the Final Rule Section VI.B.2 (*EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way*), EPA expects CERCLA to continue to function normally after the designation of PFOA and PFOS as it has for over forty years for the over 800 hazardous substances already designated under CERCLA.

Designation does not alter CERCLA's liability framework. Designation does not expand the definition of "potentially responsible parties," nor does it amend, change, or curtail existing statutory limitations on liability EPA expects to continue to operate as it has for decades to equitably resolve who should pay. See Preamble to the Final Rule Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute

significantly to contamination and concluded that CERCLA would still function in a rational way), and Section VII.J. (Summary of the Public Comments and Responses – Enforcement).

As referenced in the preamble to the Final Rule Section II.E.7, (What enforcement discretion is available when exercising CERCLA authority?), although CERCLA's liability structure is broad, EPA has used both statutory protections and enforcement discretion policies to ensure equitable results when possible. CERCLA provides statutory provisions for exemptions from and affirmative defenses against liability. These statutory protections and enforcement discretion policies historically have given and continue to give EPA the needed flexibility to offer liability protections. See the preamble to the Final Rule Section I (Executive Summary) and VI.B.2 for more information on enforcement discretion.

EPA understands that CERCLA's categories of "covered persons" (otherwise known as "potentially responsible parties") is broad and that this raises concerns about the number of parties or entities that could potentially be subject to CERCLA litigation. However, CERCLA's statutorily defined list of covered persons has been in place since CERCLA was enacted in 1980. Designation does not expand the definition of "potentially responsible parties" nor does it amend, change, or curtail existing statutory limitations on liability. CERCLA includes affirmative defensives and limitations on liability that operate to mitigate, if not eliminate, liability in certain circumstances. Such defenses and limitations are, in Congress' judgment, sufficient to ensure that CERCLA operates to achieve its two primary objectives—the timely cleanup of hazardous waste sites and "Polluter Pays." EPA's existing enforcement discretion policies also compliment CERCLA's liability framework and aim to achieve equitable outcomes. Indeed, EPA has a well-proven track record of developing enforcement discretion policies that have been effective, well-received, and upheld by courts. EPA has decades of experience implementing enforcement discretion policies, and our experience has proven that they can be useful tools in convincing major responsible parties not to pursue parties covered by these enforcement discretion policies. These enforcement discretion policies historically have given EPA the needed flexibility to offer liability protections.

Consistent with EPA's 2021-2024 PFAS Strategic Roadmap, EPA is committed to holding responsible those who significantly contribute to the release of PFAS into the environment, such as major manufacturers, federal facilities that are significant sources of PFAS, and other industrial parties. EPA does not intend to pursue entities where equitable factors do not support assigning CERCLA responsibility, such as water utilities. In addition to holding responsible parties accountable, there are funds available through the Drinking Water State Revolving Fund (DWSRF) to address emerging contaminants (including PFAS). Eligible projects include upgrading treatment technologies, technical assistance, water quality testing, and contractor training.

EPA can play a significant role in facilitating CERCLA settlements, which can greatly minimize costs associated with litigation and the amount of response costs a PRP may be required to pay. Under CERCLA Section 113, a party that resolves its potential liability with the United States or a State in a judicially approved settlement is entitled to contribution rights—the right to pursue liable parties for a share of response costs—and contribution protection—the ability to block third-party claims for matters addressed in the settlement. Contribution rights and protection are two of the major incentives CERCLA provides parties to resolve their potential liability through settlement. Contribution allows a court to apply the equitable *Gore* factors and assign liable

parties shares of responsibility for response costs. Although parties may still be incur legal costs to resolve liability claims, these CERCLA mechanisms greatly limit potential financial risk associated with CERCLA liability and litigation.

EPA understands that many states have state Superfund laws that are similar to CERCLA and that designation may provide state programs with authority to address PFOA and PFOS releases. Commenters have not provided data or support demonstrating how designation will impact those programs, and so EPA is unable to fully assess potential impacts to state programs. However, to the extent that PFOA and PFOS are incorporated by reference as "hazardous substances" in state programs, EPA believes this is beneficial because it promotes consistency between federal and state efforts to address PFOA and PFOS contamination. Although commenters do not provide additional information about state programs, EPA presumes that many programs also include a similar response framework to the federal program in which the most significant releases that present unacceptable risk to human health and the environment are prioritized for response. That is, not every instance of PFOA and PFOS releases will warrant a response action, under either federal or state law.

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. EPA believes, absent information to the contrary, that the safeguards and limitations on CERCLA liability discussed Section VI.B of the Preamble to the Final Rule 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 arise out of a federal-led CERCLA action. EPA's experience over the past four decades administering CERCLA shows that CERCLA, and presumably state Superfund programs, will continue to function in a rational manner, with those primarily responsible for pollution bearing the costs of cleanup.

Commenters also fail to provide support for many of the allegations of extensive liability that commenters fear will arise as a result of designation. As an initial matter, EPA questions the assumption that designation creates liability where liability may not have existed absent designation. EPA expects that, more often than not, PFOA and PFOS will be co-located or commingled with other hazardous substances—of which there are more than 800. Therefore, EPA believes that, in many circumstances, liability or potential liability will not attach solely because of the presence of PFOA and PFOS. The more likely scenario is that a party may be a CERCLA PRP because of releases of multiple hazardous substances in addition to PFOA and PFOS. Indeed, data available to EPA suggests that CERCLA hazardous substances are present in water sources across the country and in the influent that passes through sewage treatment plants. Best Practices memorandum for NPDES pretreatment coordination to address toxic and hazardous chemical discharges to POTWs (2016). Relatedly, sewage sludge and biosolids can contain CERCLA hazardous substances. See, e.g., Chemicals in Biosolids (2022), available here, https://comptox.epa.gov/dashboard/chemical-lists/BIOSOLIDS2022.(listing chemicals in biosolids that are CERCLA hazardous substances, such as 1,4-dioxane and copper.). It's a reasonable conclusion, then, that absent designation, these facilities may face some CERCLA liability risk because their facilities receive water that contains hazardous substances.

Also, the presence of a hazardous substance is only one element of liability. For example, there must also be a "release" of a hazardous substance and the person must be determined to be a "potentially responsible party." CERCLA section 107(a)(1)-(4). In addition, there must be an actual response to a release of a hazardous substance, which results in a party incurring response

costs, for there to be a potential financial consequence. Even under those circumstances, a plaintiff may 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). Finally, CERCLA defenses or limitations may also operate to limit liability. These aspects of CERCLA liability are site-specific and highly fact intensive.

Because CERCLA liability is dependent on interrelated issues and actions, assumptions that whole sectors of the economy or entities will instantly be liable and subject to millions or even billions of dollars of costs as a result of designation are unsubstantiated and unsupported. EPA understands that designation may result in CERCLA liability for PFOA and PFOS releases, but EPA disagrees with the scale of potential liability that commenters assert would arise from this action. Failure to designate would be inconsistent with science and the Polluter Pays principle underpinning CERCLA. Moreover, contrary to commenters' assertions, failure to designate (rather than designation) would be more likely to result in situations where municipalities or government entities (i.e., taxpayers) are the only entities responsible to address PFOA and PFOS releases that pose a risk to public health or the environment. Failure to designate ensures that those responsible for significant PFOA and PFOS contamination will ultimately escape financial liability for the crisis they created.

Certain commenters also expressed concern that POTWs would be the target of CERCLA citizen suits. Commenters do not elaborate on how CERCLA citizen suits may arise after designation. EPA understands that commenters' concern is that, even absent EPA action to address releases from POTWs, the very presence of PFOA and PFOS at their facilities may put them at risk for CERCLA citizen suits; however, that is not the case. CERCLA citizen suits are only appropriate for sites where a CERCLA response is being taken. CERCLA citizen suits are limited to situations where there is an alleged violation of a specific CERCLA requirement or an alleged failure of the federal government to perform a mandatory duty. CERCLA section 310(a)(1)-(2). In effect this means that in the absence of a CERCLA action to address a release of a hazardous substance, there is no authority to bring a CERCLA citizen suit. Therefore, the mere presence of PFOA and PFOS at a POTW does not put a POTW at risk for a CERCLA citizen suit. Furthermore, it remains wholly unknown whether or how many response actions may occur at or around POTW facilities that could form a basis for a CERCLA citizen suit. In sum, it's unclear how designation will result in a significant increase in CERCLA citizen suits to compel POTWs to comply with CERCLA.

Commenters also raise specific examples of alleged liability that will arise from designation that are unsupported. Commenters do not provide support for the suggestion that "retail stores that have sold legal PFAS-containing products" will be brought into CERCLA litigation. In EPA's experience, it's not common for sellers of useful products to be brought into CERCLA litigation. CERCLA liability is premised on there being a "release" from a facility, and sellers are presumably not releasing PFAS into the environment through the retail sale of a useful product.

Commenters do not provide support for the assertion that PFOA and PFOS plumes may be found without identifiable sources nor do commenters provide data suggesting the volume or concentrations of potential contamination. Commenters also seem to suggest that such sites will

⁶ The U.S. Government or a State or an Indian Tribe can recover costs "not inconsistent" with the NCP. CERCLA section 107(a)(4)(A).

have "miniscule quantities" but also "large areas of contamination," and commenters do not reconcile these potentially conflicting statements. With regard to sites where there is no identifiable and/or viable PRP, EPA makes every effort to identify the parties responsible for the contamination to clean up the sites. Where liable, viable potentially responsible parties (PRPs) can be found, EPA negotiates settlement agreements or orders those PRPs to pay for or carry out cleanup work. Where EPA cannot find liable, viable PRPs, the Agency will use the Fund.

Parties can also approach EPA to discuss resolving their liability through a CERCLA settlement, which can provide significant protections for parties, like water utilities, that played no role or a limited role in creating the contamination.

EPA also disagrees with commenters that designation will require any specific remediation or impose specific waste management obligations pertaining to treatment, disposal, or storage of PFOA and PFOS contaminated wastes. Designation does not require facilities to take any specific response actions, such as sampling, treatment, or disposal. CERCLA is not a traditional "command and control" statute that prospectively limits pollution. Instead, CERCLA is a remedial statute that addresses contamination already released into the environment on a site-specific basis to ensure that communities and ecosystems do not face unacceptable levels of risk. Comprehensive facilities' plans for utilities' collection and treatment systems of needed capital improvements are an inherent cost of business regardless of whether PFOA and PFOA are designated as hazardous substances under CERCLA. Activities generating PFAS waste already occur and will continue. Furthermore, CERCLA is designed to address unacceptable risk, not eliminate risk.

CERCLA is designed to target and prioritize sites that present unacceptable risk to human health and the environment and serves those communities that are most vulnerable to potential adverse health risks from exposure. EPA evaluates unacceptable risk based on criteria in the NCP as informed by site-specific risk assessment. The NCP provides that "[r]emediation goals shall establish acceptable exposure levels that are protective of human health and the environment." 40 CFR 300.430(2)(i). In evaluating what those exposure levels are, EPA considers, among other things, the "concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime." 300.430(2)(i)(A)(1). For known or suspected carcinogens, the acceptable risk range is defined as 10⁻⁴ and 10⁻⁶ using information on the relationship between dose and response. For non-cancerous effects, CERCLA generally manages risk greater than a hazard index of 1⁵. Role of the Baseline Risk Assessment in Remedy Selection Decisions (1991). EPA has extensive guidance on conducting site-specific risk assessments under CERCLA, available here: https://www.epa.gov/risk/superfund-risk-assessment.

For removal actions, EPA also considers a number of risk-based factors. The NCP provides that the following factors shall be considered in determining the appropriateness of a removal action: "(i) Actual or potential exposure to nearby human populations, animals, or the food chain from hazardous substances or pollutants or contaminants; (ii) Actual or potential contamination of drinking water supplies or sensitive ecosystems; (iii) Hazardous substances or pollutants or contaminants in drums, barrels, tanks, or other bulk storage contains, that may pose a threat of release; (iv) High levels of hazardous substance or pollutants or contaminants in soils largely at or near the surface that may migrate; (iv) Weather conditions that may cause hazardous substances or pollutants or contaminants to migrate or be released; (vi) Threat of fire or explosion; (vii) The availability of other appropriate federal or state response mechanisms to

respond to the release; and (viii) Other situations or factors that may pose threats to public health or welfare of the United States or the environment." 40 CFR 300.415(b)(2). These provisions ensure that the most significant releases that pose actionable risk to human health and the environment are prioritized for action. Not every instance of PFOA and PFOS releases will warrant a CERCLA response.

EPA disagrees that the Chamber of Commerce cost analysis provides a reasonable representation of potential costs associated with 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 additional information see infra Section 6.A.2 EPA needs to consider the actual costs associated with the Proposed Rule.

Comments regarding the presence of PFOA and PFOS and its impact on real estate transactions or private agreements are outside the scope of this rule and require no response. Nonetheless, EPA understands that the presence or potential presence of any of the more than 800 CERCLA hazardous substances is relevant to brownfields transactions, as well as other real estate transactions. For additional information see infra *Section 4.G.5-4*.

With respect to commenters suggestions regarding legislative options for addressing liability concerns, EPA routinely works with Congress on legislative efforts and is available to provide technical assistance to Congress on legislation if requested.

Federal funding for water and wastewater utilities is outside the scope of this response. However, in February 2023, EPA announced the availability \$2 billion in Bipartisan Infrastructure Law funding to address emerging contaminants, including PFAS, in drinking water. https://www.epa.gov/infrastructure. In addition, under CERCLA 104(d), states, tribes and local governments may be eligible for Superfund cooperative agreements (i.e., federal money to support Superfund program implementation) to conduct CERCLA response activities including pre-remedial, removal, and remedial action and should contact their EPA regional office for more information."

See also Preamble to the Final Rule Section VII.I (Comments on Economic Assessment/Regulatory Impact Analysis); infra Section 4.G (Impacts on Specific Sectors); Section 6.B-6.E. (comments regarding direct and indirect costs); Preamble to the Final Rule, Section VII.E and supra Section 4.D.2 for more information regarding designation and NPL sites; Preamble to the Final Rule Section IV.A.3 (Authority to Create Exclusions); Preamble to the Final Rule Section II.E (What are CERCLA's Primary Objectives); Preamble to the Final Rule Section VI.A.2.d (Environmental Justice Considerations for Designation).

4.F.4 Liability can arise without a site being listed on the NPL.

One commenter stated that CERCLA liability can arise without a site being included on the National Priorities List; EPA has authority under hazardous substance designation to hold potentially responsible parties accountable regardless of NPL status – EPA can take emergency action through CERCLA section 106(a). The commenter expressed concern that utilities may be implicated as potentially responsible parties because under CERCLA section 107 and NPL listing, unless the costs can be reasonably apportioned, a PRP that contributed only a de minimis amount of hazardous substances may be responsible for all of the response costs.

Response

The commenter is correct that EPA can take action under CERCLA section 10 (a), but the decision on whether any response actions are appropriate, depends on site and fact-specific analyses. Additionally, designation does not automatically confer liability, nor does it alter CERCLA's statutory or regulatory framework for liability. Although no additional action is necessary to ensure that statutory limitations and existing enforcement policies continue to operate as they have for decades, EPA intends to develop a policy that explains EPA's priorities for enforcement in the context of PFOA and PFOS releases. See Preamble to the Final Rule Section II.E.7 (What enforcement discretion is available when exercising CERCLA authority), Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way); Section VII.J (Enforcement); and FY 2024-2027 National Enforcement and Compliance Initiatives. See supra Section 4.F.4.

4.F.5 The Agency needs to clarify how enforcement discretion would work, particularly for water utilities.

Many commenters were supportive of the EPA's plan to develop enforcement tools and guidance to minimize the liability for water and wastewater agencies. However, some commenters were not clear how these enforcement tools and guidance would protect water agencies from potential litigation and requested that the Agency clarify how the proposed enforcement tools will counterbalance potential liability for water and wastewater agencies. For example, guidance and policy documents do not establish legally enforceable rights or responsibilities, and do not protect against CERCLA's strict liability. Also, even if the EPA (or a state agency under state hazardous substance cleanup law) is diligently prosecuting an action involving water agencies, there is no guarantee that will protect water agencies from third party claims. In Blackstone Headwaters Coalition, Inc. v. Gallo Builders, Inc., et al. (1st Cir. April 26, 2022), the court recently found that alleged violators are no longer shielded by the Clean Water Act's bar on citizen suits seeking declaratory and injunctive relief, even when a state has commenced and is diligently prosecuting enforcement under state law. Therefore, these commenters requested that the EPA clarify how enforcement tools and guidance will offset the potential CERCLA liability for water and wastewater utilities. They suggested that one way EPA could do this would be to adopt new enforcement guidance clarifying how water utilities' compliance with applicable laws governing the conveyance, treatment, and disposal of water and treatment wastes containing PFOA and PFOS is a defense to CERCLA liability. For example, until EPA adopts national primary drinking water quality standards for PFOA and PFOS, the guidance could state that water utilities' compliance with such laws is sufficient to establish the "due care" element of CERCLA's third party defense [see 42 U.S.C. § 9607(b)(3)]. [0321-Tillamook Co; 0339-ASDWA; 0340-ASTSWMO; 0349-Broome Co; 0376-Kent Co; 0400-Windsor; 0403-Purcellville; 0404-U.S. Chamber of Commerce et al.; 0413-ACWA; 0415-AMCA; 0431-Lexington; 0434-Manhattan KS; 0437-Dubuque; 0448-Thousand Oaks; 0451-Harford Co; 0482-MWDSC; 0489-Shelby Co AL; 0492-SCWQA; 0497-Orange Co FL; 0498-SCV; 0506-Conference of Mayors; 0514-Wasatch; 0518-WWP; 0522-WMC; 0529-Augusta Co; 0537-AMWA; 0539-NCWQA; 0808-NASF]

With all the critical complications, a commenter recommended that EPA provide a detailed example in the final rule that details how the Agency will manage cleanups and potential impacts to water utilities. The Agency could run a tabletop exercise using a known PFAS-contaminated site to run through the entire process and include simple visualizations of the process in the

guidance, such as using a flow chart in each phase, so the process is easily understood. This detailed example could help alleviate valid concerns of the water utilities. Another commenter pointed out that drinking water utilities are not cited in any of the five broad categories the EPA has listed as potentially affected parties, so it is important that the EPA acknowledge the potential burdens this designation will impose on drinking water systems and their customers. The EPA should quickly release its plan for enforcement discretion for the water sector, one which guarantees that the legal disposal of water treatment byproducts containing PFOA or PFOS by a drinking water system cannot trigger a CERCLA enforcement action by EPA or any other party. The Agency should also establish a mechanism to ensure that this guarantee will be honored by different administrations in the future. If such a step is beyond EPA's ability or authority, then the proposed hazardous substance designation should not be finalized. [0537-AMWA]

Numerous commenters from local governments appreciated that the Agency does not intend to target local governments and will instead use enforcement discretion to avoid unintended consequences of the rule but noted that how the EPA will implement this discretion has not been clearly stated. This creates several costly uncertainties for local governments as they not only attempt to address PFAS at the local level but additionally make other much needed infrastructure investments. [0321-Tillamook Co; 0376-Kent Co; 0400-Windsor; 0403-Purcellville; 0431-Lexington; 0434-Manhattan KS; 0437-Dubuque; 0448-Thousand Oaks; 0451-Harford Co; 0489-Shelby Co AL; 0497-Orange Co FL; 0514-Wasatch; 0529-Augusta Co]

Some commenters asked that the EPA clarify that a CERCLA designation will not impact the land application of municipal biosolids in any way before taking any regulatory action. They found the EPA's suggestion that it will use enforcement discretion to protect innocent public utilities very concerning because it suggests that public utilities may be subject to liability by the proposed CERCLA designation, which would likely result in public utilities having to pay for litigation and, potentially, remediation for PFAS contamination they did not cause. Further, these commenters noted that such an outcome is not consistent with EPA's asserted "polluter pays" approach. Commenters stated that if EPA is sincere about the "polluter pays" approach, then the Agency must not proceed until Congress revises the Superfund law to protect public utilities and their ratepayers from this unwarranted and unintended liability; without such protections, the commenters stated that EPA risks misleading the public when the Agency states that the CERCLA designation will allow the EPA to ensure that polluters pay for PFOA/PFOS contamination. [0415-AMCA; 0492-SCWQA; 0518-WWP; 0539-NCWQA; 0814 WVMWQA]

Although most comments on enforcement discretion were made by public water utilities, an industry commenter also requested that the EPA provide information on what specific consequences the Agency intends to minimize through enforcement discretion and what the Agency's clear policy to avoid those consequences will be. Without this information, the commenter stated that stakeholders cannot assess the potential impacts on their company/industry/sector. [0808-National Assoc for Surface Finishing]

Response

See *supra* Section 4.F.4, which addresses comments and issues related to potential liability and response actions that may arise after designation as well as comments suggesting that designation will require facilities to adjust waste treatment, disposal, and management practices.

As part of this final action, EPA evaluated comments and concerns regarding designation's potential impact on water utilities. See [RIA]. EPA also expanded its non-exhaustive list of potentially affected entities in the Preamble to the Final Rule. See table in Section II.C.

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. For more information on liability and costs to public utilities, see the Preamble to the Final Rule Section VII.I.1 (*Liability and Costs to Public Utilities*).

EPA declines commenters request to evaluate hypothetical situations for water utilities that may process water containing PFOA and PFOS. 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. In addition to these considerations, there are statutory and regulatory criteria relevant to determining whether a response action is appropriate. *See, e.g.*, CERCLA section 104(a)-(c), 121(a)-(d); 40 CFR 300.415, 300.430.

EPA acknowledges the Agency has a policy against "No Action Assurances," and therefore, it would be inappropriate for EPA to provide one for PFOA and PFOS releases. Nonetheless, 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. See Preamble to the Final Rule Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way.)

In addition, EPA's CERCLA enforcement discretion policies may be relevant to whether any action to pursue a party is taken. EPA may also choose, as applicable, to utilize a non-CERCLA authority to address situations that require some response action at water utilities. Each situation is different and raises a number of complex, interrelated considerations; therefore, EPA declines to provide an evaluation of hypothetical situations because such an exercise would not fully capture how decisions may be made on a site-by-site basis. Additionally, comments regarding EPA establish mechanisms to ensure that enforcement discretion policies will be honored by different administrations in the future is outside the scope of this rule making, and therefore requires no additional response.

4.F.6 Enforcement discretion is not sufficient to protect public sectors that do not create PFAS—such as water utilities and municipal landfills—from liability.

Many commenters noted that enforcement discretion on the part of the Agency is not sufficient protection, because CERCLA allows private parties and states to force and enforce cleanup responsibility without action on the same by the EPA. The impact of the proposed rule cannot be

siloed from the entirety of CERCLA. In the proposed rule, the EPA states that "designation alone does not require the EPA to take response actions, does not require any response action by a private party, and does not determine liability for hazardous substance release response costs" (Proposed Rule at 54423). The EPA's comments do not take into consideration why a hazardous substance is designated under CERCLA in the first place, which is primarily to allow the EPA, states, tribes, and citizen groups to hold polluters accountable by forcing cleanups of sites deemed contaminated by one or more hazardous substances. If the designation of a hazardous substance under CERCLA were only to permit site designation and reporting, then it would have been made clear in the statute that polluter responsibility for cleanups was not associated with the designation of a hazardous substance. Furthermore, a commenter points out that the EPA's own website contradicts the position taken by the Agency in the proposed rule: the CERCLA and Federal Facilities page (https://www.epa.gov/enforcement/comprehensive-environmentalresponse-compensation-and-liability-actoercla- and-federal) states that Citizen Enforcement is permitted under § 310(d) of CERCLA, and states they are warranted when there is an "alleged violation of any [CERCLA] standard, regulation, condition, requirement, or order " [42 U.S.C. § 9659(a)(1)]. CERCLA permits a Court to award attorney fees, expert witness fees, as well as award other costs of litigation [42 U.S.C. § 9659(c)]. [0315-Tallahassee; 0328-FWEA; 0341-AFBF; 0342-AEA; 0367-ECDSM; 0372-NEW Water; 0390-NMPF; 0391-SSP; 0392-NAWC; 0394-OSEE, ODEQ; 0404-U.S. Chamber of Commerce et al.; 0407-WCA PFAS; 0413-ACWA; 0419-API; 0421-ACC; 0424-ACI-NA; 0449-Weatherford; 0464-JEA; 0480-NWRA/SWANA; 0493-POWER!; 0495-PFAS Regulatory Coalition; 0496-NEORSD; 0506-Conference of Mayors: 0523-WSPA; 0523-WSPA; 0538-NACWA; 0543-AWWA; 0550-DSWA; 0568-WWEMA; 0310-NEWWA, 0311-MWWA, 0395-MWRA, 0438-Aurora, 0439-Sunnyvale, 0443-Tampa, 0459-GFL, 0521-WMWD, 0545-FSAWWA, 0565-USWAG; 0429-Fort Worth]

Numerous commenters cited a recent review of historical CERCLA sites that demonstrated that enforcement discretion is not a shield of protection, noting that nearly 650 entities, similar to and including water systems, have been sued as potentially responsible parties (PRPs) under CERCLA (Salzman & Thompson, 2019, Environmental Law & Policy (Fifth Edition) at 263). One such case includes a domestic sewage treatment facility that was found liable under CERCLA for a hazardous substance that was present in the wastewater collection system and released to the environment through leaky pipes (US District Court for Maryland, 1993). [0392-NAWC; 0413 ACWA; 0407-WCA PFAS; 0543-AWWA; 7 comments supported one of these comments: 0310-NEWWA, 0311-MWWA, 0395-MWRA, 0438-Aurora, 0464-JEA, 0521-WMWD, 0545-FSAWWA]

Commenters provided detailed information on the number of water utilities potentially impacted. Nearly 144,000 individual drinking water treatment systems across the U.S. are responsible for providing safe drinking water to the public (EPA, Safe Drinking Water Information System, 2022). Nearly all (99.3%) serve less than 50,000 people. Even if only a fraction of water systems were implicated with CERCLA liability due to the low levels of PFAS in their drinking water sources, the number of systems is still staggering considering the occurrence of PFOA and PFOS, at low levels, as determined by the EPA. A recent publication by the EPA staff in the AWWA Water Science Journal, estimates that the drinking water of nearly 50 million Americans potentially has PFOA or PFOS at detectable levels (Cadwallader, 2022). This is approximately one-sixth of the population of the U.S. and, using available national and state monitoring data for PFOA and PFOS corresponds to approximately 7,278 community water systems of 49,452 community water systems nationwide, or 14.7% of systems (Corona, 2022; Black & Veatch,

2022). Assuming this pattern is agnostic to the type of water system, a total of 21,107 drinking water treatment systems could potentially have observable levels of PFOA and PFOS. As detection limits decrease with analytical method improvements, this number could increase (Eurofins, 2022). Furthermore, given the ubiquitous use of PFAS in household and commercial applications, research has shown that PFOA and PFOS have been found in more than 99% of wastewater systems, impacting virtually all wastewater treatment facilities (Thompson, 2021). While the exact number of systems may be uncertain, it is obvious that the number of water systems that stand to be impacted by this designation is numbered in the tens of thousands, ranging from 40,000 to 162,000 systems. A majority of these systems are local governments and/or small systems serving less than 50,000 people. [0543-AWWA; 0310-NEWWA, 0311-MWWA, 0395-MWRA, 0438-Aurora, 0464-JEA, 0521-WMWD, 0545-FSAWWA]

Many commenters noted that enforcement discretion is inherently arbitrary, temporary, and subject to change with each Administration or change in Agency leadership or priorities. Furthermore, enforcement is generally delegated to EPA Regional offices, so a discretionary policy could result in a patchwork of unequal and inconsistent enforcement across the country. As a result, there will be enormous uncertainty as to when and why it will be invoked or whether it will provide reliable benefits. This level of uncertainty is not workable for the regulated community. [0341-AFBF; 0407-WCA PFAS; 0421-ACC; 0424-ACI-NA; 0460-ILTA; 0493-POWER!; 0495-PFAS Regulatory Coalition; 0496-NEORSD; 0506-Conference of Mayors; 0523-WSPA;0569-Chamber of Commerce et al; 0521 (WMWD); 0565 (USWAG)]

Although some commenters appreciated and encouraged the EPA's efforts aimed at limiting the CERCLA-related costs imposed on public utilities, they stated that it is important for the Agency to acknowledge that, should the proposed designations of PFOA and PFOS as CERCLA hazardous substances be finalized, the Agency will have limited authority to shield local agencies from the potentially massive amounts of liability stemming from those designations. While it is true that the EPA has the authority on NPL-listed sites to enter into settlement agreements with public utilities (which must be approved by a court) limiting their financial responsibility for a cleanup and precluding other PRPs from bringing contribution claims against them for that cleanup, the Agency is limited in its ability to provide assurances of no action outside the context of a particular enforcement action. EPA policy prevents such "no action" promises except when specified by statute or regulation or in "extremely unusual" cases to serve the public interest that "no other mechanism can address adequately." [EPA. Memo from Courtney Price, Policy Against "No Action Assurance" (November 16, 1984). https://www.epa.gov/enforcement/guidance-no-action-assurances-policy] The policy explains that assurances of no action "may erode the credibility of EPA's enforcement program by creating real or perceived inequities in the Agency's treatment of the regulated community." EPA has explicitly affirmed that its general policy concerning "no action assurances" applies to sites subject to CERCLA. [Memorandum from Barry Breen, "Applicability of Policy Against 'No Action' Assurances to CERCLA," June 16, 2000:

https://www.epa.gov/enforcement/guidance-applicability-policy-against-no-action-assurances-cercla.] In cases where EPA has established no-action policies, moreover, the Agency generally does not provide a blanket waiver. In its recent policy regarding enforcement of environmental obligations during the COVID-19 pandemic, [https://www.epa.gov/enforcement/covid-19-enforcement-and-compliance-resources#naa] for example, the Agency's determination not to seek penalties for noncompliance was based on a case-by-case determination that the noncompliance was caused by the pandemic. [EPA. EPA Corrects the Record after Reckless

Reporting on Temporary Compliance Guidance (March 20, 2020, Press Release). https://www.epa.gov/newsreleases/epa-corrects-record-after-reckless-reporting-temporarycompliance-guidance] It is possible that the EPA could craft an enforcement policy that exempts certain parties from liability for cleanup of PFOA and PFOS (once deemed hazardous) that is in the national interest. The policy would need to be based, however, on traditional considerations of de minimis (or de micromis) contribution to the contamination or of the parties' ability to pay. [EPA. General Policy on Superfund Ability to Pay Determinations. Memo from Barry Breen, Office of Site Remediation Enforcement (September 30, 1997). EPA-HQ-OLEM-2019-0341-0198.] It is difficult to imagine how the Agency could make such determinations for an entire sector, since such decisions are generally site specific. [0372-NEW Water; 0390-NMPF; 0419-API; 0421-ACC; 0460-ILTA; 0538-NACWA; 0569-Chamber of Commerce et al]

A commenter stated that the EPA's acknowledgment of the need for enforcement discretion is evidence that CERCLA is the wrong vehicle to address PFAS in the environment and that a more targeted approach is warranted. The commenter stated that PRPs at sites where PFOA and PFOS were not manufactured, used, or released are as innocent, with respect to PFOA and PFOS, as the parties the EPA would provide relief through enforcement discretion. Where PFOA and PFOS are not site-related, there would be no basis to provide favorable treatment to any PRP. In the end, enforcement discretion will only exacerbate inequity and increase transaction costs. The EPA will be hard pressed to ameliorate the impacts of this designation through the implementation of enforcement discretion because the Agency will not be able to insulate all parties. Targeted PRPs will need to pursue others to share costs. [0391-SSP]

Response

For this final rule, and after consideration of public comments, EPA evaluated potential liability outcomes that may arise after designation and determined that designation is warranted. See Preamble to the Final Rule, Section VI (*The Totality of the Circumstances Confirms that Designation is Warranted*); supra-Section 4.F.4, which addresses comments and issues related to potential liability and response actions that may arise after designation as well as comments suggesting that designation will require facilities to adjust waste treatment, disposal, and management practices.

As explained in the preamble to the Final Rule Section VII.B.1 (Comments suggesting that other authorities are better suited to address PFAS contamination), EPA disagrees with comments suggesting that CERCLA is not an appropriate tool to address the challenges posed by PFOA and PFOS contamination.

EPA acknowledges the Agency has a policy against "No Action Assurances," and therefore, it would be inappropriate for EPA to provide one for PFOA and PFOS releases. Nonetheless, 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. See Preamble to the Final Rule Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way.)

EPA strives for nation-wide consistency in the implementation of CERCLA. EPA's numerous CERCLA guidances, internal procedures, and regular coordination with its regional counterparts support nationally consistent outcomes. Although policies are subject to change, federal agencies

are generally expected to provide a reasoned explanation for amending, revising, or deviating from prior policy. See, e.g., Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42, (1983) (providing that an agency must provide "a resonsed analysis for the change"); American Wild Horse Preservation Campaign v. Perdue, 873 F.3d 914, 923 (D.C. Cir. 2017) ("A central principle of administrative law is that, when an agency decides to depart from decades-long past practices and official policies, the agency must at a minimum acknowledge the change and offer a reasoned explanation for it.").

EPA agrees with the commenter that a comprehensive approach to address the risks posed by PFAS is necessary. For further information regarding EPA's strategic approach to PFAS, see the Preamble to the Final Rule Section III.C. (EPA's PFAS Strategic Roadmap).

See RTC 4.F.3 for additional information on liability and enforcement.

4.F.7 The EPA should exempt from liability and reporting requirements various public organizations, including public water utilities, solid waste utilities, local governments, airports, firefighters, landowners affected by offsite sources, agricultural producers; specific activities such as land application of biosolids and paper mill sludge or and specific wastes.

Many commenters stated that various sectors or activities should be exempt from liability, including water utilities, municipal landfills, local governments, landowners or utilities that land apply biosolids or paper mill sludge, landowners adjacent to offsite sources. All assert that they are providing a needed service, following all regulations and laws, and should therefore be exempt from liability and reporting requirements as these would impose a large and undeserved cost burden. Commenters also called out specific wastes, including landfill leachate, biosolids, paper mill sludge, research waste, and medical waste. Some also want to exempt specific practices such as sequestration of biosolids.

Commenters made various suggestions as to how such an exemption could be implemented, including the federally permitted release exemption (for water utilities), the normal application of fertilizer (for biosolids and paper mill sludge), or championing a Congressional exemption.

[0276-DCWS/City of Vancouver; 0299-City of Thornton; 0303-Claremont County; 0309-SESD; 0310-NEWWA; 0311-MWWA; 0313-AWPA; 0314-Maine WUA; 0316-MeWEA; 0318-MMSD; 0342-AEA; 0346-CASA; 0348-BGMU; 0350-City of Henderson; 0351-City of St Charles; 0353-CWWA; 0354-City of Roseville; 0355-LASAN; 0356-CT COST; 0359-GCWW; 0360-GLWA; 0363-EPWater; 0364-WRA; 0367-ECDSM; 0370-Oregon ACWA; 0372-New Water; 0374-JCSD; 0375-MSD-St Louis; 0380-Little Blue Valley Sewer District; 0381-DNRP; 0383-NWB/MABA/MBA/NEBRA; 0385-NYSAWWA/NYWEA/NYRWA; 0386-ReWa; 0388-SCWA; 0389-Town of Ledgeview; 0392-NAWC; 0394-OSEE, ODEQ; 0396-MWEA; 0401-Village of Ashwaubenon; 0415-AMCA; 0416-AlexRenew; 0420-CTAWWA; 0422-AWWI; 0425-Cascade Water Alliance; 0430-Elyria; 0432-Columbus; 0435-Columbus, IN; 0438-City of Aurora; 0443-Tampa Water Dept; 0447-CRROPS; 0449-Weatherford; 0455-IEUA; 0462-LA Sanitation Districts; 0470-MEG Wastewater; 0471-Louden Water 0475-NARUC; 0478-NYC; 0482-MWDSC; 0488-RAW; 0490-PMAA; 0493-POWER!; 0496-NEORSD; 0504-VA Biosolids Council; 0505-VAMWA; 0509-TDEC; 0510-WEAT/TACWA; 0511-WateReuse; 0513-Trinity River; 0515-Upper Blackstone; 0518-WWP; 0531-EBMUD; 0534-KDHE; 0535-MRWA; 0538-NACWA; 0539- NCWQA; 0543-AWWA; 0554-DC Water; 0557-SWACO; 0568-WWEMA; 0798-Citizen; 0809-OC San; 0813-DPWP; 0307-Elsinore Valley; 0378-MSD; 0406-WAC; 0429-Fort

Worth; 0457- GCDCWWS; 0814 WVMWQA. Supporting: 0352-Clark County; 0357-HRSD; 0379-Stafford County; 0395-MWRA; 0453-Monterey; 0464-JEA; 0465-JCW; 0478-NYC; 0521-WMWD; 0527-Metro; 0545-FSAWWA; 0562-NBC; 0804-SPR; 0806-BACWA]

Some commenters noted that EPA's PFAS Strategic Roadmap indicates that the EPA will "hold polluters accountable." Publicly owned treatment works (POTWs) and municipal separate storm sewer systems (MS4s) are not polluters, but under the proposed rule to designate PFOA and PFOS as CERCLA hazardous substances, these facilities could very easily become liable for pollution they did not cause and cannot prevent. POTW operators can utilize pretreatment authority to address industrial sources but that authority does not extend to domestic wastewater, which makes up the majority of POTW influent, nor can it be applied to stormwater. On page 54418 of the Federal Register publication, one of the effects of CERCLA designation lists that EPA and other entities could recuperate cleanup costs for PFOA and PFOS from "potentially responsible parties" rather than having taxpayers cover these costs. CERCLA was designed as a polluter pays model such that the general public would not be responsible for contamination caused by entities that produce various contaminants. However, because of the broad definition of PRPs under CERCLA, under which negligence is not required for a party to be deemed responsible (42 U.S.C. § 9607), and the ubiquitous nature of PFOA and PFOS, the number of water and wastewater utilities that could become potentially responsible parties (PRPs) under the proposed rule is large. Private sector parties can—and often do—bring public utilities into CERCLA contribution actions, where they are subject to the same potential liability as all other PRPs, despite simply being passive receivers of PFAS. Even where EPA attempts to limit their exposure, utilities can be forced to spend exorbitant amounts of public funds defending themselves in such actions. Public ratepayers must be shielded not only from paying for the cleanups ultimately necessitated by such listings, but also from the significant legal costs public utilities will incur to defend themselves in complex CERCLA litigation absent a clear statutory exclusion. Without a clear exemption for POTWs and MS4s from this CERCLA designation, this rule will invalidate its purpose and ultimately, put the burden back on residential taxpayers. [0276-DCWS/City of Vancouver; 0299-City of Thornton; 0303-Claremont County; 0309-SESD; 0310-NEWWA; 0311-MWWA; 0313-AWPA; 0314-Maine WUA; 0316-MeWEA; 0318-MMSD; 0342-AEA; 0346-CASA; 0348-BGMU; 0350-City of Henderson; 0351-City of St Charles; 0353-CWWA; 0354-City of Roseville; 0355-LASAN; 0356-CT COST; 0359-GCWW; 0360-GLWA; 0363-EPWater; 0364-WRA; 0367-ECDSM; 0370-Oregon ACWA; 0372-New Water; 0374-JCSD; 0375-MSD-St Louis; 0380-Little Blue Valley Sewer District; 0381-DNRP; 0383-NWB/MABA/MBA/NEBRA; 0385-NYSAWWA/NYWEA/NYRWA; 0386-ReWa; 0388-SCWA: 0389-Town of Ledgeview; 0392-NAWC; 0394-OSEE, ODEQ; 0396-MWEA; 0401-Village of Ashwaubenon; 0415-AMCA; 0416-AlexRenew; 0420-CTAWWA; 0422-AWWI; 0425-Cascade Water Alliance; 0430-Elyria; 0432-Columbus; 0435-Columbus, IN; 0438-City of Aurora; 0443-Tampa Water Dept; 0447-CRROPS; 0449-Weatherford; 0455-IEUA; 0462-LA Sanitation Districts; 0470-MEG Wastewater; 0471-Louden Water 0475-NARUC; 0478-NYC; 0482-MWDSC; 0488-RAW; 0490-PMAA; 0493-POWER!; 0496-NEORSD; 0504-VA Biosolids Council; 0505-VAMWA; 0509-TDEC; 0510-WEAT/TACWA; 0511-WateReuse; 0513-Trinity River: 0515-Upper Blackstone: 0518-WWP: 0531-EBMUD: 0534-KDHE: 0535-MRWA: 0538-NACWA; 0539- NCWQA; 0543-AWWA; 0554-DC Water; 0557-SWACO; 0568-WWEMA; 0798-Citizen; 0809-OC San; 0813-DPWP. 20 additional comments either duplicated (6) or expressed support for (14) one of these comments and were not excerpted. Duplicates: 0307-Elsinore Valley; 0378-MSD; 0406-WAC; 0429-Fort Worth; 0457- GCDCWWS; 0814 WVMWQA.

Supporting: 0352-Clark County; 0357-HRSD; 0379-Stafford County; 0395-MWRA; 0453-Monterey; 0464-JEA; 0465-JCW; 0478-NYC; 0521-WMWD; 0527-Metro; 0545-FSAWWA; 0562-NBC; 0804-SPR; 0806-BACWA]

CERCLA provides an exemption for the owners and operators of airports using PFAS firefighting foam, there is no exemption for Public Water Systems that merely receive and dispose of PFAS found in water supplies for the purpose of providing potable drinking water. This would mean that municipal drinking water ratepayers could face increased costs to clean up PFAS that was legally disposed of following the water treatment process. This would unfairly punish and hold ratepayers liable for contamination they did not create. An exemption for airports, but not for public water systems, is not an equitable approach. [0310-NEWWA; 0311-MWWA, 0314-Maine WUA, 0488-RAW]

Commenters state that Municipal solid waste landfills neither manufacture nor use PFAS; these entities merely receive discarded PFAS-contaminated materials that are ubiquitous in residential and commercial waste streams. Landfills and water and wastewater treatment facilities currently operate interdependently to manage PFAS disposal, as many landfills rely on wastewater treatment facilities for leachate management, while wastewater and drinking water facilities increasingly rely on landfills to dispose of biosolids, granular activated carbon filters, and other PFAS-containing water treatment discharges. Under CERCLA's strict, joint and several liability structure, the proposed designation of PFOA and PFOS as hazardous substances may expose passive receivers of PFAS such as public landfills to enormous liability as "potentially responsible parties" under CERCLA. Commenters stated that the proposed designation would unfairly assign environmental cleanup liability to these essential public service providers and their customers, leading to significant cost increases to ratepayers. This may lead landfills to restrict inbound wastes and/or increase disposal costs for media contaminated with PFAS, including biosolids. To avoid disrupting the critical interdependence between public landfills and public water and wastewater utilities, and to preserve existing methods of PFAS disposal, EPA should consider ways to insulate public water and wastewater systems, landfills, and other passive receivers of PFAS from CERCLA's joint and several liability. Although the proposed designation indicates EPA's intent to exercise its "considerable discretion" in bringing enforcement actions against passive receivers, commenters noted that this policy assurance alone is insufficient in protecting public water systems and landfills from broad liability under CERCLA. Absent a statutory amendment to CERCLA exempting certain passive receivers from liability for PFOA and PFOS, public water systems and landfills may still be exposed to claims for contribution from manufacturers and heavy users of PFAS, likely resulting in significant litigation costs. Responsible parties will try shift costs to the taxpayers by bringing claims against the public landfills for contribution when determining damages in the litigation, even though the public agencies are merely passive receivers of the material. [0394-OSEE, ODEO; 0509-TDEC; 0534-KDHE; 0557-SWACO; 0560-PHSKC

A commenter from a local government stated that the costs to special districts could be significantly reduced with the exclusion of specified local governments – including special districts – from liability for cleanup and remediation costs. Given that such a clarifying exclusion is consistent with existing federal statutes and consistent with the CERCLA "polluter-pays" model, it would be prudent to include a clarifying exemption to prevent the public from having to bear the cost of cleaning up contaminated sites and would reduce the overall cost of the proposed rule. [0528-NSDC]

Many commenters stated that in the final Rule, EPA should exempt from CERCLA liability wastewater treatment plants who land apply or otherwise dispose of biosolids containing PFOA and PFOS. The generation and subsequent management of biosolids is an integral part of running a POTW because solids remain after the completion of the treatment cycle. The Proposed Rule, coupled with EPA's Standards for the Use or Disposal of Sewage Sludge, 40 CFR Part 503, leave POTWs largely at risk for CERCLA liability, no matter how an entity chooses to lawfully use or dispose of its biosolids and residuals. Under CERCLA, a potentially responsible party ("PRP") is any person who could be liable for response costs incurred by the United States. See 40 CFR 304.12(m). Those who could be so liable include the owner and operator of a facility, a person who arranged for disposal or treatment of hazardous substances, and a person who accepts hazardous substances for transport to disposal or treatment facilities. Among other things, PRPs are liable for removal and remediation costs, plus interest. If the Proposed Rule is finalized as proposed, wastewater treatment facilities that rely on land application of biosolids could be considered PRPs and be forced to pay for removal and remediation costs. Indeed, the Proposed Rule highlights wastewater treatment facilities as one of five broad categories of entities "potentially affected" by the rule (see Proposed Rule at 54416). Should this occur, wastewater treatment plants will be forced to raise sewer rates for their residents, placing the burden squarely on members of the public. This contradicts one of EPA's stated goals in drafting the Proposed Rule—to hold polluters accountable for cleaning up their contamination. [0276-DCWA/City of Vancouver; 0309-SESD; 0318-MMSD; 0322-Env Compliance Mgr; 0346-CASA;0348-BGMU; 0354-City of Roseville; 0355-LASAN; 0360-GLWA; 0363-EP Water; 0365-EPN; 0370-Oregon ACWA; 0372-NEW Water; 0373-MMSD; 0381-DNRP; 0383-NWB/MABA/MBA/NEBRA; 0386-ReWa; 0395-MWRA; 0396-MWEA; 0423-AF&PA; 0430-Elyria; 0447-CRROPS; 0455-IEUA; 0462-LA Sanitation Districts; 0470-MEG Wastewater; 0473-MESERB; 0478-NYC; 0485-MI Farm Bureau; 0490-PMAA; 0504-VBC; 0505-VAMWA; 0507-Wasatch; 0508-WEF; 0511-WateReuse; 0513-Trinity River; 0531-EBMUD; 0534-KDHE; 0538-NACWA; 0547-ME DACF; 0554-DC Water; 0557-SWACO; 0568-WWEMA; 0798-Citizen; 0350-Henderson; 0351-St Charles; 0352-Clark County; 0375-St. Louis; 0397-MWRA Advisory Board; 0453-Monterey; 0465-JCW; 0496-NEORSD; 0520-WPC; 0521-WMWD; 0527-Metro; 0562-NBC; 0804-SPR; 0806-BACWA; 0809-OC San; 0307-Elsinore Valley; 0378-MSD; 0406-WAC; 0457-GCDCWWS]

A commenter states that EPA should also exempt concentrate as part of this rulemaking and instead, continue to regulate concentrate management through the existing permitting process. EPWater depends on inland desalination as both a current and future water supply. Our inland desalination plant treats water from a vast brackish aquifer. We are very concerned about the cost and regulatory burdens from the Proposed Rulemaking as it related to concentrate management. EPWater has worked constructively with EPA in the permitting process for the management of concentrate from our desalination plant. That process has allowed us to let science guide our decision-making on the best solutions to protect the environment. We urge EPA to exempt concentrate as part of this rulemaking and instead, continue to regulate concentrate management through the existing permitting process. [0363/EPWater]

A few commenters stated that paper mill residuals are used as a fertilizer or a soil conditioner, similar to biosolids, and PFOA and PFOS incidentally contained in such residuals should be similarly excluded from the scope of this rule. [0423-AF&PA; 0502-USW; 0520-WPC]

A few commenters state that there is a strong case for the safe and beneficial land application of paper mill residuals. First, the U.S. pulp and paper industry paper sector stopped using long-chain PFOA and PFOS for limited specialty applications, such as grease- and moisture-resistant packaging, over a decade ago and shifted to short-chain PFAS approved by the FDA as safe for food packaging (U.S. EPA, 2021, "Multi-Industry Per- and Polyfluoroalkyl Substances (PFAS) Study – 2021 Preliminary Report"); the industry has now virtually completed their voluntary transition out of FDA approved short-chain PFAS to PFAS-free alternatives. As a result, the presence of PFAS in mill residuals is incidental and extremely minimal compared to ambient background levels (household dust) (U.S. EPA, 2022, "PFAS Explained"). [0423-AF&PA; 0502-USW]

A commenter [0423-AF&PA] provided data on PFOA and PFOS in paper mill residuals showing they are not a significant source of new loadings into the environment above background concentrations. The commenter reviewed samples of paper mill residuals which were tested for PFOA and PFOS. Many samples did not show detectable levels of PFOA or PFOS, but because PFOA and PFOS are widespread in the environment, they have been detected in some samples of paper mill residuals, albeit at very low levels. The commenter's data on paper mill residuals samples show median values of non-detect for PFOA and 4.05 parts per billion (ppb) for PFOS. This is below median values of PFOA and PFOS in many biosolids and also below levels found in common household dust. For example, a study of PFOA and PFOS concentrations in biosolids by the Ecology Center and Sierra Club (2021) reports median concentrations of 1.53 ppb for PFOA and 13.2 ppb for PFOS. Information on common house dust, which is often used as an environmental integrator of chemical deposition, and which we believe is representative of background contamination of PFOS, shows median values ranging from 24 ppb to 9 ppb for PFOA and 27 ppb to 4 ppb for PFOS for samples taken between 2013 and 2016 (Hall et al., 2020). PFOA and PFOS concentrations in the environment have declined over time as uses have been curtailed; consequently, the sample collection timeframe is very important in making proper comparisons. For example, as provided by Hall et al., 2020, PFOS concentrations in common house dust for the period of 2000 to 2020 have declined by 98% from 201 ppb to 4 ppb. For PFOA, concentrations have declined by 94% in this same time frame, from 142 ppb to 9 ppb (median values). Similar declining trends have been identified in other matrices (Graber et al, 2019).

A commenter notes that land application of paper mill residuals is a sustainable and growing alternative to landfilling and subject to oversight. About 2.5 million dry MT/yr of paper mill residuals are produced in the United States (National Council for Air and Stream Improvement, "Solid Residual Generation and Beneficial Use, and Wastewater Treatment Performance and Practices of the North American Pulp and Paper Industry," T.B. No. 1063 (Dec. 2019), Sec. 3.1, at p. 22). These residuals are largely composed of wood fibers. Land application of these residuals continues to increase, shifting away from landfilling, and reflects a sustainable use of materials. Land-applied residuals are beneficial for farmlands and forestlands because they can increase soil nutrient-holding capacity, reduce soil erosion and the need for irrigation, and reduce soil compaction (U.S. EPA, 2022, "Basic Information About Biosolids"). Many state programs coordinate and monitor the use of paper mill residuals for land application – including Wisconsin and Michigan. State programs operate under management plans authorized by their environmental agency to ensure the safe and beneficial use of paper mill residuals as soil amendments. The management plans often test the chemical and physical characterization of the

material, restrict application of the residual near streams, wells, and residential or public buildings, and implement requirements on proper storage of the material (MI State University, 2017. "Paper mill residuals: Free soil amendment available to Upper Peninsula farmers"; WI DNR, 2022, "Beneficial Use of Industrial Byproducts"). Finally, the commenter was concerned about unintended consequences. Given the incidental presence of these substances in everyday life, policies that create stigma and perceived risk to continuing to use these residuals as soil amendments could lead to managing these residuals as hazardous wastes, adding unnecessary costs for paper mills to transport residuals as hazardous substances to landfills without any added benefits to public health. This outcome not only could have adverse economic impacts on many mills and significant job loss, but also would lead to increased landfilling and trucking of these residuals to the detriment of the environment and many local communities. The pulp and paper sector is trade exposed, and from our union's experience in other trade exposed industries, additional unreasonable costs, like these potential disposal costs, leads to offshoring production. [0502-USW]

Some commenters stated that EPA should provide for a waiver or exemption to the strict liability provisions of CERCLA to innocent landowners, when it can be clearly established that the PFAS contamination was caused by no fault of their own and that the PFAS contaminating party bear one hundred percent of the financial and legal responsibility for the cleanup, storage and reporting of the contamination. The Agency's well-intentioned decision to list PFAS chemicals as hazardous substances under CERCLA will have catastrophic unintended consequences on farmers and other landowners impacted by offsite PFAS contamination. Existing policy makes it clear that the burden of establishing an exemption falls on the innocent landowner, who must presumably incur all the attendant expenses of geologists, attorneys, and additional scientists to prove their innocence under a bureaucratic construct that should, in reality, be governed by the common sense conclusion that PFAS contamination responsibility lies exclusively with its manufacturers and those who have allowed the chemicals to enter the groundwater in the first instance (see for example, the Agency's May 24, 1995 memorandum "Final Policy Toward Owners of Property Containing Contaminated Aquifers," which makes it clear that innocent landowners with a groundwater well may not be exempt from enforcement action and that landowner exceptions are at the discretion of EPA). While this policy appropriately outlines the goal of protecting the marketability of land affected by groundwater contamination, it provides drastically insufficient protection for landowners who are using groundwater wells for myriad purposes and who could, as a result, be denied an exemption based on the sole discretion of EPA. More recent EPA guidance reaffirms the existing regulatory landscape. The July 29, 2019, memorandum, "Enforcement Discretion Guidance Regarding Statutory Criteria for Those Who May Qualify as CERCLA Bona Fide Prospective Purchasers, Contiguous Property Owners, or Innocent Land Owners ('Common Elements')," demonstrates that for the average landowner near an industrial or military source of PFAS, a CERCLA designation for PFAS chemicals will only serve to throw them into a labyrinth of regulatory complexity which hinges entirely on the discretion of EPA. The EPA is therefore encouraged to publish, along with the rule, a statement of policy that clearly articulates that landowners, including farmers, who received PFAS in their water supplies from another polluter should be in a 'safe harbor' from liability associated with the costs of clean-up under CERCLA. [0333-Farmer; 0444-DPNM; 0559-RuttenKern; 0747-Roettger: 0757-Cogan: 0772-Sack: 0780-Jones]

A commenter stated that EPA should clarify the scope of responsible parties. Agricultural producers and their lands may receive inputs that contain PFOA, PFOS, or their precursors, from various sources, including groundwater, biosolids and pesticides. Those producers who do not generate PFOS, PFOA, or any other PFAS should be exempt and not defined as a responsible party if PFOA and/or PFOS are found on their premises, whether through the application of contaminated biosolids, pesticides, groundwater, or any other contaminated substance used on agricultural operations. [0393-NMED]

A commenter stated that EPA should clarify that the legal use of registered pesticides and insecticides would not trigger liability under the proposed rule. Pesticides are highly regulated products that have been applied safely for decades in accordance with Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) labeling requirements. The rigorous FIFRA and Federal Food, Drug and Cosmetic Act (FFDCA) registration requirements for new products and the registration review process for existing products have ensured the safety of pesticides, including through complete risk assessments of aggregate and cumulative risks. CERCLA provides significant protections from liability for the application of registered pesticides. Section 107 of CERCLA currently prohibits a person from recovering any response costs or damages resulting from the application of a registered pesticide (42 U.S.C. § 9607(i)). Section 103(e)(1)(A) of CERCLA also contains an exemption from hazardous substance release notification requirements for the application of registered pesticides and handling and storage of these pesticides by an agricultural producer. Thus, EPA exempts from the release reporting requirements pesticides that are used in normal applications in ways that are consistent with the pesticide's purpose (in accordance with their labeling requirements) and it does not allow EPA or third parties to recover response costs for cleanup where pesticides applied according to their label could be in involved. Although current exemptions under CERCLA provide significant protection for registered pesticide application, we request that if EPA moves forward in this rule, it clarify that the use of pesticides consistent with FIFRA requirements continue to be exempt from the scope of this final rule and CERCLA generally. We also remind EPA that CERCLA's currently exempts from the definition of "release" "the normal application of fertilizer," 42 U.S.C. § 9601(22). Many pesticide manufacturers make combined fertilizer/pesticide product that should also be covered by this exemption. [0542-CLA]

A commenter stated that well drillers should be protected from becoming hazardous waste generators as they participate in the remediation of hazardous waste sites and should not be subjected to CERCLA liability in this regard. A specific list of activities that are exempt from punitive actions should be developed to enable remediation of hazardous sites and protect participants in the remedial process that may involve movement of hazardous substances offsite for further disposition. [0468-NGWA]

Implementation:

Clarify or modify the "federally permitted release" exemption Several commenters stated that EPA should update its regulations at 40 CFR 117.12 to clarify that discharges made pursuant to a National Pollutant Discharge Elimination System (NPDES) permit from publicly owned treatment works and municipal stormwater systems are "caused by events occurring within the scope of relevant operating or treatment systems" for purposes of CERCLA. This language is necessary to ensure that CERCLA's "federally permitted release" exemption applies to discharges from public agencies at least on par with those from industrial dischargers. [0562-NBC; 0804-SPR; 0806-BACWA; 0809-OC San]

Many commenters noted that under CERCLA (42 U.S.C. § 9607(j)), protection from liability is provided when there is a release of a CERCLA hazardous substance and the release occurs pursuant to federal authorization. As defined in the statute, "federally permitted discharges" includes those done in compliance with an NPDES permit, RCRA, SDWA, CAA, or CWA (42 U.S.C. § 9601(10)). Most clean water agency facilities operate under NPDES permits which have extensive requirements to ensure protection of public health and the environment. [0346-CASA; 0355-LASAN; 0383-NWB/MABA/MBA/NEBRA; 0386/ReWa; 0447-CRROPS; 0455-IEUA; 0493-POWER!; 0534-KDHE; 0568-WWEMA; 0521-WMWD]

A few commenters note that the exclusion contained in EPA's regulations at 40 CFR 117.12 only applies where (1) a permittee is in compliance with specific limits on the hazardous substance contained in the permit, or (2) the hazardous substance was identified in the permit application process and the discharges at issue are "caused by events occurring within the scope of relevant operating or treatment systems." The commenters noted that EPA has not yet developed either technology or water quality-based requirements for PFOA or PFOS, and most NPDES and other permits do not yet contain such limits. Furthermore, while some local agencies are monitoring for the potential presence of PFAS in discharges, in most cases (except drinking water) EPA-approved analytical methods are still under development and inclusion of monitoring requirements in permits is still not routine. Thus, most permittees are unlikely to have addressed potential PFAS concentrations in past permit applications. [0396-MWEA; 0462-LA Sanitation Districts; 0493-POWER!; 0521-WMWD]

Additionally, a few commenters stated that the phrase "caused by events occurring within the scope of relevant operating and treatment systems" is vague, and it is unclear if it is applicable to publicly owned treatment works. Therefore, it appears that the "federally permitted release" exclusion in CERCLA will provide, at most, extremely limited coverage against CERCLA liability for local public agencies for PFOA or PFOS releases. [0396-MWEA; 0462-LA Sanitation Districts]

A commenter noted that the "federally permitted releases" exemption has not been tested in court in the context of public clean water utility operations, so it is unclear how effective they would be. EPA clarification that the exemptions cover municipal wastewater operations would provide increased certainty. [0360-GLWA]

One commenter stated that not all activities that involve water require a federal permit, and thus public water utilities remain exposed. Numerous commenters stated that another or additional approach to protecting land application of biosolids is to clarify the "federally permitted release" exemption. As it relates to biosolids, "releases" of hazardous substances from the land application of sewage sludge authorized under 40 CFR part 503 constitute a "federally permitted activity" under existing CERCLA statutes and should be acknowledged as such as part of this rule (the Preamble to the Part 503 rule states that "[u]nder CERCLA, protection from liability is also provided when there is a release of a CERCLA hazardous substance and the release occurs pursuant to Federal authorization. Thus, under CERCLA, in defined circumstances, the application of sewage sludge to land in compliance with a permit required by section 405 of the Clean Water Act is a Federally permitted release as defined in CERCLA. Recovery for response costs or damages under section 107 of CERCLA is not authorized for Federally permitted releases. [CERCLA] defines Federally permitted releases as, among others, discharges in compliance with an NPDES permit under section 402 of the Clean Water Act.... Consequently, releases of hazardous substances from the land application of sewage sludge authorized under

and in compliance with an NPDES permit would constitute a Federally permitted release" (58 Fed. Reg. 9248, 9262 Feb. 19, 1993). While these statements by EPA have provided a reasonable level of comfort to POTWs that if they dutifully follow one of EPA's Part 503 pathways and any applicable NPDES permitting requirements, they will not subsequently be ensnared in CERCLA's liability net. The preamble to the Proposed Rule, however, is silent at best. At worst, it could be read as a retreat from EPA's thoughtful positions. At a minimum, EPA missed an opportunity in the discussion of the Proposed Rule, and the commenters urged EPA to steadfastly reaffirm--through all necessary companion rulemaking proceedings or otherwise--the CERCLA liability positions it articulated in the context of the Part 503 rule. Supporting such an assessment, biosolids treatment and management conditions are determined by robust risk assessments and often incorporated into a utility's NPDES permit. This approach is consistent with both statutory intent and legislative history. Explicit acknowledgment and inclusion of these exemptions is critical since the proposed rule and accompanying narrative fails to reference these conditions and practices. These clarifications would remove arbty surrounding the intent of the rule, preserve the polluter pays principle, and avoid shifting costs and burdens on to the public. [0493-POWER!; 0521-WMWD; 0354-City of Roseville; 0372-NEW Water, 0373-MMSD; 0383-NWB/MABA/MBA/NEBRA; 0395-MWRA; 0447-CRROPS; 0470-MEG Wastewater; 0478-NYC; 0505-VAMWA; 0357-HRSD; 0379-Stafford County]

A commenter noted that biosolids land application activities are exempt under EPCRA as well as CERCLA. The importance of dovetailing federal regulations so they neither conflict nor confuse has been recognized by EPA in the past. Under Section 311(e)(5), any substance - when used in routine agricultural operations - is exempt from reporting under Section 311 and 312. This exemption is designed to eliminate the reporting of fertilizers, when stored, applied, or otherwise used at a farm facility as part of routine agricultural activities. Land application of biosolids has been recognized as a routine agricultural activity. Acknowledging land application of biosolids as a federally permitted release under CERCLA will maintain the consistency of regulation with the recognition of biosolids land application as a routine agricultural practice and concomitant exemption from reporting under EPCRA. [0383-NWB/MABA/MBA/NEBRA]

Clarify that land application of biosolids and paper mill residuals is a "normal application of fertilizer":

Many commenters stated that EPA should undertake a notice-and-comment rulemaking clarifying that the exclusion of the "normal application of fertilizer" from CERCLA's definition of "release" [CERCLA §101(22)] includes farmers applying biosolids to farm fields even where the biosolids contain CERCLA hazardous substances, if done in accordance with the Part 503 biosolids regulations. That position is contained in the preamble to EPA's biosolids regulations at 40 CFR Part 503 (58 Fed. Reg. 9248, 9262 Feb. 19, 1993; see also, EPA, A Plain English Guide to the EPA Part 503 Biosolids Rule, 52-53, Sept. 1994). However, EPA never formalized this preamble statement into a regulation, and several courts have held that the presence of hazardous substances precludes application of fertilizer from being considered "normal" under CERCLA, creating a legal "grey area" [see Sheridan v. D&D Grading, Inc., No. 16-CV-5085(JS)(ARL), 2019 WL 1433086, at *5, E.D.N.Y. Mar. 29, 2019; Fallowfield Dev. Corp v. Strunk, No. CIV. A. 89-8644, 1994 WL 498316, at *1, E.D. Pa. Sept. 2, 1994, aff'd sub nom. Fallowfield Dev. Corp. v. Strunk, 96 F.3d 1432, 3d Cir. 1996; United States v. Morrison-Quirk Grain Corp., No. CV88-L-720, 1990 WL 482139, at *4, D. Neb. May 4, 1990; City of Tulsa v. Tyson Foods, Inc., 258 F. Supp. 2d 1263, 1288, N.D. Okla. 2003, vacated pursuant to settlement,

July 16, 2003). Formalizing it into regulation now could provide public clean water utilities and the agricultural community with significant relief from potential liability related to land-applied biosolids. The commenters note this regulation could be updated if necessary following EPA's ongoing PFOA and PFOS biosolids risk assessment process. [0276-DCWA/City of Vancouver; 0309-SESD; 0318-MMSD; 0322-Env Compl Mgr; 0346-CASA; 0348-BGMU; 0354-City of Roseville; 0355-LASAN; 0360-GLWA; 0363-EP Water; 0365-EPN; 0370-Oregon ACWA; 0372-NEW Water; 0373-MMSD; 0381-DNRP; 0386-ReWa; 0395-MWRA; 0396-MWEA; 0423-AF&PA; 0455-IEUA; 0462-LA Sanitation Districts; 0470-MEG Wastewater; 0473-MESERB; 0478-NYC; 0485-MI Farm Bureau; 0504-VBC; 0505-VAMWA; 0508-WEF; 0513-Trinity River; 0531-EBMUD; 0534-KDHE; 0538-NACWA; 0547-ME DACF; 0554-DC Water; 0557-SWACO; 0568-WWEMA; 0798-Citizen; 0350-Henderson; 0351-St Charles; 0352-Clark County; 0357-HRSD; 0375 (St. Louis); 0379-Stafford County; 0395 (MWRA); 0397-MWRA Advisory Board; 0453-Monterey; 0465-JCW; 0478-NYC; 0496-NEORSD; 0520-WPC; 0521-WMWD; 0527-Metro; 0562-NBC; 0804-SPR; 0806-BACWA; 0809-OC San; Duplicates (4): 0307-Elsinore Valley; 0378-MSD; 0406-WAC; 0457-GCDCWWS]

A few commenters noted that the application here of the "normal application of fertilizer" exemption would be an application of the "identity principle," which EPA has relied on for forty years to define the limits of RCRA jurisdiction. Under this principle, waste-derived materials are not "solid wastes" when those materials contain hazardous constituents at levels that are "typical" for the commercial materials for which they are substituted (67 Fed. Reg. 48393, 48402; July 24, 2002). EPA has applied this logic specifically in the case of fertilizers, excluding zinc fertilizers made from hazardous secondary materials from the definition of solid waste when their chemical makeup is "essentially identical" to that of zinc fertilizers made from virgin materials (see 65 Fed. Reg. 70954, 70957; Nov. 28, 2000). The ultimate basis of this logic is that "any potential risks posed by hazardous and non-hazardous zinc feedstock materials would be substantially similar" (see 65 Fed. Reg. 70959; Nov. 28, 2000). This risk-based approach has been repeatedly upheld by the D.C. Circuit (see Safe Food and Fertilizer v. EPA, 350 F.3d 1263, 1269-71, D.C. Cir. 2003—upholding the zinc fertilizer exclusion from the definition of solid waste; American Petroleum Institute v. EPA, 862 F.3d 50, 59-61, D.C. Cir. 2017—reaffirming the logic of Safe Food where constituent levels are "comparable"). [0423-AF&PA; 0520-WPC]

A few commenters asked whether the existing CERCLA exemption for the use of "fertilizer" pursuant to 42 USC 9601(22) extends to the byproducts on a farm that contain PFAS used as fertilizers (compost, manure, etc.) and asked that EPA specify that farms, inputs, agricultural products, and soil amendments (including the use of fertilizers, pesticides, irrigation water, livestock watering, land application of manure, and other agricultural activities constitutes an exempt activity such as the exemption under Sec. 9604(e) of CERCLA that exempts farms from CERCLA for pesticides and animal waste) are explicitly exempt from CERCLA liability. [0485-MI Farm Bureau; 0547-ME DACF]

A few commenters noted that when Congress enacted CERCLA in 1980, it provided four exclusions from the definition of "release," one of which is "the normal application of fertilizer" (42 U.S.C. § 9601(22)(D)). Given that Congress intended for the normal application of fertilizer to be excluded from CERCLA coverage; that paper mill residuals are used as a fertilizer or soil conditioner; and that the Agency has previously found another form of wastewater treatment residuals, when land applied for this purpose, to fall within the CERCLA fertilizer exclusion, this suggests that paper mill residuals could also be covered under an exemption for the "normal

application of fertilizer." EPA has never previously relied solely on its Section 102(a) authority to list a substance as a CERCLA hazardous substance. EPA therefore will be writing on a blank slate, exercising its full authority under that provision, unconstrained by any previous listing actions or statements regarding that authority. EPA should receive substantial deference for any Section 102(a) listings, moreover, as that subsection is a clear delegation of legislative rulemaking authority. The breadth of EPA's authority under the "as may be appropriate" language of Section 102(a) applies equally to its ability to include substances within a listing and its ability to exclude them. The phrase "as may be appropriate" certainly gives the Agency at least as much discretion as, if not more than, "as provided for." Therefore, EPA has the authority to provide, in a PFOA and PFOS listing, that PFOA and PFOS incidentally contained in paper mill residuals that are beneficially land-applied as a fertilizer or soil conditioner are excluded from that listing on the basis of the fertilizer exclusion. [0423-AF&PA; 0502-USW]

Support the adoption by Congress of an exclusion from CERCLA liability:

Many commenters stated that the EPA should support the enactment by Congress of an exclusion from CERCLA liability for PFAS releases from public clean water, stormwater, and drinking water agencies. Commenters stated that the "federally permitted release" exclusion under CERCLA will likely provide, at most, extremely limited coverage against CERCLA liability for discharges that are properly permitted under the NPDES program for public clean water agencies in the context of PFOA or PFOS. The federally permitted release exclusion only applies where (1) a permittee is in compliance with specific limits on the hazardous substance contained in the permit, or (2) the hazardous substance was identified in the permit application process and the discharges at issue are "caused by events occurring within the scope of relevant operating or treatment systems." (40 CFR 117.12) To item 1, the EPA has not yet developed either technology- or water quality-based requirements for PFOA or PFOS, and NPDES permits therefore do not yet contain such limits. To item 2, past permit applications did not typically address potential PFAS discharges from treatment processes. Moreover, although EPA's regulations clearly point to manufacturing and cooling water discharges as being "caused by events occurring within the scope of relevant operating and treatment systems," they are less clear about which municipal wastewater and stormwater discharges may qualify for such a categorization, and thus for exclusion as "federally permitted releases." [40 CFR 117.12(d)] Furthermore, members of Congress have sought to establish exemptions but have yet to determine the full scope of facilities that should qualify under such a definition. The commenters stated that EPA should work with Congress to enact a statutory exclusion. [0313-AWPA; 0363-EPWater; 0364-WRA; 0470-MEG Wastewater; 0471-Loudoun; 0515-Upper Blackstone; 0537-AMWA; 0538-NACWA; 0543-AWWA; 0554-DC Water; 0798-Citizen; 0813-DPWP; 0310-NEWWA; 0311-MWWA; 0350-Henderson; 0351-St Charles; 0352-Clark County; 0375-St. Louis; 0395-MWRA; 0438-Aurora; 0464-JEA; 0465-JCW; 0478-NYC; 0496-NEORSD; 0521-WMWD; 0527-Metro; 0545-FSAWWA; 0562-NBC; 0804-SPR; 0809-OC San; 0378-MSD; 0406-WAC: 0457-GCDCWWS]

A commenter suggested that an exemption could be done in a manner similar to the Resource Conservation and Recovery Act (RCRA) Domestic Sewage Exclusion (DSE; 42 U.S.C. § 6903(27); 40 C.F.R. § (a)(1)(i).). This exclusion exempts mixtures of domestic sewage and other waste traveling through sewer systems to POTWs from being considered hazardous waste. Wastewater reporting is regulated under the Clean Water Act (CWA) and should continue as such to meet the original intent of both RCRA and CERCLA. [0513-Trinity River]

Specific Wastes:

Landfill leachate: A few commenters stated that the discharge of leachate at landfills performed in compliance with federal or state law and all applicable permits should be exempt from CERCLA liability. In the event EPA opines that it has limited authority to provide the solid waste sector with relief from third-party contribution litigation, the Administration should work with Congress to support a narrow legislative exemption from CERCLA liability in cases where a landfill discharges leachate in compliance with all applicable laws and regulations. Doing so would keep CERCLA liability on the industries that created and profited from these PFAS compounds —not on taxpayers. [0381-DNRP; 0459-GFL 0480-NWRA-SWANA; 0439-Sunnyvale]

Water treatment residuals:

Some commenters stated that EPA should clarify that the management and disposal of water treatment technologies and residuals are subject to RCRA Subtitle C hazardous waste disposal standards, if applicable, and should not be captured by CERCLA liability due to any PFAS hazardous substance designation. Some water recycling facilities employ technologies such as nanofiltration (NF), reverse osmosis (RO), granulated activated carbon removal (GAC), ion exchange (IX), and PFAS-selective novel adsorbents to ensure a high-quality alternative supply of water. These technologies are also some of the most effective removal technologies for PFOA and PFOS. However, these treatment processes generate residuals, such as spent media, NF, RO concentrate (reject) streams that can include PFAS. Under CERCLA, water recycling facilities' management of the generated spent media and residuals may fall under "releases" and "disposals," exposing utilities to liability, and their ratepayers to the associated clean-up costs. [0354-City of Roseville; 0511-WateReuse; 0569-U.S. Chamber of Commerce et al; 0350-Henderson; 0352-Clark County; 0453-Monterey; 0521-WMWD]

Research waste:

A commenter stated that EPA should consider the fiscal impact on research waste disposal as this cost is central to these researchers' ability to conduct the kind of work that EPA needs as guidance for the Roadmap. Perhaps consideration of a partial or full exemption from the hazardous substance designation and hazardous waste regulations for these wastes and/ or allowance for innovative treatment techniques. [0487-Purdue]

Medical waste:

A commenter stated that many states have refrained from banning PFAS in medical devices (see, for example, Cal. Health & Safety Code §§ 108945(c)(2), (d).) If the producers of these devices are permitted to continue to introduce products containing PFAS (including PFOA and PFOS), then waste management companies should not be held liable for environmental response costs. The commenter acknowledged that the EPA may not have the authority to grant such exclusions but urged the Agency to work with Congress to amend CERCLA to enable the Agency to create exemptions and/or create a mechanism to raise money from specific businesses to offset cleanup/corrective action liabilities incurred by passive receivers. [0512-Stericycle]

Biosolids:

Two commenters stated that the final hazardous substance listings could simply exclude PFOA and PFOS contained in biosolids that are beneficially land applied as a fertilizer or soil

conditioner, and EPA could reserve the right to set PFOA and PFOS levels at a future date. [0423-AF&PA; 0520-WPC]

Biosolids quality should be regulated in Part 503 regulations:

Several commenters stated that biosolids quality should continue to be regulated through the existing Clean Water Act programs using 40 CFR Part 503 requirements. The Part 503 rule does not currently contain standards for PFOA or PFOS, but EPA is currently embarked on a multipathway risk assessment designed to serve as the basis for an update of the Part 503 standards. This update could set standards for PFOA and PFOS, but not before Winter 2024 at the earliest. [0370-Oregon ACWA; 0423-AF&PA; 0538-NACWA; 0350-Henderson; 0351-St Charles; 0352-Clark County; 0375-St. Louis; 0395-MWRA; 0465-JCW; 0478-NYC; 0496-NEORSD; 0520-WPC; 0521-WMWD; 0527-Metro; 0562-NBC; 0804-SPR; 0809-OC San; 0378-MSD; 0406-WAC; 0457-GCDCWWS]

Paper mill residuals:

A commenter stated that it would be far better, for multiple reasons, if the final rulemaking were to contain an exclusion for PFOA and PFOS contained in paper mill residuals that are beneficially land applied. If EPA does not do that, the Agency can and should follow the precedent of the Part 503 rules and propound our recommended exclusion in the preamble to final rule, as an interpretation of the fertilizer exclusion. If necessary, EPA could limit the exclusion to cases where PFOA and PFOS are present at concentrations in the residuals comparable to biosolids and other fertilizers and soil conditioners. As an interpretive rule, this interpretation would be entitled to deference – as Kelley noted, EPA is free to issue interpretive rules, "based on specific statutory provisions [of CERCLA,] represent[ing] the agency's construction of the statute" (See 15 F.3d at 1107-1108). [0423-AF&PA]

Biosolids/organic waste sequestration: A commenter stated that EPA should clarify that deep underground management of biosolids is exempt from CERCLA for PFOA/PFOS residuals in domestic waste and, given the combination of permanence of the sequestration, cost, and protectiveness of USDWs and ground water, should allow and encourage more deep underground management. [0343-Advantek Waste Management Services LLC]

Response

As explained in the preamble to the Final Rule Section VII.A.3 (*Authority to Create Exclusions from the Designation*), EPA declines to create exceptions for certain uses of PFOA and/or PFOS in this rulemaking. See also RTC, Section 2.A.4 (*Authority to Create Exclusions/Exemptions*). Commenters suggest that CERCLA includes an exemption for owners and operators of airports that use PFAS firefighting foam. EPA is unaware of such an exemption and commenters provide no legal authority in support of the comment. Commenters also provide information or data regarding the concentration of PFOA and PFOS in paper mill residuals; however, such data is insufficient to support a conclusion that certain types of releases of PFOA and PFOS do not present a substantial danger. EPA cannot conclude, based on the data provided, that potential releases from paper mill residuals will never present substantial danger such that a CERCLA response action may be warranted. Whether releases present actionable risk is determined on a site-specific basis using site-specific data.

A number of comments asked EPA to clarify that the exclusion of the "normal application of fertilizer" from CERCLA's definition of "release" [CERCLA §101(22)] includes farmers applying biosolids to farm fields even where the biosolids contain CERCLA hazardous substances. As explained in the Preamble to the Final Rule in Section VII.A.3, EPA believes the "normal application of fertilizer" language is best read as requiring a site-specific analysis. EPA will take under advisement whether a rulemaking or a guidance may be appropriate to clarify CERCLA's definition of "release" at some point in the future.

For this final rule, and after consideration of public comments, EPA evaluated potential liability outcomes that may arise after designation and determined that designation is warranted. See Preamble to the Final Rule, Section VI (*The Totality of the Circumstances Confirms that Designation is Warranted*); *supra*-Section 4.F.3 and 4.F.4, which address comments and issues related to potential liability and response actions that may arise after designation as well as comments suggesting that designation will require facilities to adjust waste treatment, disposal, and management practices; *infra* Section 4.G for comments and responses regarding Impacts on Specific Sectors; see also see RIA Section 6.2 for the analysis of the impact of direct costs on small businesses and governments, Section 5.1 for costs and transfers associated with different types of response activities.

For specific information regarding CERCLA protections for residential landowners, please see Preamble to the Final Rule Section VI.B.2. Additional information is available on EPA's website. Superfund Landowner Liability Protections, available here: https://www.epa.gov/enforcement/superfund-landowner%20liability%20protections%20are,the%20requirements%20of%20the%20statute.

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 enforcement in the context of PFOA and PFOS releases.

As EPA states in the FY 2024-2027 National Enforcement and Compliance Initiates (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..." The NECI also clarifies that "OECA 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 OECA exercises CERCLA enforcement discretion in other areas."

Consistent with CERCLA and the key goals of the PFAS NECI, EPA expects to implement its enforcement program to achieve site characterization, control ongoing releases that pose a threat to human health and the environment, ensure compliance with permits and other agreements (e.g., Federal Facility Agreements) to prevent and address PFAS contamination, and address endangerment issues as they arise.

A number of comments asked EPA to clarify that the exclusion of the "normal application of fertilizer" from CERCLA's definition of "release" [CERCLA §101(22)] includes farmers

applying biosolids to farm fields even where the biosolids contain CERCLA hazardous substances. As explained in the Preamble to the Final Rule in Section VII.A.3, EPA believes the "normal application of fertilizer" language is best read as requiring a site-specific analysisFor specific information regarding CERCLA protections for residential landowners, please see Preamble to the Final Rule Section VI.B.2. Additional information is available on EPA's website. Superfund Landowner Liability Protections, available here: https://www.epa.gov/enforcement/superfund-landowner%20liability%20protections%20are,the%20requirements%20of%20the%20statute.

Comments requesting clarification on CERCLA liability for the use of registered pesticides and insecticides are outside the scope of the rule. One commenter asked for clarity regarding the exception contained in CERCLA section 104(e); however, EPA believes commenter intended to refer to CERCLA section 107(i). EPA agrees that the proper application of a registered pesticide product is given protection under CERCLA 107 and 103. And EPA acknowledges that the "normal application of fertilizer" is excluded from CERCLA's definition of release. Whether the use of a pesticide or insecticide falls within these provisions is determined on a case-by-case basis and dependent on site-specific facts. It would not be appropriate or reasonable to provide a more definitive statement on these provisions in this rulemaking as the outcome can vary depending on the site-specific circumstances.

In response to comment regarding the exemption provided in EPCRA for routine agricultural operations, the Agency has not interpreted this phrase to include application of biosolids. EPA will take it under advisement.

The "identity principle" suggested by commenters is a RCRA, not a CERCLA concept; this comment is outside the scope of this rulemaking and requires no response. In any event, commenters misunderstand the zinc fertilizer rule. While the cited zinc fertilizer rule conditionally excluded certain hazardous secondary materials from the EPA *regulatory* solid waste definition, it did not exclude them from the RCRA *statutory* solid and hazardous waste definitions. See 67 FR at 48398 ("The conditional exclusion provided in today's rule is an exclusion only from the RCRA subtitle C regulations, and not from the emergency, remediation and information-gathering sections of the RCRA statute [sections 3004(u), 3007, 3013, and 7003].") Thus, the rule made clear that the materials would remain subject to the RCRA corrective action authority and other authorities governed by the statutory definition. Consequently, we disagree with the commenter's assertion that EPA has established an "identity principle" that defines the limits of RCRA jurisdiction.

With respect to comments concerning landfill leachate and compliance with applicable laws, regulations, and permits, determination of whether a particular release qualifies as a "federally permitted release" requires a case-by-case analysis that is outside the scope of this rule. EPA does acknowledge that the federally permitted release exemption or exclusion may act as a shield against CERCLA liability in that it may limit the recovery of response costs pursuant to 42 U.S.C. 9607(j); CERCLA Section 107(j). Permits that allow for certain releases of PFOA and PFOS may qualify for the FPR defense if PFOA and PFOS are identified in the and do not exceed the limits of the permit. the existence of a permit, however, does not automatically create a shield against liability. The federally permitted release exemption to CERCLA cost recovery is an affirmative defense for which a defendant bears the burden of proof. *United States v. Freter*, 31 F.3d 783, 788 (9th Cir. 1994); *United States v. Iron Mountain Mines, Inc.*, 987 F.Supp. 1244,

1249 (E.D. Cal. 1997). Even if a defendant meets the burden of establishing that some releases are federally permitted, response costs may be recovered where releases: "(1) were not expressly permitted, (2) exceeded the limitations of the permit, or (3) occurred at a time when there was no permit." 812 F. Supp. At 1541 (E.D. Cal. 1992) (quoting Idaho v. Bunker Hill, 635 F. Supp. 665, 673-74 (D. Idaho 1986)). In the case where there are both permitted and unpermitted releases, recovery of response costs related to a federally permitted release is prevented only where the defendant proves that the costs are divisible. *Iron Mountain*, 812 F. Supp. At 1541. Consequently, it would not be appropriate or reasonable for EPA to make any definitive statements regarding the federally permitted release exemption and its applicability to POTWs, or any other entity, in this rulemaking as the outcome can vary depending on site-specific circumstances. The absence of a court decision concerning federally permitted releases and POTWs does not prejudice this response. Any POTW facing a cost recovery action under CERCLA may raise the federally permitted release exemption as an affirmative defense and will bear the burden of proof, just as with other potential defenses – such as the third party or innocent landowner defense available under 42 U.S.C. § 9607(b)(3); CERCLA § 107(b)(3). See Preamble to Final Rule Section VII.D.1.h. Finally, EPA also acknowledges that this provision applies to public entities just as it does to private entities.

Comments stating that EPA should clarify the management and disposal of water treatment residuals is outside the scope of this rule. Regulatory programs and corresponding management practices to address PFAS in water, and the associated costs, are already underway and are not attributable to designation. See Preamble to Final Rule Section VI.B.2 and RTC 4.E.2-1 and RTC 4.F.4.

In order to designate hazardous substances, EPA must find that the substance may present a substantial danger to public health or welfare or the environment when released into the environment. CERCLA section 102(a). Water use, treatment, and reuse practices are not relevant to that determination. Designation has no impact on RCRA's list of "hazardous wastes." PFAS, including PFOA and PFOS, are not currently listed, nor being proposed to be listed, as RCRA hazardous wastes, and designation of PFOA and PFOS as CERCLA hazardous substances does not automatically require that PFOA- and/or PFOS-contaminated waste be treated or disposed of at RCRA Subtitle C facilities. The CERCLA designation does not result in any specific RCRA requirements. See RTC 4.E.2-1

Comments regarding research and development waste are outside the scope of the rule and require no response. Designation does not require waste to be treated in any particular fashion nor disposed of at any particular type of landfill. RCRA provides requirements for the disposal of solid and hazardous wastes, not CERCLA. RCRA does not include regulatory exemptions or exceptions for management of hazardous wastes derived from research and development. However, RCRA hazardous waste regulations do not identify any solid wastes as listed hazardous wastes due to the presence of PFOA or PFOS (40 CFR Part 261), and PFOA- or PFOS-containing solid wastes would not otherwise be identified as RCRA regulatory hazardous wastes unless they exhibit a characteristic (§261.20-261.24).

Comments regarding well drillers status under RCRA are outside the scope of the rule and require no response. Nevertheless, EPA doesn't typically consider well drillers as hazardous waste generators when they perform work at Superfund sites. Drill cuttings and purge water generated during well installation are considered investigative derived waste (IDW), In addition, generally, hazardous waste is not moved offsite by anyone other than someone who has the

required training/documentation to be a hazardous waste hauler. In summary, EPA disagrees with the commenter that well drillers should be protected from becoming hazardous waste generators and that there's a need to develop a list of specific activities that are exempt from punitive actions to enable remediation of hazardous waste sites.

Comments seeking guidance on general management of sewage sludge and/or biosolids are outside the scope of this rulemaking and require no response. Superfund response decisions are made site specifically and must meet CERCLA and NCP threshold requirements of protectiveness and compliance with ARARs unless waived. In addition to evaluating alternatives to select a remedy, attaining these requirements generally involves internal, e.g., another EPA office outside of OLEM and external coordination, e.g., a State or another federal agency, depending upon site specific circumstances. These site-specific circumstances include, but are not limited to, environmental media and contaminants of concern.

Due to the site-specific nature of response decisions, Superfund generally does not promote, endorse, encourage, etc the use of any specific remediation technology, treatment, etc. Therefore, EPA disagrees with the commenter's suggestion to encourage use of a specific technology to address a specific media.

EPA acknowledges that deep well injection of waste can be an effective means for disposing liquid waste, potentially including liquids from biosolids that may contain PFAS. The designation of PFOA and PFOS as CERCLA Hazardous Substances does not prohibit the use of deep well injection and therefore does not need to be exempt from the rule. EPA encourages managers of waste containing PFAS to consider the nature of the waste, the concentrations of PFAS, and other lines of evidence when deciding the best methods for destruction or disposal.

Commenters may refer to EPA's "Interim Guidance on the Destruction and Disposal of [PFAS] and [PFAS] Substances and Materials Containing [PFAS] and [PFAS] Substances -Version 2 (2024)" for additional information, available here:

https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf.

To learn more about the Biosolids Program, please visit: https://www.epa.gov/biosolids. EPA is working diligently to complete its biosolids risk assessment for PFOA and PFOS and expects to complete the assessment by December 2024. More information, please visit: https://www.epa.gov/biosolids/risk-assessment-pollutants-biosolids#pfas

With respect to commenters suggestions regarding legislative options for addressing liability concerns, EPA routinely works with Congress on legislative efforts and is available to provide technical assistance to Congress on legislation if requested.

4.G Impacts on Specific Sectors

4.G.1 POTW/Water Treatment Sector

4.G.1-1 CERCLA designation would significantly impact beneficial reuse of wastewater and treatment processes.

A few commenters stated that EPA has embraced beneficial reuse in the past, but it might no longer be feasible for a wastewater treatment plant under this Proposed Rule. If EPA's proposed CERCLA designation would impact the use of treated wastewater for spray irrigation (and other effluent reuse programs), that would dramatically affect agricultural and municipal operations around the country with potentially devastating consequences to businesses that invested in and rely on such irrigation. These operations include irrigation for agricultural production, golf courses, landscaping of municipal facilities, and many other public and private applications. Many of these applications provide significant in-stream water quality benefits (such as minimizing nutrient loadings to impaired waters). EPA must demonstrate that a CERCLA listing will not undermine these essential environmental programs for PFOA and PFOS. [0386-ReWa; 0492-SCWQA; 0506-Conference of Mayors; 0518-WWP]

A commenter stated that changes to the tertiary treatment process used to produce non-potable recycled water would be required to address the proposed designation. Costs to add an additional treatment to remove these compounds will be reflected in the cost of water to the local growers. This cost will then get passed on again to the American taxpayer as increased production costs. The commenter asked whether utilities would have to implement expensive treatment processes to eliminate rare exceedances of PFOA/PFOS (e.g., once in a 60-day cycle), and stated that a well-thought out and risk-based process is needed for determining acceptable accumulations of these compounds on produce. [0483-Monterey]

Response

Issues pertaining to water treatment, irrigation practices, water reuse, and the like, are outside the scope of this rulemaking and require no response. Regulatory programs and corresponding management practices to address PFAS in water, and the associated costs, are already underway and are not attributable to designation.

In order to designate hazardous substances, EPA must find that the substance may present a substantial danger to public health or welfare or the environment when released into the environment. [CERCLA section 102(a)]. Water use, treatment, and reuse practices are not relevant to that determination. See Preamble to the Final Rule Section IV.

Designation does not require any response action by a private party and does not determine liability for hazardous substance release response costs. Response actions are contingent, discretionary, and site-specific decisions made after a hazardous substance release or threatened release. They are contingent upon a series of separate discretionary actions and meeting certain statutory and regulatory requirements.

EPA also expects CERCLA to continue to operate in a rational way for PFOA and PFOS, as it has for decades with respect to 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. EPA expects to continue to operate as it has for decades to equitably resolve who should pay. See Preamble to the Final Rule Section VI.B and Section VII.J.

4.G.1-2 A comprehensive approach to PFOA and PFOS regulation that accounts for the myriad issues facing the utility sector is needed; the rule has the potential to seriously harm water utilities.

Several commenters cited a variety of challenges that would be faced by the utility sector with regard to PFOA and PFOS should they be designated as CERCLA hazardous substances and called on EPA to work with the clean water community, states, and across its internal offices to develop a more explicit plan of action for public water utilities, and the communities that depend on them, that will achieve environmental objectives without putting local clean water agencies in untenable positions for managing and treating wastewater, stormwater and biosolids. Traditional wastewater treatment plants are not designed to treat or remove PFOA or PFOS, and effluent discharged to receiving surface water bodies may contain PFOA and PFOS that poses a threat to human health and aquatic life. PFOA and PFOS also may concentrate in biosolids, which are typically sent to landfills or applied to land as fertilizers or soil amendments. EPA should consider the potential cleanup and liability implications for a variety of land application types, including but not limited to spray irrigation of treated municipal wastewater, rapid infiltration basins, land application of biosolids, land application of septage, and other land applied materials. [0322-Environmental Compliance Manager; 0350-City of Henderson; 0393-NMED; 0566-University of Arizona]

A commenter shared EPA's concerns about the potential harm to people and the environment from per and polyfluoroalkyl (PFAS) compounds, but stated that EPA's approach in the proposed rule has the potential to harm sectors and facilities that provide essential daily functions in our communities, such as wastewater treatment facilities and landfills (i.e. facilities which do not generate or use PFAS compounds but which may, in the regular course of business, receive waste or wastewater containing PFAS compounds). Considering the heavy reliance on these facilities for sanitary conditions in our communities, the consequences for public health and safety would be significant if these facilities could no longer remain financially solvent due to the enormous cleanup costs associated with the proposed rule. [0394-OSEE, ODEQ]

Response

Issues pertaining to wastewater treatment, irrigation and farming practices, general waste management and the like, are outside the scope of this rulemaking and require no response. Regulatory programs and corresponding management practices to address PFAS in water and waste, and the associated costs, are already underway and are not attributable to designation.

The Agency recognizes that certain stakeholders are concerned about CERCLA liability and impacts resulting from the designation of PFOA and PFOS as hazardous substances. As explained in the preamble to the Final Rule Section VI.B.2 (*EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way*), EPA expects CERCLA to continue to function normally after the designation of PFOA and PFOS as it has for over forty years for the over 800 hazardous substances already designated under CERCLA.

For more information, please refer to the Preamble to the Final Rule, Section VI.B-C and Section VII.A.3, B.1, H, J.; see *supra* Section 4.E, 4.F.4-8.

4.G.1-3 Impact on non-biosolids waste such as GAC and leachate have not been fully assessed.

A number of commenters asked what impact the proposed CERCLA designation would have on wastewater spray irrigation and effluent reuse programs nationwide such as for agricultural production, spray irrigation of golf courses, municipal facility landscaping, and other public and private applications, especially since many of these applications provide significant instream water quality benefits (such as minimizing nutrient loadings to impaired waters). Similarly, commenters were concerned that the designation will prevent the regeneration of granulated activated carbon media used by water treatment facilities and others to reduce PFAS levels in finished drinking water and other media if GAC must be treated as hazardous waste. Also, drinking water facilities detecting PFOS or PFOA in their system will face expenses necessary to purchase and install energy-intensive removal technology (i.e., Granulated Activated Carbon, Reverse Osmosis, or Ionization). Liability issues and burden to ratepayers need to be considered. A commenter noted that this rule is expected to lead to the generation of at least 275,000 tons of spent adsorption media annually and provided an example of the impact on a drinking water treatment system's recent contract for granular activated carbon (GAC) supply and management (CFPUA, 2022) "Should regulatory changes, including but not limited to changes to ..CERCLA...classify certain or all PFAS compounds as a hazardous compound...may be restricted from reactivating spent GAC at its potable reactivation sites...hazardous spent GAC will be processed at an approved industrial reactivation facility...Reclassification may result in amendment to this Contract for changes in processing and handing, pricing of the spent return freight, waste handling, and any additional cost incurred for hazardous material transportation, handling, and processing. In addition, the Contract may be further amended to remove custom reactivated carbon as an option and/or apply virgin contract pricing." [0539-North Carolina Water Quality Association (NCWQA), 0415-Association of Missouri Cleanwater Agencies (AMCA), 0543-American Water Works Association (AWWA, 0386-Renewable Water Resources (ReWa), 0492-South Carolina Water Quality Association (SCWQA), 0506-U.S. Conference of Mayors et al, 0518-Wet Weather Partnership (WWP), 0483-Monterey One Water, 0374-Jurupa Community Services District (JCSD)]

A commenter noted that while the EPA mentions in the designation that PFAS accumulation in landfills is of concern, that this is also an additional concern for landfills that accept shale gas development waste. [0366-Environmental Health Project (EHP)]

A commenter stated that landfills are receivers, not producers and will not be able to eliminate PFAS from their leachate until manufacturers eliminate PFAS from their consumer products and the products still in the marketplace are depleted. The commenter noted that the Proposed Rule identifies as a potential source of PFAS, a "landfill without environmental controls[.]" 87. Fed. Reg. at 54917 (3); 54427(1) and stated that PFAS containing leachate in their landfills which have environmental controls does not create the sort of environmental risk that CERCLA was intended to address. While a landfill does not have the ability to deliver "PFAS-free" leachate to a WWTP, it can however bar the receipt of PFAS containing waste generated during remedial actions, including those undertaken by EPA and other agencies. This would have a detrimental impact upon PFAS remediation projects and available disposal options. The commenter cites a

NC Collective Study which concluded that "landfill leachate represents a minor contribution of PFOS [and] [PFOA] . . . mass to overall WWTP influent mass for these compounds." The commenter dismissed pretreating leachate as not being a practical option due to lack of proven technology, pretreatment standards, concentration thresholds for a hazardous substance and stated that PFAS treatment is a finishing step at the drinking water utility. The commenter pointed out that estimated capital costs to implement leachate pretreatment at a moderate-sized landfill to the extent necessary to significantly reduce PFAS range from \$2 million to \$7 million, with nationwide costs totaling \$966 million to \$6.279 billion per year for the solid waste sector. Trace concentrations of PFAS nevertheless would remain in leachate following pretreatment, exposing landfills to CERCLA liability. [0361-Hazardous Waste Management Program; 0459-GFL Environmental]

Response

Issues pertaining to wastewater treatment, irrigation and framing practices, general waste management and the like, are outside the scope of this rulemaking and require no response. EPA does not agree with the commenter(s) that designation of PFOA and PFOS as CERCLA hazardous substances will impose a cost burden on entities that provide drinking water treatment, wastewater treatment, or solid waste management. Regulatory programs and corresponding management practices to address PFAS in these sectors, and the associated costs, are already underway and are not attributable to designation. In addition, the designation would not affect drinking water standards.

Similarly, no PFAS are currently listed, nor being proposed to be listed, as hazardous wastes under RCRA, and the designation of PFOA and PFOS as CERCLA hazardous substances does not require waste (e.g., biosolids, treatment residuals, spent GAC etc.) to be treated in any particular fashion, nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills. See *supra* Section 4.E, 4.F.4, 7, and 8.

The Agency recognizes that certain stakeholders are concerned about CERCLA liability resulting from the designation of PFOA and PFOS as hazardous substances. The only direct impact to the public 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 or their salts and isomers 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 addition, designation does not automatically result in CERCLA liability for any specific release.

For more information concerning CERCLA liability that may arise after designation see Preamble to the Final Rule VI.B.2 (*EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way*). See also the Preamble to the Final Rule Section I (*Executive Summary*).

4.G.2 Biosolids-Related (including Pulp and Paper)

4.G.2-1 The designation will discourage land application of biosolids, which is a beneficial practice and provides a valuable low-cost fertilizer with regulatory safeguards that are lacking for ordinary fertilizers.

Pulp and Paper Industry

The adoption of this proposed Rule will create a significant impact on biosolids management and associated costs for ratepayers, wastewater utilities and biosolids management facilities. The designation will discourage land application of biosolids, which is a beneficial practice and provides a valuable low-cost fertilizer with regulatory safeguards that are lacking for ordinary fertilizer. The designation will shift biosolids management from land application to landfilling, straining capacity of municipal landfills, and potentially causing those landfills to refuse biosolids and shift their disposal to Subtitle C landfills. Utilities, municipalities, POTWs, industrial users, landfills, and others who accept biosolids for land application need viable biosolids management options (safe, environmentally sound, affordable, sustainable practices) and ample time to adapt to new modes of operation, if necessary, to come into compliance with any new regulations regarding PFAS substances. Unless more research is done and standards are published identifying limits of PFOS and PFOA necessary to protect human health and the environment, any amount of PFOA and PFOS in biosolids could potentially lead to liability for utilities, farmers, landowners, and any other party based on their land application. In addition, the pulp and paper industry is already underway a voluntary transition to PFAS-free alternatives, which should be reflected in the preamble. Some commenters pointed out the essential nature of land applied biosolids to farming activities nationwide and noted that EPA's own analysis shows that more than half of the municipal sewage sludge produced in the U.S. is land applied as biosolids (see Interim Guidance on PFAS Destruction and Disposal, U.S. EPA, 2020, at Table 2-3). This benefits both the water utilities who generate biosolids (by providing a viable management option) and all farmers, whether they use biosolids or not, because without the availability of biosolids as a low-cost fertilizer, the costs of traditional fertilizers would skyrocket. The price of fertilizers is already up over 200 percent in 2022 alone. That plus the increases in the price of gas and, especially, diesel fuel, has harmed agricultural production and distribution leading to shortages and skyrocketing prices in the grocery store for all Americans. This is not the time to take regulatory action that exacerbates this already near-crisis situation. [0341-AFBF; 0415-AMCA; 0495-PFAS Regulatory Coalition; 0518-WWP; 0539-NCWQA; 0549-CA Farm Bureau; 0558-SDFBF; 0565-USWAG; duplicate: 0814-WVMWQA]

Impact on POTWs and wastewater

Several commenters noted that in terms of direct costs to local wastewater agencies, the reporting requirements for land application of biosolids would not seem to pose a significant impact on most California clean water agencies that land apply biosolids, to the extent that the statutory default reportable quantity (RQ) is used. However, the commenter noted that it is not clear whether that is true nationally. Specifically, the default reportable quantity is one pound per day for PFOA and PFOS, a mass which is unlikely to be reached in a normal land application scenario and based upon the highest levels found in the recent analytical results from the California State Water Board's 2021 Investigative Order for Publicly Owned Treatment Works (POTWs). In addition, our understanding is that sampling on a daily basis would extremely

costly, particularly considering that there is still no USEPA approved method for sampling PFAS in biosolids. The commenter asserted that any threshold lower than the default is proposed and implemented in the future, this could impose a significant financial impact to wastewater agencies that land apply biosolids. [0346-CASA; fully supported by 0453 (Monterey); 0521 (WMWD); 0531 (EBMUD); 0806 (BACWA); 0809 (OC San); 0307 (Elsinore Valley)]

Several commenters further note that the application of biosolids is also only performed through a legal and permitted process and the use of biosolids is part of a larger sustainability effort. Biosolids are regulated at the federal, state, and local level to ensure protection of public health and the environment, which brings important safeguards (agronomic rate applications; buffers from water sources, wells, etc.; testing; and reporting to State and federal authorities). None of those environmental and public health safeguards apply when fertilizer is used rather than biosolids. [0386-ReWa; 0415-AMCA; 0518-WWP; 0558-SDFBF]

Some commenters noted that under the proposed CERCLA Designation (which notes that "biosolids from wastewater treatment plants and some industrial wastewater that is land applied are also potential sources of contamination" [87 FR 54415, 54427]), biosolids management and disposal would likely fall under the wide umbrella of "releases" and "disposal" and therefore expose public wastewater agencies to liabilities. Further, the placement of a CERCLA hazardous substance on property automatically creates potential remedial liability for the parties involved in the transportation and placement of the hazardous substances on the land, as well as the landowner. Ultimately, these PFOA and PFOS CERCLA designations and the attendant liability could severely curtail this sustainable management option of land application of biosolids, even the levels of PFOA and PFOS in biosolids may ultimately not be found to create significant health or environmental risks. The mere perception of risk will reduce public acceptance of land application of biosolids, and in the absence of risk-based information, biosolids users and the general public will assume that the only safe level is zero, and the most sustainable method of biosolids management will be put in serious jeopardy. Land application of biosolids containing low levels of existing CERCLA hazardous substances has occurred safely under federal and state regulations for decades. Before taking any regulatory action, EPA must clarify that a CERCLA designation will not impact the land application of municipal biosolids in any way. Moreover, EPA should only proceed once Congress revises the Superfund law to protect public utilities and their ratepayers from this unwarranted and unintended liability. [0341-AFBF; 0386-ReWa; 0453-IAWA; 0485-MI Farm Bureau; 0495-PFAS Regulatory Coalition; 0506-Conference of Mayors; 0509-TDEC; 0549-CA Farm Bureau; 0565-USWAG]

A commenter noted that the State of Maine has already implemented a ban on the land application of municipal biosolids regardless of PFAS concentration, which has made costs for wastewater treatment skyrocket, prevented farms from using their nutrients, and exposed farms that have already accepted biosolids to liability. The proposed CERCLA designations would exacerbate these issues nationwide. [0485-MI Farm Bureau]

A commenter stated that EPA must ensure that safe, environmentally sound, affordable, and sustainable biosolids management practices exist for POTWs. Currently, there are no biosolid management options that would allow a POTW to avoid CERCLA liability, despite being passive receivers of PFAS. POTWs must be given the time and tools to address the challenge of biosolids management without being faced with unprecedented CERCLA liability in the interim. [0496-NEORSD]

A commenter requested that EPA allow municipalities, POTWs, industrial users, landfills, and others who accept biosolids for land application ample time to adapt to new modes of operation, if necessary, to come into compliance with any new regulations regarding PFAS substances. [0430-Elyria]

A number of commenters asserted that the premature designation of PFOA and PFOS as hazardous substance under CERCLA would create a significant impact on biosolids management and associated costs ratepayers, wastewater utilities and biosolids management facilities. Commenters stated that there are only three management options (land application, landfilling, and incineration) for the more than 7 million dry tons of municipal biosolids generated by U.S. treatment plans each year. These options which all pose their own risks and concerns as it relates to CERCLA's application of cleanups and liability could be significantly impacted by the Rule. Some commenters also noted that limiting beneficial use and replacing with landfilling will simply result in PFOA and PFOS being returned to treatment plants as leachate perpetuating the cycle or emitted into the air from incineration. [0355-City of Los Angeles Sanitation and Environment (LASAN), 0538-National Association of Clean Water Agencies (NACWA), 0493-Protecting Our Water, Environment, and Ratepayers Coalition (POWER!), 0318-Madison Metropolitan Sewerage District (MMSD), 0372-NEW Water, 0325-Oak Ridge National Laboratory (ORNL), 0480-National Waste & Recycling Association (NWRA) and Solid Waste Association of North America (SWANA), American Public Works Association (APWA) et al, 0396-Michigan Water Environment Association (MWEA)]

Liability

A number of commenters noted the absence of risk-based information on PFOA in biosolids and called for EPA to conduct a biosolids risk assessment. They mentioned that there are few options for disposal and management of biosolids (e.g., landfilling, incineration), each carrying its own risks. Some commenters expressed concerns that the designation could simply change the type of risk rather than eliminate the risk, as parties sought alternatives. In addition, the designation could result in greater disposal liability and landfill disposal costs which may be passed on to ratepayers and utilities. Further, the rule change might (1) increase costly and expensive cross-state long-hauling and (2) reduce opportunities for reusing the solids for compost land applications. Many commenters urged EPA to delay the rule change until better solutions could be identified.

Numerous commenters urged EPA to complete its PFAS biosolids risk assessment which is not expected until 2024 to provide clarity and a science-based approach and guide ongoing land application where appropriate. Commenters also stated that a biosolids risk assessment could be the basis for a future biosolids regulatory standard. A biosolids disposal standard might provide a CERCLA defense to the biosolids liability going forward but would not provide liability relief retrospectively. The administrative record for this rule fails to consider the implication on the management of biosolids retrospectively and prospectively. [0538- National Association of Clean Water Agencies (NACWA), 0372-NEW Water, 0453-Illinois Association of Wastewater Agencies (IAWA), 0318-Madison Metropolitan Sewerage District (MMSD),0397-Massachusetts Water Resources Authority (MWRA) Advisory Board, 0505-Virginia Association of Municipal Wastewater Agencies, Inc. (VAMWA), 0508-Water Environment Federation (WEF), 0395-Massachusetts Water Resources Authority (MWRA), 0341-American Farm Bureau Federation (AFBF), 0549-California Farm Bureau, 0365-Environmental Protection Network (EPN)]

A commenter stated that at this time only non-renewable, non-destructive methods for PFAS removal exist and that therefore they are responsible for disposing of concentrated PFAS containing biosolids and filter media. The commenter was concerned that the rule creates disposal liability, substantially increases landfill disposal costs and reduces opportunities to beneficially reuse treatment solids for compost land applications. [0299-City of Thornton, CO]

A few commenters also noted that although the levels of PFOA and PFOS found in biosolids may not pose health or environmental risks, the mere perception of risk and the threat of future liability as potential responsible parties (PRP) will reduce demand. In the absence of risk-based information, biosolids users will assume that the only acceptable level is zero. [0355-City of Los Angeles Sanitation and Environment (LASAN), 0538- National Association of Clean Water Agencies (NACWA)]

A few commenters state that these considerations require that EPA not designate PFOA and PFOS as hazardous wastes under CERCLA and instead, work with Congress to address this concern through a Superfund amendment before establishing any PFAS chemicals as hazardous substances under CERCLA. [0386-ReWa; 0492-SCWQA; 0518-WWP]

Landfilling:

One commenter stated that the designations could also have serious environmental and health costs. For example, transporting biosolids to Subtitle C hazardous waste sites also potentially could require a huge effort, on the order of 250,000 dump trucks (carrying 20 tons each) traveling 500 miles each year. The result could be a significant increase in emissions of greenhouse gases and conventional air emissions, as well as increased vehicle accident risks and more traffic in disadvantaged communities. Given current truck driver shortages, this also could disrupt the supply chain. [0423-AF&PA]

Many commenters expressed concern that a CERCLA designation for PFOA and PFOS will limit biosolids management options. POTWs currently manage their biosolids through landfilling, land application, or incineration. Under the Proposed Rule, biosolids management would likely fall under the wide umbrella of "releases" or "disposal" and therefore expose POTWs to liability. Each of the three management options could therefore be significantly impacted by the proposed rule. A reduction in land application of biosolids would lead to greater demand for landfill disposal of these products. [0351-City of St Charles; 0386-ReWa; 0423-AF&PA; 0449-Weatherford; 0485-Michigan Farm Bureau; 0492-SCWQA; 0496-NEORSD; 0506-Conference of Mayors; 0518-WWP; 0429-Fort Worth; 0520-WPC]

Some commenters note that municipal landfills may refuse to take biosolids for fear of incurring CERCLA liability, forcing POTWs to dispose of biosolids at a Subtitle C landfill. [0351-City of St Charles; 0386-ReWa; 0449-Weatherford; 0492-SCWQA; 0518-WWP; 0429-Fort Worth]

Further, a few commenters noted that if municipal landfills do accept biosolids, the existing landfill capacity will quickly be strained. Potentially large amounts of biosolids that have no available method of disposal will be stored on-site at POTWs for extended periods of time. [0423-AF&PA; 0496-NEORSD; 0506-Conference of Mayors; 0520-WPC]

A few commenters stated that these management shifts will result in significant costs. Increased demand for landfilling services will drive up the cost of Subtitle D disposal; if Subtitle D landfills refuse to accept biosolids, utilities will be forced into Subtitle C disposal at greater cost.

These cost increases will be passed through to consumers and water/wastewater customers. [0351-City of St Charles; 0485-Michigan Farm Bureau; 0496-NEORSD]

A few commenters also pointed out that EPA has long encouraged and supported the application of biosolids to agricultural property as a valuable low-cost means of managing biosolids. While beneficially used on farm fields, it also prevents these substances from taking up landfill space or requiring expensive and energy-intensive treatment and disposal. [0341-AFBF; 0549-CA Farm Bureau; 0558-SDFBF]

Land application of biosolids provides a valuable service to communities by sustainably utilizing the byproduct instead of taking up landfill space. While PFAS chemicals have been found in biosolids, landowners that have responsibly applied these substances according to all laws and regulations should not be penalized for these actions.

Some commenters stated that the CERCLA designation would result in increased landfilling which may be problematic in states like Maine which completely banned land application of municipal biosolids prior to any risk assessment of PFAS and without any statewide effort to understand the scope of the issue (e.g., presence or concentration) or whether landfills have the capacity to accept the sheer tonnage of biosolids created. Bans on landfilling may result in long hauling distances to fewer landfills that will accept biosolids. A commenter stated that to landfill all biosolids and residuals at a Massachusetts treatment plant would result in an additional cost of at least \$10 million annually. Another commenter stated that it would cost their sewer district \$2.5 million annually to divert all biosolids from land application to landfills. Furthermore, increased landfilling may also adversely impact EJ communities which tend to be located near landfills. [0355-City of Los Angeles Sanitation and Environment (LASAN), 0396-Michigan Water Environment Association (MWEA), 0395-Massachusetts Water Resources Authority (MWRA), 0318-Madison Metropolitan Sewerage District (MMSD), 0372-NEW Water, 0325-Oak Ridge National Laboratory (ORNL), 0538-National Association of Clean Water Agencies (NACWA)]

A few commenters were concerned that the CERCLA designation for PFOA and PFOS may preclude public wastewater (and drinking water) utilities from sending biosolids and drinking water residuals to municipal (non-hazardous waste) landfills. These commenters suggested that EPA should work with Congress to address this (and other) concerns through a Superfund amendment instead of designating PFOA and PFOS as hazardous wastes under CERCLA at this time.

Because the proposal likewise creates legal risks for landfills, it may also lead to Subtitle D landfills refusing to accept materials known or suspected to contain PFAS compounds. Such an outcome would not only increase the distances biosolids may have to be transported, but also further tax the limited number of Subtitle C landfills throughout the country. As such, the proposal could create situations where public clean water agencies cannot find places to bring their biosolids or are faced with limits on tonnage that landfills can accept. [0539-North Carolina Water Quality Association (NCWQA), 0415-Association of Missouri Cleanwater Agencies (AMCA)]

Incineration:

A commenter stated that forced change to incineration or landfilling as hazardous waste is neither cost-effective, nor protective of the environment and would impact water and sewer affordability for EJ populations. The capital investment in the incinerator infrastructure alone

would be \$144,630,000 between two Columbus wastewater plants not taking into account additional staffing, maintenance, and ash disposal costs. [0432-City of Columbus OH, Department of Public Utilities (CDPU)]

Several commenters pointed to decreasing incineration capacity due to stricter regulations and that reverting to increasing capacity would not be quick, inexpensive, or easy to permit. Another commenter stated that it would cost their sewer district upward of \$4 million annually to divert all biosolids from land application to incineration. [0396-Michigan Water Environment Association (MWEA), 0372-NEW Water, 0325-Oak Ridge National Laboratory (ORNL), 0538-National Association of Clean Water Agencies (NACWA)]

Beneficial reuse land application:

Absent an Exemption, Designation will Severely Limit Biosolids Land Application: Numerous commenters stated that lengthy experience supports that biosolids are safe and highly beneficial for local communities; biosolids provide farmers with an excellent source of nutrients and combat climate change by enabling carbon sequestration into the soil and helping farmers and property owners avoid energy-intensive manufactured inorganic fertilizer. A 30-year international study published in 2011 stated the increasing body of evidence demonstrates that the majority of compounds studied do not place human health at risk when biosolids are land applied on farmland (Clarke, B. O., & Smith, S. R. (2011). Review of 'emerging' organic contaminants in biosolids and assessment of international research priorities for the agricultural use of biosolids. Environment International, 37, 226–247.

https://doi.org/10.1016/j.envint.2010.06.004). Results from a long-term Washington State University study have shown that, despite likely trace amounts of PFAS in biosolids, significant continuing yield increases from biosolids applications compared with the control or mineral fertilizer additions (Cogger, C. G., Bary, A. I., Kennedy, A. C., & Fortuna, A.-M. (2013). Long-Term Crop and Soil Response to Biosolids Applications in Dryland Wheat. Journal of Environmental Quality, 42, 1872–1880. https://doi.org/10.2134/jeq2013.05.0109.) Additionally, most farms do not apply biosolids annually. Rather, it is more common for biosolids to be applied every four years with regional long-term studies indicating that it would take applying biosolids annually for more than 300 years to achieve the lowest levels of harmful cumulative loading in groundwater or humans (WA PFAs Chemical Action Plan, pg. 429). Commenters stated that the proposed designation's severe liability implications will have a chilling effect on land application, not to mention affect the public's perception thereof. Commenters further noted that concerns that the proposed designation will inhibit the market for biosolids are far from speculative: Maine has already enacted a total land application ban due to PFAS concerns. POTWs could see increased difficulties in storing and land applying biosolids, which cannot be eliminated from the treatment process. Should this rulemaking proceed without the requested exemptions, municipal biosolids will quickly become a national issue. An exemption is necessary to preserve the critical, sustainable, and environmentally beneficial practice of biosolids land application; absent this option, facilities would have to dispose of such materials in a Subtitle D landfill, resulting in huge expense to systems nationwide. [0276-DCWA/City of Vancouver; 0370-Oregon ACWA; 0372-NEW Water; 0373-MMSD; 0395-MWRA; 0396-MWEA; 0504-VBC; 0505-VAMWA; 0508-WEF; 0511-WateReuse; 0538-NACWA; 0350-Henderson; 0351-St Charles; 0352-Clark County; 0375-St. Louis; 0395-MWRA; 0453-Monterey; 0465-JCW; 0478-NYC; 0496-NEORSD; 0521-WMWD; 0527-Metro; 0562-NBC; 0804-SPR; 0809-OC San; 0378-MSD); 0406-WAC; 0457-GCDCWWS]:

Several commenters pointed out that farmers are not the only entities land applying biosolids: many other businesses and industries rely on biosolids. These include composting, local nurseries, rental unit managers, and individual residents who pick up free biosolids from utilities nationwide or purchase compost that is mixed with treated biosolids for residential use on lawns and gardens. How will such a designation affect the use of biosolids for these ubiquitous purposes as well as their past use? If PFOS or PFOA is found in the compost or biosolids fertilizers, landowners and other users would risk becoming subject to CERCLA's liability or clean up requirements. [0415-AMCA; 0449-Weatherford; 0506-Conference of Mayors; 0509-TDEC; 0518-WWP; 0429-Fort Worth]

A few commenters were concerned that the proposed rule will eliminate or curtail the option for sustainable and beneficial reuse of biosolids as fertilizer for agriculture, recreational properties, and general households. Another commenter stated that landfilling biosolids as waste rather than a resource contradicts its city climate change commitments by reducing landfilled organic waste. [0380-Little Blue Valley Sewer District, 0432-City of Columbus OH, Department of Public Utilities (CDPU), 0538- National Association of Clean Water Agencies (NACWA)]

A number of commenters stated that communities need time and tools to address biosolids management and avoid unfair liability and cannot rapidly change biosolids management options and treatment technologies due to investments in local and regional facilities and infrastructure to support biosolids management, and contracts with haulers, farmers, and other recipients for their use and transport. Also, in areas with limited surface disposal, landfill, or incineration capacity, hauling to other locations will translate into significant transportation efforts and costs, including further greenhouse gas emissions. One commenter reported total investments of \$50.5 million in biosolids land application in less than a decade for a new biosolids land application facility at one of the city's WWTPs to handle up to 8 million gallons of biosolids and renovation of biosolids storage tanks at another WWTP handling 5.6 million gallons of biosolids. Another commenter pointed to a \$145 million investment of rate payer dollars into a Residuals Pellet Plant. Another commenter stated that the Rule could result in significant additional disposal cost if land application was no longer an option. Also, any amount of PFOA and PFOS in biosolids will lead to utilities, farmers and landowners falling into one of CERCLA's potential responsible party (PRP) categories because of land application which contradicts EPA's "polluter pays" approach. [0348-Bowling Green Municipal Utilities (BGMU), 0432-City of Columbus OH, Department of Public Utilities (CDPU), 0355-City of Los Angeles Sanitation and Environment (LASAN), 0396-Michigan Water Environment Association (MWEA), 0395-Massachusetts Water Resources Authority (MWRA), 0372-NEW Water, 0397-Massachusetts Water Resources Authority (MWRA) Advisory Board, 0538- National Association of Clean Water Agencies (NACWA)]

A commenter provided survey results of unit costs for residuals management which found that the costs of hazardous waste disposal was 10 to 50 times more expensive compared to land application of biosolids and that the economic impact of a CERCLA designation shifting from the present typical practice to hazardous waste incineration is more than \$3.5 billion, an increase of 80 to 230% in biosolid management costs which typically represents 8-17% of total operating costs (Hazen & Sawyer, 2022). The commenter stated that EPA estimates that more than 4.5 million dry metric tons of wastewater biosolids are produced on an annual basis, more than 40%

of which are land applied (EPA, 2022f) and that, according to the Water Environment Federation (WEF), the average person generates about 37 pounds of biosolids annually, collectively 5.8 million dry tons each year (WEF, 2022; NBDP, 2022a). It is also estimates that 2.3 million dry tons of biosolids are used by agriculture; in fact, 29 states used more than half of their biosolids for beneficial use (NBDP, 2022a; NBDP, 2022b). [0543-American Water Works Association (AWWA)]

A few commenters stated that the available use and disposal options for biosolids and residuals are already limited and protective by Part 503 joined with applicable NPDES permit conditions. A commenter stated that "releases" of hazardous substances from the land application of sewage sludge authorized under 40 CFR 503 also constitute a federally permitted activity under existing CERCLA statutes and should be acknowledged by EPA as part of the rule. [0355-City of Los Angeles Sanitation and Environment (LASAN), 0395-Massachusetts Water Resources Authority (MWRA)]

A commenter noted that despite Maine's cessation of sludge application, some produce and animal byproducts – manure, compost, milk, and carcasses – inevitably will contain some level of PFAS. Nutrient management on farms (using these byproducts to recycle nutrients back into fields and crops) is an essential and practical aspect of farming. Therefore, the commenter stated that EPA must become more aware of the interplay between PFAS and agricultural operations and recognize that designating PFOA and PFOS as a hazardous substance complicates the landscape where farmers are trying to adapt in real-time to PFAS on their farms and create management strategies that continue to utilize soils, water, and byproducts containing PFAS. [0547-Maine Department of Agriculture, Conservation and Forestry (DACF)]

A commenter states that as drafted, the preamble does not accurately describe the pulp and paper industry's transition out of PFAS (see 87 Fed. Reg. 54418-19 outlining uses of PFAS in the U.S.). If EPA finalizes the rule, commenter requested that the preamble be revised to accurately reflect the industry's timely and voluntary transition out of PFAS. Members of the pulp and paper industry have in recent years transitioned to PFAS-free alternatives and have virtually completed their voluntary transition out of FDA-approved short-chain PFAS. Currently, FDA-approved PFAS is used in less than 0.1% of AF&PA company members' total production (based on information collected in 2020, company member products containing intentionally added PFAS represented less than 0.1 percent of AF&PA members' paper and paperboard production). AF&PA anticipates its members will entirely complete the ongoing transition out of FDA-approved short-chain PFAS by the end of 2023, if not sooner. [0423-AF&PA; 0520-WPC]

These commenters state that the preamble for the proposed rule does not address the potential impact of the hazardous substance designations on biosolids or mill residuals, nor does it analyze the questions on the impact of the proposed designations on municipal biosolids or mill residuals. If the designation created significant stigma and perceived risk about continuing to use mill residuals as soil amendments, and mill residuals were sent to Subtitle C landfills, the impacts could be very substantial, potentially jeopardizing mill jobs that pay well above the prevailing wage in small rural communities without providing an appreciable benefit. [0423-AF&PA; 0520-WPC]

Response

As explained in the preamble to the Final Rule Section VII.A.3 (*Authority to Create Exclusions from the Designation*), EPA declines to create exceptions for certain uses of PFOA and/or PFOS in this rulemaking. See also Section 2.A.4 (*Authority to Create Exclusions/Exemptions*) in this document.

For this final rule, and after consideration of public comments, EPA evaluated potential liability outcomes that may arise after designation and determined that designation is warranted. See Preamble to the Final Rule, Section VI (*The Totality of the Circumstances Confirms that Designation is Warranted*); *supra* Section 4.E, 4.F.4 and 4.F.8, which addresses comments and issues related to potential liability and response actions that may arise after designation as well as comments suggesting that designation will require facilities to adjust waste treatment, disposal, and management practices.

With respect to comments concerning "federally permitted release" as defined in CERCLA section 101(10), please see Preamble to Final Rule Section VII.D.1.h; *supra* Section 4.A.8. Whether a particular release is a "federally permitted release" is determined on a case-by-case basis. See supra Section 4.F.7 for more information.

EPA acknowledges that CERCLA section 107(d)(1)-(2) limits CERCLA liability for certain actions in which a person, state government, or local government is "rendering care or advice," but declines commenters suggestion that EPA should explicitly provide that this provision creates an exception for emergency responders that use AFFF (including training exercises that use AFFF). Whether 107(d) is applicable to a certain actor or actions is fact-specific and the defense is unavailable in cases of negligence or gross negligence. CERCLA section 107(d)(1) provides that "no person shall be liable under [CERCLA] as a result of actions taken or omitted in the course of rendering care, assistance, or advice in accordance with the [NCP] or at the direction of an on-scene coordinator . . . with respect to an incident creating a danger to public health or welfare or the environment . . . "unless the person acted negligently. Section 107(d)(2) applies only to state or local governments and limits CERCLA liability for "actions taken in response to an emergency created by the release or threatened release of hazardous substance generated by or from a facility owned by another person," The limitation on liability is unavailable for costs or damages that result from "gross negligence or intentional misconduct by the state or local government." Not only does it remain unclear what factual scenarios would likely suit the confines of these defenses, but EPA also questions whether it has the authority to prescribe such a limitation on liability. For example, the D.C. Circuit has held that, in enacting CERCLA, Congress reserved resolution of liability issues to the judiciary, not the Agency. 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.").

Comments concerning the management, use, disposal, landfilling, treatment, and transport of biosolids, mill residuals, or other fertilizers and soil amendments, including potential costs, are outside the scope of this rule. Regulatory programs and corresponding management practices to address PFAS in biosolids and mill residuals are already underway and are not attributable to designation. See Preamble to Final Rule Section VI, V.H, I, and J, and *supra* Section 4.E; 4.F.4, 7, and 8; *infra* Section 6.A.2,-3, 5, 7-8, 6.B.1, 5-6, 6.E.5.

EPA is aware of the challenges facing facilities that produce and apply biosolids. In July 2023, EPA published Joint Principles for Preventing and Managing PFAS in Biosolids. These principles define key areas for regulators and stakeholders to work collaboratively to ensure the

fate and transportation of PFAS contaminated biosolids do not result in harm to human health or the environment. Federal and state agencies, wastewater utilities, community partners, farmers and agribusinesses, engineers, environmental justice leaders, educators, residents, and businesses are all part of the solution. These shared principles affirm the importance of working collaboratively and strategically to make progress toward effectively managing biosolids and protecting public health.

Pursuant to these principles, EPA commits to: (1) protect communities, (2) reduce the discharge of PFAS to prevent the contamination of biosolids, (3) aim to preserve flexibility and availability of options for the use and disposal of biosolids, while prioritizing public health protection, (4) ensure continued safety of the food supply and support impacted farmers and ranchers, (5) educate stakeholders and communicate risk, (6) build capacity, and (7) embrace transparency and innovation. EPA will also identify what efforts are needed to maintain a range of options to manage municipal biosolids that contain PFAS safely and effectively, including the three main biosolids management practices: land application, disposal in solid waste, landfills, and incineration.

EPA disagrees with comments that EPA must establish cleanup levels in advance of designating PFOA and PFOS as CERCLA hazardous substances. CERCLA and the NCP provide a framework for identifying those releases that pose unacceptable risk and warrant a response. Please see preamble to the Final Rule Section VII.B.1. For more information regarding how CERCLA and the NCP operate to prioritize response and identify unacceptable risk, please see Preamble to the Final Rule Section II.E and *supra* 4.F.7

Comments regarding state laws and regulations pertaining biosolids are outside the scope of this rule. Nevertheless, EPA does not agree with the commenter's suggestion that the impacts of the designation would be similar to impacts associated with Maine's ban on the land application of municipal biosolids regardless of PFAS concentration. This example is not transferrable to the proposed CERCLA since designation does not result in a ban of biosolids applications.

EPA disagrees that the Agency should not designate because the commenter believes there are insufficient methods to treat, destroy, and dispose of PFOA and PFOS. There are currently methods available to address PFOA and PFOS contamination, and the Agency and other parties continue to work to improve those methods. EPA's PFAS Destruction and Disposal guidance describes commercially available methods. EPA does not preclude the use of emerging technologies, which may also be appropriate, depending on the materials. See *supra* 4E1-5 (responding to comments on treatment, destruction and disposal of PFAS; see also the Preamble to the rule VII.H. Commenters may also refer to EPA's "Interim Guidance on the Destruction and Disposal of [PFAS] and [PFAS] Substances and Materials Containing [PFAS] and [PFAS] Substances – Version 2 (2024)" for additional information, available here: https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002 content.pdf.

To learn more about the Biosolids Program, please visit: https://www.epa.gov/biosolids. EPA is working diligently to complete its biosolids risk assessment for PFOA and PFOS and expects to complete the assessment by December 2024. More information, please visit: https://www.epa.gov/biosolids/risk-assessment-pollutants-biosolids#pfas.

Contrary to commenters assertions, EPA expects designation to have a positive impact on environmental justice communities. The Agency believes that this action is likely to reduce

existing disproportionate and adverse effects on people of color, low-income populations, and/or indigenous peoples. EPA also expects that cleaning up sites also promotes economic benefits, such as improved property values and making land available for reuse. See the Preamble to the Final Rule Sections VI.B. (*Advantages of Designation*) and VI.A.1.d. (*Environmental Justice (EJ) Considerations for Designation*)).

With respect to commenters suggestions regarding legislative options for addressing concerns, EPA routinely works with Congress on legislative efforts and is available to provide technical assistance to Congress on legislation if requested.

4.G.3 Airports/Aviation/Transportation/Firefighting Sector

4.G.3-1 The EPA has not considered the impact that designation will have on airports, aviation, and firefighting activities, including the use of AFFF

Some commenters noted that the FAA requires Part 139 airports to comply with relevant DOD Military Specifications ("MIL-SPEC") in certain firefighting efforts. The FAA's compliance guidance on Aircraft Firefighting Agents states that foam concentrates used by Part 139 airports in their firefighting equipment must meet the performance test requirements of the MIL-SPEC MIL-F-24385F to comply with federal regulations (FAA Advisory Circular [AC] 150/5210-6D, Aircraft Fire Extinguishing Agents, July 8, 2004). Additionally, the most recent FAA CertAlert on Extinguishing Agent Requirements notes that while MIL-SPEC MIL-F-24385F no longer requires the use of fluorinated chemicals, "the existing performance standard for firefighting foam remains unchanged" and Part 139 certificate holders must remain in compliance through use of an approved firefighting foam that satisfies the performance requirements set forth in the MIL-SPEC (FAA, National Part 139 Cert Alert No. 21-05, Part 139 Extinguishing Agent Requirements, Oct. 4, 2021). While the current MIL-SPEC allows for the use of AFFF that is PFAS-free, there is no product available on the market that meets the MIL-SPEC requirements as currently written (MIL-SPEC MIL-F-24385F, Fire Extinguishing Agent, Aqueous Film Forming Foam [AFFF] Liquid Concentrate, for Fresh and Seawater, Jan. 7, 1992 and DOD Office of the Assistant Secretary of Defense for Energy, Installations, and Environment, Report on Department of Defense's Per- and Polyfluoroalkyl Substances Task Force Activities at B-3, September 2022). While DOD published a draft MIL-SPEC for a new fluorine-free foam in May 2022, a final MIL-SPEC for fluorine-free foam has not yet been issued. The EPA's Proposed Rule is not consistent with the guidance issued by DOD and FAA, creating confusion for many regulated entities. The lack of coordination between federal agencies – FAA requiring the use of AFFF and EPA declaring AFFF components to be hazardous substances – puts airports in an untenable position and could cause aviation disruptions and potential air safety concerns. Commenters urged the EPA to coordinate with FAA and DOD on the timeline for these initiatives and the development of critically needed guidance on the issues identified and stated that the EPA should withdraw the Proposed Rule until the DOD and the FAA determine a path forward for an AFFF alternative that is equally as protective and commercially available. [0411-A4A; 0424-ACI-NA; 0436-Manhattan, KS; 0530-IAFC; 0555-AAAE]

A commenter added that Federal military bases and other federal facilities also were expected to use the military specification. If a local fire department was first-due for a fire at an airport or federal facility or it was supplying assistance through mutual aid, the local fire department also would use AFFF foam. These fire departments would be expected to use AFFF foam when

fighting fires and also to train to fight fires that required ARFF response. In addition, the local fire department would store AFFF on its property for use. Further, the 2018, NFPA 403, Standard for Aircraft Rescue and Fire-Fighting Services at Airports, lists AFFF as one of the primary agents for fighting aviation fires using hydrocarbon fuels ("Primary Agents," NFPA 403, Standard for Aircraft Rescue and Fire-Fighting Services at Airports, National Fire Protection Association, 2018 Edition). These NFPA standards are voluntary consensus standards that set performance benchmarks for a variety of fire service operations ranging from firefighting operations; staffing; training; and even firefighter physicals. Fire departments strive to meet these standards. If the federal government and NFPA recommend the use of AFFF foam, then fire departments will use AFFF to fight airport and hazmat fires. [0530-IAFC]

A few commenters also point out that GA airports (those not certified under Part 139) have complied with FAA guidance on minimum ARFF standards and requirements in accordance with their federal grant obligations. The FAA identified 3,287 airports that are deemed significant and important to the nation's air transportation system (Federal Aviation Administration, National Plan of Integrated Airport Systems [NPIAS] 2023–2027 [2022]; about 518 of these airports are certificated under Part 139, while the remaining 2,769 are considered uncertificated and generally known as GA airports because they serve primarily or exclusively non-commercial aircraft operations. However, because of their importance to the national airport system, Congress makes these GA airports eligible for federal grant funding through the Airport Improvement Program (AIP) and, most recently, the Infrastructure Investment and Jobs Act (IIJA), popularly known as the Bipartisan Infrastructure Law (BIL) (Pub. L. No. 117-58, 135 Stat. 429; 2021). All airports, including GA airports, identified in the NPIAS are eligible for both AIP and BIL grants. The commenter notes that GA airports have relied upon FAA guidance and requirements as it relates to ARFF services, including, but not limited to, the procurement, storage, and use of AFFF. [0411-A4A; 0555-AAAE]

These same commenters asserted that the regulation of aircraft, aircraft operations, and safety falls within the primary and exclusive jurisdiction of the FAA. The Federal Aviation Act of 1958 ("Aviation Act") establishes "a uniform and exclusive system of federal regulation" of aircraft operations that preempts state and local regulation (City of Burbank v. Lockheed Air Terminal, Inc., 411 U.S. 624, 639 [1973]; see also Am. Airlines v. Dep't of Transp., 202 F.3d 788, 801 [5th Cir. 2000] quoting Northwest Airlines, Inc. v. Minnesota, 322 U.S. 292, 303 [1944]; 49 U.S.C. §§ 40101, 40103, 44701: "[f]ederal control [over aviation] is intensive and exclusive.") This pervasive federal regulatory scheme extends not only to aircraft in flight, but also to aircraftrelated operations on the ground [See, e.g., 49 U.S.C. § 40103(b)(2)(B)-(C); City of Houston v. FAA, 679 F.2d 1184, 1195 (5th Cir. 1982).] For over 50 years, FAA has regulated ARFF services and programs at commercial service airports for the purpose of ensuring the safety of the traveling public. In 1970, Congress provided FAA with the authority to issue "airport operating certificates" (AOC) to airports that serve air carriers certificated to conduct passenger airline service and establish minimum safety standards for the operation of such airports (see Airport and Airway Development Act of 1970, Pub. L. No. 91-258, § 51, 84 Stat. 219, 234). This authority specifically directed FAA to include standards and requirements in the AOC relating to the "operation and maintenance of adequate safety equipment, including firefighting and rescue equipment" capable of accessing airport runways 37 Fed. Reg. 12,278; June 21, 1972, final rule). Because the Aviation Act reserves to the FAA primary and exclusive jurisdiction over matters related to aircraft operations and safety, the use of AFFF as the safest method of protection against aviation-related fires therefore falls within the purview of the FAA and cannot be

regulated or infringed upon by the EPA [See City of Burbank, 411 U.S. at 639. See also Abdullah v. Am. Airlines, Inc., 181 F.3d 363, 370 n.10 (3d Cir. 1999) (aviation regulation is an area where "[federal control is intensive and exclusive")]. EPA has previously recognized that it should not set forth regulations that could have the effect of compromising the safety of aircraft operations or unduly constraining aircraft operations [See EPA Final Rule, Effluent Limitations Guidelines and New Source Performance Standards for the Airport Deicing Category, 77 Fed. Reg. 29168, 29177 (May 16, 2012) (EPA declines to mandate use of specific technologies at space constrained airports like LGA, JFK and EWR because it was "unable to develop regulatory provisions that would give airports the flexibility they need to avoid significant operational issues and delays"); at 29178-79 (technology mandates inappropriate where they may "lead to unacceptable safety concerns" and "EPA agrees that delays must be a factor in considering today's possible requirements and recognizes that such delays fundamentally affect U.S. and international business and recreational interests")]. In light of these considerations, EPA previously declined to impose strict regulations on airport de-icing processes due to safety and operational concerns. The same considerations apply in this rulemaking. EPA's Proposed Rule could affect the airline industry in numerous ways, as discussed above. In addition to increasing the likelihood of safety and operational issues for the aviation industry, the Proposed Rule is likely to slow operations that support airline operations due to supply chain issues with replacements for AFFF. Such delays will impact a wide variety of support operations. EPA should consult with the FAA and DOD to understand fully the potential safety and operational concerns regarding implementation of the Proposed Rule to the aviation industry. In the meantime, EPA should not move forward with finalizing the Proposed Rule. [0411-A4A: 0555-AAAE

Several commenters asserted that the proposed rule is premature because the Federal government has not identified a technically feasible PFAS-free AFFF for use in aviation fire suppression activities. Pursuant to Section 332 of the 2020 National Defense Authorization Act (NDAA), the Secretary of the U.S. Navy is required to publish a new MIL-SPEC by January 31, 2023 (NDAA of 2020, Pub. L. 116-92, div. A, title III § 322(a)(1), 133 Stat. 1307-1310, Dec. 20, 2019). The DOD PFAS Task Force directed the U.S. Navy to ensure that qualified PFAS-free agents have viscosities similar to AFFF to minimize time and cost necessary to change from AFFF to PFAS-free agents in existing systems (DOD Office of the Assistant Secretary of Defense for Energy, Installations, and Environment, Report on Department of Defense's Per- and Polyfluoroalkyl Substances Task Force Activities at 11, September 2022). As a result, the FAA expects that the U.S. Navy will provide a specification for a fluorine-free agent by January 31, 2023, and this specification will subsequently be adopted by the FAA for use by Part 139 jurisdictional airports. As these deadlines have been previously extended, the date on which the PFAS-free MIL-SPEC is issued could be delayed beyond that date. [0411-A4A; 0424-ACI-NA; 0436-Manhattan, KS; 0555-AAAE]

[0411/A4A]: A commenter stated that the Proposed Rule is duplicative of other existing statutory schemes that are better suited to protect public health and the environment from PFOA and PFOS. The EPA has stated the proposed rule is necessary to increase transparency of PFAS releases to federal, state and local governments. The commenter's members operate almost exclusively upon properties managed by local government entities. Airport authority leases impose environmental rules and regulations that are often broader and more expansive than state and federal laws, and commenter members are required to report releases of AFFF to these airport authorities. As such, the Proposed Rule is not necessary to enhance the transparency of

aviation-related releases of PFAS that might occur. Additionally, several states have adopted stringent standards for PFOA and PFOS. This framework, combined with the fact that PFOA and PFOS have not been manufactured in the United States in more than a decade, render the benefits of the Proposed Rule marginal in terms of protecting the public from PFOA and PFOS contamination, and serve only to impose strict liability upon entities such as the airlines without regard for the consequences of doing so.

A commenter's members (liquid terminal facilities) are subject to federal Occupational Health and Safety Agency (OSHA) requirements relating to firefighting and safety. Specifically, OSHA requirements in 29 C.F.R. § 1910.106 (2022) mandate how liquid terminals, which handle and store flammable liquid products, must use systems to combat the unique fire characteristics of these liquid products. For decades, OSHA requirements have meant liquid terminals must use PFAS-based firefighting foams, which have been until recently the only options approved by fire protection standard-setting bodies. As many as 35 fluorine-free foam products in total have credible approvals/listings from approval authorities like UL. However, not all of these foams are approved under UL 162 – which is required for a foam to be certified for use at a storage tank or bulk liquid terminal per OSHA regulation. UL 162 is unique in that it effectively lists the foam as a system versus as just a concentrate. When a foam is submitted for a test, it must be accompanied by the discharge device(s) and proportioning equipment with which it will be listed (See https://www.ul.com/services/firefighting-foam-protection-class-b-combustible-liquids). This is because a particular foam and a particular model of a foam applicator may each be listed but may not be compatible with each other. While some fluorine-free foams have recently become UL listed, those foams must still be listed with applicator equipment.

Furthermore, those foams "are not a 'drop in' replacement for AFFF. However, some can be made to perform effectively as an AFFF alternative with proper testing and design (i.e., with higher application rates/densities)" (Fire Protection Research Foundation, Evaluation of the fire protection effectiveness of fluorine free firefighting foams, at xii, 2020). FPRF reported that FFFs typically required between 1.5 to 3 times the application rates to produce comparable performance (i.e., 2:00 extinguishment times) for the hydrocarbon fuels (i.e., heptane and MILSPEC gasoline) (Id. at 70). FPRF also called for further research for certain fuel types (i.e., crude oil, kerosene based, polar solvents); general chemical compatibility between surfactants and fuels, and larger fire sizes, among other research areas (Id at 77).

In addition, toxicity assessments can change over time and do not necessarily tell the full, long-term impacts that are important for consideration in the transition to fluorine-free foams. When PFAS chemicals were introduced, their toxicity and persistence in the human body and environment were not known. The industry could face replacement remorse if the new chemistries in alternative foams are not thoroughly examined because of a transition timeline that is adopted too quickly. The EPA has acknowledged, "[w]hile modern fluorotelomer-based AFFF formulations have the potential to be less harmful to human health and the environment than legacy formulations, much remains unknown about the short-chain PFAS used" [EPA, Multi-Industry Per- and Polyfluoroalkyl Substances (PFAS) Study – 2021 Preliminary Report at 9-2 (2021)]. In addition, the Agency concedes, "EPA has documented these short-chain PFAS [6:2 FTSA, 6:2 FTOH, PFBS, and HFPO-DA] are present in industrial discharges, are environmentally persistent, and do demonstrate potential for adverse impacts to ecological and human health receptors" [Id. at 3-10]. Accordingly, EPA should ensure that everything that can

reasonably be done is done to safeguard and ensure that the replacement foams are not toxic. This should include requiring toxicity and environmental persistence testing.

Consequently, until such alternatives are readily available, the proposed designation of PFOA and PFOS as hazardous substances poses a risk that bulk liquid terminal operators will be held legally and financially responsible for having followed the best safety practices to reduce health effects from fires to firefighters, terminal employees, and the community when suppressing terminal fires in the rare occasion that they occur.

The FAA mandates the use of AFFF containing PFOA and PFOS at airports; thus, the adoption of this proposed Rule will place airport operators in a "Catch 22," effectively punishing them (by creating enormous potential legal liabilities) for remaining in compliance with FAA regulations. While airports will soon be transitioning to fluorine free foams (F3), previous use of AFFF and resulting runoff from these facilities have contaminated drinking water and soils, and the proposed listing further opens local governments up to legal liabilities when PFAS is detected, particularly from municipal airports. Communities with or located near military installations are similarly at risk for legal liability under this Proposed Rule, as these same firefighting foams have been used for training exercises at military bases.

Until FAA eliminates the mandate to use AFFF containing PFOA and PFOS, a commenter requests that EPA consider an exception for the application of the proposed rule to airport operators. The adoption of this proposed Rule will place the commenter and other airport operators in a "Catch 22." Otherwise, the application of this rule will in effect punish the commenter and other airport operators (by creating enormous potential legal liabilities) for remaining in compliance with FAA regulations. This is contrary to the testimony of the Honorable Radhika Fox, Assistant Administrator, Office of Water, U.S. Environmental Protection Agency to the Senate's Environment and Public Works Committee on October 20, 2021 where she stated in response to a question from Senator Jim Inhofe (R. Okla.) that "I can assure you, Senator, we are not looking to punish airport operators if they are following direction and they are following guidance provided by FAA." [0234-ILTA]

Several commenters stated that the use of AFFF on adjacent lands poses a threat to landowners. Many wildfires occurring in the west are in the higher elevations and on federal lands which means that PFAS can migrate from federal lands onto the private lands or be present in the water that livestock drink. Fire retardants are a necessity for a large portion of the western US and would further complicate PFAS reporting and mitigation for landowners that were merely unfortunate to only be close in proximity to a wildfire. The Department of Defense's use of AFFF and their egregious breach of care to allow it to reach groundwater at their facilities would unfairly punish adjacent landowners who rely on that groundwater. Many agricultural areas are adjacent to industrial facilities that also use PFAS that could migrate off-site. The use of the AFFF and other PFAS containing materials near agricultural fields, groundwater recharge areas, surrounding surface water and soils could cause an extremely damaging situation in terms of decreased property values and increased liability should this rule as proposed be adopted. Even prior appropriate use of AFFF at industrial facilities will have an impact on the value of that industrial land. [0402-WyFB, 0444-DPNM, 0460-ILTA, 0559-RuttenKern]

Numerous commenters stated that PFOA- and PFOS-containing firefighting foam used in emergencies or legacy uses of same should be exempt from the proposed hazardous substance designation. Until the recent development of fluorine-free foams, AFFF was the best available

substance for fire departments to use when discharging their legally required emergency response duties and was the accepted industry standard when responding to fuel or certain electricity-driven fires. The release of AFFF to extinguish such fires provides an immediate benefit to airplane crash victims and others that outweighs the long-term environmental impacts that may result, which can be mitigated through risk-based exposure reduction. This risk-benefit balance supports using AFFF to fight airplane and hangar fires, and consequently, an exemption from this proposed Rule for airport owners and operators with respect to this limited fire-fighting function. Facility owners and firefighters confronted with a significant fuel fire or similar emergency should be encouraged to take immediate action, including the use of AFFF, to prevent injury, loss of life, and damage to infrastructure without being subject to potential CERCLA cleanup liability due to such use. [0234-ILTA; 0368-EPSA; 0369-HCAA; 0419-API et al; 0424-ACI-NA; 0446-Congressional Fire Services Institute; 0460-ILTA; 0530-IAFC; 0551-CCIG; 0553-NATA; 0555-AAAE]

A commenter stated that CERCLA §107(d)(1) provides that "no person shall be liable under this subchapter for costs or damages as a result of actions taken or omitted in the course of rendering care, assistance, or advice in accordance with the National Contingency Plan ("NCP") or at the direction of an on-scene coordinator appointed under such plan, with respect to an incident creating a danger to public health or welfare or the environment as a result of any releases of a hazardous substance or the threat thereof. This paragraph shall not preclude liability for costs or damages as the result of negligence on the part of such person." This provision embodies Congress' directive that CERCLA liability should not be imposed on persons that render care or assistance in response to incidents – such as fires – that create a danger to public health, welfare, or the environment. [0419-API et al]

Other commenters noted that CERCLA already recognizes that in some instances, state and local governments may be exempt from liability for contamination. The existing exemption for emergency response [42 U.S. Code § 9607(d)(2)] should be extended to explicitly provide an exemption from liability for PFAS contamination to emergency responders (namely fire departments, fire training facilities, and other fire service entities) that used AFFF in response to fires that threatened property and life; in training to prepare for such emergencies; and in storing the foam needed to respond to these situations. Such an interpretation would not inhibit the EPA's ability to continue to respond to contamination but would protect the local emergency response agencies that used AFFF, not for gain or profit, but to protect the lives and property of citizens. Any sites where AFFF was used or stored by fire departments, fire training facilities, and other fire service entities in the course of their work are best remediated by the other statutory remedies included under CERCLA, up to and including federal government funding, as a part of ensuring the public good. Furthermore, one commenter requested that the EPA include self-incorporated volunteer fire departments, airport fire departments, military or federal fire departments, fire districts, and fire departments at industrial facilities as instrumentalities of state and local governments under this exemption. [0446-Congressional Fire Services Institute; 0530-*IAFC*]

A commenter acknowledged that the EPA does not believe it has the legal authority to issue a use-based exemption of a hazardous substance from being a triggering contaminant for Superfund liability. The commenter requested that the EPA consider providing a "no action" assurance to bulk liquid terminal operators that acted in good faith as required by regulation to use and train with PFAS-based firefighting foams, until legislation can be passed protecting them

(and noted that the EPA is considering similar enforcement discretion policies for other industries, including airports, water utilities, and the biosolids management sector). The EPA should then support congressional action to provide an explicit, narrowly defined exemption from CERCLA liability for the bulk liquid terminal industry, limited to facilities with PFAS contamination resulting from legacy use of AFFF in accordance with OSHA regulations (again, members of the water and waste industries have made similar proposals). The provision could define appropriate measures that terminal operators could take to prevent migration of PFAS contamination from their sites, as a prerequisite for an exemption from future liability under CERCLA. The commenter further proposed specifically that Congress amend CERCLA to (1) add a new 'good faith actor' defense similar to the protections afforded to innocent third parties and bona fide prospective purchasers (BFPPs); this would not be unprecedented given that Congress has amended CERCLA to clarify and add new protections to CERCLA liability, including the BFPP defense; (2) revise the definition of "owner or operator" to explicitly exclude owners or operators acting in good faith in accordance with regulatory requirements to use and train with PFAS-based firefighting foams; and (3) revise the definition of "hazardous substance" to explicitly exclude PFAS-based firefighting foams. Indeed, this would not be unique given that Congress has provided an explicit exclusion from the definition of hazardous substance for petroleum, natural gas or synthetic gas usable for fuel. [See 42 U.S.C. § 9601(14)] To narrowly tailor these exclusions, the commenter proposed a provision to ensure that releases, discharges, or disposals (or threatened releases or discharges) resulting from gross negligence, willful misconduct, or noncompliance with any law or permit are not shielded from CERCLA liability. [0234-ILTA; 0460-ILTA]:

A few commenters noted that airports have been required by federal law to use AFFF for decades (and still are). Congress has recognized the unique situation that airports were forced into by the federal government and signaled support for exempting airports from CERCLA liability. The House of Representatives has passed the PFAS Action Act on two separate occasions, once in January 2020 during the 116th Congress (H.R. 535) and again in July 2021 during the 117th Congress (H.R. 2467). Both versions of the bill included a liability exemption for airports that were required to use AFFF in accordance with Part 139 and FAA guidance. EPA officials have also recognized the unique position that FAA has imposed on airports over the past several decades. In October 2021, Assistant Administrator for the Office of Water, Radhika Fox, testified before the Senate Committee on Environment and Public Works, indicating that the agency needs to coordinate with DOD and FAA to ensure that airports are not being "punished" for complying with federal mandates and guidance. Thus, commenter requested that the EPA provide airports with the appropriate liability protection for using AFFF to perform live-saving services and protect the traveling public. [0369-HCAA; 0424-ACI-NA; 0553-NATA; 0555-AAAE]

A commenter noted that specific to airports, the costs of this designation to the Federal government will be direct and significant. AFFF use has been and continues to be a federal requirement. As a result, the Federal government has the responsibility associated with any necessary clean-up and remedial actions resulting from AFFF use in compliance with those Federal requirements. Responsibility will have to be proportioned between the federal government, current airport operators, and airport tenants. Many airports have active military installations, former military installations, or the airport may have been transferred from the military to the current airport operator. Responsibility must be identified and shared between the Department of Defense, Department of Transportation/FAA, and airport operator. Other airports were previously owned by the Department of Civil Aviation or FAA, and then transferred to the

current airport operator. Any PFOA and PFOS releases before the transfer would be the responsibility of the Federal government. Those lines of responsibility should be clearly specified and agreed upon before the Proposal is finalized. [0424-ACI-NA]

Several commenters stated designating PFAS-containing substances, such as AFFF, as hazardous under CERCLA is not appropriate to address concerns regarding PFAS. CERCLA would cause substantial impacts and costs at airports, in addition to other industries, that would inhibit EPA from achieving the primary goal of the statute, which is to reduce the environmental and health hazards associated with the substance. Instead of imposing strict, joint and several liability on all generators, transporters, and facility owners/operators through CERCLA, EPA should instead take a risk-based approach by focusing on actions that would reduce human exposure to these substances. This would be a more cost-effective approach that acknowledges the existing limitations with remediation technology and the lack of standards rather than promoting cleanup of all sites where PFOA and/or PFOS contamination may exist, regardless of whether a past release or contaminated site poses a threat to human health or the environment. Airports that released PFOA or PFOS as part of mandated firefighting training exercises or insurancemandated testing of Class B firefighting systems which discharged AFFF are also likely be targets of litigation. Currently, there are no suitable alternatives to AFFF for airports, and therefore it is unclear how the Agency will handle liability for their use. Other industries, such as the power supply industry, use AFFF due to OSHA regulations for life preservation and safety and proposed designation could result in power suppliers being drawn into long and costly litigation based on previous compliance with federal laws and regulations. [0555-AAAE, 0417-Aircraft Rescue & Fire Fighting Working Group Inc., 0424-ACI-NA, 0553-NATA]

Some commenters stated that the proposed rule fails to acknowledge how and why PFAScontaining AFFF are used, particularly that they are deployed at highly diluted concentrations in emergency firefighting situations. In the event of an emergency involving a hydrocarbon fire, firefighting foams that allow swift and definitive extinguishing power are required to protect the lives of first responders, workers, and the public, as well as the environment. The remaining availability and use of such foams may represent one of few effective tools for controlling the fire and preventing serious threats to surrounding communities and avoiding potentially catastrophic outcomes. In addition, lower quality fire-fighting systems will increase the risk of various elements being released into the environment due to less controlled fires that may destroy containment and secondary containment systems. As a strict liability statutory scheme, CERCLA does not distinguish that an entity was using AFFF for the salutary purpose of protecting life safety. But CERCLA should differentiate this type of use. Facilities that deploy AFFF are doing so to protect life safety in limited circumstances. Regulatory management of PFOA and PFOS should thus be risk-based rather than strict liability. Penalizing those who use AFFF by applying a strict liability remedial scheme is unjust and contradicts our nation's commitment to workplace safety. [0234-ILTA; 0368-EPSA; 0411-A4A; 0419-API et al; 0484-NACD; 0569-U.S. Chamber of Commerce et al

A commenter stated that an unintended consequence of designating PFOA and PFOS as hazardous under CERCLA could be the decreased availability of effective fire-fighting materials. Although the EPA is not proposing to ban the use of these chemicals, the designation alone puts pressures on facilities to transition their AFFF systems that contain PFOA/PFOS to alternative but less effective systems. The commenter has heard from its members that insurance companies

are pressuring them to replace their PFOA/PFOS containing AFFF systems due to liability concerns and the multiple major government actions to address the materials. [0484-NACD]

Several commenters acknowledged that a transition away from AFFF to new fluorine-free foams (F3) was underway but stated that the EPA must allow for an adequate period of time for any transition to occur: a minimum 3 to 5 years. Specifically, airports will need to address the following issues:

- New aircraft rescue and firefighting (ARFF) techniques and tactics for F3 will be needed and ARFF personnel trained on these. This includes functionality of the new foams with existing ARFF vehicles, systems, and other equipment and how to properly train firefighters with the new foam.
- Even with a qualified fluorine-free firefighting agent, questions remain about how airports are expected to transition from AFFF to the new foam and are in need of guidance on acceptable standards and methods for decontaminating existing ARFF vehicles, systems and other equipment. The commenter has estimated approximately 4,300 ARFF vehicles are located at over 3,250 airports across the country, including over 1,500 vehicles at Part 139 certificated airports. Under Part 139 airport certification standards, airports would have to remove each vehicle from service separately to conduct decontamination and cleaning procedures. For larger airports, which may have a half dozen vehicles, this would be very time consuming and would require significant advanced planning to ensure safety of ongoing operations is not jeopardized. If decontamination is not possible, vehicles and equipment will need to be replaced, at significant cost (and time).

Designating PFAS as a hazardous substance will create new challenges for airports that will eventually need to dispose of AFFF and any PFAS-containing rinsate that is generated as ARFF vehicles are decontaminated and cleaned, again assuming that an effective method for cleaning is identified. To date, EPA has provided no guidance on how to dispose of AFFF or PFAS-containing materials aside from recommending that holders of these materials "store" them until effective methods are identified. [See U.S. Environmental Protection Agency, "Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances," at 3 (2020)] Options and methods for disposing of these materials would be further limited after a final designation is made, making it that much harder for airports to transition.

Demand for F3 products will likely exceed supply for the first year or two of availability. The Department of Defense (DOD) will be a major purchaser of the new foam, along with thousands of other users across the country such as local fire departments and petroleum refineries and terminals. Moreover, it will take many airports, as state and local governmental bodies, months, if not longer, to get a supply contract in place to procure the new foam. At the same time, finalizing the hazardous substance designation would make it more difficult, if not impossible, for airports to procure AFFF while they wait to transition from AFFF to a fluorine-free firefighting agent. After the designation, AFFF manufacturers and/or distributors would likely stop selling the product to airports in many, if not all, locations. State laws and anticipated EPA regulatory actions have already deterred manufacturers and distributors from selling AFFF in certain geographic areas, making it challenging for airports to comply with existing federal requirements. A final rule would only exacerbate these procurement issues that airports are

already trying to manage. The timing for finalizing the proposed rule (sometime in summer 2023) means most if not all airports will still be using AFFF pursuant to FAA's mandate and because of the factors and challenges described here. This would put airports in the challenging position of either using a designated hazardous substance in an emergency situation or jeopardizing the safety of the traveling public and not complying with FAA regulatory requirements. The timeline for airports to receive guidance in these areas is uncertain, and the lack of clarity on these issues could delay the industry's transition efforts and increase costs. [0234-ILTA; 0555-AAAE; 0569-U.S. Chamber of Commerce et al; 0424-ACI-NA]

In the meantime, commenters encouraged the EPA to consider either appropriate exclusions for life-saving firefighting operations or modifying the listing in another manner such that reporting obligations and liability related to the use of fluorine foams are not imposed before users of these foams have an adequate time to make the transition. [0569-U.S. Chamber of Commerce et al]

Finally, another commenter with the bulk liquid terminal sector also noted that a measured and focused transition to PFAS-free firefighting foams will take years. Meanwhile, during this time and because of historic use of PFAS-based firefighting foams at liquid terminal sites, EPA's listing of PFAS as a CERCLA-related hazardous substance will turn every liquid terminal site into a Superfund site overnight. This will lead to the closure and likely dismantling of liquid terminals and facilities. Once these vital locations are closed and razed, they will not be replaced in the commercially foreseeable future. And, with these sites being declared Superfund sites with the significant financial liability, this will frustrate and inhibit future economic uses for these sites in many congressional districts. These sites will likely not be used for local family-sustaining job-generating e-commerce or logistics facilities. [0234-ILTA PFAS Letter to Congressman Hudson 8-2022]

A commenter noted that bulk liquid terminals will face similar pressures as the aviation industry: significant investments in equipment that may or may not be compatible with replacement foams and the need for end user training on the less forgiving F3 foams. To be effective, the replacement foams may require higher foam volumes, additional labor, and different application techniques and equipment. Developing and acquiring these will take time. Additionally, there are potential safety risks associated with the transition without allowing appropriate time for coordination between regulators and industry stakeholders (including bulk liquid terminal owners and operators, firefighters, foam manufacturers, and disposal vendors) for testing, training, equipment replacement, disposal, mutual aid, and other critical activities. According to NFPA, AFFF is extremely forgiving and versatile, able to put out fires in a single pass regardless of how aspirated, or foamy, the substance is coming through the hose. The new [fluorine-free] formulations, however, are highly dependent on what [Jerry] Back calls "foam quality," meaning dense, highly aspirated bubbles. Even with a denser foam blanket, tests have shown that firefighters must discharge more fluorine-free foam on a liquid fuel fire to achieve the same results as AFFF. "AFFF also tends to be more forgiving when you're trying to flow around obstructions in the fire field," said Back, who conducted the fire tests and coauthored the 2020 [NFPA] Research Foundation report. (Back's work won the 2020 Foundation Medal, awarded to the project that best exemplifies the Research Foundation's fire safety mission.) The bottom line, he said, is that it takes roughly twice as long to put fires out with these new products compared to AFFF.

This commenter also noted that terminal operators rely on the principle of mutual aid to ensure they can provide adequate responses to incidents. During an event, neighboring facilities may provide foam, equipment, or fire-fighting personnel. For the largest fires, foam may be provided from other facilities across the region or even from across the country. If assets arrive at the emergency site from neighboring jurisdictions that allow AFFF, emergency responders should not be distracted by issues of liability when their focus should be on worker and public safety. This inherent interdependence of terminals makes it necessary to allow additional time for the entire industry to move together to eliminate PFAS containing foams. [0460-ILTA]

A commenter states that while airports will soon be transitioning to F3 foams, previous use of AFFF and resulting runoff from these facilities have contaminated drinking water and soils, and the proposed listing further opens local governments up to legal liabilities when PFAS is detected, particularly from municipal airports. Communities with or located near military installations are similarly at risk for legal liability under this Proposed Rule, as these same firefighting foams have been used for training exercises at military bases. Even after the transition to F3, communities may be found liable to address contamination originating from DOD facilities prior to the transition. While the commenter applauds the federal effort to develop new firefighting foam, EPA has failed to consider the cost burdens on local governments in the interim, including the costs and available technology for cleaning up these sites, as well as the costs of having to purchase new equipment. [0506-Conference of Mayors]

One commenter stated that when parties are concerned about CERCLA liabilities from the use of certain products such as PFAS-containing AFFF they might be more hesitant to use those products which may actually negatively impact health and safety. [0565-USWAG]

A commenter noted that the remediation costs for airports that had used AFFF could be in excess of \$11 billion excluding legal costs (p. 14, "PFAS Waiting Game Continues in 2022," Environmental Business Journal, Vol. XXXV, Numbers 7/8, 2022). The commenter strongly disagrees with the implication put forward by EPA that commercial service airports, along with Publicly Owned Treatment Works (POTWs), should be treated as "polluters" and that forcing clean-up costs on airports as "polluters" is a benefit of the proposed rule. In reality, the costs will be borne by ratepayers and the traveling public at-large. [0424-ACI]

Response

Issues pertaining to use, disposal, and regulation of PFAS-containing firefighting foam, including alternatives to AFFF, are outside the scope of this rulemaking and require no response. Issues pertaining to purchasing AFFF or fluoride-free alternatives, purchasing equipment, updating infrastructure, and potential supply and demand issues for AFFF or alternatives are also outside the scope of this rulemaking and require no response. Regulatory programs and corresponding management practices to address AFFF, and the associated costs, are already underway and are not attributable to designation. Designation has no regulatory impact on airports or firefighting entities. EPA cannot specifically speak to FAA and OSHA regulations. Nonetheless, EPA understands challenges that users of AFFF face in light of a growing body of scientific evidence that PFAS chemicals can cause adverse impacts to public health and the environment. The federal family is working together to navigate these important cross-Agency issues.

The White House is coordinating a government-wide approach to emerging PFAS science and policy. The Council on Environmental Quality leads the Interagency Policy Committee on PFAS

and the Office of Science and Technology Policy continues to coordinate accelerated PFAS research within the National Science and Technology Council's Joint Subcommittee on Environment, Innovation, and Public Health. Both groups continue to assess the need for new policies and scientific research that result from emerging information about PFAS. There is also enhanced coordination by senior leadership and staff from the EPA, DOD, and Council on Environmental Quality under the Interagency Policy Committee on PFAS concerning issues around military installations and their communities to accelerate solutions and increase transparency.

As directed by Congress in documentation accompanying the December 2022 Omnibus Spending Bill, the Federal Aviation Administration (FAA) worked jointly with the DoD and EPA to develop and publish the Aircraft Firefighting Foam Transition Plan in May 2023. The purpose of the plan is to assist airports in their transition from PFAS-containing aqueous film forming foam (AFFF) to a new fluorine-free foam (F3). In January 2023, the DoD published a new F3 military specification (MILSPEC) to comply with the requirements of the 2020 National Defense Authorization Act. Once DoD certifies that a foam meets the new MILSPEC, it will be added to the Qualified Product List (QPL). Foams listed on the QPL are considered by the FAA as acceptable to use for purposes of satisfying the regulatory requirements of Part 139. The published transition plan provides timelines for the release of policy and guidance relating to Part 139 airport implementing plans for obtaining approved MILSPEC F3 products, and information for Part 139 airports on obtaining EPA guidance on acceptable environmental limits. The plan also details best practices for the decontamination of existing aircraft rescue and firefighting vehicles, systems, and other equipment previously used to deploy firefighting foam and provide airports information on any supplemental equipment needed to utilize approved MILSPEC products.

This rule is specific to PFOA and PFOS releases into the environment and does not impose requirements on the formulation of AFFF. While the transition to fluorine-free foam is still in process, a major milestone in the transition to AFFF that is free from PFOA and PFOS occurred in 2017. In 2017, DoD published a new MILSPEC, MIL-PRF-24385F(SH) w/AMENDMENT 2, concerning AFFF. The new MILSPEC stated that PFOA and PFOS must be below the limit of quantitation, which at the time was 800 ppb, in the concentrate. To reach the Reportable Quantity of PFOA or PFOS of 1 pound using the 2017 MILSPEC, 2.5 million gallons of AFFF would need to be released. It is very unlikely that that much foam would be needed to fight a fire in a 24-hour period, and no training exercise would use that much foam.

The designation does not require, change, recommend or restrict AFFF use for entities, such as airports or firefighting entities. CERCLA is not a traditional "command and control" statute that prospectively limits pollution. Instead, CERCLA is a remedial statute that addresses contamination already released into the environment on a site-specific basis to ensure that communities and ecosystems do not face unacceptable levels of risk.

Designation does not require any response action by a private party and does not determine liability for hazardous substance release response costs. Response actions are contingent, discretionary, and site-specific decisions made after a hazardous substance release or threatened release. They are contingent upon a series of separate discretionary actions and meeting certain statutory and regulatory requirements. The only direct requirement for private parties pertaining to CERCLA are EPCRA notification requirements. After designation, any person in charge of a vessel or facility is required to report releases of PFOA and PFOS of one pound or more within a

24-hour period. For more information, see Preamble to the Final Rule Section VII.I.1(Summary of Public Comments and Responses/Liability and Cost to Public Utilities).

For this final rule, and after consideration of public comments, EPA evaluated potential liability outcomes that may arise after designation and determined that designation is warranted. The Agency recognizes that certain stakeholders are concerned about CERCLA liability resulting from the designation of PFOA and PFOS as hazardous substances. As explained in the preamble to the Final Rule Section VII.A.3 (Authority to Create Exclusions from the Designation), EPA declines to create exceptions for certain uses of PFOA and/or PFOS in this rulemaking. See also supra-Section 2.A.4 (Authority to Create Exclusions/Exemptions) and RTC 4.G.3-2. However, EPA expects that CERCLA's liability limitations and existing enforcement policies helps address concerns about potential CERCLA liability that may result from the designation of PFOA and PFOS as hazardous substances. The Agency believes CERCLA's liability and litigation framework will continue to operate as intended after designation of PFOA and PFOS. Designation does not alter CERCLA's liability framework. Forty years of CERCLA experience suggests that designation should not result in unusual CERCLA liability or litigation outcomes as a result of this designation. Designation does not expand the definition of "potentially responsible parties," nor does it amend, change, or curtail existing statutory limitations on liability. EPA expects to continue to operate as it has for decades to equitably resolve who should pay.

The 1984 Policy Against "No Action" Assurances and the 1995 memorandum on Processing Requests for Use of Enforcement Discretion firmly articulates the Agency's long-standing policy against providing a definitive assurance that the government will not proceed with an enforcement response for a violation of an environmental requirement outside the context of an enforcement action (a "no action assurance"). EPA is focused on holding responsible those who have manufactured and released significant amounts of PFOA and PFOS into the environment. As EPA states in the FY 2024-2027 National Enforcement and Compliance Initiates (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" The NECI also clarifies that "OECA 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 OECA exercises CERCLA enforcement discretion in other areas."

PFOA or PFOS detection or use at a site does not imply that response action is necessary. Neither a release nor a report of a release automatically triggers cleanup action under CERCLA. 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. Decisions are made on a site-by-site basis informed by site-specific information. The only direct requirements for private entities that result from designation are certain reporting and notification requirements, as described in the Preamble to the Final Rule Section VIII.B. (Direct Effects of Designating PFOA, PFOS, and their Salts and Structural Isomers as Hazardous Substances). See preamble to the Final Rule Section VII.D.1.a-c (Reporting and Notification Requirements) for further explanation. CERCLA is designed to ensure that highly contaminated sites are prioritized relative to other sites. The site-specific and discretionary nature of CERCLA safeguards against cleanups that are not necessary to protect human health and the environment and safeguards against unwarranted liability outcomes.

EPA acknowledges that CERCLA section 107(d)(1)-(2) limits CERCLA liability for certain actions in which a person, state government, or local government is "rendering care or advice"

but declines commenters request that EPA explicitly provide that this provision creates an exception for emergency responders that use AFFF (including training exercises that use AFFF). Whether 107(d) is applicable to a certain actor or actions is a fact-specific inquiry and thus inappropriate for a preemptive determination. CERCLA section 107(d)(1) provides that "no person shall be liable under [CERCLA] as a result of actions taken or omitted in the course of rendering care, assistance, or advice in accordance with the [NCP] or at the direction of an onscene coordinator . . . with respect to an incident creating a danger to public health or welfare or the environment . . ." unless the person acted negligently. Section 107(d)(2) applies only to state or local governments and limits CERCLA liability for "actions taken in response to an emergency created by the release or threatened release of a hazardous substance generated by or from a facility owned by another person." The limitation on liability is unavailable for costs or damages that result from "gross negligence or intentional misconduct by the state or local government." It is impossible to know at this time whether a particular factual scenario would suit the confines of these defenses. EPA also questions whether it has the authority to prescribe such a limitation on liability. For example, the D.C. Circuit has held that, in enacting CERCLA, Congress reserved resolution of liability issues to the judiciary, not the Agency. 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.").

EPA disagrees with commenters' that suggest 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. Please See Preamble to the Final Rule Section VII.B.1.

Please refer to the Preamble to the Final Rule, Section VI.B-C and Section VII.A.3, B.1, H, J.; see *supra* Section 4.E, 4.F.4-8, 4.G.2 and *infra* 4.G.4 for more information regarding designation's potential impact on entities that handle PFAS or PFAS containing materials. Also see *infra* Section 6.A.2,-3, 5, 7-8, 6.B.1, 5-6, 6.E.5 for more information about EPA's economic assessment for this final action. Please see Section 5B-2 for more information on federal facilities.

For specific information regarding CERCLA protections for residential landowners, please see Preamble to the Final Rule Section VI.B.2. Additional information is available on EPA's website. Superfund Landowner Liability Protections, available here: https://www.epa.gov/enforcement/superfund-landowner%20liability%20protections%20are,the%20requirements%20of%20the%20statute.

EPA disagrees with comments suggesting that the number of NPL sites will substantially increase after designation or that designation "will turn every liquid terminal site into a Superfund site overnight." EPA does not expect the number of sites on the NPL to substantially increase after designation. EPA already has the authority to list sites with PFOA and PFOS on 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 PFOA and PFOS. *See supra* Section 4.D.2.

EPA disagrees with commenters assertion that appropriate lines of responsibility for federal property transfers needs to be established prior to the Final Rule. CERCLA requires Federal

agencies to provide a covenant warranting that "all remedial action necessary to protect human health and the environment with respect to any [PFOA or PFOS] 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." 42 U.S.C. § 120(h)(3). By facilitating the transfer of property that poses no unacceptable risks, these provisions protect purchasers and help communities benefit from faster reuse and redevelopment of property impacted by PFOA/PFOS contamination. See supra Section 4.B.1 and 4.B.2 for more information more information regarding designation's potential impacts to Requirements Upon Transfer of Government Property.

EPA disagrees that the Agency should not designate because there are insufficient methods to treat, destroy, and dispose of PFOA and PFOA. There are currently methods available to address PFOA and PFOS contamination, and the Agency and other parties continue to work to improve those methods. EPA's PFAS Destruction and Disposal guidance describes commercially available methods. EPA does not preclude the use of emerging technologies, which may also be appropriate, depending on the materials. See *supra* 4E1-5 (responding to comments on treatment, destruction and disposal of PFAS; see also the Preamble to the rule VII.H. Commenters may also refer to EPA's "*Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances—Version 2 (2024)* " for additional information, available here: https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf.

Comments concerning general waste management practices wholly unrelated to CERCLA response actions are outside the scope of the rule and require no response. Regardless, commenters did not provide evidence to demonstrate that designation of PFOA and PFOS will cause disposal costs to increase or result in disposal facilities wholesale rejecting waste because the waste contains or could contain PFOA and PFOS. Such claims are unsupported. Treatment and disposal facilities are largely already aware of issues associated with PFOA and PFOS treatment and disposal, and a number of potential issues described by commenters, such as increased disposal costs, are not a result of designation. A citation provided by a commenter stated that remediation costs for airports could be in excess of \$11 billion but provides no information on how this value was calculated. The citation also states that the majority of airports in the U.S. are regional or private and only a small percentage of these types of airports (3-5%) would be expected to have PFAS present from AFFF, which conflicts with the commenters statement in their letter that most airports would be expected to have PFAS present.

Additionally, EPA does not agree with the commenter(s) that designation of PFOA and PFOS as CERCLA hazardous substances will impose a cost burden on state and/or local governments that provide drinking water treatment, wastewater treatment, solid waste management, or airport services. Efforts to address PFAS in these sectors, and the associated costs of those efforts, are already underway in the absence of the proposed designation of PFOA and PFOS as CERCLA 1hazardous substances. See supra Section 6.E, and Chapter 5 of the RIA.

4.G.3-2 Releases of AFFF will not result in Reportable Quantities.

[0421-A2 American Chemistry Council] A commenter stated that releases of AFFF will not result in reportable quantities of PFOA or PFOS and referred to the military specification for AFFF which allows no more than 800 parts per billion (ppb) of either PFOA and PFOS in the liquid concentrate. Assuming the presence of a maximum allowable concentration of PFOA in MILSPEC-compliant foam one would need to release more than 140,000 gallons of fluorotelomer-based AFFF concentrate (more than 2.8 million gallons of water/ concentrate assuming a 20:1 mixture) in a 24-hour period to total one pound of PFOA.

In addition to requests for exemption from CERCLA liability for the use of AFFF, a commenter stated that proper application of AFFF should not trigger release reporting and remediation obligations. Very few products have been so essential to life safety across the nation. The commenter proposes that releases associated with the proper application of AFFF, whether as a result of actual firefighting or emergency preparedness/testing/training, be exempt from CERCLA's release reporting and cleanup requirements. We believe that the EPA can and should exempt PFOA and PFOS releases resulting from properly applied AFFF from its designation. This should be incorporated into the designation or declared a permitted release (perhaps with a companion permit by rule). It is completely reasonable for the public to continue to fund removing unacceptable concentrations of contaminants in drinking water (which we, the public, already do), given the benefits of AFFF. [0368-EPSA]

Response

As explained in the preamble to the Final Rule Section VII.A.3 (*Authority to Create Exclusions from the Designation*), EPA declines to create exceptions for certain uses of PFOA and/or PFOS in this rulemaking. See also Preamble to the Final Rule Section VII.A.3 and *supra* Section 2.A.4 (Authority to Create Exclusions/Exemptions).

EPA expects that AFFF use will not result in significant reporting obligations under CERCLA section 103(a). For example, the 2017 DoD MILSPEC stated that PFOA and PFOS must be below the limit of quantitation, which at the time was 800 ppb, in the concentrate. Assuming the concentration is 800 ppb., the Agency's best estimate is that 2.5 million gallons of AFFF would need to be released to meet the reportable quantity for PFOA and PFOS of 1 pound It is very unlikely that that much foam would be needed to fight a fire in a 24-hour period, and no training exercise would use that much foam.

4.G.4 Agriculture Sector (Excluding Biosolids and Pulp and Paper)

4.G.4-1 EPA has not fully considered the impact of designation on farms.

A few commenters note that biosolids are not the only source of PFAS on farms. Pesticide holding containers have also been identified as a potential source of PFAS on farms. Recent EPA data indicates that plastic containers made of fluorinated high-density polyethylene (HDPE) are likely to leach PFAS into pesticides and other liquid products that are stored in them. EPA's review also suggests that the amount of PFAS that migrates into liquid products increases with storage time. Additionally, inert ingredients and pesticide adjuvants are additional potential sources of PFAS to farms, but they are not products the farms seek or wish to have as part of

their farm management programs. Nevertheless, farms who do not want to use PFAS substances on their farms may be blamed for their presence. [0485-MI Farm Bureau; 0558-SD Farm Bureau Federation]

A commenter noted that the State of New Mexico has proposed to equate the federal drinking water standard upon wastewater generated in dairy operations. This standard skips right over the regulation of water used in dairy operations and would punish dairies for any intrusion of PFAS compounds into their waste-water supplies. This would be a crucial measure to protect the industry against a standard which does not impact the American food chain, but could further punish unwitting, and innocent bystanders in the dairy industry. [0559-RuttenKern]

A few commenters state that the CERCLA statute does not address the loss of value in property and income or other operational losses that farmers and ranchers will face due to the contamination of their land and groundwater with PFAS. If farmers can no longer use their land for farming, that's a devastating loss that the proposed rule does nothing to address. Without correction, these issues cast uncertainties over the agricultural community. Our farmers, who produce the food, fiber, and fuel which drives the nation, should be provided with some form of security should contamination issues arise on the properties they utilize in their production. [0358-GA Farm Bureau; 0546-AZ Farm Bureau; 0547-ME Dept Ag]

A commenter provided several examples of farms that have gone out of business or remained in business only through enormous cost and effort due to PFAS contamination in recent years, some due to prior biosolids application by previous owners, considering the application of biosolids. Does the existing CERCLA exemption for the use of "fertilizer" pursuant to 42 U.S.C 9601. apply to sludge? Does it also extend to the byproducts on a farm that contain PFAS used as fertilizers (compost, manure, etc.,)? Does the application of PFAS-containing fertilizer (i.e., byproducts) pursuant to nutrient management activities on a farm constitute a "release" under CERCLA? Does a farm become a Potentially Responsible Party under CERCLA if it continues to actively farm despite PFAS contamination? Rather than see PFAS-contaminated land as irreparably contaminated, research, technology, and adaptive farm management This commenter asked several questions about the impact of PFAS on farms, especially techniques can and will allow farming to continue. The cloud of CERCLA liability over farming threatens forward progress in this area.

The commenter also inquired about how EPA will quantify a release (e.g., 1 lb. of PFOA or PFOS in 24 hours)? A dairy farm can spread thousands of gallons of liquid manure (an approved activity under Maine law and USDA's NRCS regulations for farms with an approved Nutrient Management Plan) in a day. How would EPA quantify PFAS-contaminated manure with levels in the parts per billion, and would any utilization of manure or other soil amendments require extensive testing for a specific salt or isomer? [0547-ME DACF]

Response

As EPA states in the FY 2024-2027 National Enforcement and Compliance Initiates (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 ..." The NECI also clarifies that "OECA 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 OECA exercises CERCLA enforcement discretion in other areas."

Consistent with CERCLA and the key goals of the PFAS NECI, EPA expects to implement its enforcement program to achieve national consistency, undertake site characterization to support enforcement cases, use enforcement authorities to control ongoing releases that pose a threat to human health and the environment, ensure compliance with permits and other agreements (e.g., Federal Facility Agreements) to prevent and address PFAS contamination, and address endangerment issues as they arise.

EPA also doesn't expect that every instance of PFOA and PFOS detected at a site will result in EPA taking response actions or litigation. CERCLA is designed to ensure that highly contaminated sites that pose unacceptable risk to human health and the environment are prioritized relative to other sites. The site-specific and discretionary nature of CERCLA safeguards against cleanups that are not necessary to protect human health and the environment and safeguards against excessive liability outcomes.

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 enforcement in the context of PFOA and PFOS releases.

Comments suggesting that establishing federal drinking water standards for PFOA and PFOS will create hardship for farms are outside the scope of the rule. Nonetheless, commenters don't explain how establishing federal drinking water standards, presumably those proposed under the Safe Drinking Water Act (SDWA), will impact dairy farms. National Primary Drinking Water Regulations (NPDWR) established under SDWA are applicable to "public water systems". *See* 42 U.S.C. 300f (4). If finalized as proposed, the NPDWR for select PFAS would establish 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 MCLGs as Applicable or Relevant and Appropriate Requirements (ARARs) cleanup levels on a site-specific basis. CERCLA section 121(d). For more information about potential ARARs and the NPDWR, please see Preamble to the Final Rule Section VII.B.3 (*Relationship between SDWA and CERCLA*).

Comments regarding operational expenses for farms are outside the scope of the rule. Nonetheless, EPA disagrees with comments that suggest that designation alone will force farms out of business. Examples of farms going out of business after detected PFAS demonstrate that there could be multiple causes that contribute to such outcomes that would be at issue, in the absence of designation. For example, examples of farms in Maine going out of business after detecting PFAS at their farms appear to suggest that non-CERCLA laws and regulations contributed to the decline of the farms. Designation of a hazardous substance does not require a farm to take any affirmative action, absent a reportable release. Designation does not require any response action by a private party and does not determine liability for hazardous substance release response costs. Response actions are contingent, discretionary, and site-specific decisions made after a hazardous substance release or threatened release. They are contingent upon a series of separate discretionary actions and meeting certain statutory and regulatory requirements.

CERCLA is designed to target and prioritize sites that present unacceptable risk to human health and the environment and serves those communities that are most vulnerable to potential adverse health risks from exposure. For example, EPA conducts a site-specific risk assessment to determine site-specific remedies, including whether any removal, disposal, treatment, or monitoring is necessary to mitigate unacceptable risk. Additionally, designation does not alter CERCLA's liability framework. Designation does not expand the definition of "potentially responsible parties," nor does it amend, change, or curtail existing statutory limitations on liability. Designation does not determine liability. EPA expects CERCLA to continue to operate as it has for decades to equitably resolve who should pay. See Preamble to the Final Rule Section VI.B and Section VII.J. See also Preamble to the Final Rule Section II.E and VI; *supra-Section* 4.F.4 and 4.F.8.

As stated in the Preamble to the Final Rule Section VII.D, this final designation rule 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). Facilities may use their professional judgement to report a release as soon as they have knowledge of a release of a hazardous substance that meets or exceeds the RQ. See 4.A.6. of this document.

4.G.5 Other Sectors

4.G.5-1 Key sectors have been omitted from the EPA's list of affected industries and should be added.

A commenter acknowledged that the EPA recognized the list of affected industries was not "exhaustive", however, the following sectors should be added: Port and Harbor Operators (488310), Dry Cleaner and Laundry Operators (812300), Freight Rail (482111) and Truck Freight (484110) services operators. In most instances, these entities have used, handled, transported, or are the recipients of PFOA and PFOS in their daily operations and will be significantly affected by this designation and the reportable quantity being proposed. [0369/HCAA]

Response

EPA expanded the list of potentially affected industries in the Preamble to the Final Rule, including the four NAICS code sectors identified by the commenter. See Preamble to the Final Rule Section II.C. The list is non exhaustive and intended only to provide notice to those entities most likely affected by the designation. Whether a party's activities may fall within CERCLA's scope is dependent on a number of statutory factors, including whether there has been a release into the environment and whether an entity is a "potentially responsible party."

4.G.5-2 The Proposed Rule should include discussion of shale gas development as a source of PFOA and PFOS contamination given the potential exposure to those living in proximity to gas and oil facilities and environmental justice implications.

A commenter noted that while EPA included several potential sources of PFOA and PFOS, shale gas development (or hydraulic fracturing – fracking) was not mentioned. Research has indicated that gas and oil developments use PFAS; additionally, in 2011, EPA approved three chemicals for use in gas and oil drilling that degrade into PFAS. Those chemicals and similar ones were then found in more than 1,200 gas and oil wells across several states. According to the Oil and Gas Threat Map, over 17 million people live in proximity to gas and oil facilities in the United States. The commenter further noted how residents living in proximity to those operations may experience PFAS exposure. For instance, the chemicals can leach into aquifers and groundwater during drilling activities, and the chemicals can seep into groundwater during spills. There are also environmental justice implications for EPA to consider with respect to this PFAS exposure; research has shown that communities of color and low-income communities are disproportionally impacted by the negative health risks associated with exposure to PFOA and PFOS. Ultimately, commenter urged EPA to consider PFOA and PFOS contamination through shale gas development and ensure that levels of those chemicals are also being measured in those industrial activities, as well as consider the needs of the most vulnerable frontline environmental justice communities in its decision-making process. The commenter also recommended EPA to examine the additional PFAS potential in landfills from shale gas waste and consider alternate methods of disposal that would protect residents' health. [0366 – EHP]

Response

EPA is aware that non-ionic fluorosurfactants have been reported to occur in hydraulic fracturing fluids for oil and gas production. EPA has previously assessed the practice of hydraulic fracturing and the chemicals used in this practice and the study conclusions are available on EPA's website (https://www.epa.gov/hfstudy). The assessment reviewed the available scientific literature and data to assess the potential for activities in the hydraulic fracturing water cycle to impact the quality or quantity of drinking water resources, and to identify factors that affect the frequency or severity of those impacts. [Executive Summary, Hydraulic Fracturing Study – Final Assessment 2016]

As shown in Section II.C. (Does this Action Apply to Me?) of the Preamble to the Final Rule, the oil and gas extraction industry is included in the list of entities that may be potentially affected by the action. Similarly, Chapter 3 of the final rule RIA, which discusses downstream users of PFOA/PFOS products, identifies surfactants as an associated product historically containing PFOA/PFOS for oil and gas extraction facilities.

Designation does not require facilities to take any specific response actions, such as sampling or monitoring. CERCLA is not a traditional "command and control" statute that prospectively limits pollution. Instead, CERCLA is a remedial statute that addresses contamination already released into the environment on a site-specific basis to ensure that communities and ecosystems do not face unacceptable levels of risk.

Regarding environmental justice implications with respect to PFAS exposure, 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. 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. See Preamble to the Final Rule Section VI.A.2.d. (*Environmental Justice (EJ) Considerations for Designation*).

The comment requesting EPA examine the additional PFAS potential in landfills from shale gas waste or provide guidance to alternatives is outside the scope of this rule. These are addressed in EPA's Interim Guidance on the Destruction and Disposal of PFAS. For additional discussion regarding the concern for guidance on disposal and treatment of certain PFAS, please refer to the Preamble to the Rule, Section VII.H; RTC Section 4.E on EPA's Interim Guidance on the Destruction and Disposal of PFAS.

4.G.5-3 Extending the proposed rule to downstream users of PFOA and PFOS could damage the convenience and fuel retailing industry and undercut existing regulatory schemes dealing with petroleum storage and releases.

A commenter noted that the EPA's proposed rule will apply to petroleum manufacturers as well as petroleum refineries and terminals. Additionally, while this proposed rule appears to be aimed at PFOA and PFOS manufacturers, storage facilities, and waste disposal sites, the EPA has expanded the rule to cover "downstream product manufacturers and users of PFOA and/or PFOS products." The commenter stated that this expansion will have a significant impact on the convenience and fuel retailing industry. Convenience stores and fuel retailers are not responsible for manufacturing of the petroleum they sell. Yet, under the proposed rule, these operators would be forced to monitor the chemical make-up of the petroleum they provide and will be held responsible for the full cost of the clean-up should a spill occur. Due to the prevalence of PFOA and PFOS currently in the environment, there is high likelihood that these substances could be found to have commingled with petroleum releases. Because CERCLA lability is retroactive and extends back indefinitely, every petroleum release ever reported at any fuel retailing station – regardless of how many times the property has been exchanged between operators – would have to be reopened and sampled for PFOA and PFOS. Convenience stores and fuel retailers would incur significant costs despite a lack of evidence that PFOA and PFOS pose a significant threat in consumer petroleum fuel. [0479-NACS, NATSO, SIGMA]

Response

EPA disagrees with commenters characterization that EPA "expanded" the designation to include petroleum manufacturers, refineries, or terminals. The Preamble to the Final Rule includes a non-exhaustive list of potentially affected entities. *See Preamble to the Final Rule Section II.C.* The list is intended only to provide notice to those entities most likely affected by the designation. Whether a party's activities may fall within CERCLA's scope is dependent on a number of statutory factors, including whether there has been a release into the environment and whether an entity is a "potentially responsible party."

Comments regarding prospective monitoring and management of petroleum facilities are outside the scope of this action and no response is required. Designation does not require facilities to take any specific response actions, such as sampling or monitoring. CERCLA is not a traditional "command and control" statute that prospectively limits pollution. Instead, CERCLA is a remedial statute that addresses contamination already released into the environment on a site-specific basis to ensure that communities and ecosystems do not face unacceptable levels of risk.

Please see Preamble to the Final Rule Section VI, VII.B.1 and *Supra* Section 4.F.4, 4.F.8 for more information about potential liability and how CERCLA operates to prioritize response actions for situations that present unacceptable risk.

CERCLA's definition of "hazardous substance" does not include "petroleum, including crude oil or any fraction thereof which is not otherwise specifically listed or designated as a <u>hazardous substance</u>. . . 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)." CERCLA section 101(14). Whether a release falls within this exclusion to the definition of hazardous substances is determined on a site-specific basis based on site-specific information. For more information, please see "Scope of the Petroleum Exclusion under Sections 101(14) and 104(a)(2), available at: https://www.epa.gov/sites/default/files/2013-09/documents/petro-exclumem.pdf

For information about retroactive application of CERCLA, please see *supra-Section* 2.A.3.4.G.5-4 The proposed designation would negatively impact real estate transactions and create uncertainty in standard industrial lease agreements.

Some commenters shared concerns that the proposed rule would delay and otherwise negatively impact real estate transactions at any site where even trace levels of PFOA and/or PFOS are detected given the lack of promulgated cleanup standards. [The fact that PFAS have been detected in rainwater only adds to the complexity of assigning cleanup responsibility. See, e.g., Cousins et. al, Outside the Safe Operating Space of a New Planetary Boundary for Per- and Polyfluoroalkyl Substances (PFAS), Envt'l Sci. Tech. 56, 16, 11172–11179 (Aug. 2, 2022) (the levels of PFOS in rainwater often exceed EPA's drinking water lifetime health advisory for PFOS, except for two studies conducted in Tibet and Antarctica)]. Brownfields: potential liability without certainty in cost or disposal options would drive developers away from Brownfields and towards never-developed land, which could lead to other unintended consequences that undermine the Brownfields program (i.e., habitat loss, unused properties, and urban sprawl). [0419-API et al., 0468-NGWA; 0512-Stericycle; USWAG; 0495/PFAS Regulatory Coalition; 0394–OSEE/ODEQ]

Commenters expressed concern about potential liability associated with real estate transactions. Commenters asserted that the EPA has not considered the economic and other practical consequences that the Proposal would have on real estate transactions. Prospective buyers would be rightfully concerned about the potential liability they could face as owners or operators of PFOA- or PFOS-impacted properties. While CERCLA's landowner liability protections provide some protection for buyers that conduct "all appropriate inquiry" ("AAI") in accordance with EPA's AAI rule prior to acquiring new property, prospective buyers and sellers may view these protections as unreliable given the many uncertainties associated with identification and assessment of PFAS chemicals [0549-US Chamber of Commerce].

Another commenter also stated that PFOA and PFOS the designation would also impose substantial costs in real estate transactions, due to the new and possibly large new cleanup liabilities associated with many sites, and the uncertainty involved. Unlike with other contaminants that may be typically addressed during property transfer/redevelopment, there are no readily available, cost-effective remediation technologies for PFOA and PFOS in soil. The liability uncertainty and lack of practical, technical solutions has and would continue to impede

projects to develop properties and therefore slow needed economic growth, including potentially critical projects being funded by the Infrastructure Investment and Jobs Act (Pub. Law No. 117–58) that was enacted into law this past summer. [0495-PFAS Regulatory Coalition]

The commenter asserted that CERCLA liability has always stood to have a chilling effect on real estate transactions. The commenter notes the CERCLA amendments set forth in the Brownfields Revitalization and Environmental Restoration Act of 2001 largely reflected this reality, as well as Congress' desire to provide relief for innocent parties that seek to return environmentally impaired properties to productivity (see the definition of a "Brownfield site" at 42 U.S.C. § 9601(39), which covers "real property, the expansion, redevelopment, or reuse of which may be complicated by the presence or potential presence of a hazardous substance, pollutant, or contaminant"). The commenter states that the prospect of entering into an interminable and costly environmental remediation project – as would be expected of any party seeking to avail itself of Brownfields protections at a site contaminated with PFOA and PFOS – would be expected to have dissuasive effect, thereby undermining one of the key objectives of the 2001 legislature. [0512-Stericycle]

Finally, one commenter points out that the EPA is certainly aware that many industrial lease agreements contain environmental provisions which allocate not just remedial liability between private parties but also impose specific obligations – usually qualified prohibitions on tenants – regarding the introduction onto the leased premises of "hazardous substances," a term that is often defined in commercial agreements with reference back to the CERCLA definition. The commenter further asserts that the proposed rule threatens to drastically alter the scope and severity of such commercial terms. The commenter notes that this is especially true for passive receivers of waste. Not only will such businesses be at risk of potentially assuming a greater share of any remedial liabilities than that for which they had initially bargained, but they may be put in breach of standard clauses prohibiting the introduction of "hazardous substances" onto the leasehold, unless they undertake the onerous and ultimately unfruitful task of attempting to ascertain the PFOA and PFOS content of the wastes generated by their customers. [0512-Stericycle]

Response

Commenters regarding the presence of PFOA and PFOS and its impact on real estate transactions or private agreements are outside the scope of this rule and require no response. Nonetheless, EPA understands that the actual or potential presence of any of the more than 800 CERCLA hazardous substances is relevant to brownfields transactions, as well as other real estate transactions. As is the case with all hazardous substances, including PFOA and PFOS, the risks to human health and the environment may need to be addressed prior to development. That is true even in the absence of designation. Potential purchasers of commercial properties should conduct due diligence, including at least a phase I environmental site investigation, prior to purchasing property so that the purchaser understands the conditions of the property and can best assess the value of the property prior to purchase. Having knowledge of the estimated costs associated with cleaning up a property, should it be contaminated, will help to inform parties of the value of the property and can inform the purchaser's negotiated price offered for the property.

EPA's enforcement office develops policy and guidance documents and site-specific tools that address landowner liability concerns so that protective cleanup and reuse can take place at

contaminated properties. Specifically, EPA develops enforcement discretion guidance that clarifies potential liability and provides certainty and comfort to parties seeking to redevelop contaminated sites so that EPA is not involved in every contaminated property transaction. EPA also develops site-specific tools [including comfort/status letters and settlement agreements] to facilitate contaminated site transactions when perceived liability remains an obstacle and EPA involvement is critical.

The U.S. Environmental Protection Agency recognizes the environmental, economic, and community benefits of cleaning up and reusing impacted properties. The Agency also understands that a party interested in acquiring an impacted property for reuse may be concerned with whether the property has environmental contamination and, if it does, what the potential associated liabilities and costs of cleaning up the existing contamination are under the federal Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, also known as Superfund). Comfort letters can address many of the interested party's concerns by providing a summary of relevant publicly-available information EPA may have about a specific property and information about the potential applicability of statutory provisions, regulations, and EPA guidance.

EPA understands that CERCLA's categories of "covered persons" (otherwise known as "potentially responsible parties") is broad and that this raises concerns about the number of parties or entities that could potentially be subject to CERCLA litigation. However, CERCLA's statutorily defined list of covered persons has been in place since CERCLA was enacted in 1980. Designation does not expand the definition of "potentially responsible parties" nor does it amend, change, or curtail existing statutory limitations on liability. CERCLA includes affirmative defensives and limitations on liability that operate to mitigate, if not eliminate, liability in certain circumstances, including in circumstances where parties are considering acquiring properties impacted by CERCLA hazardous substances. See, Enforcement Discretion Guidance Regarding Statutory Criteria for Those Who May Qualify as CERCLA Bona Fide Prospective Purchasers, Contiguous Property Owners, or Innocent Landowners ("Common Elements"), available here: https://www.epa.gov/enforcement/common-elements-guidance.

In 2023, EPA's All Appropriate Inquiries ("AAI") Final Rule went into effect incorporating the American Society for Testing and Materials ("ASTM") E1527-21 standard on the AAI requirement under CERCLA's landowner liability protections. The ASTM standard clarifies that until a contaminant is listed as a CERCLA hazardous substance, it is not required to be to be addressed in a Phase I Environmental Site Assessment ("ESA"). Emerging contaminants, including PFOA and PFOS, while not currently within the required scope of a Phase I ESA, will be required to be evaluated as part of Phase I reports when they are designated as CERCLA hazardous substances. While this designation will require an assessment of PFOA and PFOS to satisfy the AAI requirement under a CERCLA landowner liability protection, prospective buyers may still qualify for a protection by being diligent during property ownership through satisfying certain continuing obligations. These obligations include taking "reasonable steps" with respect to hazardous substance releases affecting the property and providing cooperation, assistance, and access to persons authorized to conduct response actions or natural resource restoration.

For transfers of federal property to non-federal transferees, designating PFOA/PFOS as hazardous substances should not slow property transfers. CERCLA section 120(h) provides that federal property can be transferred before (or after) cleanup with certain conditions. Because federal agencies are required to investigate and cleanup pollutants and contaminants, as

appropriate at NPL federal facilities, cleanups should already be underway and the designation should not impede transfers of such federal property. A federal agency may have additional cleanup responsibilities at non-NPL sites should PFOA/PFOS be designated as hazardous substances, but transfers can proceed. Already, at federal facility NPL sites, federal agencies are required to investigate and clean up contaminants such as PFAS, as appropriate, pursuant to their CERCLA section 120 Federal Facility Agreements, which means that a hazardous substances designation would have little bearing on these types of transfers. Please see Chapter 4 of the RIA for more information on potential costs of the rule related to the section 120(h) requirements.

For more information about potential liability and land transfers please see Preamble to the Final Rule Section VI, VII.I., VIII.B. For more information on guidance on destruction and disposal, please see Preamble to the Final Rule, Section VII, H.

EPA disagrees that the Agency should not designate because there are insufficient methods to treat, destroy, and dispose of PFOA and PFOA. There are currently methods available to address PFOA and PFOS contamination, and the Agency and other parties continue to work to improve those methods. EPA's PFAS Destruction and Disposal guidance describes commercially available methods. EPA does not preclude the use of emerging technologies, which may also be appropriate, depending on the materials. See *supra* 4E1-5 (responding to comments on treatment, destruction and disposal of PFAS; see also the Preamble to the Final Rule VII.H. Commenters may also refer to EPA's "*Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances—Version 2 (2024)* " for additional information, available here: https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf.

4.G.6 State, Tribal, and Local Governments

4.G.6-1 Additional funds are needed for the remediation and redevelopment of PFAS-contaminated sites.

A commenter encouraged EPA to make brownfield grant and loan funds available to promote the cleanup and redevelopment of PFAS-contaminated sites and use the Superfund Emergency Response Program to assist in responding to acute public health situations. Potential developers have expressed concerns about acquiring and redeveloping brownfields due to the Proposed Designation. Once the Proposed designation is finalized, states can help potential developers manage risks related to potential PFAS contamination under its CERCLA Section 128(a) program capacity grant. The funds will be critical for local and state partners to foster the process of converting brownfields to redeveloped properties that contribute to local economies. [0812 – WDNR]

Response

EPA's Brownfields Program provides funding, in the form of competitive grants, for the assessment and cleanup of properties contaminated (or potentially contaminated) with hazardous substances, pollutants, contaminants, and petroleum. Properties contaminated with PFAS (or other hazardous substances, pollutants, and contaminants) are eligible for brownfields funding. More information on how to apply for EPA Brownfields multipurpose, assessment, revolving

loan fund, and cleanup grants can be found on the program's website at www.epa.gov/brownfields. EPA's Land Revitalization Program provides technical assistance to communities faced with challenges associated with the redevelopment and reuse of brownfields properties. More information on EPA's Land Revitalization Program can be found at www.epa.gov/land-revitalization. EPA regularly coordinates with state and tribal brownfields programs to promote brownfields assessment and cleanup and the revitalization and redevelopment of brownfields properties. EPA's Brownfields Program also provides funding to support the establishment and enhancement of state and tribal response programs, which oversee assessment and cleanup activities at brownfields properties. Please refer to RTC 4.G.5-4 for more information about hazardous substances and brownfields.

As described in Section VI.A of the Preamble to the Final Rule, EPA expects to take more Fund-lead removal actions for PFOA and PFOS contamination, including emergency actions. These removal actions, as well as any remedial actions taken as a result of the rule, will support the redevelopment and revitalization of residential and commercial properties. 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. 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.

4.G.6-2 Clarification needed on how EPA will address what it identifies as "equity concerns," and clarification needed on "users."

A commenter questioned how EPA plans to address what it identifies as "equity concerns" as it was recognized in PowerPoint presentation regarding the Proposal currently found on the EPA's website (Notice of the Proposed Rulemaking, dated August 2022). [0490 – PMAA]

A commenter requested EPA to clarify the definition of "users of PFOA and/or PFOS products." "Users" as applied in the current context is overly broad and may be interpreted to include any party, such as residential homeowners or renters. [0398 – PA DEP]

Response

EPA expects to implement its enforcement program in a manner that supports equitable outcomes. To that end, EPA is focused on holding responsible those who have manufactured and released significant amounts of PFOA and PFOS into the environment. As EPA states in the FY 2024-2027 National Enforcement and Compliance Initiates (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" The NECI also clarifies that "OECA 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 OECA exercises CERCLA enforcement discretion in other areas."

As explained in the preamble to the Final Rule Section VI.B.2 (*EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way*), EPA expects

CERCLA to continue to function normally after the designation of PFOA and PFOS as it has for over forty years for the over 800 hazardous substances already designated under CERCLA.

Designation does not alter CERCLA's liability framework. Designation does not expand the definition of "potentially responsible parties," nor does it amend, change, or curtail existing statutory limitations on liability. Liability determinations are site-specific, and designation does not determine liability. EPA expects to continue to operate as it has for decades to equitably resolve who should pay. See Preamble to the Final Rule Section VII.B.2 and Section VII.J (Enforcement).

As referenced in the preamble to the Final Rule Section II.E.7, (What enforcement discretion is available when exercising CERCLA authority?), although CERCLA's liability structure is broad, EPA has used both statutory protections and enforcement discretion policies to ensure equitable results when possible. CERCLA provides statutory provisions for exemptions from and affirmative defenses against liability. These statutory protections and enforcement discretion policies historically have given and continue to give EPA the needed flexibility to offer liability protections. See the preamble to the Final Rule Section I (Executive Summary) and VI.B.2 for more information on enforcement discretion.

Although domestic manufacturing of PFOA has been phased out, many sectors are potential users of manufactured products that contain PFOA or PFOS. PFOA or PFOS have historically been a component of firefighting foams, surfactants, etching agents, stain- and water-resistant applications, car waxes, architectural coatings, and antistatic control. Current PFOS uses, however, are limited to anti-erosion additives in fire-resistant aviation hydraulic fluid; fume/mist suppression in metal finishing and plating; etching and plating uses, including mist suppression, in electronics manufacturing; a photo-microlithography process in semiconductor production; coatings on imaging materials; and as a chemical intermediate to produce substances for some of the aforementioned uses.

4.G.6-3 The designation should further discuss the direct and indirect benefits that would be experienced by tribal communities.

A commenter expressed support for the designation because the proposed mandates annual disclosures and reporting for controlled uses and released will provide communities (including rancherias, tribes, and villages) greater awareness of PFOA and PFOS uses and releases in their vicinity. Additionally, commenter expressed support for the designation because it provides the authority to recover costs to replace or restore natural resources to conditions that would have existed without the hazardous substance release. The commenter specifically cited the significance for tribal governments and Native Alaskan Villages to compensate for harm to natural resources and recover damages caused by the releases of PFOA and PFOS. The commenter provided additional benefits that were not originally included in the EA. A direct benefit included keeping PFOA and PFOS out of tribal subsistence resources, such as fish, game, plants, and wild foods. Keeping such chemicals out of those species impact both ecological and human health. Additionally, an indirect benefit included a reduction of impacts on human health, such as diminished cancer, immunological disorders, and thyroid disorders, due to increased reporting and response actions. [0326 - NTWC]

Response

EPA agrees that final designation of PFOA and PFOS as CERCLA hazardous substances will yield benefits to tribal nations and communities. Designation is expected to improve transparency around and awareness of releases of PFOA and PFOS for tribal communities. And additional investigations and response actions are expected to reduce unacceptable risk to public health and the environment.

As described in Section VI.A.3 (Property Reuse and Social, Economic, and Ecological Benefits that may Result from Designation) of the preamble to the Final Rule, the clean-up of sites contaminated with PFOA/PFOS 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 improvements and recreational reuse activities, which include waterbodies, wildlife sanctuaries, nature preserves, wetlands, pollinator habitats, forests, grasslands, beaches, and forests. In addition, when exposure pathways are mitigated or eliminated, communities living around contaminated sites will have lower rates of adverse health effects because they are exposed to less PFOA and PFOS. See Preamble to the Final Rule Section VI.A.2 for an illustrative analysis of health benefits related to birth weight, cardiovascular disease (CVD), and renal cell carcinoma (RCC)-avoided morbidity and mortality associated with reductions in PFOA and PFOS. For a discussion of other environmental and health benefits affecting tribal and other communities, see Chapter 5 of the final rule RIA.

EPA agrees that designation will provide a mechanism to address injuries to natural resources that may have resulted from PFOA and PFOS releases. CERCLA provides that where there is a release or threat of release of a hazardous substance, federal or State agencies and Indian tribes, can recover from a liable party "damages for injury to, destruction of loss of natural resources, including the reasonable costs of assessing such injury, destruction, or loss resulting from such release". CERCLA section 107(a)(4)(C); see also CERCLA section 107(f)(1), 43 USC 11.

In addition, CERCLA and EPCRA 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 agrees that access to CERCLA's cost recovery authorities will promote response actions that will protect public health and the environment. EPA considers the ability to use the full suite of CERCLA authorities – including cost recovery and enforcement – to be an advantage of the rule because it eliminates barriers to timely cleanup of contaminated sites and allows EPA to ensure that those parties responsible for significant contamination bear the costs of cleaning it up, which in turn makes more resources available for additional cleanups. Every contaminated site that is addressed reduces the disproportionate burden to the communities at risk.

4.G.6-4 The designation should further elaborate on how the ruling designation affects disadvantage communities or communities with environmental justice concerns.

A commenter expressed significant concern regarding PFOA and PFOS contamination in their community, specifically the South Tucson and Native American lands. Even with the Air National Guard Base at Tucson International Airport stopping all use of PFAS in firefighting foam in 2018, PFAS concentrations have continued to increase and led Tucson Water to cease usage of the southside water treatment plant indefinitely. The commenter noted that PFAS concentrations will continue to increase without intervention. The commenter also stated that it is already clear that the proposed designation of PFOA and PFOS as hazardous substances will benefit disadvantaged communities and communities with environmental justice concerns. The commenter cited the International Society for Environmental Epidemiology (ISEE) that concluded "Tribal Nations and their public water systems have been overlooked for systematic testing of PFAS" and represent a "large data gap." Furthermore, ISEE reported that Native American reservations are often within six miles of an active military installation where the use of PFAS is more pervasive. Finally, commenter expressed that potential links surrounding environmental justice should be addressed further in the final designation, especially given that EPA has an environmental justice mandate which is to extend to all of the agency's work. The commenter specifically pointed to PFAS as a major threat to drinking water, where according to the Water & Tribes Initiative of the Colorado River Basin, around 50% of tribal households lack access to clean water. [0566 - University of Arizona]

Response

EPA agrees that designation best protects communities with environmental justice concerns and that swift action to address harmful releases can reduce the need for more expensive, more expansive cleanup in the future. As explained in the final Preamble Section VI.A.2.d (Environmental Justice (EJ) Considerations for Designation) and Section IX.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), EPA believes that this action is likely to reduce existing disproportionate and adverse effects on people of color, low-income populations, and/or indigenous peoples. 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.

Designation is expected to promote earlier, more widespread cleanup of PFOA and PFOS. This should result in CERCLA responses that prioritize activities in and around communities living near highly contaminated sites. 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 ensure that those parties responsible for significant contamination 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 and/or earlier cleanups will better protect vulnerable populations and communities living near contaminated sites. Further, these cleanups will have meaningful health benefits commensurate with 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,

welfare and the environment will improve quality of life and reduce health care expenditures for the communities living near PFOA and PFOS contaminated sites.

For further discussion on the direct and indirect benefits that may be experienced by tribal communities as a result of the Final Rule, see the Preamble to the Final Rule Section VI and RTC 4.G.6-3.

5. Status of EPA, Federal, State, and International Actions

5.A Other Actions Being Taken by EPA

5.A.1 Support for EPA to address PFAS under the Roadmap and need for EPA program offices to work together.

A commenter stated that EPA should continue to address PFAS compounds under the Clean Water Act (CWA), concurrent with efforts to address PFAS through RCRA, as outlined in the PFAS Strategic Roadmap by establishing national technology-based regulatory limits for PFAS discharges from industrial sources through the Effluent Limitations Guidelines program, issuing guidance and proposing monitoring requirements for NPDES permits, and finalizing a risk assessment for PFOA and PFOS in biosolids. Another commenter asserted that EPA is not working collaboratively on an intra-Agency basis to implement the PFAS Strategic Roadmap and to grapple with the potential unintended consequences of EPA's regulatory actions. Two commenters emphasized implementation of the Strategic Roadmap and cross-regulatory actions. [0393-New Mexico Environment Department (NMED), Des Moines Metropolitan Wastewater Reclamation Authority (WRA); 0538-National Association of Clean Water Agencies (NACWA)]

Another commenter listed parallel efforts identified by EPA's PFAS Strategic Roadmap and argued that these rules could achieve similar objectives as the Agency claimed the propose designation will achieve, including: (1) reporting and recordkeeping requirements for PFAS under TSCA; (2) Effluent Limitation Guidelines for the organic chemicals, plastics, and synthetic fibers point source category and metal finishing point source category under the CWA (EPA, 2021d); (3) listing four PFAS substances as hazardous constituents under RCRA (EPA, 2021c); (4) changes to the reporting requirements for PFAS under EPCRA (OIRA, 2022a; EPA, 2021b); and (5) issuing guidance memoranda on addressing PFAS through the NPDES. Further, the commenter questioned the benefits of reporting requirements under the proposed designation given several other forthcoming regulations under TSCA, EPCRA, and the CWA that will also require data reporting. [0543-American Water Works Association (AWWA)]

A commenter noted that CERCLA reporting requirements do not apply to federally permitted releases but that there is currently no guidance or regulation under the CWA, RCRA, or Clean Air Act (CAA) regarding PFAS monitoring requirements or effluent limits in state-issued permits. The commenter urged EPA to provide permitting guidance for these statutes in parallel with the proposed designation to avoid disjointed regulatory action between solid waste facilities, wastewater treatment plants, waste incineration facilities, and clean-up sites. Another commenter asserted that EPA has not acknowledged the regulatory landscape in earnest, let alone discussed the potential for these alternatives to potentially achieve the goals of the

hazardous substance designation as well as to avoid unduly burdening small entities as required by UMRA. [0374-Minnesota Pollution Control Agency (MPCA), 0543-American Water Works Association (AWWA)]

Response

EPA acknowledges the commenter's statement urging the Agency to address PFAS through actions under the CWA and RCRA. For further discussion of EPA's integrated approach to PFAS, including information on Effluent Limitations Guidelines and guidance to states on how to use the CWA's NPDES permitting program to reduce harmful PFAS pollution, *see* the Preamble to the Final Rule Section III.C. (*PFAS Strategic Roadmap*) and visit the Agency's website at: https://www.epa.gov/pfas/key-epa-actions-address-pfas. For more information regarding the status of EPA's risk assessment work on PFAS found in biosolids, please visit the Agency's website at: https://www.epa.gov/biosolids/risk-assessment-pollutants-biosolids.

EPA disagrees with the commenter's position that its programmatic offices are not working together to address PFAS as discussed in the PFAS Strategic Roadmap. Each of EPA's media offices are working together to utilize all of the statutory authorities at the Agency's disposal to address the risks posed by PFAS.

The Agency disagrees with the commenter's position that EPA has failed to provide any guidance regarding PFAS monitoring requirements or effluent limits in state-issued permits. In fact, in December 2022 the Agency issued a guidance—Addressing PFAS Discharges in National Pollutant Discharge Elimination System Permits and Through the Pretreatment Program and Monitoring Programs—to states for addressing PFAS discharges when they are authorized to administer the NPDES permitting program and/or pretreatment program. In the future, EPA may issue further guidance to states regarding other media permitting programs as appropriate.

EPA disagrees with the commenter's assertion that the Agency has not adequately considered whether the objectives of the designation could be achieved through other statutory tools. CERCLA represents the best mechanism to address the legacy of sites contaminated with PFOA and PFOS and to address additional releases of these chemicals in the future. See the Preamble to the Final Rule Section I. (*Executive Summary*), VII.B.1. (*Comments suggesting that other authorities are better suited to address PFAS contamination*). The Agency also disagrees with the commenter's suggestion that the benefits of reporting requirements under the designation could be achieved through data reporting mechanisms under other statutes. First, EPA notes that statutory and regulatory programs maintain reporting thresholds that are intended for different purposes. Second, reporting under CERCLA and EPCRA will result in increased transparency about releases of PFOA and PFOS, which will inform the Agency's understanding of these substances in the environment and allow EPA to respond as necessary. Additionally, state, tribal and local officials will receive immediate notification of these releases so these entities can take actions to protect the community where releases occur.

5.A.2 The PFOA/PFOS hazardous substance designation does not confer a hazardous waste designation under RCRA.

A few commenters stated that the hazardous substance designation does not confer a hazardous waste designation under RCRA, so utilities will not be required to dispose of their PFOA/PFOS

treatment wastes following RCRA hazardous waste requirements once this rule is finalized. The commenter noted, however, that EPA is developing a RCRA rule to designate PFOA, PFOS, GenX, and PFBS as hazardous wastes which would clarify that emerging contaminants like PFOA, PFOS, and other PFAS can be addressed through RCRA corrective action. However, this rulemaking may not be complete before EPA finalizes the PFOA and PFOS drinking water standard in 2024, but it will eventually require treatment waste disposal following hazardous waste requirements. In anticipation of both the new SDWA and RCRA rules, EPA should provide technical assistance now to publicly owned treatment works and community drinking water systems on how to dispose of these wastes in a safe, cost-effective manner. Other commenters added that alternatives like RCRA corrective action can more quickly and effectively address contamination and bring relief to states and communities. [0365-Environmental Protection Network (EPN), 0552-Environmental Working Group (EWG)]

Response

Comments regarding the Agency's action to list specific PFAS as RCRA hazardous constituents under 40 CFR Part 261 Appendix VIII are outside the scope of the final rule. For further information regarding disposal of PFOA and PFOS-contaminated waste see the Preamble to the Final Rule Section VII.H. (Managing PFOA and PFOS Contaminated Waste); see also infra RTC Section 4.E.

5.A.3 Agreement with EPA's source control measures under TSCA

Several commenters supported source control measures to limit production and use of PFAS substances in commercial products and to incentivize a shift away from all nonessential use of PFAS using the Agency's authority under statues such as TSCA, consistent with EPA's Strategic Roadmap. [0515-Upper Blackstone Clean Water; 0394-Oklahoma Secretary of Energy and Environment and Oklahoma Department of Environmental Quality, 0471-Loudoun Water, 0538-National Association of Clean Water Agencies (NACWA)]

A commenter noted that under TSCA's Chemical Data Reporting rule, chemicals in U.S. commerce, including PFOA and PFOS, are subject to a 2,500-pound threshold at a single site. Under TSCA's Toxics Release Inventory facilities must report annually on releases and other waste management of certain listed toxic chemicals that they manufacture, process, or otherwise use above certain threshold quantities (e.g., 100 pounds for PFOA and PFOS). The commenter stated that both thresholds appear overly permissive. [0398-Pennsylvania Department of Environmental Protection]

A commenter stated that currently EPA only requires public water systems to publish and make available PFAS monitoring data but that public water systems and the public are limited in their ability to find and access PFAS release data from manufacturers and users. The commenter stated that for EPA's proposed PFAS Data Reporting and Recordkeeping Rule under TSCA, a publicly available, geospatially represented database is needed in form of a web based, interactive mapping platform that allows users to view and sort data regionally including the release year; PFAS compounds produced, used, and released; amount max concentration and disposal method per release; and adequate facility information. Further, the commenter argued that the proposed database should not be standalone, rather it should work with other EPA offices (e.g., the Office of Water, Office of Chemical Safety and Pollution Prevention, etc.) as well as other entities (e.g., the Department of Defense). [0543-American Water Works Association (AWWA)]

Response

EPA acknowledges the position of the commenters that source control represents an important tool in addressing the hazards posed by PFAS contamination. And, in fact, in its PFAS Strategic Roadmap, the Agency identified several source control methodologies, including a proposal to require pretreatment programs to include source control and best management practices to protect wastewater treatment plant discharges and biosolid applications.

Comments regarding the relative "permissiveness" of reporting standards under the Chemical Data Reporting rule or TSCA's Toxics Release Inventory are outside the scope of the final rule and no response is required. Relatedly, the commenter's request for a geospatially represented database is outside the scope of the final rule and no response is required.

5.A.4 The CERCLA designation must consider the impact of the Office of Water's SDWA proposal

A commenter stated that historically, there has been little engagement with EPA's Office of Land and Emergency Management (OLEM) and other EPA offices. The commenter noted that the Office of Water is working on a proposal to regulate PFOA and PFOS under the Safe Drinking Water Act (SDWA) and stated that the PFOA and PFOS designation under CERCLA must consider the impact of the drinking water rulemaking. OLEM and OW must work together to ensure these two rulemakings work in tandem. [0339-Association of State Drinking Water Administrators (ASDWA)]

Response

EPA disagrees with the commenter's claim that its programmatic offices do not coordinate efforts to address multi-media contamination issues. EPA is committed to a cross-Agency approach to address the challenges posed by PFAS on multiple fronts at the same time. For further discussion of EPA's efforts with respect to the interplay between this designation and the National Primary Drinking Water Regulation, see the Preamble to the Final Rule Section VII.B.3. (*Relationship between SDWA and CERCLA*).

5.A.5 The proposed rule impact on the Leaking Underground Storage Tank (LUST) Trust Fund.

A commenter stated that the proposed designation could have a significant effect on existing state and federal regulatory schemes to deal with underground petroleum leaks by reopening all past leak sites and testing each site for PFOA and PFOS which could severely burden the Leaking Underground Storage Tank (LUST) Trust Fund, resulting in significant costs to both taxpayers and operators of fuel retailer stations. The commenter stated that the LUST Trust Fund is already effective at preventing and overseeing cleanups at leak sites and that a CERCLA expansion to cover underground storage tank (UST) sites could complicate these state and federal regulatory schemes and leave fuel retailers without the necessary funds under the LUST Trust Fund to effectively clean-up future leaks. [0479-National Association of Convenience Stores (NACS)]

Response

EPA disagrees with the commenter's claims both that the designation will result in the reopening of all past UST leak sites and that the action will "severely burden" the LUST Trust Fund.

Rather, designating PFOA and PFOS as CERCLA hazardous substances will not frequently impact petroleum release sites, as PFOA or PFOS are not typically present in petroleum. Only UST sites where PFOA and PFOS were stored would be regulated by EPA's UST regulations. Where releases of PFOA and PFOS occurred as a contaminant from a non-UST source, comingled with the petroleum release, the remediation of the PFOA and PFOS would not be regulated under the UST regulatory structure. In neither situation would the cost of cleanup of PFOA and PFOS be eligible for reimbursement from the LUST Trust Fund because its use is restricted to petroleum releases. If PFOA or PFOS were present in small quantities in a petroleum UST, below the concentration that would designate the substance as hazardous, and a release occurred from that UST, then in those limited circumstances, cleanup of PFOA or PFOS might directly impact a UST release cleanup and be indirectly eligible for reimbursement as part of the petroleum cleanup.

5.A.6 The rule could jeopardize No Further Action designations under the Risk Based Corrective Action (RBCA) and trigger PFOA and PFOS to become subject to ASTM Due Diligence site assessment standards.

A commenter stated that many of the approximately 60,000 petroleum clean ups remaining as of May 2022 have been provided No Further Action through Risk Based Corrective Action (RBCA) processes as directed by various state agencies. The RBCA process allows for residual amounts of exempt contaminants to remain in the environment once it has been demonstrated that they pose no threat to human health or the environment. If the designation of PFOA and PFOS in the proposed rule is implemented, these compounds will become the subject of ASTM Due Diligence site assessment standards. The commenter stated that due to the prevalence of the compounds in the environment, the proposed designation could potentially lead to thousands of hazardous waste designated properties which will overwhelm State and Federal agencies as well as private businesses. [0479-National Association of Convenience Stores (NACS), NATSO and SIGMA]

Response

EPA disagrees that the designation will lead to the outcome described by the commenter. With the finalization of the rulemaking, PFOA and PFOS will need to be addressed to complete an ASTM-compliant Phase I Environmental Site Assessment (ESA). A Phase I ESA can be used to satisfy the statutory requirements for conducting All Appropriate Inquiries (AAI). AAI may be conducted to obtain protection from potential liability under CERCLA as an innocent landowner, a contiguous property owner, or a bona fide prospective purchaser. The commenter, however, provides no evidence to support their conclusion that the designation will require the designation of particular properties as Superfund sites.

5.B Actions Being Taken by Other Federal Agencies

5.B.1 Commenters pointed to pre-existing federal actions and a necessary cradle to grave and fate and transport regulatory approach.

A commenter stated that the proposed designation represents a continuation of pre-existing federal actions aimed at reducing the impacts of PFAS chemicals but argued that more must be done. Specifically, the commenter listed actions such as the 2010/2015 PFOA Stewardship

Program; the 2019 Interim Recommendations to Address Groundwater Contaminated with PFOA and PFOS; the proposed PFAS Action Act of 2021; the Environmental Council of States (ECOS) Resolution 21-1; a 2018 PFAS Caucus to share best practices on PFAS and a PFAS Coordinating Committee of state and federal agency leaders to share updates on PFAS activities; a 2020 published a white paper on state processes and considerations for setting state PFAS standards; provisions in the National Defense Authorization Act and the introduction of a 2020 rule requiring EPA notice and review of the use of long-chain PFAS; and efforts of other federal agencies such ATSDR, DoD, DoE, the Interstate Technology and Regulatory Council and FDA. A few commenters encouraged EPA to partner with the FDA and HHS to ensure a comprehensive cradle to grave and fate and transport regulatory approach to optimize PFAS risk reduction and take a holistic comprehensive agency approach to address concerns about unprecedented legal liability and cost burden on local communities. [0324-Citizen, 0393-New Mexico Environment Department (NMED), 0396-Michigan Water Environment Association (MWEA), 0538-National Association of Clean Water Agencies (NACWA)]

Response

EPA agrees with the commenter that a comprehensive approach to address the risks posed by PFAS is necessary. For further information regarding EPA's strategic approach to PFAS, see the Preamble to the Final Rule Section III.C. (*EPA's PFAS Strategic Roadmap*).

5.B.2 The Department of Defense must be held accountable under the CERCLA designation.

A commenter stated that under its Installation Restoration Program policy DOD has taken steps to address PFOA and PFOS-impacted drinking water sources and obligated \$1 billion through FY 2020 for investigating and cleaning up PFAS releases at military facilities but estimates budget requirements of more than \$2 billion annually for PFAS remediation. Under Section 335 of the National Defense Authorization Act (NDAA) for Fiscal Year 2021, Congress required DoD to publicly disclose the results of any testing for PFOA, PFOS, and other PFAS conducted on military installations or formerly used defense sites regardless of who conducted the testing, and under Section 332 required that DoD achieve the most stringent of any enforceable state and federal drinking, surface, or groundwater standards or health advisories issued pursuant to the SDWA when conducting removal or remediation of PFOA and/or PFOS contamination. [0421-A2 American Chemistry Council]

A commenter stated that they have identified 708 military sites with known or suspected PFAS contamination and asserted that DoD has used the absence of a "hazardous substance" designation under CERCLA to delay cleanups. The commenter referred to a violation notice for failure to meet Michigan cleanup standards for PFAS at the former Wurtsmith Air Force Base in 2018 to which the Air Force responded that "PFOS and PFOA do not qualify as CERCLA hazardous substances; they are CERCLA pollutants or contaminants under 42 U.S.C. § 9601(33). PFOS and PFOA are also not hazardous wastes, and they obviously are not petroleum . . . [T]he federal government is immune under 42 U.S.C. § 9620(a)(4) from a state enforcing its laws for the release of anything other than CERCLA hazardous substances." Therefore, the commenter supported the designation under CERCLA to hold the DoD accountable, accelerate the cleanup process, help add DOD sites to the NPL as needed, and help ensure that DOD respects state and federal cleanup standards. [0552-Environmental Working Group (EWG)]

Similarly, another commenter stated that without revoking or overturning E.O. 12580 CERCLA abatement and settlement authorities associated with DOD properties are delegated to the Secretary of Defense and the proposed listing of PFOA and PFOS as CERCLA hazardous substances will further leave communities unprotected as DOD uses E.O. 12580 to avoid transparency and coordination with state regulators which results in public confusion, ineffective risk communication and wasted taxpayer dollars on mitigation and remedial measures as currently demonstrated at Cannon and Holloman Air Force Bases in New Mexico. The commenter urged EPA to engage the White House Council on Environmental Quality and other appropriate officials to rescind or substantively revise E.O. 12580 in conjunction its efforts to develop the final action on the proposed rule. The commenter also believed that DOD's current position is that it will not mitigate impacts to water used for agricultural purposes except when specific conditions are met (DOD Guidance for Implementing Section 343 of the National Defense Authorization Act of Fiscal Year 2020, Provision of Water Uncontaminated with [PFAS] for Agricultural Purposes, August 4, 2020) and therefore suggested that CERCLA designation of PFOA and PFOS combined with executive action on E.O. 12580 and EPA listing various PFAS as hazardous constituents pursuant to RCRA, should compel DOD to take full responsibility for its legacy PFAS disposals and their impacts on and off base. The commenter also requested an executive order on PFAS directing DoD to (1) fully implement the NDAA, especially pertaining to sections 332 on state cooperative agreements, 343 on providing water not contaminated with PFAS for agricultural purposes, and 7333 on nationwide sampling for PFAS, including through developing and implementing guidance that provides the broadest coverage and protection allowable under the NDAA provisions; (2) create and timely update a webpage for states and the public that lists DoD action items from the NDAA and DoD's progress on meeting those directives, sampling data for all media and potable and monitoring wells, a listing of sites and DoD's progress on cleaning them up, and a posting of state requests for assistance under section 332 of the 2020 NDAA and DoD's response to each state; (3) create and timely update a webpage for states and the public that lists DoD action items from the NDAA and DoD's progress on meeting those directives, sampling data for all media and potable and monitoring wells, a listing of sites and DoD's progress on cleaning them up, and a posting of state requests for assistance under section 332 of the 2020 NDAA and DoD's response to each state; and (4) provide funding to States that are overseeing assessments, investigations, emergency responses, and cleanups at DoD sites, including those of the U.S. Air Force, Navy, Army, and at federal and state national guard through the Defense and State Memorandum of Agreement or other appropriate funding vehicles. [0393-New Mexico Environment Department *(NMED)*]

Response

Comments regarding the Department of Defense are outside the scope of the final rule and no response is required.

5.C Actions Being Taken by States or Municipalities

5.C.1 States and municipalities have already taken a number of actions to address PFOA and PFOS, and the Agency should coordinate with them.

Because the potential designation of PFOS and PFOA as CERCLA hazardous substances potentially impacts State environmental regulatory programs, a few commenters urged EPA to work with communities, States, and across its internal offices to develop PFAS strategies. [0348-Bowling Green Municipal Utilities (BGMU), 0374-Minnesota Pollution Control Agency (MPCA)]

A commenter stated that cleanup under State programs can be more flexible than the NPL process. The commenter listed States that already treat PFOA and PFOS as hazardous substances under their state cleanup laws and referred to twenty-nine states have developed or are developing recommended soil or groundwater cleanup levels for PFOA, PFOS, and other PFAS.

Some commenters noted that their States have expended significant taxpayer resources to protect their residents and natural resources; undertake sampling and assessment of groundwater and ambient surface waters, soil, landfill leachate, wastewater effluent and residuals and land application sites; adopt standards, screening levels and guidance values, address contamination and introduce regulations designating PFOA and PFOS as hazardous substances under State laws. One of these commenters stated they have also engaged in litigation against manufacturers and distributors of PFAS and affected products to recover cleanup costs and natural resource damages and pursued remediation of PFAS at U.S. Department of Defense (DOD) sites. Additionally, many states have urged both Congress and EPA to take other prompt and aggressive actions to respond to PFAS issues. [0522-Environmental Working Group (EWG), 0414-Attorneys General of the States of New York, et al, 0534-Kansas Department of Health and Environment (KDHE), 0547-Maine Department of Agriculture, Conservation and Forestry (DACF), 0341-Massachusetts Department of Environmental Protection (MassDEP), 0520-Wisconsin Paper Council (WPC), 0398-Pennsylvania Department of Environmental Protection]

One commenter pointed to their Storage Tank and Spill Prevention Act (STSPA) that regulates aboveground and underground storage tanks that contain hazardous substances. The commenter asserted that if EPA finalizes the rule, those storage tanks that contain PFOS and PFOA compounds would become regulated under the STSPA, driving hazardous substances to be stored in aboveground storage tanks. [0398-Pennsylvania Department of Environmental Protection]

Another commenter stated that EPA actions, including the designation of landfills without environmental controls as Superfund sites would substantially disturb existing and long-standing agreements with their state and other regulatory authorities. Such actions would also create significant financial liability regarding to monitoring and possible remediation costs. [0478-New York City]

Response

EPA agrees that working with a wide range of partners to address the risks posed by PFOA and PFOS, including both states and communities, is critical to addressing the challenges posed by these substances.

EPA disagrees with the commenter's assertion that designation will necessarily result in the storage of PFOA and PFOS in aboveground storage tanks. The commenter has offered no support for this claim and the designation of PFOA and PFOS as CERCLA hazardous substances does not require waste to be treated in any particular fashion nor disposed of at any particular type of landfill. EPA also disagrees with the commenter's position that the designation will necessarily result in the identification of certain landfills as Superfund sites, thereby disrupting existing agreements with State regulatory authorities. A designation alone does not require the EPA to take response actions, does not require any response action by a private party, and does not determine liability for hazardous substance release response costs. Response actions are contingent, discretionary, and site-specific decisions made after a hazardous substance release or threatened release. They are contingent upon a series of separate discretionary actions and meeting certain statutory and regulatory requirements. *See* the Preamble to the Final Rule Section VI.B. (*Disadvantages of Designation*).



6. Cost and Economic Assessment

6.A General Comments Associated with the Economic Analysis

6.A.1 EPA's economic assessment with the proposed rule was insufficient, the EPA must prepare and publicly report a full economic and regulatory impact analysis that meets the requirements of EO 12866 and 13563 and Circular A-4.

Multiple commenters stated that the EPA's economic assessment was incomplete. They called for a full Regulatory Impact Analysis (RIA) that addresses financial, health, and environmental impacts on citizens, business, and publicly owned facilities. They also stated the RIA should consider direct and indirect costs and benefits. The economic impacts evaluated should be broad and include operational and disposal activities, lost opportunities to implement systems improvements, and litigation/liability. [0510/WEAT/TACWA; 0507/Wasatch; 0511/WaterReuse - 0350 (Henderson), 0352 (Clark County), 0453 (Monterey), 0521 (WMWD); 0809/OC San; 0438-City of Aurora; 0394/OSEE, ODEQ; 0322-Environmental Compliance Manager; 0554/ District of Columbia Water and Sewer Authority; 0455/IEUA; 0470/MEG Wastewater; 0348-BGMU; 0355-LASAN; 0396-MWEA; 0807-CNSAWWA;0491/OCWD; 0538/NACWA - supported by 0350 (Henderson), 0351 (St Charles), 0352 (Clark County), 0375 (St. Louis), 0395 (MWRA), 0465 (JCW), 0478 (NYC), 0496 (NEORSD), 0521 (WMWD), 0527 (Metro), 0562 (NBC), 0804 (SPR), 0809 (OC San); 0378/MSD; 0406/WAC; 0457/GCDCWWS; 0462/LA Sanitation; 0449/Weatherford; 0396/MWEA]

Multiple commenters also noted that the OMB designated the Proposed Rule as economically significant, requiring EPA to prepare a cost benefit analysis in keeping with Executive Order 12866 and OMB Circular A-4. One of these commenters noted the need to perform a regulatory impact assessment on the indirect impacts of the proposed rule, including but not limited to the financial impact to citizens, businesses, and publicly owned facilities. Another recommends that the EPA conduct a comprehensive Regulatory Impact Analysis that fully considers direct and indirect costs and benefits, including compliance, legal liability, and costs stemming from cleanup actions undertaken or mandated by EPA, as well as those undertaken voluntarily by other parties. [0510/WEAT/TACWA; 0507/Wasatch; 0511/WateReuse - 0350 (Henderson), 0352 (Clark County), 0453 (Monterey), 0521 (WMWD); 0809/OC San; 0438-City of Aurora; 0394/OSEE, ODEQ; 0322-Environmental Compliance Manager; 0554/ District of Columbia Water and Sewer Authority; 0455/IEUA; 0470/MEG Wastewater; 0348-BGMU; 0355-LASAN; 0396-MWEA; 0807-CNSAWWA; 0491/OCWD; 0538/NACWA - supported by 0350 (Henderson), 0351 (St Charles), 0352 (Clark County), 0375 (St. Louis), 0395 (MWRA), 0465 (JCW), 0478 (NYC), 0496 (NEORSD), 0521 (WMWD), 0527 (Metro), 0562 (NBC), 0804 (SPR), 0809 (OC San); 0378/MSD; 0406/WAC; 0457/GCDCWWS; 0462/LA Sanitation; 0449/Weatherford; 0396/MWEA]

Numerous commenters noted that although the rule has been deemed economically significant by the Office of Management and Budget (OMB), sufficient analysis has not been performed by EPA. The commenters urged the Agency to withdraw the proposed rule until such analysis has been conducted. [0436/Manhattan, KS; 0434-City of Manhattan KS; 0506/Conference of Mayors; 0321/Tillamook County Board; 0529-Augusta County Service Authority (ACSA); 0437/City of Dubuque; 0431-City of Lexington; 0448-City of Thousand Oaks; 0451-Harford Co;

0376/Kent County; 0498/Santa Clarita Valley Water Agency (SCV Water); 0489-Shelby Co; 0400-Town of Windsor; 0403- Town of Purcellville, VA; 0493-POWER! fully supported by 0521 (WMWD)]

Some commenters asserted the need for the EPA to follow the requirement for economically significant rules, prepare and publicly report a full economic and regulatory impact analysis of the proposed action. These commenters asserted that the EPA is required to produce a Regulatory Impact Analysis ("RIA") and release the RIA for public review and comment before taking any further action on the proposed rule. The commenters note that Executive Order 12866 ("EO 12866") requires that an agency provide a Regulatory Impact Analysis ("RIA") for all significant regulatory actions the agency takes. Another commenter emphasized that the EPA's economic assessment is not an RIA and does not satisfy the requirements of an RIA. [0413-ACWA; 0245-USCOM/NLC/NACo; 0744-Young; 0476-Michigan Manufacturers Assoc (MMA); 0493-POWER! supported by 0521 (WMWD); 0371/The State Chamber of Oklahoma and the Environmental Federation of Oklahoma; 0512/Stericycle]

Another commenter asserted that the EPA should pause the rulemaking process and conduct a comprehensive Regulatory Impact Analysis before proceeding. The commenter notes that the designation of PFOA and PFOS as hazardous substances under CERCLA will be complex and have far reaching implications. The proposed rule requires a robust analysis of all the potential impacts, as well as the novel legal and policy issues presented. EPA should conduct a comprehensive Regulatory Impact Analysis, as required by OMB Circular A-4, before proceeding with the proposal to allow the public to review the potential impacts and adequately comment on the implications. [0413-ACWA]

This commenter further asserted that the EPA's economic analysis of the proposed rule does not fully capture the broad potential impacts of the contemplated CERCLA hazardous substance designation. The economic assessment does provide some qualitative assessment of direct reporting costs; however, the assessment leaves many important questions unanswered regarding other direct and indirect costs including response actions. EPA acknowledged this reality in concluding "the following barriers prevent developing a quantitative analysis of costs, benefits, and transfers associated with potential response actions: lack of adequate data availability about the extent of existing PFOA and PFOS use and contamination, evolving assessment technology and health science, and developing treatment and disposal technologies." (EPA, EA at 26). [0413-ACWA]

Another commenter noted that EO 12866 requires that an agency provide an RIA that includes "but is not limited to, the direct cost both to the government administering the regulation and to businesses and others in complying with the regulation and any adverse effects on the efficient functioning of the economy" and private markets, including the natural environment. The Government Accountability Office has in turn defined direct costs of a government regulation to include the direct compliance costs such as additional paperwork, development and installation of new or modified equipment, and testing procedures. The commenter asserted that the lack of an RIA to support the proposed rule highlights the overall lack of certainty regarding the likely impacts of EPA's proposed action. Moving forward with the proposed rule under these circumstances would violate existing Administration policy. In Circular A-4, the Office of Management and Budget ("OMB") states that when proposing a federal regulation, a federal agency must "do more than demonstrate the possible existence of incomplete or asymmetric information" (OMB, Circular A-4 at 5 (Sept. 17, 2003)). Further, when an agency proceeds with

a rulemaking, despite uncertainty having a significant effect on the cost analysis, the agency should explain what the harm from delay would be (OMB, Circular A-4 at 39 (Sept. 17, 2003)). When "uncertainty is due to a lack of data," it is recommended the federal agency defer the rulemaking (OMB, Circular A-4 at 39 (Sept. 17, 2003)). [0413-ACWA; 0245-USCOM/NLC/NACo; 0744-Young; 0476-Michigan Manufacturers Assoc (MMA); 0493-POWER! supported by 0521 (WMWD); 0371/The State Chamber of Oklahoma and the Environmental Federation of Oklahoma; 0512/Stericycle]

The commenter stated that the EPA's economic assessment is inadequate and does not provide the required cost analysis for review and comment on. This commenter and another commenter emphasized that the EPA should conduct a comprehensive Regulatory Impact Analysis that fully considers the compliance and clean-up costs of the proposal, including direct and indirect costs and benefits. Conducting a Regulatory Impact Analysis will assist stakeholders with understanding and assessing the potential impacts of the proposed rule and providing appropriate feedback to EPA. The commenters request that the rulemaking be paused and the EPA repromulgate a supplemental proposed rule with a Regulatory Impact Analysis to allow comprehensive public comment to take place. 0371/The State Chamber of Oklahoma and the Environmental Federation of Oklahoma;

Some commenters identified several deficiencies in the content of the proposed rule: (1) EPA had not identified a problem that needs to be addressed via CERCLA, (2) there was no defined baseline describing what the situation would look like if no action were taken, (3) the relationship between designation of the hazardous substances and enforcement of the rule was not clear, and (4) alternative approaches were not considered.

Another commenter asserted that the proposed rule has been in Executive Order 12866 review for several months and urged the Office of Information and Regulatory Affairs to ensure that prior to completing its review, the proposal is accompanied by and consistent with a robust economic analysis in keeping with both Office of Management and Budget and EPA guidance for such analyses (i.e., Executive Order 12866, Circular A-4, and EPA's Guidelines for Preparing Economic Analyses). Adding PFAS Chemicals to the list of hazardous substances is a definitional change akin to EPA's rulemakings for the definition of "Waters of the United States" – for which extensive economic analysis was conducted.

[0421-American Chemistry Council; 0239/US Chamber of Commerce; 0522/Wisconsin Manufacturers & Commerce (WMC); 0345/3M Company;0523-WSPA; 0418-ACG; 0477-Kean/Miller on behalf of Louisiana Chemical Association ("LCA"); 0234/ILTA; 0419-The American Petroleum Institute (API), the American Fuel & Petrochemical Manufacturers (AFPM), the Alaska Oil and Gas Association (AOGA), the Louisiana MidContinent Oil and Gas Association (LMOGA), the New Mexico Oil and Gas Association (NMOGA), The Petroleum Alliance of Oklahoma (PAO), the Petroleum Association of Wyoming (PAW), and the Utah Petroleum Association (UPA) (collectively, "the Associations")]

Additional Comment Details on 6.A.1.

Some commenters state that the EOs 12866 and 13563 together establish the requirement that economically significant regulatory actions must be supported by a RIA that includes an assessment of the benefits and costs anticipated from the regulatory action, quantified to the extent feasible, as well as a similar assessment and quantification for identified potential alternatives. EO 13563 further requires that these assessments "use the best available techniques

to quantify anticipated present and future benefits and costs as accurately as possible." The best available technique for quantifying the benefits of EPA regulations that are directed toward reducing risks is risk assessment. To implement these directives, agencies are instructed to follow OMB Circular A-4, which describes the elements that must be in the regulatory impact analysis of an economically significant regulation.

Another commenter asserted that the EPA's limited Economic Assessment illustrates that EPA has not measured costs and enumerated benefits associated with the Proposed Rule, as required by the APA.

Multiple commenters asserted that upon completing this important analysis, EPA should issue a supplemental proposal providing a full discussion of issues relevant to the estimated costs and benefits to allow the public to provide adequate, needed input on those estimates and on all relevant considerations. Also asserted was that the Agency cannot dismiss such an exercise simply because precise information is unavailable. Rather, the Agency' failure to capture the uncertainties and to appropriately weigh them as a reason to withdraw the proposed CERCLA listing. Commenters also noted was that the lack of available information strongly suggests that the Agency should not move forward with this action until more data are gathered. Another commenter requests that EPA withdraw the rule until it performs a full RIA to accurately measure the costs and benefits of the Proposed Rule, as it has done for similarly significant rules in the past.

Another commenter asserted that the EPA's proposed rule and the associated Economic Assessment do not meet the most basic requirements of a regulatory impact analysis as required by EOs 12866 and 13563 and Circular A-4.

First, Circular A-4, consistent with EO 12866, requires a statement of need for the regulatory action. This statement should describe the problem that the agency seeks to address. In the Economic Assessment, while EPA has a section entitled "Need for Regulatory Action," EPA does not describe any problem or problems that need fixing. EPA does state that the action would "further CERCLA's primary goal of protecting public health and welfare," but this is not a problem. EPA has not explained why CERCLA, as it currently exists, is not protecting public health and welfare. EPA notes that the designations of PFOA and PFOS as hazardous substances would improve information quality and improve our understanding of PFOA and PFOS releases. However, there is no discussion of a problem that exists due to poor quality information, nor is there a discussion of problems caused by an information insufficiency. The other actions proposed by EPA's Strategic Roadmap do not obviously require designation under CERCLA to achieve the key outcomes. Without identifying a problem, there is no justification for the proposed PFOA and PFOS designations.

Second, Circular A-4, consistent with EO 12866, requires an examination of alternative approaches that the agency considered. Neither the proposed rule nor the Economic Assessment provide any discussion of alternatives that EPA considered. The lack of consideration of even one viable alternative is an egregious error that must be corrected.

Third, Circular A-4, consistent with EOs 12866 and 13563, requires an evaluation of the benefits and costs, quantitative and qualitative, of the proposed action and the main alternatives identified by the analysis. Unfortunately, EPA quantifies only reporting costs and ignores the reasonably foreseeable and predominant quantifiable cleanup costs that would be associated with designating PFOA and PFOS as hazardous substances. Not only does EPA ignore costs to

private parties, but it also ignores costs to states, tribes, municipalities, federal facilities, publicly owned treatment works, and landfills. Arguing that most impacts are "indirect effects" is not compelling, as Circular A-4 makes clear that the economic analysis "should look beyond the direct benefits and direct costs" of the rulemaking. Similarly, EPA's arguments that the information is too uncertain also fall flat. Uncertainty is not an acceptable excuse for providing a subpar analysis that ignores the costliest aspects of the proposal. Circular A-4 provides agencies with many options for quantitatively treating uncertainty, including but not limited to sensitivity analyses and probabilistic analyses.

Finally, as we have noted previously, as no alternatives are presented, there is no analysis of alternatives.

Multiple commenters asserted that the EPA has not conducted a robust regulatory impact analysis of the impacts required for an economically significant rule. The commenter noted that in its proposal EPA explains that CERCLA was enacted to promote the timely cleanup of contaminated sites and to provide the federal government with authority to respond to releases or threatened releases of hazardous substances in order to protect the public health and the environment. Further, the commenter notes that the Agency attempts to decouple the decision to designate PFOA and PFOS as "hazardous" under CERCLA from the enforcement process that it notes was the intent of the legislation. Rather than avoid the direct connection, EPA must recognize that the hazardous substance designation process and the Agency's implementation of cleanup activities are inherently linked. The commenter notes that in light of the significant impacts and numerous uncertainties associated with the designation of the two substances under CERCLA, it is critically important that EPA fully consider the costs associated with the proposal.

This commenter also asserted that the EPA fails to establish a clear baseline for its analysis. The commenter noted that to conduct a benefit-cost analysis, the Agency must first construct a baseline. According to Circular A-4, this baseline should be "the best assessment of the way the world would look absent the proposed action" and "may require consideration of a wide range of potential factors," including other federal and state regulations. The Circular notes that "[I]t may be reasonable to forecast that the world absent the regulation will resemble the present." The commenter asserted that the Agency's economic assessment briefly discusses the baseline by acknowledging some other regulations to address PFOA/PFOS. The commenter further asserted that this brief discussion, however, is insufficient. What is necessary is a quantitative and monetized estimate of costs associated with a baseline that reflects ongoing "upstream" waste management behavior to address PFOA and PFOS and ongoing "downstream" costs associated with the cleanup of PFOA- and PFOS-contaminated sites on the NPL. Such a baseline could be then used to identify the incremental costs associated with the proposed rule and its alternatives.

Response

EPA does not agree with the comments that the EA issued with the proposed rule was insufficient. As it developed the EA, EPA followed its own Guidelines for Preparing Economic Analysis and OMB's Circular A-4 which provides guidance to Federal agencies on developing regulatory analyses to assure compliance with related E.O.s and statutory requirements. Prior to approving release of the proposed rule and the associated EA, OMB reviewed both documents to ensure that the methods applied in the analysis were methodologically sound and that the EA met the requirements articulated in those related executive orders and in Circular A-4. OMB's review

also provided assurance that the EA provided the public with adequate information to understand the rule's potential impacts. Thus, the proposed rule EA provided the economic analyses as required for a RIA attendant to significant Federal agency rulemaking. See RTC Section 7.A.1 for a response to comments asserting that EPA may not take final action until the Agency takes comment on the Final Rule RIA.

Further, the EA issued with the proposed rule considered multiple potential impacts of the designation, including a quantitative estimate of direct costs associated with reporting a release that meets or exceeds the RQ, as well as an in-depth discussion of qualitative direct benefits, indirect costs, potential cost transfers, and indirect benefits. With respect to indirect costs, the EA described: EPA's improved authority to require PRPs to cleanup contamination and transfer response costs to PRPs in certain circumstances, increase R&D expenditures, and earlier response activity that may increase the costs of cleanup in present value terms. The direct benefits evaluated in the proposed rule EA included improved quality of information, increased data disclosure regarding individual companies' releases, and better waste management practices for facilities handling PFOA and PFOS. The proposed rule EA also considered other indirect benefits including potential health benefits associated with response actions, the speed of response actions, and a potential increase in the number of contaminated sites identified, assessed, and remediated. In addition, the proposed rule EA included a breakeven analysis to assess the likelihood of whether the rule would result in a significant impact for a substantial number of small entities and, for the assessment of potential environmental justice impacts, assessed the demographic characteristics of populations living near sites in affected industries. With this breadth of analysis, the EA provided sufficient information to the public to consider the potential impacts of the rule, including downstream indirect impacts associated with potential liability and response actions. In addition, EPA requested public comment on potential costs and benefits of the proposed rulemaking (e.g., whether indirect costs and benefits should be considered for the final rule). 87 FR at 54423. EPA received several comments relevant to direct and indirect costs and benefits and, among other things, asserted that EPA must consider costs and benefits in designation decisions pursuant to CERCLA section 102(a). In the final rule, EPA exercised its discretion to conduct an additional totality of the circumstances analysis. As part of that analysis, EPA identified and weighed the advantages and disadvantages of designation relative to CERCLA's purpose alongside the formal RIA, including quantitative and qualitative benefits and costs provided in the Regulatory Impact Analysis⁷ accompanying this final rule. Based on that "totality of the circumstances" analysis, EPA concluded that designation is warranted because the advantages of designation outweigh the disadvantages. See Preamble to the Final Rule Section VI.C. (Results of the Totality of the Circumstances Analysis).

EPA disagrees that the EA issued with the proposal required more detailed evaluation of direct costs. According to EPA's Guidelines for Preparing Economic Analyses (published in 2010 and updated in 2016), "direct costs are those which fall directly on regulated entities as the result of the imposition of a regulation." The only direct impact to the public of this CERCLA designation is the requirement that any person in charge of a vessel or facility report a release of PFOA

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⁷ 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.

and/or PFOS of one pound or more within a 24-hour period. EPA provided, in the economic assessment released with the proposed rule, an estimated low and high range of potential reporting requirement frequencies and associated direct costs. No commenter identified a direct cost to the public other than the reporting requirement the Agency evaluated.

EPA also disagrees that the EA issued with the proposal required more detailed evaluation of indirect costs and benefits. Neither a release nor a report of a release automatically triggers cleanup or other response action under CERCLA. Such actions occur only after EPA makes a determination that response is necessary to protect human health and the environment. Prior to EPA reviewing the available data for each site after learning of a release, it is not possible to determine the number of sites where response action may be necessary, the specifications of the response, or the associated costs and benefits.

Building on the information presented in the proposed rule EA and considering newly available information since proposal, the RIA accompanying this final rule includes expanded analyses of direct/indirect costs, transfers, and benefits relative to the analysis developed for the proposed rule, to better inform the public of potential direct and indirect costs, transfers, and benefits (See Preamble to Final Rule Section IV.C (*CERCLA section 102(a) and Cost Considerations.*). The final RIA addresses financial, health, and environmental impacts on citizens, businesses, and industries. It includes a quantitative analysis of indirect costs and benefits associated with potential enforcement actions that may follow promulgation of the rule and potential cost transfer impacts associated with site remedial and removal actions. The final RIA also evaluates impacts related to liability and litigation that may arise after designation. Please see RIA Chapters 4 and 5 for more information about EPA's methodologies and discussion of direct and indirect costs, benefits, and transfers.

The RIA accompanying this final rule includes a comprehensive baseline discussion describing the CERCLA process as well as potentially affected entities including upstream manufacturers, importers, and processors of PFOA and/or PFOS, and downstream users. EPA also conducted a quantitative analysis of benefits associated with baseline response to PFOA/PFOS contamination at NPL sites and provided information on costs associated with current response and cleanup methods for PFAS. See RIA Chapter 3 (*Characterization of Entities Affected by the Final Rule and Baseline Benefits of Addressing PFOA/PFOS Exposure*) and RIA Section 5.1.1 (*Available Data on Response and Cleanup Methods for PFAS and Associated Costs*) for more details on the baseline. Additionally, the final rule RIA includes consideration of two alternatives to the final rule – one more stringent regulatory alternative and one less stringent regulatory alternative. See RIA Appendix ("Potential Regulatory Alternatives") for a description and analysis of these alternatives. Please refer to RTC, Section 7.A.1.

Additionally, designation does not impose any automatic regulatory requirements on private facilities or entities. EPA's analysis uses NAICS codes to identify those industry groups which may be potentially affected by the final rule but does not quantitively assess costs to all entities within a given NAICS category since the rule does not impose regulatory requirements on them. See RIA Section 3.2 (*Entities and Industries Potentially Affected by the Rule*) for further details.

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⁸ Designation imposes notification requirements for certain releases; however, these requirements are only applicable in certain circumstances and are not automatic, industry-wide regulatory requirements.

Based on its final analysis, which included a consideration of uncertainties, EPA determined that designation is warranted. See Section VI (*The totality of the circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted.*). See also Response to Comment 2.B.1 (*Consideration of Cost and 102(a)*).

The final rule RIA is consistent with guidance in OMB's Circular A-4 on how to address and account for uncertainty. See Preamble to Final Rule Section VI (*The totality of the circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted*). The analyses of potential costs, transfers, and benefits in the final rule RIA estimate such impacts under a range of scenarios designed to reflect uncertainty in several key parameters. For potentials costs and transfers, this includes the use of three different cost premiums and the calculation of high- and low-end removal cost estimates and enforcement cost estimates. For benefits, this includes presenting a range of benefits based on different PFOA/PFOS concentration reductions and different assumptions regarding the baseline occurrence of PFOA/PFOS in private drinking water wells. Real probability distributions that are required to develop robust Monte Carlo and similar uncertainty analyses are not available.

EPA does not agree with the comments stating that the Agency must defer the designation. The commenter inaccurately cites Circular A-4's language on uncertainty due to lack of data, stating "it is recommended the federal agency defer the rulemaking." Circular A-4 does not make any such recommendation, instead stating the following: "When the uncertainty is due to a lack of data, you might consider deferring the decision." The available scientific information demonstrates that PFOA and PFOS may present a substantial danger to human health, welfare, and the environment when released and, if not addressed, these substances will continue to migrate, further exacerbating exposure risk and potential cleanup costs. The information also demonstrates that there are many historical releases of PFOA and PFOS because they have been in use since the 1940s, and that unless those sites are evaluated and, if necessary, cleaned to address identified risks, those risks will not go away. The argument for delay thus fails to adequately consider the risks that communities and the environment are currently subject to as a result of over 60 years of substances that we now know may pose a hazard to human health and the environment when released. These findings not only demonstrate why delaying CERCLA designation would be harmful, but also show that EPA's justification for designation is not based on incomplete or asymmetric information, as asserted by the commenter. See RIA Section 1.2 (Need for Regulatory Action) and Preamble to Final Rule Section VI (The totality of the circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted.) for further details.

6.A.2 EPA needs to consider the actual costs associated with the Proposed Rule.

Some commenters stated that EPA's economic analysis was insufficient in assessing the full cost impacts of the rule, calling for a full Regulatory Impact Analysis (RIA) that assesses direct and indirect costs associated with nationwide investigation and response of PFOA and PFOS. Certain commenters felt that the EA conducted by EPA was insufficient for several reasons: (1) the analysis included only quantified reporting costs and not cleanup costs, (2) several types of costs (e.g., cleanup costs) had been classified as indirect rather than direct, and (3) some costs (e.g., regulatory familiarization) had been excluded entirely. Commenters also disagreed with EPA's characterization of the costs as "unquantifiable." In addition, commenters noted that EPA failed to capture all of the expected additional costs of the proposed rule in which the suggested RIA should also address three anticipated outcomes: (1) costs incurred in response to natural

occurrences of the substances, (2) increased costs of waste management practices, and (3) imposing more costly remediation strategies at sites added to the NPL. [0569-US Chamber of Commerce Coalition

Several commenters stated that EPA's cost analysis did not rely on precise cost inputs. They cited several cost assessments (e.g., one done by Department of Defense) and urged EPA to identify data sources and incorporate them into a full RIA. Pending these changes in approach, commenters felt that efforts to implement a rule change should be paused. They felt that if precise cost data were not available, then it was premature to issue a rule change. [0391/SSP]

The commenter also points out that CERCLA has been utilized, and therefore a matrix of associated costs has been available, since 1981, when 4,000 drums were removed from the "Valley of Drums" site in Kentucky. Thus, there are over four decades of cost information available that EPA seemingly has chosen to ignore, apparently deciding that actual costs accrued – costs that have been well documented for almost half a century – do not merit incorporation or even recognition in the Proposed Rule. It is the case that EPA will have a very difficult time estimating the costs specific to potential cleanups associated with PFOA and PFOS given the fact that EPA does not yet know how to remediate PFAS substances or to what levels they need to be remediated to protect public health and the environment. But that fact does not remove EPA's responsibility to assess the true impacts of its action; rather, it speaks to the potential rashness of the current proposal. [0407-WCA PFAS]

The commenter states that EPA must consider more than reporting costs in determining whether any final rule is economically significant and should be transparent in the costs that will result if the rule is finalized as proposed. In the event EPA does not analyze these costs in determining economic significance in the final rule, EPA must explain why these costs are not necessary for evaluation, given the functional certainty of their occurrence. [0407-WCA PFAS]

One commenter asserts that EPA has not fully described or considered the impacts of the proposed designation. The commenter points out that the proposed rule, and any proposed rule under § 102(a) will have two categories of direct and automatic consequences: (1) Reporting requirements, when a known release of the reportable quantity of the hazardous substance occurs; and (2) The financial and liability responsibilities and concerns that result directly from the designation of a substance as a hazardous substance under CERCLA. [0493- Protecting Our Water, Environment, and Ratepayers Coalition (POWER!); 0521 (WMWD)]

Another commenter emphasized that EPA should perform the RIA deemed necessary by OMB. The commenter asserts that the EPA's EA hardly rises to the level of an RIA and provides only an estimate of the relatively low "direct costs" associated with the release reporting requirements. The commenter further noted that release reporting is just one aspect of a CERCLA "hazardous substance" designation; the imposition of liability for environmental response costs is the other (and more costly) component. The commenter pointed out that the costs associated with release reporting are negligible compared to environmental cleanup costs. The commenter also points to the Proposed Rule noting that the EPA asserts that it is impractical to quantitatively assess the indirect costs (for response actions) because of the uncertainty about such costs at this early stage in the process. The commenter highlighted that the purpose of the RIA program is to ensure efficiency, accountability and transparency in the rulemaking process (See Executive Orders 13562, 12866). The commenter emphasized that this cannot be achieved in this case if EPA is allowed to throw up its hands on the basis that the work required to

estimate response costs, which commenter asserts are "direct" rather than "indirect," is too difficult. The commenter also noted that CERCLA Section 102 does not preclude the consideration of cost. The commenter stated that the EPA's lack of attention to the full cost implications of the Proposed Rule is unacceptable. [0512/Stericycle]

One commenter asserted the need for a proper regulatory impact assessment (RIA) to accurately determine costs and to identify the true regulatory reach. The commenter also noted that the proposal is a significant economic concern and will also create unpredictability across the economy. [0744-Young]

Additional Comment Details on 6.A.2.

Multiple commenters asserted that the EPA should consider all relevant direct and indirect costs and benefits in its EA as the consideration of these costs and benefits, including their quantification when feasible, is necessary to comply with Executive Orders 12866 and 13563. In particular, EPA must consider the costs associated with imposing CERCLA liability on PFOA/PFOS releases and the costs associated with nationwide investigation, response and removal actions, as cleaning up contaminated sites is the core mission of the CERCLA program. The commenter further asserted that numerous existing NPL sites are likely to have some PFOA/PFOS present due to their widespread occurrence in the natural environment. As a result, the commenter stated that the EPA's analysis fails to include the costs associated with completing hundreds of five year review submittals and related PFOA/PFOS sampling for these sites, once these substances become subject to new federal ARAR. The commenter also points out another set of costs to be considered include the costs to the U.S. Department of Defense to clean up sites impacted by PFOA/PFOS. The commenter also noted that the EPA must consider and thoroughly evaluate the incremental benefits to human health and the environment of this proposed listing when compared to the baseline of existing authorities in place today to address PFOA and PFOS releases at the federal and state level.

A commenter asserted that CERCLA is not a new program and the costs associated with compliance are established. EPA has sufficient expertise and knowledge developed over four decades to make reasonable estimations of potential costs associated with the exercise of this broad authority. Distributing cleanup costs is a basic purpose of CERCLA and must be accounted for in any proposed CERCLA rule.

A commenter also asserted that Circular A-4 recommends monetizing quantitative estimates whenever possible. It was noted by the commenter that the EPA's EA identifies and quantities, in cursory fashion, reporting of releases; disclosure of the storage or release during the sale or transfer of federal property; and listing by the DOT in the Hazardous Materials Regulations under the Hazardous Materials Transportation Act. However, the commenter asserted that the description fails to capture all of the expected additional costs of the proposed rule. The commenter points to three categories of social costs and noted that two of these categories of indirect costs are not limited to PFOA and PFOS. The commenter then asserted that EPA's actions could be seen as a precedent for future designations of additional PFAS – a group of thousands of chemicals with vastly different properties and risk profiles.

First—costs associated with reporting of future releases—are acknowledged in the Agency's economic assessment. To the extent the proposal yields little to no new information on releases (given that these chemicals have been phased out of production and use in the US), it lacks practical utility — raising a significant question about the merit of the information collection

request accompanying the proposal. (Note: The Paperwork Reduction Act (PRA) requires that agency information collections must "maximize practical utility and public benefit" and "minimize burden." The proposed rule represents an information collection and therefore is subject to the standards of the PRA.)

Second —cost relates to waste management practices. The Agency devotes scant attention to this behavioral response, simply suggesting that waste management activities will adjust to encourage prevention of potential releases. Although some adjustment can be beneficial, too much can be detrimental—an issue left unaddressed in the economic assessment. An overadjustment problem occurs when social costs exceed social benefits. For example, a slower pace for cleanup under the Brownfields Program (42 U.S.C. Section 9601(39)) will reduce the number of brownfields transactions, which have a very favorable benefit-cost ratio (Haninger K et al. The value of brownfield remediation. J Assoc Environ Resource Economists, 4(1):197-241 (2017)). More municipalities will be required to treat landfill leachate before sending it to a publicly owned treatment work (POTW), raising costs. POTWs will reduce the amount of biosolids sold for agricultural application and will be forced to find other options for handling this material, reducing revenues and increasing costs. Industrial waste managers will divert higher-PFAS-concentrated waste from Class D municipal landfills to more expensive Class C landfills. The expected costs are likely to increase significantly as responsible parties scramble to identify the limited options available to meet CERCLA requirements. Competition and price increases due to a dwindling capacity available in the Class C landfills will drive out low bids, putting PFAS disposal at a premium, which will result in passing cost down to consumers and the US economy as a whole. And, as waste management practices change, so might the availability of products made from perfluorinated substances as some manufacturers seek to limit potential liability, which will reduce consumer demand and producer supply. The commenter asserted that the over-adjustment can be expected due to CERCLA's unique liability provisions.

Third—cost relates to CERCLA's remediation program. The proposed designations would allow EPA and other agencies to require cleanups and recover response costs and allow private parties to file claims for cost recovery and contribution. The designations could result in some sites being added to the NPL, (Note: In the past, EPA has adopted Safe Drinking Water Act Lifetime Health Advisories (LHAs) as interim cleanup levels via guidance. States have adopted LHAs as groundwater cleanup levels for state superfund program sites. With the new interim LHAs for PFOA/PFOS (where the cleanup level is now close to zero), sites with trace levels of PFOA or PFOS could be eligible for NPL listing. This could greatly expand the number of potentially responsible parties, citizen suits, and private party actions) significant increases in sampling, analysis, and delineation at existing sites, amendments to sites implementing EPA selected remedies, triggering the reopening of previously closed CERCLA sites, and the initiation of costly private party litigation unbounded by any Agency discretion or any reasonable evaluation of risk. PFOA and PFOS could be included in the scope of all Phase I Environmental Site Assessments in order to satisfy numerous "hazardous substance" aspects of the "all appropriate inquiries" rule. EPA has completely failed to identify and evaluate these potential costs – which are expected to be substantial. Although some additional use of CERCLA can be beneficial, too much can be detrimental. An over-use problem arises when sites are addressed by mandating a remedy for PFOA and PFOS under CERCLA versus other, more cost-effective remediation programs (see discussion below). We believe overuse can be expected because the size of the CERCLA Superfund budget (which is expected to increase significantly due to recent

legislation) will provide funds for regulators tasked with overseeing remediation of hazardous waste sites.

A commenter asserted that the EPA has failed to consider, and in some cases has ignored, many of the Proposed Listing's direct costs. The commenter [0565] noted that the EPA specifically solicits comment on "the unquantifiability of indirect cost, benefit, and transfer impacts" associated with the Proposed Listing.14 While the commenter expressed appreciation for the opportunity to comment on these important cost issues, they noted as a threshold matter that several of the categories of costs EPA discusses in Section 3.5 of the EA are more appropriately considered direct consequences and impacts of the Proposed Listing. The commenter noted, as a general matter, that they disagree with EPA's position that the Agency cannot make projections for these costs. The commenter further asserted that it appears that the Agency considered the costs in question "unquantifiable" simply because EPA did not gather or assess any of the underlying information necessary to quantify them.

Another commenter expressed belief that many of the "indirect" costs claimed by EPA are in fact "direct" costs. The commenter asserted that the EPA characterizes its list of indirect effects as providing "meaningful" benefits, yet as to indirect costs – which the commenter asserted are substantial, running into the hundreds of millions or even billions of dollars – EPA refuses to quantify those costs, stating that the costs are too uncertain and that the Agency lacks sufficient information to quantify them (while making no effort in advance to obtain that information and thereby make its estimates less uncertain).

This commenter also pointed out that other entities have successfully quantified the Proposal's anticipated regulatory costs. As an example, the commenter references the U.S. Chamber of Commerce recently issued report entitled PFOS and PFOA Private Cleanup Costs at Non-Federal Superfund Sites (the "Chamber Report"), which estimates private party compliance costs associated with the Proposed Listing between \$11 billion and \$22 billion, with annualized private party costs estimated between \$700 million and \$800 million (U.S. Chamber of Commerce, PFOS and PFOA Private Cleanup Costs at Non-Federal Superfund Sites, at 3-4 (June 2022)). The commenter [0495] also noted that other parties have been able to identify and quantify potential regulatory costs including the North East Biosolids & Residuals Association ("NEBRA"), the National Association of Clean Water Agencies, and the Water Environment Federation have a cost analysis of the impacts of PFAS policies and regulations on municipal utilities and biosolids management entities. The commenter [0495] asserted that in addition to the information in these reports, EPA has access to data on existing CERCLA sites, which also will be greatly affected by this Designation.

Another commenter also asserted that the EPA underestimates the costs of the proposed designation. The commenter noted that EPA's RIA only focuses on the reporting requirements of the rule. The commenter also noted that the Agency estimates that the annual notification costs for all reporters would be between \$0 and \$370,000 annually. The commenter asserted that the EPA's analysis fails to account for both direct or indirect costs of the listing to the public and the government. The commenter, similar to others, referenced an analysis conducted by the U.S. Chamber of Commerce that reports the cleanup costs for the private sector are between \$700 and \$800 million. The commenter asserted that the U.S. Chamber's numbers include an assessment of the actual cleanup costs versus the EPA's assessments, which only analyze the reporting requirements costs (U.S. Chamber of Commerce, "PFOS and PFOA Private Cleanup Costs at Non-Federal Superfund Sites" U.S. Chamber, June 2022). The commenter stated that they also

solicited their own economic analysis to assess the costs for chemical distributors to replace their AFFF systems. The commenter reported that on average it would cost \$130,000 for a single facility to replace its fire protection systems. The commenter noted that utilizing data from EPA's regulatory impact analysis, as well as chemical facility data from the Bureau of Labor Statistics and the commenter's most recent Membership and Safety Report, the overall cost of the rule to chemical distributors would be \$98.161 million. Lastly, the commenter asserted that the EPA must consider other factors to its RIA beyond the reporting costs. For instance, society currently lacks adequate methods to effectively clean up and effectively destroy PFAS chemicals. The commenter pointed out that without proper destruction methods, the agency cannot accurately assess the costs of the proposed rule.

Other commenters also referenced the U.S. Chamber analysis that concludes the cost would be "over \$17.4 billion for existing non-federal national priority sites alone." This does not include federal, state, local, and tribal sites. It also does not include the costs related to reopening existing sites or adding additional sites to the NPL or costs due to disruptions at many ongoing remediation sites.

A commenter asserted that the fact that an economic analysis quantifying such large potential costs has already been completed calls into question EPA's assertions as to the impracticality of such analysis, particularly as EPA has used Monte Carlo analyses itself in connection with, among other things, development of the social cost of carbon. Further the commenter noted that while the Economic Assessment acknowledges DoD information, it dismisses it because it's not specific to PFOA or PFOS and because EPA assumes federal sites will differ from non-federal sites. With regard to the former, EPA takes the same tack in recognizing peer-reviewed studies providing insight regarding costs of liability, management and cleanup for PFAS but dismisses them also because they are for all PFAS, not PFOA and PFOS. The commenter asserts that this approach is not justified. The commenter agreed that some federal sites will be different from non-federal sites, but that does not mean that DoD's experience provides no insight into investigation, laboratory analysis, treatment and the associated costs. DoD has conducted extensive research and development, some in concert with EPA. Further, the Commenter asserted that the Economic Assessment justifies EPA's failure to quantitatively analyze indirect costs based on a "lack of data availability about the extent of existing PFOA and PFOS use and contamination, evolving assessment technology and health science, and developing treatment and disposal technologies." While EPA can make reasonable estimates of costs, this lack of data demands that EPA, at a minimum, pause until EPA is in a better position to adequately assess the impact of the designation on the Superfund program.

Another commenter also pointed out that the EPA's projected costs are significantly underestimated, only the reporting costs are quantified. Regarding indirect costs, the commenter referenced that the EPA's Guidelines for Preparing Economic Analyses (2010) states: "Indirect costs are the costs incurred in related markets or experienced by consumers or government agencies not under the direct scope of the regulation. These indirect costs are usually transmitted through changes in the prices of the goods or services produced in the regulated sector." The commenter asserted, consistent with the direct liabilities that come with a CERCLA designation, impacts to the public, governments (federal, state, local, and tribal), municipalities, publicly owned treatment works, and landfills must be considered by EPA. CERCLA Section 107, 42 U.S.C. § 9607, in discussing liability, clearly defines persons covered by the statute and the direct coverage is quite inclusive: (1) the owner and operator of a vessel or a facility, (2) any

person who at the time of disposal of any hazardous substance owned or operated any facility at which such hazardous substances were disposed of, (3) any person who by contract, agreement, or otherwise arranged for disposal or treatment, or arranged with a transporter for transport for disposal or treatment, of hazardous substances owned or possessed by such person, by any other party or entity, at any facility or incineration vessel owned or operated by another party or entity and containing such hazardous substances, and (4) any person who accepts or accepted any hazardous substances for transport to disposal or treatment facilities, incineration vessels or sites selected by such person, from which there is a release, or a threatened release which causes the incurrence of response costs, of a hazardous substance. The statute states those persons shall be liable for (A) all costs of removal or remedial action incurred by the United States Government or a State or an Indian tribe not inconsistent with the national contingency plan; (B) any other necessary costs of response incurred by any other person consistent with the national contingency plan; (C) damages for injury to, destruction of, or loss of natural resources, including the reasonable costs of assessing such injury, destruction, or loss resulting from such a release; and (D) the costs of any health assessment or health effects study carried out under section 9604(i) of this title.

This commenter also asserted that EPA's quantified cost upper end value of \$370,000 is simply not representative of the direct liabilities that come with a PFOA and PFOS CERCLA designation, which are not only foreseeable but EPA's intended end goal of this rulemaking. The commenter further asserted the following: (1) The EPA's qualitative discussion of direct costs is also insufficient, as it covers only costs associated with CERCLA Section 120(h) notifications; (2) The EPA's discussion of indirect qualitative costs is insufficient. EPA must consider not only the costs associated with site cleanups, investigations, and associated litigation, but also the direct impacts that this rulemaking will have on slowing the speed of ongoing state cleanups and brownfield remediations; (3) Agricultural impacts (due to impacts on biosolids) should also be considered, along with the increased waste management challenges that will be created by the soil that could be deemed to be a hazardous substance; and (4) The EPA also fails to consider the cost of "regulatory familiarization" in the economic analysis. Regulatory familiarization costs account for the value of time and effort that every potentially affected individual or business must undertake to determine if the regulation applies to their situation or not, and how their activities must adapt to comply. It is often the largest component of the initial year economic cost of any regulation. When an agency takes careful notice of the regulatory familiarization issue, it writes the rulemaking notice and accompanying public communications in a manner that makes it immediately clear to unaffected persons and entities that the new rule does not apply to them. This attention to communication detail minimizes the familiarization time. Neglecting this analysis can unintentionally impose an enormous familiarization cost burden on the general public. In this proposal, EPA has assumed that there will be no incremental costs associated with rule familiarization. The commenter asserted that this assumption is flawed.

This commenter further asserted that as proposed, this rule could potentially impact 261,477,000 persons and 7.96 million business establishments. The commenter further asserted that the EPA should also consider ways in which individuals and business establishments could be exempted from the proposal in order to decrease the cost burdens of rule familiarization.

The commenter noted that under the heading "Does this rule apply to me?" EPA states "any person ... as soon as they have knowledge of any release ... at or above the reportable quantity must immediately report such releases" (87 Fed. Reg. at 54,416). This imposes on every person a

duty to be aware and to be alert. The initial year familiarization cost will most likely exceed the \$100 million threshold of EO 12866's designation of an "economically significant" rulemaking and the \$150 million threshold for designation of a "major" rule under the Congressional Review Act. Using a de minimis one hour time frame to read EPA's public information materials, the cost to individual citizens would be \$8.5 billion, and the cost to business establishments would be \$466.1 million. Because the actual time burdens to read and understand the EPA public information materials and the regulatory text are likely much greater than the one hour parameters used in these hypothetical examples, and because the opportunity cost time values may also be greater, the actual familiarization cost burden of the proposed rule as published is likely much more than the \$8.95 billion sum of the calculations shown above.)

Response

Please see Response to Comment 6.A.1. for a detailed response to comments asserting that the EA issued with the proposed rule was insufficient and required a more detailed evaluation of direct costs and indirect costs and benefits and that EPA was required to issue an RIA with the proposed rule.

Additionally, regarding the commenter(s) assertion that the discussion of direct costs is insufficient, RIA Section 4.1 (*Direct Costs*) provides a thorough qualitative discussion of direct costs, addressing CERCLA Sections 103(a), 111(g), and 306(a) in addition to 120(h). For further discussion of the data gathered and assessed by EPA, as well as an explanation of why they were not sufficient for quantifying certain costs, please see Response to Comment 6.A.8 (*The EPA should use publicly available information to estimate the number reportable releases and associated costs*).

Regarding unpredictable effects of designation on the economy, EPA notes that there is a certain degree of unpredictability associated with any CERCLA action. As with all CERCLA actions, the resulting costs and economic effects depend on the risk posed and the level of response deemed necessary by EPA to address those risks.

The commenters assert that numerous existing NPL sites are likely to have some PFOA/PFOS present. The final rule RIA addresses this by estimating indirect response costs for sites currently on the NPL, proposed for addition to the NPL, and deleted from the NPL. PFAS do not occur naturally but are widespread in the environment. EPA does not agree that the RIA must address costs incurred for PFOA and PFOS site-related releases since CERCLA designation is intended to target those parties that have played a significant role in releasing or exacerbating the spread of PFAS into the environment, such as those who have manufactured PFAS or used PFAS in the manufacturing process, rather than natural occurrences.

Regarding the commenter(s) assertion that the RIA must assess increased costs of waste management practices, EPA notes that designation has no direct impact on waste management facilities. With the exception of certain release reporting and notification requirements, designation does not impose any regulatory requirements on any specific facilities. Designation also does not require EPA or any other person to take response actions. Any future response actions are determined on a site-specific basis. In addition, facilities using PFOA and PFOS are improving waste management and treatment practices absent CERCLA designation. The study cited by the commenter(s) to support claims of an over-adjustment problem (*Haninger K et al. The value of brownfield remediation. J Assoc Environ Resource Economists*, 4(1):197-241 (2017)) does not demonstrate that slower cleanup reduces the number of brownfield transactions.

In fact, the study emphasizes potential benefits of the designation i.e., Haninger et al. find that cleanups conducted under the program yield a positive, statistically significant, but highly localized effect on housing prices between 5 percent and 15.2 percent. EPA has every expectation that similar economic benefits will accrue when sites contaminated with PFOA and PFOS are addressed.

Relatedly, EPA agrees with the commenter(s) that the final rule would provide an incentive for more careful waste management but disagrees with the commenters' suggestion that there will be over-responses. EPA is unaware of data suggesting that an over-response is likely, and the commenter provided no such data. The study cited by the commenter(s) to support claims of an over-response ("Congressional Budget Office. The Total Costs of Cleaning Up Nonfederal Superfund Sites, Congress of the United States (1994)") is not a good representation of current costs. The year of publication (1994) was only 14 years after CERCLA became law, when cleanups were much more complex than in present day. Further, EPA is not aware of any information supporting the commenter(s) expectations that this rule will result in an overadjustment problem. Absent such information, EPA cannot reasonably evaluate the claims that waste management practices will significantly change, much less evaluate, the costs of amorphous changes in practices. PFAS have been high profile substances of concern for over a decade and even without hazardous substance designation EPA believes it likely that affected and responsible parties have already adjusted waste management practices to account for those concerns. For example, EPA disagrees with the commenter(s) statement that POTWs will reduce the amount of biosolids sold for agricultural application as a result of the rule. This phenomenon is already occurring absent CERCLA designation of PFOA and PFOS because of concerns about PFAS generally, and thus the Agency disagrees that such costs are a result of or attributable to the designation.

In the Preamble to the Final Rule and the RIA, EPA addressed the relationship between designation and future response actions, including Fund-lead and PRP-lead actions. EPA also addressed the role that cost recovery may play in enabling EPA to take more, and earlier, actions. See Preamble to the Final Rule Section VI (*The Totality of the Circumstances Confirms that Designation of PFOA and PFOS as Hazardous Substances is Warranted*).

EPA disagrees with the commenter(s) assertion that regulatory familiarization will be a major cost of the rule. Facilities should already be familiar with baseline requirements associated with reporting releases of non-PFOA/PFOS hazardous substances to the NRC under CERCLA 103 and to state, tribal, and local emergency entities as required under EPCRA 304. While this designation rule increases the number of substances whose release above the RQ triggers reporting to the NRC and state, tribal and local emergency agencies, the rule does not change existing CERCLA or EPCRA release reporting requirements or procedures already in existence. This is stated in RIA Section 4.1.1 (*Notification Costs per Release*).

EPA disagrees with the commenters that this rule will not yield any new information because these chemicals have been phased out of production and use in the U.S. Although PFOA and PFOS are not produced domestically by the companies participating in the 2010/2015 PFOA Stewardship Program, PFOA and PFOS may still be produced domestically by non-participating companies. EPA's Toxic Release Inventory Program (TRI) report 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 which indicate there may be potential releases, accidental or intentional, of these substances.

Such release information will provide EPA to assess if any response is necessary to protect public health and the environment. See the Preamble to the Final Rule Sections I (*Executive Summary*), III.B. (*PFOA and PFOS Production and Use*) and VII.G. (*Phase-out and PFOA Stewardship Program*). Furthermore, as discussed in the Final Preamble, the long use of PFOA and PFOS has left a legacy of contaminated sites that can be best evaluated for risk and, if necessary, cleaned up using CERCLA. CERCLA designation is particularly important with historic releases because designation provides EPA with authority necessary to collect information and require PRPs to collect information to determine whether a risk exists due to a historic release of PFOA or PFOS.

EPA does not agree with the comments that designation of PFOA and PFOS as CERCLA hazardous substances will impose a significant cost burden on entities that provide drinking water treatment, wastewater treatment, or solid waste management. Regulatory programs and corresponding management practices to address PFAS in these sectors, and the associated costs, are already underway and are not attributable to designation. For further discussion, see Response to Comment 6.A.3 and 4.G.1. and 4.G.2.

EPA disagrees with the comments asserting that this rule will slow the speed of ongoing state cleanups and brownfield remediations since a number of these programs already address PFAS. PFOA and PFOS hazardous substance designation would be consistent with and supportive of many other actions taken by EPA, other Federal agencies, states, Tribal Nations and international bodies. These entities have set PFOA and PFOS benchmarks and standards and have undertaken PFOA- and PFOS-based regulatory activities and enforcement actions. See Preamble to the Proposed Rule Section VII (*Regulatory and Advisory Status at EPA, Other Federal, State, and International Agencies*), and Sections 2.2 and 2.3 of the RIA for the Final Rule.

EPA declines to create exceptions for certain uses of PFOA and/or PFOS in this rulemaking. 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"). See Preamble to the Final Rule Section VII.A.3 for more information.

EPA disagrees with the commenter(s) that EPA must consider costs incurred by DoD for assessment and cleanup activities related to PFAS. These activities are already proceeding in absence of the rule. In 2017, the DoD updated its military specification for AFFF to include no more than 800 parts per billion, the quantitation limit by DoD Quality Systems Manual 5.1, of PFOA and PFOS in the concentrate. The DoD is working to remove AFFF containing PFOA and PFOS from the supply chain. In addition, DoD has initiated actions to test for, investigate, and mitigate elevated levels of PFOA and PFOS at or near installations across the military departments. Additionally, DoD is implementing the CERCLA process to remediate for PFAS where necessary. As of December 31, 2021, the DoD was performing the PA/SI for PFAS at 700 DoD installations and National Guard Facilities. Please see Section 5B-2 for more information on federal facilities.

EPA agrees that DoD's experience with PFAS provides some insight into the investigation, laboratory analysis, treatment and costs associated with the designation of PFOA and PFOS as CERCLA hazardous substances. EPA included discussion on DoD's experience regarding PFAS

efforts, including its extensive research and development, within Chapter 2 of the RIA. EPA also addressed the cost information from the DoD's PFAS response efforts within Chapter 5 of the RIA accompanying the final rule.

However, EPA disagrees with the commenter's assertion for EPA to use DoD's cost data as the basis for estimating costs likely to result from the designation. As the commenter(s) stated, because federal sites are larger and more complex than non-federal sites, 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 likely be representative of costs associated with non-federal CERCLA sites as the types, quantity, and handling of PFAS are expected to vary greatly. EPA expects the size and scope of, and therefore costs associated with, DoD PFAS cleanup to be larger than for non-federal facilities in part because federal facilities are generally larger in size than non-federal sites. Among other factors, this may also reflect that AFFF use is disproportionately higher at DoD sites relative to other sites; AFFF is a major source of PFAS contamination. Additionally, the CERCLA process for long-term remedial response actions generally occurs once a site is placed on the NPL, however, federal sites are addressing PFAS in the baseline as required by the NDAA and federal facilities agreements, and in some instances voluntarily. Therefore, while the DoD follows CERCLA guidelines to address releases of PFAS and determine the appropriate remedies at military installations, facilities of the National Guard, and FUDS in the United States, only some of these facilities at which DoD is addressing PFAS are NPL sites. Facilities where DoD addresses PFAS includes sites on the Federal Agency Hazardous Waste Compliance Docket. Section 120(c) of CERCLA requires EPA to establish the Federal Agency Hazardous Waste Compliance Docket of federally owned facilities which are actively managing or have managed hazardous waste; or have had a release of a hazardous substance in a quantity equal to or greater than the reportable quantity pursuant to CERCLA 102. See Preamble to the Final Rule Section II.E.7 (What Enforcement Discretion is available when exercising CERCLA authority).

EPA disagrees that the Chamber of Commerce cost analysis provides a reasonable representation or estimate of potential costs associated with 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, the COC analysis assumes that the proposed designation would require all existing non-federal NPL sites to look for PFOA/PFOS 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.

The Chamber of Commerce analysis also assumes that PFOA/PFOS contamination will add 20 sites annually to the NPL over the next decade, for a total of 200 sites requiring remedial investigation/feasibility study (RI/FS) and subsequent remediation. This assumption is based on EPA's average NPL listing rate from FY1998 through FY2007. NPL listing rates from FY2014-2023 are approximately 11 sites per year. However, 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, and not

systematically to all existing non-federal NPL sites. Further, not all future NPL sites will have PFAS contamination. EPA is still listing sites with other contaminants such as lead, PCE, metals, VOCs, dioxin, etc. In addition, EPA evaluates a number of options before determining the most effective approach for site cleanup. Alternatives to NPL listing may include state cleanup, cleanup by other federal agencies, EPA removal, deferral to another EPA program, and various enforcement mechanisms. Therefore, releases that contain PFAS may be addressed through non-NPL mechanisms.

The Chamber of Commerce analysis also assumes that non-federal NPL sites advance to RI/FS at the same frequency as Department of Defense (DoD) sites with known PFAS contamination. The analysis applies cost estimates from DoD for PA/SI and other cleanup steps as well. Because DoD sites are larger and more complex than most non-federal sites, DoD data are not a reasonable proxy for advancement frequencies or cleanup costs. Further, the Chamber study assumes that each new or reassessed site has three operable units and multiplies costs per operable unit. The use of this multiplier is inappropriate since sites will likely address new contaminants under a new operable unit or existing operable units. Additionally, the initial advancement frequency rate from PA/SI to RI/FS used in the study's model is unrealistically high and inflates any subsequent workflow estimates. Other limitations of the Chamber study include its reliance on probability distributions that are based on discussions with industry rather than empirical data and its reliance on 30-year-old data for a sample of 18 sites as the basis for its estimates of transitional costs.

Overall, the Chamber study's model is based on an inaccurate application of the Superfund process for addressing contamination at NPL sites. The report also conflates costs to address PFOA and PFOS contamination with costs attributable to designating PFOA and PFOS as hazardous substances. Importantly, remediation costs are not directly associated with listing a site on the NPL. The NPL is intended primarily to guide EPA in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with a release of hazardous substances, pollutants or contaminants. The NPL does not assign liability to any party or to the owner of any specific property. Also, placing a site on the NPL does not mean that any remedial or removal action necessarily needs to be taken.

The commenter(s) also references a cost analysis of the impacts of PFAS policies and regulations on municipal utilities and biosolids management entities conducted by the North East Biosolids & Residuals Association ("NEBRA"), the National Association of Clean Water Agencies, and the Water Environment Federation. While the information provided in the study is useful to understanding the impacts of PFAS policies and regulations on municipal utilities and biosolids management entities, the costs considered in this cost analysis are related to PFAS-related policies included in the baseline for the rule designating PFOA and PFOS as hazardous substances under CERCLA. The analysis does not examine costs specific to the designation of PFOA and PFOS as CERCLA hazardous substances.

Issues pertaining to treating leachate and changes in biosolids management are outside the scope of the rule. See RTC 4.F.2 and 4.G.2

Neither a release nor a report of a release automatically triggers cleanup action under CERCLA. 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. Decisions are made on a site-specific basis based on site-specific information. The only direct requirements for private entities that result from designation are certain reporting and notification requirements, as described in the Preamble to the Final Rule Section VIII.B. (*Direct Effects of Designating PFOA, PFOS, and their Salts and Structural Isomers as Hazardous Substances*). See preamble to the Final Rule Section VII.D.1.a-c (*Reporting and Notification Requirements*) for further explanation.

CERCLA is designed to ensure that highly contaminated sites are prioritized relative to other sites. The site-specific and discretionary nature of CERCLA safeguards against cleanups that are not necessary to protect human health and the environment and safeguards against excessive liability outcomes.

As explained in the preamble to the Final Rule Section VI.B.2 (*EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way*), EPA expects CERCLA to continue to function normally after the designation of PFOA and PFOS as it has for over forty years for the over 800 hazardous substances already designated under CERCLA.

There are currently methods available to remediate, destroy and dispose of PFOA and PFOS contamination and new methodologies are being evaluated. See *supra* 4E1-5 (responding to comments on treatment, destruction and disposal of PFAS; see also the Preamble to the Final Rule VII.H (*Managing PFOA and PFOS Contaminated Waste*). Commenters may also refer to EPA's "Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances – Version 2 (2024)" for additional information, available here:

https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf

Designation will not change the HRS process, nor does EPA believe that the rule will change EPA's approach to assigning resources and staffing. See Preamble to the Final Rule Section VII.E (*National Priorities List Sites – Existing and Future Contamination*) and RTC Section 4.D.2.

Designation does not change how that waste must be handled. See Preamble to the Final Rule Section VII.H (*Managing PFOA and PFOS Contaminated Waste*) and RTC 4.E.2.

6.A.3 EPA should conduct a Regulatory Impact Analysis (RIA) that considers the impact on landfill operation, drinking water and wastewater utilities, and cost to the public. EPA needs to ensure that the "polluter pays" principal will not be replaced with the "public pays" principal.

Multiple commenters assert that the EPA needs to conduct a more complete economic analysis or RIA considering liability impacts and costs, especially to drinking water and wastewater agencies and ratepayers. [0807-CNSAWWA]

Commenters highlighted concerns about impacts to water and wastewater utilities. Commenters noted that these utilities might face greater liability risk from the designation of PFOA and

PFOS. Commenters asserted that they are passive receivers of water contaminated by other entities. In addition, they noted that costs for litigation and remediation will likely be borne by ratepayers rather than responsible parties (as intended by CERCLA). [0482-MWDSC]

A commenter asserts that EPA's analysis in the Proposed Rule does nothing to even acknowledge certain types of costs – costs that will ultimately be incurred by water systems and the public at large. This lack of analysis further demonstrates EPA's failure to ensure that the "polluter pays" principle will not be replaced with the "public pays" principle. The same commenter stated that while EPA maintains the Proposed Rule is not "economically significant," this is solely because of EPA's grossly inadequate position that the costs stemming from the final rulemaking are limited to reporting. The reality is that the reporting costs, while themselves having the potential to become economically significant based on the cost of preparing a report as well as the frequency of doing so, will pale in comparison to the other quantitative impacts water systems, among others, will incur. These impacts will include new expectations for the disposal of PFOA- and PFOS-laden filtration media and biosolids. [0407-WCA PFAS]

This commenter also noted that there are a host of costs that water systems will incur if the Proposed Rule is finalized as drafted. These include costs associated with becoming a "potentially responsible party" (PRP) under CERCLA or defending the water system against these claims, as well as those additional management and operations costs associated with the CERCLA construct. Unfortunately, water systems are not able to absorb these potentially staggering costs increases, meaning they will be passed directly to the ratepayer. In the direct of situations, these types of costs could result in a water system not being able to sustain the costs of operation and maintenance, resulting in communities struggling to balance competing vital public services or facing the prospect of potential system closures. These scenarios, which have not been contemplated by EPA in the Proposed Rule, have the potential to significantly impact public health and to leave the public holding the bag on paying for cleanups for which they are not culpable. [0407-WCA PFAS]

Further, this commenter noted that beneficial biosolids reuse programs are likely to be immediately impacted by the Proposed Rule, potentially spurring a shift toward greater landfilling, and increasing the cost of biosolids management by orders of magnitude. This also includes the economic impacts arising from implication as a PRP. [0407-WCA PFAS]

Another commenter asserted that the CERCLA hazardous substance designation for PFOA and PFOS would lead to increased management costs for byproducts created during the normal water and wastewater treatment processes. Public and private utilities could face unwarranted liability and legal defense costs at Superfund sites—such as landfills or agricultural sites—and through our discharges, diverting vital resources from their primary responsibilities of protecting public health and the environment. This is the case because under CERCLA any party who has contributed in any part to disposing of hazardous substances, even trace amounts, may be held liable for remediation. [0392-NAWC]

Another commenter requested that the EPA take more time to determine the true direct and indirect damage resulting from the Proposed Designation prior to finalizing the rule. The commenter asserted that the EPA is requesting comments on several topics related to indirect costs because it does not have robust information on the topic, should be an indication that more time and research is needed before making this Proposed Designation. Removing PFAS from leachate is impossible without exorbitant costs. The commenter further asserts that if advanced

treatment techniques are implemented, trace amounts of PFAS could remain in leachate exposing the commenter to CERCLA liability. The commenter requested that the EPA complete and release a Regulatory Impact Analysis (RIA). The RIA should consider the full compliance and clean-up costs, including the direct and indirect costs and benefits associated with the Proposed Designation. The commenter expressed concern about significant new financial burdens on residents related to landfill operations. [0557-Solid Waste Authority of Central Ohio (SWACO)]

Another commenter stated that the EPA's analysis in the Proposed Rule seems to go directly against the agency's own guidance for providing an economic analysis, failing to even mention or consider the "social costs" which would occur to the extent a "public pays" model becomes the norm, an accounting of true "private sector and public sector costs," and "indirect costs," all of which have significant implications on the public and likely will "ripple through the rest of the economy, causing prices in other sectors to rise or fall and ultimately affecting the incomes of consumers." Indeed, this is an exact scenario where, as EPA puts it, "the indirect costs of a regulation may be considerably greater than the direct costs." These "indirect costs" must be accounted for in any final rule or EPA must explain why this scenario merits abdicating evaluations accounted for in the agency's own guidance. [0407-WCA PFAS]

The commenter asserted that should the proposed designations be finalized as proposed, water systems could become PRPs for any EPA-led or private cleanups taking place at those land application sites or repurposing locations. EPA's proposed rule fails to even consider these costs, let alone to offer remedies or alternative scenarios. EPA has therefore not appropriately evaluated the significant unintended consequences of the Proposed Rule. [0407-WCA PFAS]

Additional Comment Details on 6.A.3.

Further, another commenter stated that if EPA wants to protect consumer confidence in public water systems, it is critical that it present the health and environmental risk assessments associated with the Proposal and the financial exposures to the public associated with the various levels of risk. The commenter also noted a need for some guidance to utilities on how they are expected to affordably remove PFAS compounds from source waters to levels below detection range under the recently released "health advisory."

Another commenter noted that expenses around potential PFAS liability, PFAS disposal, and the loss of valuable soil amendments through impacts to biosolids programs must be understood so that utilities can understand their legal liability from the proposed designation.

Another commenter notes that detecting PFAS in a water system can lead to severe and costly operational impacts, such as: (1) Taking groundwater wells out of service and relying on other alternative water supplies while establishing treatment systems for PFAS. Hazardous substance designation may increase the cost of disposing of the filter materials that these systems use; (2) Beneficial use of recycled water may be negatively impacted for direct use customers, and for groundwater recharge for indirect potable reuse, worsening the already precarious situation and reducing the already limited water supplies, especially during drought periods; and (3) Biosolids management costs may increase due to PFAS liability concerns adversely affecting the ability to land apply, and further reducing the limited biosolids alternative use and disposal options. The commenter further pointed out that in a time in which the West is facing historic drought conditions, the Proposal could have significant impacts on the ability for agencies to provide water supplies to its customers.

A commenter also noted that it is vital to better understand these costs and the potential ramifications on the ability of WWTFs to continue to provide wastewater treatment services before the rule is finalized. Another commenter recommended that the EPA embark on more vigorous analysis of PFAS potential cleanup costs that will be absorbed by water and stormwater agencies as a result of the proposed designations. This commenter also emphasized that the EPA must also continue to invest in researching and developing efficient methods for managing and destroying PFAS substances.

Another commenter further noted that in the Economic Analysis, EPA acknowledges that the agency did not analyze impacts on small municipal drinking water utilities. Further, another commenter pointed out that water agencies – regardless of whether they are small municipal drinking water utilities or larger public water systems – must treat and dispose of PFAS in drinking water, the public (ratepayers) will end up paying for these costs, even though ratepayers are not the "responsible parties". For example, the commenter referenced that the Orange County Water District, which provides 77% of the water supply to 2.5 million people, has detected PFAS in its groundwater basin and will spend \$277 million on capital costs for new PFAS treatment facilities (Quarterly PFAS Update September 2022). The commenter further noted that while CERCLA may be viewed as a tool to recover such costs, the reality is that water agencies have to deliver water that meets standards in real time. The comment asserts that CERCLA litigation is expensive (to prosecute or defend), and recovery can take 10 to 20 years or more. Thus, as CERCLA plaintiffs, water agencies would have to fund costly litigation for years, while at the same time continuing to pay for the actions required to treat and deliver water that complies with water quality standards. The commenter also asserted that nowhere does EPA indicate that CERCLA allows citizens to file a lawsuit against any person, including a federal agency, that is alleged to be in violation of any CERCLA standard, regulation, condition, requirement, order, or Interagency Agreement (42 U.S.C. § 9659(a). The prevailing (or substantially prevailing) party may then seek to recover its reasonable attorney and expert witness fees (42 U.S.C. § 9659(f)). In addition, the commenter notes that private parties may bring cost recovery and contribution actions against other PRPs under CERCLA Sections 107 and 113 ((42 U.S.C. § 9607(a)(4)(B); 42 U.S.C. § 9613(f)(1); 42 U.S.C. § 9613(f)(3)(B)). Thus, even though EPA has indicated that it does not intend to seek CERCLA remediation costs from water and wastewater agencies, other entities can – and often do – bring public agencies into protracted CERCLA citizen suits, cost recovery cases, and contribution actions. The commenter asserted that because they are: (1) at the end of the line of handling PFAS in their water supplies from third-party sources before disposal; and (2) required to report their detections of PFAS (for example, Cal. Health & Safety Code § 116455), water and wastewater agencies are the easiest to identify, while identifying all the upstream manufacturers, contributors, and other users responsible for PFAS contamination is more difficult. As a result, water and wastewater agencies are then subject to the same potential liability as other PRPs and may have to spend significant amounts of time and public funds defending themselves in such actions and/or paying for the site cleanup.

Multiple commenters assert that placing the liability and cost on public utilities, ratepayers, and taxpayers undermines CERCLA's "polluters pay" model and will impact water utilities' ability to make essential capital investments to modernize infrastructure and combat climate change. The commenter further asserted that imposing CERCLA liability on water and wastewater utilities will lead to untenable cost increases and delays, significantly hampering the implementation of essential water projects needed to meet the challenge of establishing a reliable and sustainable water supply.

Another commenter pointed out that regardless of the specific revenue source, responsible public utility and critical infrastructure management invariably require balancing affordability, sustainability, and resiliency against short- and long-term expenditures. The commenter expressed concern by the lack of such balance in EPA's proposal to interpret CERCLA section 102(a) as excluding consideration of cost in a designation. If adopted as proposed, the absence of cost-benefit consideration will likely result in mounting unfunded mandates to water and wastewater utilities to the detriment of the communities that we serve. In fact, such an outcome would accelerate the "public pays" deviation from the "polluter pays" cornerstone of CERCLA and impart a disproportionate impact on disadvantaged communities and exacerbate environmental injustice. In short, the legally nebulous proposal appears to contradict common sense as well as common interest.

Lastly, another commenter asserted that the EPA's approach in the proposed rule has the potential to harm sectors and facilities that provide essential daily functions to communities, such as wastewater treatment facilities and landfills (i.e., facilities which do not generate or use PFAS compounds but which may, in the regular course of business, receive waste or wastewater containing PFAS compounds). Considering the heavy reliance on these facilities for sanitary conditions in our communities, the consequences for public health and safety would be significant if these facilities could no longer remain financially solvent due to the enormous cleanup costs associated with the proposed rule. The commenter urged EPA to ensure that regulation of PFOA and PFOS is practical and informed by balanced consideration of costs and available treatment and destruction technologies. EPA must regulate these chemicals responsibly and realistically, taking care to consider how the consequences of the proposed rule will reverberate throughout society and the economy.

Response

Please see Response to Comment 6.A.1. for a detailed response to comments asserting that the EA issued with the proposed rule was insufficient and required a more detailed evaluation of direct costs and indirect costs and benefits and that EPA was required to issue an RIA with the proposed rule.

The commenter is correct that the proposed rule EA did not analyze impacts on small municipal drinking water utilities. This was due to the fact that drinking water utilities were not identified as likely sources of PFOA or PFOS releases that will pose a hazard to human health and the environment, and commenters have not provided data or information that supports an alternative conclusion. In addition, EPA lacked data on the number and extent of releases by small government entities, including small municipal drinking water utilities, and the commenters did not provide data to support a conclusion that such entities will have reportable releases. For the final rule RIA, EPA has expanded the small entity analysis to include a breakeven analysis specific to small governments, which concludes that the notification costs of the rule are not expected to result in a significant impact to a substantial number of small government entities.

EPA does not agree with the commenter(s) that designation of PFOA and PFOS as CERCLA hazardous substances will lead to significant implementation, management, and operations costs for drinking water and wastewater utilities, and again commenters did not provide data or information to support a conclusion that such entities will release PFOA or PFOA at levels likely to pose a hazard to human health and the environment. Further, A hazardous substance designation under section 102(a) of CERCLA does not lead automatically to any response

actions or confer liability, and the commenters did not provide examples of releases that would likely lead to a level of risk that allows cost recovery under CERCLA or, if such releases contribute to an unacceptable level of risk, that such contribution would be anything other than de-minimus or de-micromis such that liability would be minimal. See Preamble to the Final Rule Section VI for an analysis of direct and indirect potential outcomes that may arise after designation.

Designation has no direct impact on landfill operations and the comments do not provide information that supports a conclusion that landfills will be significantly impacted by this final action. With the exception of certain release reporting and notification requirements, designation does not impose any regulatory requirements on any specific facilities, including landfills. Designation also does not require EPA or any other person to take response actions. Any future response actions are determined on a site-specific basis and cleanup is only required if the release poses a risk. Additionally, EPA's analysis has determined that these indirect response costs for PFAS are similar to other hazardous substances.

Many of the commenters' concerns about costs to utilities are not costs that arise from designation. Efforts to address PFAS in drinking water and wastewater treatment, and the associated costs of those efforts, are already underway and not attributable to this designation. As one commenter indicates with its example of EPA's \$131 million loan to the Orange County Water District for PFAS treatment, investments to address PFOA and PFOS in the wastewater sector are already being made, prior to EPA's proposed designation of PFOA and PFOS as CERCLA hazardous substances. Chapter 2 of the RIA also describes a wide range of federal and state activities intended to address PFOA and PFOS that were underway prior to EPA's proposed designation.

EPA also refers the commenters to the Agency's December 5, 2022 Memorandum "Addressing PFAS Discharges in NPDES Permits and Through the Pretreatment Program and Monitoring Programs." EPA expects NPDES actions to significantly reduce PFAS in wastewater treatment plant influent, which will reduce PFAS in wastewater treatment sludge. For further discussion on the content included in the memo, please see Response to Comment 6.A.4.

EPA understands that designation may lead to some liability associated with PFOA and PFOS releases. However, after a careful analysis, EPA determined that designation should not disrupt CERCLA's liability framework and that CERCLA will continue to operate as it has for decades. 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. For more information about CERCLA and "polluter pays" see preamble to the Final Rule Section VI.C (Results of Totality of the Circumstances Analysis), and preamble to the Final Rule Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination, such as landfills and nearby residents, and concluded that CERCLA would still function in a rational way). See supra Section 4.F.3 for additional discussion regarding potential liability.

Further, consistent with CERCLA's objectives, EPA will focus on holding accountable those parties that have played a significant role in releasing or exacerbating the spread of PFAS into

the environment, such as those who have manufactured PFAS or used PFAS in the manufacturing process, and other industrial parties.

EPA does not agree with the comments stating that designation of PFOA and PFOS as CERCLA hazardous substances will transfer cost burdens to drinking water and wastewater authorities, which consequently will be passed on to ratepayers; however, the comments do not provide data or information showing that such entities are likely to release PFOA or PFOS at levels that will pose a hazard to human health or the environment. Instead, consistent with CERCLA's objectives, EPA will focus on holding accountable those parties that have played a significant role in releasing or exacerbating the spread of PFAS into the environment, such as those who have manufactured PFAS or used PFAS in the manufacturing process, and other industrial parties. A significant benefit of designating PFOA and PFOS as CERCLA hazardous substances will be EPA's ability to require manufacturers and parties that use PFOA and/or PFOS in industrial processes to cleanup PFOA and/or PFOS contamination that was released into the environment many years ago. EPA's CERCLA enforcement efforts help increase the number of sites that get cleaned up and preserve the Superfund Trust Fund for CERCLA cleanups where there are not any financially viable, liable parties. In general, enforcement actions by EPA consider the facts, circumstances, and equities of a case which dictate which parties the Agency will pursue. CERCLA includes a number of statutory protections that may limit liability and discourage litigation (e.g., the provision for settlements with "de minimis" or minor parties, CERCLA section 122(g)). Moreover, EPA has well-established enforcement discretion policies that have historically and continue to give EPA needed flexibility to offer liability protections to parties when circumstances warrant (e.g., innocent landowners, de micromis parties, owners of residential property at or near Superfund sites, and contiguous property owners). EPA's CERCLA enforcement policies help the Agency focus on sites that pose the most risk and PRPs who have contributed significantly to contamination and prioritize such sites for enforcement. EPA will seek to hold these parties accountable such sites, ensuring that they assume responsibility for remediation efforts and prevent any future releases. This is consistent with EPA's "polluter pays" approach to cleanup under CERCLA. It is unclear to EPA how drinking water and wastewater facilities will become significant PRPs at sites addressed under CERCLA, and if there is any liability at all, how it would be anything other than de minimus or de micromis. Further, commenters have not provided a credible explanation for how significant liability would accrue (e.g. by providing data showing that PFOA and PFOS releases from such facilities are significantly higher than EPA expects), much less provided information that causes the Agency to decline to designate given the critical need to address the many historical releases of PFOA and PFOS that may be currently posing a risk to human health and/or the environment. In addition, EPA maintains the ability to use the Superfund Trust Fund money for response work and state and local governments may also be able to respond using their resources and grants to protect drinking water and wastewater facilities from unwarranted liability. See the Preamble to the Final Rule Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way) and Section VI.B.3. (Potential litigation costs are uncertain, but CERCLA litigation is not expected to exponentially increase as a result of designation).

Additionally, EPA does not agree with the commenter(s) that the proposed rule will result in mounting unfunded mandates to drinking water and wastewater utilities. For further discussion of this issue see Response to Comment 7.C. As explained in the Preamble to the Final Rule Section I (*Executive Summary*), EPA does not intend to pursue entities where equitable factors

do not support CERCLA responsibility. As EPA states in the FY 2024-2027 National Enforcement and Compliance Initiates (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" The NECI also clarifies that "OECA 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 OECA exercises CERCLA enforcement discretion in other areas." For more information about CERCLA's liability framework, including how designation supports the "Polluter Pays" principle, see Preamble to the Final Rule Section VI (*The totality of the circumstances confirms that designation of PFOA and PFOS as CERCLA hazardous substance is warranted*). For enforcement and liability information, see preamble to the Final Rule Section I (*Executive Summary*) and Final Rule Section II.E.7 (*What Enforcement Discretion is available when exercising CERCLA authority*).

EPA notes the comments providing input on methods to effectively clean up and destroy PFAS chemicals. EPA's Office of Research and Development (ORD) is conducting ongoing research on the effectiveness of different disposal methods. and it is useful for EPA to have such information. Additionally, EPA believes this final rule along with the other local, state, Federal and international efforts to address PFAS contamination will result in increased R&D expenditures to develop and improve methods, approaches, tools, and technologies for addressing PFOA/PFOS contamination. Please see RIA Section 5.1.2.5 (*Research and Development*) for further details.

Finally, data available to EPA supports a conclusion that many CERCLA hazardous substances other than PFOA and PFOS are present in water sources across the country and in the influent that passes through sewage treatment plants. See EPA's November 3rd, 2016 Memorandum "Best Practices Memorandum for NPDES Pretreatment Coordination to Address Toxic and Hazardous Chemical Discharges to POTWs" (https://www.epa.gov/sites/default/files/2016-11/documents/memobestpractices npdes-pretreatment-r.pdf). Relatedly, sewage sludge and biosolids can contain many CERCLA hazardous substances other than PFOA and PFOS, and some of those hazardous substances are also ubiquitous (e.g. lead, arsenic). At a minimum, this includes substances regulated under 40 CFR Part 503, Standards for the Use or Disposal of Sewage Sludge, which are hazardous substances, and facilities likely process hazardous substances in addition to those identified in Part 503. See supra-Section 4.F.4 (Liability Can Arise Without A Site Being Listed On the NPL). Thus, it is reasonable to conclude that even absent designation, these facilities already face some CERCLA liability risk. Despite that fact, commenters assert without any support that the designation of PFOA and PFOS changes everything because those substances are everywhere. CERCLA liability has not plagued these facilities over the last 50 plus years and EPA has no reason to believe this final designation will change the way CERCLA has operated since its enactment.

6.A.4 EPA must consider the impacts of the rule on local governments (e.g., public works operations).

Numerous commenters noted impacts that the Proposed Rule will have on local governments to administer and comply with and the likelihood of additional legal implications on local governments (e.g., making modifications to public works operations). One of these commenters pointed out that the city manages the Water Treatment Plant, Wastewater Treatment Plant, and Municipal Airport Facilities that will likely be impacted by the unfunded mandate and will incur additional cost burdens and legal liabilities posed by the Proposed Rule. The same commenter

noted example modifications such as finding alternative methods of disposal of the lime sludge which is a by-product of the lime softening process at the Water Treatment Plant and difficulties finding an alternative method for biosolids disposal that is economically viable. These impacts would place a heavy economic burden on the city. [0436/Manhattan, KS; 0434-City of Manhattan KS; 0506/Conference of Mayors; 0321/Tillamook County Board; 0529-Augusta County Service Authority (ACSA); 0437/City of Dubuque; 0431-City of Lexington; 0448-City of Thousand Oaks; 0451-Harford Co; 0376/Kent County; 0498/Santa Clarita Valley Water Agency (SCV Water); 0489-Shelby Co; 0400-Town of Windsor; 0403- Town of Purcellville, VA; 0493-POWER! fully supported by 0521 (WMWD)]

Similarly, other commenters noted the analysis should consider the impact the Proposed Rule will have on local government administration, operations and budgets for drinking water, wastewater, airport firefighting and landfill facilities, and the new financial burdens that will be imposed on households and communities. The commenters asserted that only after completing and transparently reporting this analysis should the Agency move forward with developing a rule based on those findings. [0436/Manhattan, KS; 0434-City of Manhattan KS; 0506/Conference of Mayors; 0321/Tillamook County Board; 0529-Augusta County Service Authority (ACSA); 0437/City of Dubuque; 0431-City of Lexington; 0448-City of Thousand Oaks; 0451-Harford Co; 0376/Kent County; 0498/Santa Clarita Valley Water Agency (SCV Water); 0489-Shelby Co; 0400-Town of Windsor; 0403- Town of Purcellville, VA; 0493-POWER! fully supported by 0521 (WMWD)]

Response

EPA does not agree with the commenter(s) that designation of PFOA and PFOS as CERCLA hazardous substances will impose a significant cost burden on state and/or local governments that provide drinking water treatment, wastewater treatment, landfill management, or airport services. Many of the commenters' concerns about costs to utilities are not costs that arise from designation. Efforts to address PFAS in these sectors, and the associated costs of those efforts, are already underway in the absence of the proposed designation of PFOA and PFOS as CERCLA hazardous substances. Additionally, EPA also refers the commenter(s) to the Agency's December 5, 2022, Memorandum "Addressing PFAS Discharges in NPDES Permits and Through the Pretreatment Program and Monitoring Programs." The memorandum recommends guidance for states to use the most current sampling and analysis methods in their NPDES programs to identify known or suspected sources of PFAS and to take steps using their pretreatment and permitting authorities, such as imposing technology-based limits, on sources of PFAS releases. The memorandum also includes new recommendations relating to biosolids monitoring, permit limits, and coordination across relevant state agencies. EPA expects the NPDES actions described in this memo to significantly reduce PFAS in wastewater treatment plant influent, which will reduce PFAS in wastewater treatment sludge. Further, the designation does not require waste (e.g., biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills. Although designating PFOA and PFOS as hazardous substances has the potential to increase the amount of material being sent to hazardous waste landfills, it is not expected to be large increases because it is very likely future PFOA and PFOS-containing waste will be commingled with RCRA hazardous wastes that already require disposal at RCRA hazardous waste landfills. See RTC 4.G.2-2.

Commenters did not provide information or data supporting their assertions that the amount of waste that needs to be treated as hazardous waste will increase significantly.

EPA does not agree with the commenters that the final rule will result in mounting unfunded mandates to local governments and public works operations. For further discussion of this issue see Response to Comment 7.C. For more information on EPA's "polluter pays" approach to cleanup under CERCLA and EPA's intention to not pursue entities where equitable factors do not support CERCLA responsibility, please also see Response to Comment 6.A.3.

6.A.5 Economic analysis fails to take into account agency actions related to environmental justice and disproportionally impacted communities.

A commenter noted that while EPA concluded that it was not required to take cost into consideration in determining whether a substance is hazardous or not, it should still have at least considered affordability and environmental justice impacts of its action prior to taking action. [0392-NAWC]

Another commenter also pointed out that the rulemaking must also consider the costs of agency action upon the public generally and specifically on environmental justice communities and disproportionally impacted communities. Many of the impacts on this rule will impose a burden on those who can least afford it. The commenter stated that the proposed rule fails to conduct this essential analysis of costs. The commenter notes that while EPA asserts that it is unclear whether the Proposed Rule will have a significant impact on disadvantaged populations or communities with environmental justice concerns relative to other communities, this assessment is also inadequate. To the extent water systems are subject to any additional costs from anything ranging from new disposal techniques to liability from remedial actions under CERCLA, as previously discussed, these costs will be passed onto the communities they serve. The majority of water systems nationwide are public entities which do not generate profits and must raise rates or seek federal or state financing to cover new costs. [0407-WCA PFAS]

This commenter further noted that when considering the operation, management, and liability costs facing water systems, it is important to note that in many cases, smaller rural water systems and those water systems serving disadvantaged communities (where the two do not overlap) with reduced economies of scale combined with a lower-income customer base, will likely experience the largest financial impact. The commenter asserted that the EPA's Proposed Rule fails to consider this fact, providing little to no discussion or analysis of these impacts. [0407-WCA PFAS]

The commenter also noted that at a time where access to, and affordability of, services provided by water systems is a prominent concern by Democrats and Republicans alike, as well as by the public at large, EPA's proposal and the "public pays" principle it will foster will further drastically reduce affordability and access. This will in turn result in a disproportionate impact to disadvantaged communities. EPA must consider all of these impacts in any final rule, lest water systems find themselves grasping at straws to continue maintenance and operation without drowning the communities they serve in unattainable rate payments. In the event EPA does not provide an analysis of these impacts in the final rule, the agency must explain why no evaluation was necessary and how the public ultimately incurring remediation and liability costs is consistent with the "polluter pays" model EPA has committed itself to in its PFAS Action Plan and more recently PFAS Strategic Roadmap. [0407-WCA PFAS]

Another commenter stated that these foreseeable cost increases, combined with actions taken by passive receivers to curtail acceptance of influent with concentrations of PFOA or PFOS, could impact the ability of some public service providers to continue operating, frustrate EPA cleanup activities around military installations and other affected communities, and disproportionately impact low-income communities that rely on the affordability of passive receiver services. [0344-American Public Works Association (APWA) et al.]

Response

Please see Response to Comment 6.A.1. for a detailed response to comments asserting that the EA issued with the proposed rule was insufficient and required a more detailed evaluation of direct costs and indirect costs and benefits and that EPA was required to issue an RIA with the proposed rule.

EPA does not agree with the commenter(s) that designation of PFOA and PFOS as CERCLA hazardous substances will lead to significant implementation, management, and operations costs for drinking water and wastewater utilities that will lead to significant increases in rates for utility customers. Many of the commenters' concerns about costs to utilities are not costs that arise from this final designation, including additional costs to manage waste and address drinking water contamination. Please see Response to Comment 6.A.3. for discussion on cost and impact on drinking water and wastewater utilities, as well as ongoing PFAS efforts within these sectors unrelated to the designation.

Additionally, EPA does not agree with the commenter(s) that designation of PFOA and PFOS as CERCLA hazardous substances will transfer cost burdens to drinking water and wastewater authorities, which consequently will be passed on to ratepayers. EPA is not going to focus its enforcement efforts on water utilities. For more information on EPA's "polluter pays" approach to cleanup under CERCLA and EPA's intention to not pursue entities where equitable factors do not support CERCLA responsibility, please also see Response to Comment 6.A.3. Costs associated with reducing PFOA/PFOS exposure via drinking water utilities are attributable to EPA's PFAS NPDWR. Please see EPA's PFAS National Primary Drinking Water Regulation (NPDWR). For these reasons, EPA does not agree with the commenter(s) that the proposed rule will result in mounting unfunded mandates to drinking water and wastewater utilities.

EPA carefully considered how designation may impact environmental justice communities (EJ communities); however, EPA disagrees that designation will put additional burdens on these communities. Rather, EPA expects that designation will result in meaningful benefits for these communities, which are disproportionally impacted by PFOA and PFOS contamination. See Preamble to the Final Rule Section VI.A.2.d (*Environmental Justice Considerations for Designation*). EPA also expects that many of the benefits of designation described in the Preamble to the Final Rule will benefit EJ communities. Designation enables more response actions and earlier response actions, which in turn contributes to significant health benefits that come from mitigating or eliminating community exposure to PFOA and PFOS.. Designation also has a number of economic and ecological benefits. See the Preamble to the Final Rule Section VI.A (*Advantages of Designation*). For example, CERCLA and EPCRA release reporting may improve awareness of PFOA and PFOS releases for EPA and communities with EJ concerns.

6.A.6 Economic Analysis fails to consider remediation costs, and, in the absence of standards, requirements, and criteria, EPA should acknowledge the unpredictable legal risks designations will expose to municipalities.

A commenter stated that the proposal fails to include an assessment of the potential remediation costs for PFOA and PFOS cleanups which could be passed on to local communities and public clean water utility ratepayers. The commenter recognizes that the EPA acknowledges that any costs stemming from eventual PFOA and PFOS cleanups are impossible to quantify due to "numerous, significant uncertainties" surrounding issues including "how many sites have PFOA or PFOS contamination at a level that warrants a cleanup action; the extent and type of PFOA and PFOS contamination; the incremental cost of assessing and remediating the PFOA and/or PFOS contamination; and the cleanup level required for these substances." The commenter states that the EPA is essentially admitting that it is very difficult to estimate the costs of remediating substances that may be found in trace quantities nearly everywhere but that, at present, no one knows how to remediate, or even to what levels they should be remediated to protect human health in the environment. While this is undeniably true, should EPA nevertheless determine that it is appropriate to finalize the designations, it must fill in these sizable data gaps. EPA cannot excuse itself of its duty to assess what the impacts of its actions will be; local public clean water agencies will have no such luxury. [0372-NEW Water]

The commenter also states that without an assessment of potential removal and remediation costs, it is impossible for the regulated community to determine the scope of its potential legal liabilities stemming from the proposed designations. CERCLA Section 121(a) generally requires that removal and remediation actions necessitated under CERCLA achieve acceptable levels of exposure that would be protective of human health and the environment. While cleanup requirements can vary widely from site to site, CERCLA Section 121(d) broadly requires that cleanups comply with applicable, relevant, and appropriate requirements (ARARs), which typically include federal and state standards, requirements, or other criteria related to the hazardous substances present at the site. The commenter asserted that if EPA moves to finalize the proposed hazardous substance designations for PFOA and PFOS despite the current absence of such standards, requirements, and criteria, it should, at a minimum, acknowledge the significant and unpredictable legal risks those designations will expose municipalities to. [0372-NEW Water]

Another commenter requested that EPA delay finalizing the proposed rule and reconsider designating PFOA and PFOS as hazardous substances under CERCLA until appropriate standards and technologies are in place. Proceeding without the appropriate standards and adequate technologies is arbitrary and capricious. The commenter asserter that more time is needed to allow EPA to complete a full Regulatory Impact Analysis and provide an opportunity for public input on the analysis before designating PFOA and PFOS as hazardous substances under CERCLA. [0493-POWER! Fully supported by 0521 (WMWD)]

Another commenter asserted that cost cannot be ignored when CERCLA's implementation had the sole purpose of ensuring that environmental cleanup costs are borne by the appropriate parties. The commenter pointed out that the EPA must fully consider the ramifications — including costs — of the proposed hazardous substance designations on all stakeholders. The commenter also asserted that potential implications for local public clean water agencies are significant. The commenter notes that it is incumbent upon the EPA from a legal, policy, and public health standpoint to fully analyze and consider what the proposed listings will mean for

the clean water community, and to utilize its full statutory authority to mitigate any potential negative impacts to the provision of safe, affordable clean water for communities across the country. [0396/MWEA]

Response

Please see Response to Comment 6.A.1. for a detailed response to commenter(s) assertion(s) that the EA issued with the proposed rule was insufficient and required a more detailed evaluation of direct costs and indirect costs and benefits and that EPA was required to issue an RIA with the proposed rule.

EPA agrees that future response costs are uncertain; however, commenters have not explained how clean water utilities would become CERCLA PRPs after this designation, much less PRPs with significant liability for cleanup costs. The comment is also misplaced to the extent the commenters are attributing costs associated with waste management or drinking water requirements to the CERCLA designation because such costs are attributable to different EPA rules. Nonetheless, EPA discussed indirect costs in the proposed rule EA and in the final rule RIA that the Agency has quantified its best estimate of potential response costs that may result after designation. 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 agrees that the potential litigation costs are uncertain following the designation, however, EPA believes that CERCLA litigation is not expected to increase appreciably as a result of the designation. Moreover, EPA is not going to focus its enforcement resources on drinking water utilities in the Agency's CERCLA PFAS enforcement strategy. For more information on EPA's "polluter pays" approach to cleanup under CERCLA and EPA's intention to not pursue entities where equitable factors do not support CERCLA responsibility, please see Response to Comment 6.A.3.

EPA disagrees with the commenters' claim that its designation of PFOA and PFOS as CERCLA hazardous substances is premature. EPA disputes the commenters' assertion that designation under CERCLA is inappropriate in the incorrectly purported absence of pre-existing regulatory standards for PFOA and PFOS as discussed in RTC 2.C.1 and RTC 3.B. In fact, 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 and considers costs, and there are approaches available to address PFOA and PFOS contamination. Also, ARARs are identified relevant to a site-specific remedy and are determined on a site-specific basis, as are any relevant ARAR waivers. To the extent applicable PFOA and PFOS are identified, those must be considered when determining the remedy. This is true in the context of PFOA and PFOS as well as the other 800 hazardous substances subject to CERCLA. See Preamble to the Final Rule Section V (PFOA and PFOS may present a substantial danger to the public health or welfare or the environment, when released into the environment), Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way), and Section VII.B.1 (Comments suggesting that other authorities are better suited to address PFAS contamination). Also, commenters have not explained how the absence of PFOA and PFOS

specific ARARS will lead will expose municipalities to significant and unpredictable risk and EPA is unable to identify a unique risk to municipalities.

Additionally, as the commenter(s) mentioned, cleanup requirements can vary widely from site to site, as CERCLA response actions are determined on a site-specific basis based on site-specific information. EPA cannot predetermine the scope of a response action, and the potential cost of a response, until it fully evaluates the releases at issue consistent with CERCLA and the NCP. The process for identifying, selecting, and implementing a remedy can take many years, and EPA acknowledges that the comprehensive cleanup of sites with extensive PFOA and PFOS contamination could be many years in the future. However, designation provides EPA with the full suite of CERCLA tools necessary to begin the lengthy remedial process sooner rather than later and best promotes eventual cleanup of PFOA and PFOS. It also allows EPA to compel PRPs to take action, which is expected to enable EPA to address more sites than it could absent designation. Importantly, EPA may also utilize its removal authority to address PFOA and PFOS releases that require more immediate action. The tools collectively promote "cleanup," and are an advantage of designation. For further discussion of how designation promotes cleanup, please see the Preamble to the Final Rule Section VI.A.1. (Designation enables earlier, faster, broader, and more effective cleanups of contaminated sites). See RTC 4.E.1-7. For these reasons, EPA disagrees with the comments asserting that delaying the designation is warranted.

Additionally, EPA does not agree that it is necessary to identify specific control and cleanup technologies in order to designate PFOA and PFOS as hazardous substances under CERCLA. Notwithstanding, there are currently methods to address PFOA and PFOS contamination and new methodologies are being evaluated. See Preamble to the Final Rule Section VII.H (Managing PFOA and PFOS Contaminated Waste) and RTC 2.C.1., 4.E.1-5, 4.E.2-1, 4.F3.

6.A.7 EPA should follow the proper procedures as outlined in the Administrative Procedure Act, including the Federalism Consultation process.

A commenter asserted that the EPA must prepare and report with complete transparency a full economic and regulatory impact analysis. The commenter stated that the analysis of the full direct and indirect costs and benefits has not been prepared by the agency to date despite the White House Office of Management and Budget's designation of the proposed rule as economically significant. Due to this current lack of critical information, local governments request the agency work expeditiously to complete the analysis. This analysis is even more critical given EPA's failure to conduct a consultation consistent with E.O. 13132: Federalism, despite the clear economic significance of the rule and its implications for state and local governments. [0245-USCOM/NLC/NACo]

Some commenters also stated that the Agency should follow the proper procedures as outlined in the Administrative Procedure Act, including the Federalism Consultation process, which would have included a briefing and the opportunity to provide comments before the rule is proposed. [0436/Manhattan, KS; 0434-City of Manhattan KS; 0506/Conference of Mayors; 0321/Tillamook County Board; 0529-Augusta County Service Authority (ACSA); 0437/City of Dubuque; 0431-City of Lexington; 0448-City of Thousand Oaks; 0451-Harford Co; 0376/Kent County; 0498/Santa Clarita Valley Water Agency (SCV Water); 0489-Shelby Co; 0400-Town of Windsor; 0403-Town of Purcellville, VA; 0493-POWER! fully supported by 0521 (WMWD)]

Response

Please see Response to Comment 6.A.1. for a detailed response to comments asserting that the EA issued with the proposed rule was insufficient and required a more detailed evaluation of direct costs and indirect costs and benefits and that EPA was required to issue an RIA with the proposed rule.

EPA disagrees with the commenters' claim that it failed to comply with the proper procedures outlined in the Administrative Procedure Act, including the Federalism Consultation process. EPA values listening to concerns and answering questions on important public health and environmental protections. The Administrative Procedure Act requires that a "general notice of proposed rulemaking shall be published in the Federal Register." EPA published the proposed rule to designate PFOA and PFOS as hazardous substances under CERCLA in the Federal Register on September 6, 2022. Under the Administrative Procedure Act, "after notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." Following the publication of the proposed rule in the Federal Register, EPA provided a 60-day period for public comments on the proposed rule. Additionally, EPA held several meetings to listen to state agencies and stakeholders' comments. EPA held meetings with organizations representing agriculture, drinking water and wastewater utilities, industry, state environmental agencies, environmental and environmental justice organizations and others.

6.A.8 The EPA should use publicly available information to estimate the number reportable releases and associated costs.

A commenter stated that EPA should estimate the number of reportable releases rather than use the number of reportable releases of ammonia or ammonium compounds in 2020. EPA's August 2022 Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate PFOA and PFOS as Hazardous Substances states that the precise number of reportable releases of PFOA and PFOS is not known and that EPA will use the 660 reportable releases of ammonia or ammonium compounds in 2020 to estimate the upper bound of PFOA and PFOS releases. The commenter stated that while they understand that data on PFOA and PFOS may be limited, there is publicly available information that could be used to estimate the potential number of releases or PFOA and PFOS. The commenter recommends EPA use publicly available information to estimate the number reportable releases and associated costs. [0410/WDEQ]

Response

EPA understands that there are some publicly available data on PFAS releases; however, the existing data on such releases is insufficient for estimating reporting costs associated with the reporting requirements under the designation of PFOA and PFOS as CERCLA hazardous substances. Existing data does not allow EPA to definitively state the extent to which PFOA and PFOS are still in use or managed in the United States, nor the extent of the potential releases. See Preamble to the Final Rule Section VII.G. (*Phase-out & PFOA Stewardship Program*).

In EPA's analysis of direct costs in Chapter 4 (*Direct Costs*) of the final rule RIA, EPA includes a discussion on the release data of PFOA, PFOS, and their salts published in the Toxic Release Inventory (TRI) Report. However, TRI releases can in some cases include activities that are compliant with other regulations and will not require reporting under CERCLA or EPCRA. See RIA, Chapter 4.1.2 (*Number of Annual Notifications*) and RIA, Chapter 2.2.2 (*EPA Actions under The Emergency Planning and Community-Right-to-Know Act (EPCRA*)). Further, TRI

releases are reported on an annual basis while CERCLA requires releases at or above the RQ to be reported immediately. Therefore, the TRI release data cannot be utilized to estimate the number of future PFOA/PFOS releases meeting the RQ threshold with certainty. As explained in Chapter 4.2 of the RIA, one of the direct benefits of the final rule is the improvement of information about the frequency and extent of releases of PFOA and PFOS at or above the RQ for a more comprehensive understanding of the number and location of sites with future releases of PFOA and PFOS which meet or exceed the RQ.

Additionally, the commenter(s) does not identify the additional publicly available information that they recommend EPA to utilize to estimate the number of reportable PFOA and PFOS releases in the future. Therefore, EPA is unable to fully assess whether the publicly available information suggested by the commenter(s) is useful in estimating reporting costs.

6.A.9 The EPA's economic assessment for this rule should focus on the potential direct costs associated with this designation.

A commenter agrees that EPA's economic assessment for this rule should focus on the potential direct costs associated with this designation. Those direct costs are limited to reporting any release of PFOA and PFOS at or above the reportable quantity of 1 pound or more in a 24-hour period, providing notice and cleanup of federally-owned property being sold or transferred, and DOT listing and regulating these chemicals under the Hazardous Materials Transportation Act. [0365/ Environmental Protection Network (EPN)]

The commenter also agrees with EPA's assertion that it is impractical to quantitatively assess the indirect costs for response actions associated with this designation. Any estimated costs would be meaningless because they are so highly speculative. The commenter is aware that the U.S. Chamber of Commerce has prepared a report that estimates private party total compliance costs for cleanup will range from \$11B to \$22B, with annualized costs from \$700M to \$800M. The commenter asserts that these costs are based on a number of unrealistic assumptions: 1) all existing non-federal NPL sites would be required to monitor for PFOA and PFOS; 2) PFOA and PFOS contamination would add 20 sites to the NPL annually for the next 10 years; and 3) all new and existing PFOA/PFOS contaminated sites would require very costly cleanup with high legal and consultant transaction costs. [0365/ Environmental Protection Network (EPN)]

The commenter disputes the Chamber of Commerce assumptions and costs for the following reasons. First, CERCLA response authorities are triggered by a release or substantial threat of a release of either a hazardous substance or a pollutant or contaminant into the environment that poses or may pose an imminent or substantial threat to the public health, welfare, or the environment. PFOA and PFOS are already considered pollutants and are already subject to most CERCLA authorities. Designation of PFOA and PFOS as hazardous substances should not generate any new requirements for the cleanup process at sites already on the NPL. The commenter notes that the EPA already considers these pollutants in its CERCLA cleanups and in its five-year review process. The commenter also notes that it is particularly difficult to predict the resulting costs of the five-year reviews because EPA does not reopen all NPL sites every time a new contaminant is identified but instead takes a targeted approach, focusing on those types of sites most likely to be contaminated with the chemical. The commenter further notes that reopening sites with PFOA and PFOS contamination may not be necessary because the remedy for the previously identified pollutants may prevent exposure to these chemicals, obviating the need for new remedial actions. [0365/ Environmental Protection Network (EPN)]

The commenter also disputes the Chamber of Commerce assertion that this designation would add 20 sites to the NPL annually for the next 10 years. The only statutory requirement for adding sites to the NPL is the requirement that updates occur once a year. According to EPA's annual accomplishments reporting, the agency has been averaging over 800 remedial site assessment completions per year for potential addition to the NPL, but has placed on average only about 1 sites on the NPL each year over the past decade because of resource constraints and other considerations. The commenter notes that while the hazardous substance designation will enable EPA to score hazard ranking system exposure pathways for PFOA and PFOS, not every site eligible for the NPL is proposed to be added or made final, as sites can be deferred to other authorities or to the states. EPA historically has viewed CERCLA as the statute of "last resort." EPA first looks to other federal authorities such as the Clean Water Act (CWA), the Safe Drinking Water Act (SDWA), and the Resource Conservation and Recovery Act (RCRA) as preferred avenues for treatment or cleanup. The commenter asserts that EPA also works with states to evaluate their capabilities for taking action under delegated federal regulatory programs or under state programs. In many instances, states will take the lead on sites, and EPA will look to state and local authorities to take appropriate actions. [0365/Environmental Protection Network (EPN)]

The commenter also disputes the extremely high costs that the Chamber of Commerce estimates for every step of the cleanup process and for the expected transaction costs of legal and consultant services. The commenter asserts that these are unrealistic costs that cannot be justified based on the decades-long experience of our EPA alumni in the Superfund program. The commenter further notes that the unrealistically high costs estimated by the Chamber of Commerce are dwarfed by a recent estimate of the benefits of cleaning up PFOA, PFOS, and other PFAS chemicals. The New York University Grossman School of Medicine recently published a study identifying 13 medical conditions that may result from PFAS exposure.3 Those diseases generated medical bills and reduced worker productivity across a lifetime to create costs ranging from \$5.5B to \$63B per year, far exceeding the Chamber of Commerce exaggerated estimates of private party compliance costs ranging from \$700M to \$800M per year. [0365/Environmental Protection Network (EPN)]

Response

Building on the information presented in the proposed rule EA, the RIA accompanying this final rule includes expanded analyses of direct/indirect costs, transfers, and benefits relative to the analysis developed for the proposed rule, to better inform the public of potential direct and indirect effects. See Preamble to Final Rule Section IV.C (*CERCLA section 102(a) and Cost Considerations*.). See RTC 6.A.1.

EPA agrees with the commenter(s) that the Chamber of Commerce cost analysis provides an unreasonable 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. See RTC 6.A.5.

6.A.10 The EPA has not identified a compelling public need for the proposed action.

A commenter stated that according to the Office of Management and Budget's (OMB) Circular A-4,3 an agency "should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy." For

interventions apart from market failure, an agency "should also provide a demonstration of compelling social purpose and the likelihood of effective action. Although intangible rationales do not need to be quantified, the analysis should present and evaluate the strengths and limitations of the relevant arguments for these intangible values." [0421-A2 American Chemistry Council]

The commenter stated that in the economic assessment, EPA supports its proposal with four arguments: that the proposal would (1) "further CERCLA's primary goal of protecting public health and welfare and the environment" by informing EPA of the "number and location of releases that exceed the reportable quantity" and (2) signal to markets that "there is value in preventing such releases." The Agency also lists (3) the potential to transfer costs from the public to polluters. Finally, the Agency says the proposed rule is (4) consistent with many actions by federal, state, and local and tribal authorities to address PFOA and PFOS contamination. The commenter asserts that each argument is unconvincing. [0421-A2 American Chemistry Council]

The commenter points out that the use of PFOA and PFOS in commerce is extremely limited, if at all. As a result, the proposal is unlikely to prevent releases. The signal to markets that "there is value in preventing releases" ignores the signal distortion that CERCLA's liability provisions provide. Due to concerns over CERCLA's unique (strict, joint, and several) liability provisions, markets will not just adjust, but over-adjust—creating a net social cost. The commenter notes that the transfer of costs "from the public to polluters" could occur in the absence of the proposed rule, suggesting that the rulemaking is unnecessary. The commenter also states that the "consistency" between the proposed rule and ongoing actions to address PFOA and PFOS contamination is irrelevant to a determination that the proposal meets a compelling public need. [0421-A2 American Chemistry Council]

Response

EPA disagrees with the commenter that the proposed rule will cause the market to over-adjust due 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 also 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. See RIA Section 4.2 (*Direct Benefits*).

The reporting and notification requirements, as well as additional enforcement authorities that will be made available by designation, will enable EPA to address potential contamination and exercise response more quickly where necessary. Upon designation, EPA can transfer costs to viable PRPs by compelling PRPs to implement response actions at NPL sites or through cost recovery. Absent designation, EPA would incur response costs. [[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. In addition to these CERCLA reporting requirements, EPCRA section 304 also requires owners or operators of facilities to immediately notify their SERC (or TERC) and LEPC (or TEPC) when there is a release of a CERCLA

hazardous substance in an amount equal to or greater than the RQ for that substance within a 24-hour period.]] The immediate reporting and notification required under CERCLA will increase awareness of those enforcing or implementing CERCLA of the potential risks to human health and the environment and allow them to respond in a proper and 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 proposal meets a compelling public need. In any case, designation is warranted independent of other Agency actions, but it 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. In addition, science has demonstrated that PFOA and PFOS may present a substantial danger to human health, welfare, and the environment when released and, if not addressed, these substances will continue to migrate, further exacerbating exposure risk and potential cleanup costs. These findings not only demonstrate why delaying CERCLA designation would be harmful, but also further demonstrate that CERCLA designation is in fact warranted. See RIA Section 1.2 (Need for Regulatory Action) and Preamble to Final Rule Section VI (The totality of the circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted.) for further details.

Additionally, when EPA is able to transfer certain response costs to PRPs, this represents an improvement in societal equity. See RTC 6.A.1.

6.B Direct Costs

6.B.1 EPA's hazardous substance designation will create minimal direct costs.

A commenter agreed with the EPA that hazardous substance designation will create minimal direct costs and presented the following points:

- Because PFOA and PFOS have largely been phased out of active commerce, it is unlikely that there will be many releases over the RQ. In the rare instance of such a release, the administrative costs of filing a report are minimal. The EPA estimates an upper bound of costs of assuming 660 reports, which is equal to the number of reports the National Response Center received for ammonia releases exceeding its RQ in 2020, which was the most-reported hazardous substance for that year. Unlike PFOA and PFOS, which have largely been phased out, ammonia is widely produced in the United States. An estimated 14 million metric tons of ammonia was produced in 2020. It's extremely unlikely that PFOA and PFOS, produced on a significantly lower scale, will generate nearly as many reports. Given the low production volumes, the commenter asserts that the actual costs are likely to be closer to the lower bound of the EPA's estimate.
- Disclosure costs imposed by section 120(h) only apply to the federal government, so this requirement will not create any new costs for industry. Furthermore, disclosure of the information on PFAS use and exposure will provide valuable information about risks

upfront to potential buyers of government property, allowing them to proactively address any risks and save costs in the long run.

- Listing and regulating PFOA and PFOS as hazardous materials under HMTA will also create few costs. As explained above, most of the HMATA requirements relate to labeling, packaging, and shipment tracking. These requirements serve an important public health benefit but will likely apply to a small number of shipments because PFOA and PFOS are rarely used. When PFOA or PFOS are shipped, it will be minimally burdensome for entities to simply label the shipments as hazardous and track those shipments, which they are likely already doing.
- Hazardous substance designation will not create additional new ongoing regulatory compliance costs for industries using PFAS. CERCLA is a cleanup statute and does not regulate the manufacture or use of chemicals. While companies have raised concerns about indirect liability costs, mere designation does not impose any potential liability on current manufacturers and users of hazardous substances unless there has been a "release."
- Because cleanup is addressed on a site-by-site basis and cleanup costs are highly site specific, there will be no new industry-wide costs resulting from the designation. While entities have discretion to take steps to prevent future releases of PFOA and PFOS to avoid future liability, CERCLA does not mandate any measures and those costs are also likely to vary widely depending on the use, volume, and handling of PFOA or PFOS at any given site, among other factors. Any response costs and liability concerns passed onto private parties will also be highly site specific. As such, it is impractical and unnecessary to quantitatively assess indirect costs.

The commenter references an analysis that they conducted in 2019 that found that at least 79 percent of the substances on the CERCLA hazardous substances list continue to be used in commerce. Moreover, the analysis found that 44 percent of those substances are not only still produced, but produced in high volumes. Sulfuric acid is included on the CERCLA hazardous substance list and is also the most-produced chemical in the world, with more than 70-80 billion pounds produced in 2015. Even though it is listed as a CERCLA hazardous substance, sulfuric acid continues to be widely used in a variety of sectors and products, including fertilizer, petroleum products, detergents, dyes, drugs, explosives, and in metallurgical processes. Benzene is also on the hazardous substances list and is one of the 20 most-produced chemicals in the U.S, with nearly 5 million metric tons produced in 2019. An August 2007 ToxFact sheet on benzene by the Agency for Toxic Substances and Disease Registry, or ATSDR, found that it had been found at least 1,000 of the 1,684 sites on the NPL at the time. Yet it continues to be commonly used to produce plastics, resins, nylon, synthetic fibers, and some types of lubricants, rubbers, dyes, detergents, drugs and pesticides.

Eight states have also started regulating PFOA and PFOS as hazardous substances under their state cleanup laws, which has not resulted in a significant amount of new liability or costs. [0552/EWG]

Response

EPA agrees with the commenter that the proposed rule will impose relatively minimal direct costs, that the designation will not create regular ongoing compliance costs for industries that

produce or use PFOA or PFOS, and that any cleanup costs will be indirect and determined on a site-specific basis. EPA agrees that future response costs are uncertain; nonetheless, EPA has quantified its best estimate of potential response costs that may result after designation. See RIA Chapter 5.

EPA agrees with the commenter that disclosure costs imposed by CERCLA Section 120(h) only apply to the federal government and will not create any new costs for industry. 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." Furthermore, in certain circumstances, CERCLA 120(h) requires Federal agencies to provide a covenant warranting that "all remedial action necessary to protect human health and the environment with respect to any [hazardous substances] remaining on the property has been taken before the date of such transfer, and any additional remedial action found to be necessary after the date of such transfer shall be conducted by the United States."

EPA agrees that the CERCLA Section 306(a) requirement for DOT to list and regulate substances designated as hazardous under CERCLA as hazardous materials under the Hazardous Materials Transportation Act (HMTA) will not create additional new ongoing regulatory compliance costs for industries using PFAS. Domestic production and import of PFOA has been phased out in the United States by the companies participating in the 2010/2015 PFOA Stewardship Program. Small quantities of PFOA may be produced, imported, and used by companies not participating in the PFOA Stewardship Program and some uses of PFOS are ongoing (see 40 Code of Federal Regulations (CFR) 721.9582). EPA understands that placarding (49 CFR 172.500), shipping papers (49 CFR 172.200), marking (49 CFR 172.300), and labeling (49 CFR 172.400) would be required for PFOA and PFOS upon being listed by DOT as HMTA hazardous materials. However, as indicated in EPA's PFAS Analytic Tools, PFAS is typically transported with other compounds such as, for example, dimethyl sulfoxide, arsenic, chromium, and/or methanol. In some cases, PFOA and PFOS may already require shipment as hazardous materials because of their corrosivity properties. Therefore, the costs associated with HMTA are already incurred in many instances in the absence of the designation of PFOA and PFOS as CERCLA hazardous substances.

EPA has incorporated information from an ORCR report on "Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) Waste Sources, Management Practices, and Enacted Regulations" provided by commenters regarding the states that are regulating PFOA and PFOS under their state cleanup laws into the final rule RIA.

EPA agrees that 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. See RTC 4.F.4.

6.B.2 EPA's claim that the Proposal will have only limited direct economic impact is not consistent with OMB's designation.

A commenter pointed out that the U.S. Chamber of Commerce provided EPA with a detailed expert assessment of the potential costs of CERCLA hazardous substance designation. The commenter stated that EPA's initial claim that the CERCLA designation will have only limited direct economic impact was a position that OMB ultimately did not agree with as demonstrated by the change in the designation of the economic significance of the rule as it progressed through the interagency review process. Further, the commenter asserted that EPA's unwillingness to

consider the reasonably expected range of costs does not mean the costs are indirect and not capable of assessment. Lastly, the commenter noted that the proposal does not analyze the DoD cost estimates based on DoD's considerable experience with PFOA and PFOS cleanups and overall CERCLA experience. [0341- American Farm Bureau Federation (AFBF)]

Response

EPA disagrees that the Chamber of Commerce cost analysis provides a reasonable representation of the potential costs associated with the 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. See RTC 6.A.5.

EPA disagrees with the commenter(s) assertion regarding OMB's review. Prior to approving the EA for the proposed rule, OMB reviewed it to ensure that the methods applied in the analysis were methodologically sound and that the analysis met the requirements articulated in various executive orders and OMB Circular A-4. OMB's review also considered whether the EA provides the public with sufficient information to understand the impacts of the rule and to provide comment on those impacts. OMB's approval of the proposed rule EA indicates that the EA met the applicable requirements.

EPA disagrees with the comments asserting that many of the costs classified as indirect in the RIA should be considered direct. A designation alone does not require the EPA to take response actions, does not require any response action by a private party, and does not determine liability for hazardous substance release response costs. Response actions are contingent, discretionary, and site-specific decisions made after a hazardous substance release or threatened release. They are contingent upon a series of separate discretionary actions and meeting certain statutory and regulatory requirements. Building on the information presented in the proposed rule EA, the RIA accompanying this final rule includes expanded analyses of direct/indirect costs and benefits relative to the analysis developed for the proposed rule (See Preamble to Final Rule Section IV.C (CERCLA section 102(a) and Cost Considerations.). See RTC 6.A.1.

6.B.3 The EPA should revise the Proposed Rule to clarify reporting obligations and direct costs to be incurred by regulated entities, including drinking water and wastewater utilities.

A commenter asserted that the EPA should revise its EA to consider the full scope of PFOA and PFOS release reporting costs that would be incurred by regulated entities, including drinking water and wastewater utilities. As EPA acknowledges, listing PFOA and PFOS as hazardous substances would trigger reporting obligations whenever there is a release of PFOA or PFOS in an amount above the proposed one-pound reportable quantity (RQ) (87 Fed. Reg. at 54416, 54419). EPA estimates based on its own data that the cost per reporting event to regulated facilities would be \$561, but EPA concedes that "the expected number of reportable releases of PFOA and PFOS is not known" (EA at 11, 40–41). EPA requests public comment upon the reasonableness of its estimates that the nationwide aggregate annual number of reportable releases of PFOA and PFOS would be between 0 and 660 (EA at 9, 41). The commenter states that EPA has underestimated both the lower and upper bounds of foreseeable reporting costs. The assumed lower bound of zero fails to consider that CERCLA section 102(a) requires reporting of continuous releases (40 C.F.R. § 302.8 [continuous release reporting requirements]; EA at 41 [relying upon market phase-out of PFOA and PFOS from manufacturing, import, and processing in 2015 to justify a zero baseline]). The upper bound of 660 assumes without

justification that reporting of PFOA and PFOS releases will not exceed observed annual reporting of ammonia and ammonium releases, without regard to: (1) whether such releases have been accurately reported, and (2) the relative prevalence or measurability of these substances that would influence a facility's decision to report. But it should be acknowledged that these lower and upper bound cost estimates assume that zero enforcement costs and fines would be incurred where EPA determines that a regulated entity has failed to report (40 C.F.R. § 302.7). Lastly, the commenter asserts that whatever the possibility is for these costs to arise should be discussed. [0561-WUWC]

Response

EPA disagrees that the EA issued with the proposal required more detailed evaluation of direct costs. See RTC 6.A.1 and 6.A.2. See also Preamble to Final Rule Section VII.I.1 (*Liability and Costs to Public Utilities*).

EPA clarifies that the number of PFOA/PFOS releases meeting the RQ threshold is highly uncertain due to limited information on the use and management of PFOA/PFOS in the U.S. In the absence of this information, this analysis estimates direct costs as a range. See Preamble to the Final Rule Section VII.G. (*Phase-out & PFOA Stewardship Program*). The low end of the range assumes no releases and the upper end uses annual releases reported to the NRC of the largest number of any non-oil releases reported (i.e., ammonia and ammonium compounds) as an indicator of potential PFOA/PFOS releases. Ammonia and ammonium compounds which, in contrast to PFOA and PFOS, continue to be widely manufactured and used today, accounted for the largest number of non-hydrocarbon releases in 2022. EPA believes that the high-end value for releases represents a very conservative estimate. See RIA Section 4.3 (*Key Uncertainties Regarding Direct Costs and Benefits*). In addition, based on the criteria established in the regulations at 40 CFR 302.8, the owner or operator of the facility may use their professional judgement to estimate releases of CERCLA hazardous substances when filing continuous release reports. Again, due to limited information on continuous releases, this analysis does not attempt to quantify continuous release reporting requirements. See RTC 4.A.6.

EPA also clarifies that cost of enforcement actions that may be pursued by EPA following the designation of PFOA and PFOS as hazardous substances are considered indirect costs of the rule. See RIA Chapter 5.

Additionally, the commenter(s) does not identify the additional publicly available information that they recommend EPA utilize to estimate the number of reportable PFOA and PFOS releases in the future. Therefore, EPA is unable to fully assess whether the publicly available information suggested by the commenter(s) is useful in estimating reporting costs.

6.B.4 The EPA should conduct a more thorough evaluation of the potential impacts of the proposed designation on transportation of PFOA and PFOS, including the requirement for DOT to list PFOA and PFOS under HMTA.

A commenter stated that the EPA should conduct and provide a more thorough evaluation of the potential impacts of the proposed designation on transportation of PFOA and PFOS. Section 306(a) of CERCLA requires substances designated as hazardous under CERCLA be listed and regulated as hazardous materials by DOT under the Hazardous Materials Transportation Act (HMTA). EPA estimates these incremental costs associated with DOT rulemaking as zero or negligible because "production of PFOA and PFOS are understood to have been largely phased

out of production and use beginning in 2000 and it is unlikely that regulated entities would ship PFOA or PFOS in quantities equal to or above the RQ." Given EPA's acknowledgement within the Federal Register Notice and the Economic Assessment that the extent of reportable releases of PFOA and PFOS are unknown, the commenter recommends that the EPA conduct a more thorough evaluation of the potential impacts of the proposed designation on transportation of PFOA and PFOS. Another commenter points out that the Proposed Rule's lack of certainty will pose significant challenges to the Rail Service Industry that EPA has not fully considered. As proposed, the rule does not further EPA's expressed priority to "create consistency and certainty for the regulated community and to remove unnecessary or redundant regulations" (EPA Fiscal Year 2019 Annual Performance Report). The commenter asserts that the proposed designations will greatly exacerbate regulatory uncertainty and impose potential direct and indirect costs amounting to millions of dollars in the rail service industry alone. [0410/WDEQ;0362-GATX/Phelps]

Another commenter stated that the proposal would require DOT to list PFOS and PFOA as hazardous materials and thus subject them to much more stringent and costly regulations such as placarding, restricting transportation routes, and potentially limiting disposal to certain hazardous waste facilities. The commenter asks whether EPA conducted a cost analysis as to what this designation will require for waste management and remediation service providers and ultimately the public utility and their ratepayers. The commenter asserts that this should be further investigated and reported. [0568 - Water and Wastewater Equipment Manufacturers Association (WWEMA)]

Response

EPA disagrees that the CERCLA Section 306(a) requirement for DOT to list and regulate substances designated as hazardous under CERCLA as hazardous materials under the Hazardous Materials Transportation Act (HMTA) will impose significant costs. EPA acknowledges that there may be certain instances where further placarding may be required when quantities at or above the RQ for PFOA and PFOS may be present during shipment, however the associated cost of placarding is estimated to be negligible. See RTC 6.B.1. and Preamble Section VI.B.1 (*Direct Costs*).

EPA does not agree with the commenter(s) that designation of PFOA and PFOS as CERCLA hazardous substances will create cost burdens for waste management and remediation service providers, that consequently will be passed on to public utility and their ratepayers. Under CERCLA, the only automatic, private party obligation that flows from designation as a CERCLA hazardous substance under section 102(a) is the obligation to report releases (a relatively small cost). In addition, efforts to address PFAS in these sectors, and the associated costs of those efforts, are already underway in the absence of the proposed designation of PFOA and PFOS as CERCLA hazardous substances. See Section 4.F (*Potential Liability and Enforcement*), Section 4.F.3. (*Designation will shift cleanup costs from responsible parties to communities and public utility ratepayers and impose considerable liability on entities in a variety of sectors*).

6.B.5 The EPA should consider additional direct and indirect costs not previously considered in the EA.

A commenter stated that the following are considered significant costs to a utility and, hence, the customers it services: monitoring; treatment and disposal; and future liability. The commenter

also identified the additional benefits and costs that were not considered in the EA: purchase of new filtration media, e.g., granular activated carbon; purchase of flocculant materials; testing of residuals, additionally there is not an approved method to do the testing; disposal of sediment, including filter media; new treatment technologies to remove PFAS chemicals from source water; cost of additional operators and maintenance staff; and training operators in new technologies. Another commenter expressed concern that they believe the Proposed Rule is premature as it has not been thoroughly reviewed by EPA or the communities that will be significantly impacted by this rule. The commenter further noted that the following services/locations will likely be impacted by this unfunded mandate and will incur additional cost burdens and legal liabilities: drinking water and treatment; wastewater treatment; solid waste; regional airport; and local solid waste agency / landfill operations. Another commenter noted that if the proposed rules are adopted, industrial waste pretreatment regulations will need to reflect the designation of PFOA and PFOS as hazardous materials and additional sampling and pretreatment may be required by industrial customers. These costs will be passed on to industrial customers, but administrative burden will also be increased. Each test for PFOA and PFOS is approximately \$860, and results are not received for approximately 30 business days. The commenter estimates that for their customers annual testing fees will be approximately \$100,000. The commenter asserts that the 30-business day turnaround time on sample results will also present many financial and operational challenges as it relates to biosolids storage and disposal. [0438/City of Aurora; 0437/Dubuque, 0303-Claremont County]

Response

EPA does not agree with the commenter(s) that the EA issued with the proposed rule was insufficient; however, EPA has expanded the economic analyses for this Final Action after consideration of comments on the proposed designation. See RTC 6.A.1.

EPA gave careful consideration to CERCLA's liability scheme, and the impact designation may have on CERCLA liability. EPA concluded that designation will not disrupt 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. Please refer to the Preamble to the Final Rule Section VI.B for EPA analysis on the potential for liability and litigation after designation.

EPA does not agree with the commenter(s) that designation of PFOA and PFOS as CERCLA hazardous substances will impose a significant cost burden on state and/or local governments that provide drinking water treatment, wastewater treatment, solid waste management, or airport services. Efforts to address PFAS in these sectors, and the associated costs of those efforts, are already underway in the absence of the proposed designation of PFOA and PFOS as CERCLA hazardous substances. In addition, the designation does not establish any standards, such as drinking water standards, and does not require any sampling. Similarly, no PFAS are currently listed, or being proposed to be listed, as hazardous wastes under RCRA, and the designation of PFOA and PFOS as CERCLA hazardous substances does not require waste (e.g., biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills. Designation alone does not require the EPA to take response

actions, does not require any response action by a private party, and does not determine liability for hazardous substance release response costs.

Moreover, EPA does not agree with the commenter(s) that the final rule will result in unfunded mandates to drinking water utilities, wastewater utilities, solid waste services, airports, or landfill operations. For further discussion of this issue see RTC 7.C. and specifically for biosolids see RTC 4.G.2.

6.B.6 The proposal should reference CERCLA Section 120(h) requiring notification of contamination upon property transfer.

A commenter requests that there be reference to CERCLA Section 120(h), which speaks to notification of PFOA or PFOS contamination upon property transfer. This would include land transfers by the federal government to tribes, villages, rancherias and Native American entities, such as Alaska Native Corporations. The commenter asks if there is there a way for EPA to apply and mandate this or similar criteria in cases where property is transferred as part of fee land acquisition. [0326/National Tribal Water Council (NTWC)]

Response

EPA evaluated the CERCLA Section 120(h) requirements in the EA for the proposed rule and we have expanded the discussion in the preamble to the Final Rule and the RIA. This designation will ensure that Federal agencies that sell or transfer real property provide notice of the presence of PFOA and PFOS in certain circumstances. Moreover, this rulemaking will require Federal agencies to provide a covenant warranting that "all remedial action necessary to protect human health and the environment with respect to any [PFOA or PFOS] 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." 42 U.S.C. § 120(h)(3) (CERCLA 120(h)). See Preamble to the Final Rule Section VI.B.1 (Direct Costs), RIA Section 4.1.5 (Costs Associated with Sale or Transfer of Government Property), and RTC 4.B.2.

6.B.7 EPA should conduct a more detailed evaluation of the costs associated with RQ compliance.

A commenter stated that per EPA, each release report of PFOA and PFOS is estimated to cost \$561 for a total of \$370,000 per year maximum and that "incremental detection and measurement costs are assumed to be zero or negligible," as affected facilities are "likely to incur such costs in the baseline to comply with reporting requirements related to the Toxics Release Inventory (TRI)" under the Emergency Planning and Community Right-to-Know Act (EPCRA). The commenter recommended to EPA conduct a more detailed evaluation of the costs associated with the proposed rule.

The commenter was concerned that the proposed designation would unintentionally place additional regulatory burden on either repositories (landfills) or removal processors (POTWs) which play a major role in buffering the environment from PFAS loadings, should they release PFAS over the one-pound threshold. [0534-Kansas Department of Health and Environment (KDHE), 0410-Wyoming Department of Environmental Quality (WDEQ)]

Response

Building on the information presented in the proposed rule EA, the RIA accompanying this final rule includes expanded analyses of direct/indirect costs, transfers, and benefits relative to the analysis developed for the proposed rule, to better inform the public of potential direct and indirect effects. See Preamble to Final Rule Section IV.C (*CERCLA section 102(a) and Cost Considerations*). See RTC 6.A.1.

The designation has no direct impact on landfill operations or removal processors, unless such entities release quantities of PFOA or PFOS at or above the RQ, which requires release reporting. With the exception of certain release reporting and notification requirements, designation does not impose any regulatory requirements on any specific facilities, including landfills. Release reporting will have a relatively small cost burden associated, in the event such entities do release 1 pound or more of PFOA or PFOS in any 24-hour period. See RTC 6.A.3.

6.B.8 The Proposal may increase direct costs for fire departments.

A commenter stated that if the EPA were to promulgate its draft rule, many fire departments would struggle to come into compliance with its requirements. For example, the exemption in CERCLA for emergency response only applies to state and local governments. If a self-incorporated volunteer fire department, industrial fire brigade or military fire department responded to a fire that resulted in the release of one pound or more of AFFF in a 24-hour period, they would not be protected by the liability protection in 42 U.S.C. § 9607 (d)(2) (CERCLA Section 107(d)(2)), even if they were aiding a local fire department in responding to the emergency.

The commenter also expressed concerns about the requirement that the U.S. Department of Transportation list PFOA and PFOS as hazardous materials under the Hazardous Materials Transportation Act. For example, the commenter was concerned that fire apparatus containing AFFF and other PFAS firefighting foams would have to be placarded. In addition, the 2020 Emergency Response Guidebook does not include identification numbers for PFOA or PFOS. The Pipeline and Hazardous Materials Safety Administration would have to take action to help fire departments come into compliance with the EPA's draft regulations.

The commenter also noted that fire departments would have to stop using AFFF and other PFAS firefighting foams and replace them. As the EPA identifies in its draft rule, some states do have PFAS foam takeback programs, but there are only a few of them. In most states, fire departments would be stuck with the foam and be unable to get rid of it. Instead, the unused foam would present a liability as fire departments wait instruction about clean-up of the foam. Otherwise, fire departments might be able to find a contractor to remove the unused PFAS firefighting foam. Unfortunately, because the foam would be declared a "hazardous substance," the cost of removal for the fire department would be exorbitant.

Further, the commenter noted that once the Department of Defense releases its replacement or revision of MIL-PRF-24385, fire departments will be able to purchase foam that meets that performance standard. However, it is not clear if manufacturers will be able to produce enough of the new firefighting foam to meet the new performance standard. This situation can lead to a scarcity situation, when there are shortages of the new foam, and the price will be high. It is expected that the full replacement of the PFAS firefighting foam with new PFAS-free foam will be delayed and expensive, especially without federal assistance.

Additionally, the commenter stated that fire departments also may face other operational requirements with the new foam. If the new foam does not extinguish fires involving jet fuel or hazardous materials as quickly, fire departments may be forced to purchase more ARFF vehicles or increase staffing at incidents. There also are questions about the safety of the new PFAS-free foams and whether they will prevent cancer in firefighters or expose them to a different type of contamination. Since firefighters' personal protective equipment contains PFAS, the fire departments also will have to replace their personal protective equipment (coat, pants, gloves), which will be a substantial expense. All these considerations may increase costs for fire departments. [0530-International Association of Fire Chiefs (IAFC)]

Response

For enforcement and liability information, see preamble to the Final Rule Section I (*Executive Summary*) and Final Rule Section II.E.7 (*What Enforcement Discretion is available when exercising CERCLA authority*). As EPA states in the FY 2024-2027 National Enforcement and Compliance Initiates (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" The NECI also clarifies that "OECA 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 OECA exercises CERCLA enforcement discretion in other areas."

EPA disagrees that the designation would lead to a significant increase in costs for fire departments. For more information, reference Section VII.I (*Comments on Economic Assessment/Regulatory Impact Analysis*). This rule is specific to PFOA and PFOS and does not impose requirements on the formulation of AFFF. While the transition to fluorine-free foam is still in process, a major milestone in the transition to AFFF that is free from PFOA and PFOS occurred in 2017. In 2017, DoD published a new MILSPEC, MIL-PRF-24385F(SH) w/AMENDMENT 2, concerning AFFF. The new MILSPEC stated that PFOA and PFOS must be below the limit of quantitation, which at the time was 800 ppb, in the concentrate. See RIA Section 2.2.7 (*Other Federal Efforts Related to PFAS*) and RTC 4.G.3-1. Further, 1 lb. of AFFF is not equivalent to 1 lb. of PFOA or PFOS, as the commenter asserts. Most, if not all, AFFF has been transitioned to be developed with other various types of PFAS without the use of PFOA or PFOS.

EPA clarifies that the CERCLA Section 306(a) requirement for DOT to list and regulate substances designated as hazardous under CERCLA as hazardous materials under the Hazardous Materials Transportation Act (HMTA) will not impose significant costs. Additionally, the residual amounts of PFOA or PFOS potentially found in fire apparatuses that the commenter describes would unlikely amount to 1 lb of PFOA or PFOS that would require placarding, and the commenters provided no data to support a conclusion that reporting would be likely. See RTC 6.B.1. and Preamble to the Final Rule Section VI.B.1 (*Direct Costs*).

6.C Indirect Costs

6.C.1 The indirect costs of the Proposal are ignored but potential indirect benefits are promoted.

A commenter states that the EPA's Economic Assessment estimates only the costs associated with reporting activity. All costs related to potential increases in response activities and increases

in the speed of response activities are only qualitatively described. 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 (See 87 Fed. Reg. at 54,418). This disconnect is particularly noticeable in Section VI (Effect of the Designation) of the proposed rule preamble. When discussing the effect of the designations in this section, EPA makes no mention of increases in response activities and the increases in the speed of response. EPA cannot have it both ways. It cannot, and should not, tout the alleged health benefits of a proposal and then simply ignore their costs. The 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. The comment further notes that the EPA states that "the multiple, contingent, discretionary and site-specific steps between designation of a hazardous substance and the incurrence of cleanup costs contribute to the inability to quantify costs at the designation stage" (Fed Reg. at 54442). The commenter asserts that this is not convincing and that these costs are reasonably foreseeable, ascertainable, and capable of being estimated. The comment points out that external experts were able to conduct such an analysis for costs to private parties. The commenter also states that the EPA has sufficient data from which they can extrapolate and conduct a bounding or sensitivity analysis. Indeed, the proposed rule preamble describes the available data on PFOA and PFOS prevalence, which EPA could easily use as a starting point for extrapolations to inform predictions of new sites that might be designated or additional sites that may require reopening for remediation. Similarly, 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 Records of Decisions (ROD). 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. [0569-US Chamber of Commerce Coalition]

Response

EPA disagrees with the commenter('s) assertion that EPA ignored the potential indirect costs of the proposed designation of PFOA and PFOS as CERCLA hazardous substances. The EA developed for the proposed rule included a qualitative assessment of these costs. Building on the information presented in the proposed rule EA, the RIA accompanying this final rule includes an expanded analyses of direct/indirect costs and benefits relative to the analysis developed for the proposed rule, to better inform the public. See Preamble to Final Rule Section IV.C (CERCLA section 102(a) and Cost Considerations.). The final RIA addresses financial, health, and environmental impacts on citizens, businesses, and industries. It includes quantitative analysis of indirect costs and benefits associated with potential enforcement actions that may follow promulgation of the rule and potential cost transfer impacts associated with cleanups and removals. This includes estimating the potential indirect costs of remediation that may occur at sites currently on the NPL, proposed for addition to the NPL, and deleted from the NPL, as well as sites that may be proposed and added to the NPL in the future. The RIA also evaluates impacts related to liability and litigation that may arise after designation. Please see RIA Chapters 4 and 5 for more information about EPA's methodologies and discussion of direct and indirect costs, benefits, and transfers.

EPA disagrees with the commenter(s) that the costs associated with conducting response activities are a direct impact of the designation and must be considered as direct in the RIA.

According to EPA's Guidelines for Preparing Economic Analyses (published in 2010 and updated in 2016), "direct costs are those which fall directly on regulated entities as the result of the imposition of a regulation." The only direct impact to the public 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 or other response action under CERCLA. Such actions occur only after EPA determines that response is necessary to protect human health and the environment, and such costs are therefore considered indirect. See RTC 6.A.2.

6.C.2 There is a need for planning for funding cleanup and liability.

A few commenters stated there is a need for planning for funding cleanup and liability. One commenter urges the Agency to consider the implications for future cleanup funding and how rulemaking can address plans for implementing liability. Given the environmental prevalence of PFOA and PFOS, including in surface waters, groundwater, soil, and wastewater treatment plants—along with the chemicals' resistance to degradation—it would behoove the Agency to consider how this series of rules will prime the pump for broadscale cleanup across the country.

The commenter further asserts that the Bipartisan Infrastructure Law provided a shot across the bow for a national effort to facilitate the long-term cleanup of PFOA and PFOS. The law's \$10 billion in funding for underserved communities fighting disproportionate impact of PFAS in drinking water was a step in the right direction. But given the law's more than \$15 billion in dedicated funding to replace lead pipes, along with the much more pervasive nature of PFOA and PFOS in our water supply, we know that funds provided by the Bipartisan Infrastructure Law can only be seen as a small down payment in PFAS cleanup. The commenter asserts that it would be shortsighted to disregard the unprecedented financial challenge that eradicating these harmful chemicals will hold for the federal government. The commenter notes that lessons learned should not be disregarded from the previous decades of CERCLA's implementation, which initially created disincentives preventing real estate investors from redeveloping contaminated sites until the 2002 Brownfield amendments.

Another commenter recommends a dedicated cleanup fund like the Oil Pollution Act's Oil Spill Liability Trust Fund be established for PFAS and funded by industries that produce, store, transport, dispose of, or utilize PFAS compounds or chemicals in their operations. The commenter states that they understand that the Bipartisan Infrastructure Law (BIL) and the Inflation Reduction Act (IRA) have re-funded the "Fund" part of CERCLA. The commenter recommends cleanup funds above and beyond that general funding.

Another commenter asserts that if the EPA goes forward with the proposal, it must implement safeguards to ensure equitable and practical outcomes including fund costs associated with PFOA and PFOS as an orphan share where no connection can be made to any PRP.

Another commenter notes that in the past, the process of holding polluters accountable under CERCLA and getting the polluters to pay the full cost of cleanup has taken too long. The commenter recommends that if EPA moves forward with this designation that the Agency find ways to streamline the process so that funds from responsible parties can be used to remediate contaminated sites more quickly and effectively. [0566/University of Arizona; 0326/NTWC; 0391/SSP: 0339-ASDW]

Response

EPA notes the input provided by commenters regarding federal funding to address PFAS and other emerging contaminants. While allocation of federal funds is outside the scope of this rulemaking, EPA notes that the Federal government is already incurring costs to address PFOA and PFOS contamination at Federal facilities because of the potential hazards to human health and the environment posed by exposure to such contamination.

EPA gave consideration to potential liability for parties that have not played a significant role in contamination, such as parties that did not generate PFOA/PFOS contaminated waste or are passive receivers of environmental media contaminated with PFOA/PFOS. Consistent with CERCLA's objectives, EPA will focus on holding accountable those parties that have played a significant role in releasing or exacerbating the spread of PFAS into the environment, such as those who have manufactured PFAS or used PFAS in the manufacturing process, and other industrial parties. See preamble to the Final Rule Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way).

6.C.3 The Economic Assessment does not provide any quantitative assessment of anticipated indirect costs, particularly those related to increased litigation and site assessment and remediation.

A commenter stated EPA's Economic Assessment does not sufficiently address the indirect costs associated with the Proposed Rule, nor does it consider alternative regulatory proposals, as would be required for a complete RIA pursuant to EO 12866 and OMB Circular A-4. Accordingly, EPA's failure to comply with the necessary requirements and provide an assessment of indirect impacts renders the Proposed Rule arbitrary and capricious.

The commenter noted that the EPA should quantify the indirect costs of the Proposed Rule. The commenter asserted that an examination of indirect costs is important both to inform regulated industries of the potential consequences of a regulation and ensure that the government has conducted sufficient regulatory analysis.

The commenter stated that the EPA, in the Proposed Rule and accompanying Economic Assessment, failed to adequately address a number of potential costs and issues—particularly those related to increased litigation and site assessment and remediation. The following points are presented by the commenter.

The commenter first stated that the EPA did not consider increased litigation costs, which are particularly relevant for those parties that must go to court to confirm that they are exempt from CERCLA liability. For example, EPA has not considered the costs involved in defending litigation based on the federally permitted release exemption, which exempts facilities from CERCLA liability for releases that are authorized under other federal permitting schemes.41 Because the federally permitted release exemption has been interpreted differently in different jurisdictions, there is increased uncertainty and risk that a party would have to pay litigation costs for a CERCLA lawsuit from which it is ultimately deemed exempt. The commenter further points out that because CERCLA liability is strict, joint, and several, entities that were unknowingly responsible for small amounts of PFAS contamination in the past could face a significant amount of CERCLA liability under the Proposed Rule, whether they are being pursued by EPA or in contribution actions by other PRPs. Simply proving that an entity is not a PRP is a costly exercise, whether or not it happens via litigation, and EPA has not addressed the magnitude and impact of those costs.

The commenter secondly noted that the EPA has not accounted for the costs of reopening Superfund sites that have already been deemed fully remediated but for which PFOA or PFOS is subsequently detected. The commenter further asserts, the Proposed Rule does not address the All Appropriate Inquiries Rule or ASTM standards for Phase I Environmental Site Assessments ("ESAs"). As CERCLA hazardous substances, PFOS and PFOA would have to be considered when conducting Phase I and Phase II ESAs and could be deemed Recognized Environmental Conditions ("RECs"). All of these impacts would affect property transactions, the liquidation of properties and assets, and the manner and cost of cleaning up legacy pollution. [0551- Cross-Cutting Issues Group (CCIG)]

Response

EPA does not agree with the commenter(s) that the EA issued with the proposed rule was insufficient. As it developed the EA, EPA followed its own Guidelines for Preparing Economic Analysis and OMB's Circular A-4 which provides guidance to Federal agencies on developing regulatory analyses to assure compliance with related E.O.s. Prior to approving the EA for the proposed rule, OMB reviewed it to ensure that the methods applied in the analysis were methodologically sound and that the analysis met the requirements articulated in those related executive orders and in Circular A-4. OMB's review also provided assurance that the EA provided the public with adequate information to understand the rule's impacts. Thus, the proposed rule EA was sufficient for Federal agency rulemaking.

Further, EPA disagrees with the commenter('s) assertion that EPA did not sufficiently address the potential indirect costs of the proposed designation of PFOA and PFOS as CERCLA hazardous substances. The EA developed for the proposed rule included a qualitative assessment of these costs because data on such costs is not available. Building on the information presented in the proposed rule EA, the RIA accompanying this final rule includes an expanded analyses of direct and indirect costs and benefits relative to the analysis developed for the proposed rule, to better inform the public. See Preamble to Final Rule Section IV.C (CERCLA section 102(a) and Cost Considerations.). The final RIA addresses financial, health, and environmental impacts on citizens, businesses, and industries. It includes quantitative analysis of indirect costs and benefits associated with potential enforcement actions that may follow promulgation of the rule and potential cost transfer impacts associated with cleanups and removals. This includes estimating the indirect costs of remediation that may occur at sites currently on the NPL, proposed for addition to the NPL, and deleted from the NPL, as well as sites that may be proposed and added to the NPL in the future for PFOA/PFOS contamination. The RIA also evaluates impacts related to liability and litigation that may arise after designation. See RTC 6.A.2. Also see RIA Chapters 4 and 5 for more information about EPA's methodologies and discussion of direct and indirect costs, benefits, and transfers.

The consideration of alternatives is not a requirement that creates a flaw in the proposed rule or limit the Agency's authority to issue a final rule. Notwithstanding, the final rule RIA includes consideration of two alternatives to the final rule — one more stringent regulatory alternative and one less stringent regulatory alternative. See RIA Appendix (*Potential Regulatory Alternatives*) for a description and analysis of these alternatives.

The potential litigation cost impacts of the final rule, including attorneys' fees and the costs associated with settlements, are difficult to assess, and EPA was unable to quantify these costs given the number of variables that might affect potential litigation. However, the final RIA does

provide a qualitative discussion of potential litigation costs. EPA's analysis has determined that CERCLA cost recovery and contribution provide parameters that safeguard against excessive or frivolous litigation, and that CERCLA settlements may further mitigate future litigation. Thus, EPA does not expect the final rule to result in litigation costs that are significantly different than such costs associated with other CERCLA actions. See RIA Section 5.1.2.4 (*Litigation*) for a more detailed discussion. Comments on this issue provide no data or information to support an alternative conclusion.

EPA also gave consideration to CERCLA's liability scheme and the impact designation may have on CERCLA liability. EPA concluded that designation will not disrupt 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. Please refer to Preamble to the Final Rule Section VI.B for EPA analysis on the potential for liability and litigation after designation.

Further, consistent with CERCLA's objectives, EPA will focus on holding accountable those parties that have played a significant role in releasing or exacerbating the spread of PFAS into the environment, such as those who have manufactured PFAS or used PFAS in the manufacturing process, and other industrial parties. See RTC 6.A.1.

With the finalization of the rulemaking, PFOA and PFOS will need to be addressed to complete an ASTM-compliant Phase I Environmental Site Assessment (ESA). A Phase I ESA can be used to satisfy the statutory requirements for conducting All Appropriate Inquiries (AAI). AAI may be conducted to obtain protection from potential liability under CERCLA as an innocent landowner, a contiguous property owner, or a bona fide prospective purchaser. AAI, however, has no bearing on the designation of particular properties as Superfund sites. See RTC 5.A.6.

For further information on enforcement and liability, see preamble to the Final Rule Section I (*Executive Summary*) and Section II.E.7 (*What Enforcement Discretion is available when exercising CERCLA authority*).

6.C.4 Ecological and surface water restoration costs should be considered, and benefits and costs should be incorporated into the designation decision by incorporating a risk-based approach to clean-up.

A commenter stated that ecological and surface water restoration costs should be considered direct costs. The commenter explained that in Florida, the Florida Department of Environmental Protection has issued what it calls "surface water screening levels" for PFOS and PFOA. These are levels designed so an entity facing the possibility of regulatory enforcement action at the level can evaluate the potential impact of a release to surface water and the degree of its regulatory response. In the case of a Florida entity located next to surface water and potentially discharging PFOS and PFOA to surface waters, addressing PFAS regulatory response may mean retrofitting stormwater conveyance and discharge systems and installing, as of today, non-existent and unproven large-size carbon filtration, ion exchange resins, or reverse osmosis systems on conveyance canals. The commenter asserted that the aggregated costs of addressing this often-unmentioned portion of a potential regulatory response to the hazardous substance designation is incalculable due to the specific environmental context of each entity with regards to its impacts to surface waters and the lack of an economically viable remedial technology.

The commenter also pointed out that additional potential source of costs is related to whether the CERCLA reopener clause can be applied by the EPA or state agencies to CERCLA and non-CERCLA sites that may have been delisted, granted a No Further Action, or where remediation was long considered complete. The commenter noted that the reopener provision of federal and state-lead settlement agreements is broad, enforceable, and would be authorized by the hazardous substance designation; therefore, public and private entities may be saddled with unplanned and additional costs to address this issue.

The commenter suggested that benefits and costs be incorporated into the designation decision by incorporating a risk-based approach to clean-up. Based on CERCLA Section 121(d)(2)(a) whereby the degree of cleanup must assure protection to human health and the environment and remedial actions shall attain Applicable and Relevant and Appropriate Requirements (ARARs) as well as the EPA's Office of Solid Waste and Emergency Response (OSWER) Directive 9610.17, the use of risk-based decision making is compatible with CERCLA and RCRA-based response actions, is an ARAR where so promulgated by a state, and therefore, must be considered to not only meet the requirements of 42 USC § 9621(b) but also to control potentially high costs of regulatory-agency response actions under this proposed Rule. The commenter also recommended that EPA's guidance on this matter, Risk Assessment Guidance for Superfund, be thoroughly updated. [0369/ Hillsborough County Aviation Authority (HCAA)]

Response

EPA disagrees with the commenter(s) that "ecological and surface water restoration costs" should be considered as direct costs under the CERCLA rulemaking. According to EPA's Guidelines for Preparing Economic Analyses (published in 2010 and updated in 2016), "direct costs are those which fall directly on regulated entities as the result of the imposition of a regulation." The only direct impact to the public 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. EPA notes that permitted discharges into water bodies are outside of the scope of this rulemaking. EPA does, however, evaluate potential impacts of ecological and surface water restoration as indirect impacts of the rule. See RIA Section 5.2.4 (Other Indirect Benefits).

EPA disagrees with the commenter about potential source of costs under the CERCLA Reopener clause will be incurred. It is important to note that PFOA or PFOS detection or use at a site does not imply that response action is necessary. Response actions, which include investigations of hazardous substance releases and determining if removal or remedial action is necessary, are contingent, discretionary, and site-specific [NPRM Chapter 1, pg 12.]. 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. Furthermore, the designation of a hazardous substance under CERCLA section 102(a) in some cases does not create new costs, but rather often allows costs to be transferred from taxpayers to parties responsible for pollution under CERCLA. Even in those circumstances, where the government is authorized to transfer costs, a private party's ability to

pay response costs is taken into consideration under the statute and in EPA's implementation of the statute [NPRM Chapter 3].

Deletion of a site from the NPL does not affect responsible party liability in the unlikely event that future contaminants are found at a site. CERCLA 105(e); [Under Section 300.425(e) of the NCP (55 FR 8845, March 8, 1990)]. However, even where EPA determines that additional remedial action is warranted at a deleted site, EPA generally will not re-list the site on the NPL. In such circumstances, it is better to address the release or threat of release directly. To do so, EPA may conduct additional remedial actions at the deleted site itself using Fund monies or, alternatively, may take action against responsible parties with which it has not settled or exercise reopeners available in any settlement agreements with such parties. (EPA 2007 Memo Regarding Conducting Remedial Action at Sites Deleted from the NPL; pdf pg 2). While a site must have been listed on the NPL at some point to be considered eligible for Fund-financed remedial action, Agency regulations make clear that remedial actions taken in response to releases at sites deleted from the NPL are eligible for Fund-Financing. 40 CFR 300.425(e)(3).

NPL deletion is an administrative action, not a CERCLA enforcement action. CERCLA enforcement agreements, including reopeners, remain in effect. Additional response by either the EPA or private parties at a deleted site is considered when the conditions or status of the release which necessitated NPL listing and action under CERCLA occurs. This determination is on a site-specific basis and these theoretical costs are indeterminate at this time.

EPA disagrees with the comment that Risk Assessment Guidance for Superfund (RAGS) guidance will need significant updates. PFOA and PFOS designation as a hazardous substance will not likely impact how the guidance will be used to evaluate a site for pollutants and contaminates and hazardous substances. Baseline risk assessments are site-specific and therefore may vary in both detail and the extent to which qualitative and quantitative analyses are used, depending on the complexity and particular circumstances of the site, as well as the availability of applicable or relevant and appropriate requirements (ARARs) and other criteria, advisories, and guidance. After an initial planning stage, there are four steps in the baseline risk assessment process: data collection and analysis; exposure assessment; toxicity assessment; and risk characterization. The RAGS guidance is not a regulatory requirement, but rather a process of how to perform site risk evaluations. Determination of an ARAR is an EPA decision, and state promulgated risk-based decision-making requirements would need to be evaluated as a site-specific decision. ARARs must be state promulgated and have a history of being enforced.

RAGS Part A is one of a three-part series: Part B addresses the development of risk-based preliminary remediation goals; and Part C addresses human health risk evaluations of remedial alternatives. RAGS Part A: Human Health Evaluation Manual provides guidance on the human health evaluation activities that are conducted during the baseline risk assessment. The first step of the Remedial Investigation/Feasibility Study (RI/FS). The baseline risk assessment is an analysis of the potential adverse health effects (current or future) caused by hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action). The baseline risk assessment contributes to the site characterization and subsequent development, evaluation, and selection of appropriate response alternatives. The results of the baseline risk assessment are used to help determine whether additional response action is necessary at the site, modify preliminary remediation goals, help support selection of the "no- action" remedial alternative, where appropriate, and document the magnitude of risk at a site, and the primary causes of that risk.

6.C.5 The EPA should consider a variety of indirect costs for municipalities, public utilities, small entities, and special districts.

Numerous commenters mentioned indirect costs that EPA had not considered for public entities such as water and wastewater plants and landfills. These include capital costs associated with infrastructure upgrades; increased monitoring capacity; R&D for developing new treatment technologies; and installing new treatment technologies. In addition, there are operational costs associated with monitoring, sampling, and analysis; treatment and disposal, operating advanced treatment technologies, taking groundwater wells out of service while establishing new treatment systems for PFAS, increased biosolids management costs if land application is no longer feasible due to liability concerns; and increased public communication. Finally, there are costs related to site investigation and remediation, as well as liability in general.

A commenter stated that the EPA should consider costs as part of the CERCLA designation, particularly for small entities. EPA is proposing (and seeks comment on) its interpretation that the designation of a hazardous substance under CERCLA 102(a) does not require consideration of costs. While this interpretation may be appropriate, CERCLA 102(a) does not preclude EPA from considering costs associated with the proposed rule. As EPA notes in the Federal Register notice, there is limited information available on potentially reportable releases of PFOA and PFOS, yet PFOA and PFOS are ubiquitous and may occur in municipal facilities such as wastewater treatment plants, landfills, and airports. Since the proposed designation may create significant costs for small entities associated with monitoring and analyzing samples for PFOA and PFOS to ensure they comply with CERCLA, it may be cost prohibitive for some small entities to comply with the proposed designation. As such, the commenter recommended EPA evaluate and consider the real costs associated with the proposed designation through a thorough evaluation of the number of types of facilities that may release reportable quantities of PFOA or PFOS and what monitoring and analysis costs these facilities will incur to ensure compliance with CERCLA. If EPA determines that costs should not be considered as part of the designation, the commenter recommends that costs be considered as a factor for complying with CERCLA.

A commenter expressed concern regarding the financial sustainability of impacted special districts, should they be responsible for hazardous materials cleanup. The commenter notes that while funding has been authorized to assist local governments with monitoring, such as \$10 billion in the Infrastructure Investment and Jobs Act, the level of assistance would fall far short of the support necessary for counties, cities, and special districts. The commenter further noted that many special districts provide robust public services on relatively small- to mid-sized operating budgets, compared to their general government counterparts, while also meeting a number of environmental and water quality monitoring and reporting requirements. The commenter urged the EPA to reconsider foregoing the development of a rigorous cost estimate with its use of CERCLA section 102(a) in its designation of PFOA and PFOS as hazardous substances. The commenter asserted that it is imperative that the EPA account for these costs, as impacted special districts, if considered a Superfund site, would need to prepare for infrastructure upgrades, create enhanced monitoring capacity, implement effective public communication, consider how massive costs will be passed on to ratepayers – of heightened concern are services in disadvantaged and historically underserved communities – and potentially make cuts to administrative or operational services. [0410/ Wyoming Department of Environmental Quality (WDEQ), 0528/NSDC]

A commenter asserted that, had POTW owners and operators been given the opportunity to comment on EPA's PFAS Strategic Roadmap, the sequencing of EPA's actions would have surely been the topic of robust analysis and comment. By advancing the Proposed Rule, and the specter of CERCLA liability, EPA is forcing entities like POTWs to continuously reevaluate their wastewater and residuals disposal options based solely on the virtually unquantifiable indirect effects of EPA's proposed designation under CERCLA, without the benefit of specific scientific analysis to further inform such options. The commenter asserted that, directly contrary to the principles of the PFAS Strategic Roadmap, the Proposal will have severe consequences for the commenter's members by shifting PFAS investigation and remediation costs to municipal entities. [0395-Massachusetts Water Resources Authority (MWRA), 0490-Pennsylvania Municipal Authorities Association (PMAA)]

Several commenters expressed concern over significant financial implications for local governments. Some commenters noted that the U.S. Chamber of Commerce recently reported that the designation would result in \$700 million to \$800 million in costs every year for the next three decades; however, the report did not explicitly address what would be borne by local governments. The local governments, and specifically ratepayers, would face financial burdens associated with corrective actions and legal fees/third party lawsuits. Given the potential significant economic burdens on local governments, federal agencies are required to consult with local and state governments early and often in the rulemaking process. One commenter specifically called out that industrial waste facilities and other pollution hazards are predominately located in communities of color and/or low-income; therefore, ratepayers of those communities are largely bearing the financial burden of costly cleanup. The commenter stated that those communities cannot sustain major projects, such as PFAS clean-up/remediation, because of strategic disinvestment and systemic racism; therefore, the rule must be promulgated to ensure that the cleanup and subsequent costs of the hazardous facilities/sites are born by the polluters and not the communities. Another commenter stated their concern for the costs faced by government entities from increased sampling, analysis, treatment, and disposal, in addition to their concern for the costs faced by businesses.

A commenter underscored that local governments manage airports, landfills, solid waste facilities, and other public service activities and fund 98% of all capital, maintenance, and operation costs for drinking water and wastewater infrastructure through bonds and user fees. The commenter stated that according to U.S. Census data, local governments spent over \$144 billion on water and wastewater in 2020 alone and \$2.38 trillion from 1993 – 2019 (not adjusted for inflation). Despite those investments, commenter stated that communities still struggle to upgrade their drinking water and wastewater systems. Even with the availability of funding under the bipartisan Infrastructure Investments and Jobs Act (IIJA), there are not sufficient funds for local governments to meet the requirements of the Proposed Rule. Given the far-reaching impacts the rulemaking will have on several municipal operations and the lack of consultation, commenter state that EPA is moving too fast without firm knowledge of the consequences for local governments and their residents.

Another commenter requested that federal agencies provide flexible financial support including for staffing costs to states and local governments facing the threat of PFAS contamination, including activities association with hazard communications, remediation, site assessments, and water quality. [0346 - CASA, 0370 - OR ACWA, 0567 - WE ACT, 0490 - PMAA, 0393 - NMED, 0506 - U.S. Conference of Mayors et al., 0298 - SD DANR]

Several commenters expressed concern over indirect costs to state and local governments and the public including public service providers. One commenter noted that the action will put an undue burden on the public, as public water and wastewater treatment utilities are not the generators of the substances, but must deal with them as they pass through their treatment processes. Another commenter stated that because the proposed action could result in indirect costs to states, they recommend expanding federal funding to help state and local governments and other public service providers (such as publicly owned treatment works, public drinking water providers, and municipal landfills) pay for site investigation, emergency response and cleanup, and necessary drinking water and wastewater infrastructure improvements.

Similarly, another commenter noted that beyond the technical and regulatory issues, the states have identified other resource needs to support their proactive investigations and responses to PFAS contamination. The commenter pointed out that in June 2022, the EPA invited states to apply for \$1 billion in Bipartisan Infrastructure Law grant funding to address PFAS and other emerging contaminants in drinking water, specifically in small and disadvantaged communities. However, additional federal monies are needed through State and Tribal Assistance Grants and other programs, not only to implement the necessary public water and wastewater infrastructure improvements to reduce exposures and pollutant loads in the nation's water, but also to investigate and clean up contamination. The commenter further stated, states need training and guidance on PFAS investigations and response, especially related to the potential sources and source pathways, environmental fate and transport, and treatment and remediation methods. The commenter asserted that the states also need support for informing the public about PFAS and recommends that the EPA work with state programs to facilitate trainings and develop guidance on best practices for risk communication and engaging communities impacted by PFAS contamination.

Similarly, another commenter noted that Congress and EPA should ensure that the funds identified in the recent acts (Infrastructure Investment and Jobs Act and other infrastructure bills that target assistance to respond to PFAS chemicals) are fully utilized to protect everyone's health and to provide safe water to all communities with particular focus on disadvantaged and underserved communities.

Another commenter noted that the rule will mean a future in which communities will be required to spend large sums for advanced treatment technology to address PFOA-PFOS in wastewater effluent from WTE facilities and landfills (as well as PFOA-PFOS present in WTE air emissions). And in the absence of a federal grant program (which ought to be funded by those actually responsible for PFOA-PFOS contamination), local governments will have to shoulder the substantial cost to construct and operate the necessary treatment technology.

Another commenter noted that a switch to landfill disposal of biosolids would impose significant operational cost increases to wastewater treatment facilities, costs that would ultimately be passed on to ratepayers. Rather than generating revenue from the sale of biosolids for land application, wastewater treatment facilities would be forced to pay costly disposal fees to solid waste landfills. In Maine, the first state in the nation to ban land application of biosolids earlier in 2022, eliminating land application of biosolids has strained existing landfill capacity and led to significant cost increases for biosolid disposal). The commenter asserts that impacts from the proposed rule could result in replacing land application with landfilling of biosolids in Tennessee, which would potentially exacerbate ongoing landfill capacity constraints.

[0798/Citizen; 0414- Attorneys General of the States of New York, et al; 0340/ASTSWMO; 0399/Coalition for Renewable Energy; 0468/NGWA; 0509/TDEC]

In response to EPA's request for comment on the R&D expenditures that may be necessary to ensure effective removal of PFOA and PFOS, a commenter points out their ongoing discussions with Maine's Department of Environmental Protection (DEP) about R&D efforts for biosolids and effluent wastewater treatment technologies capable of treating PFAS substances. The commenter notes that incineration is not commonly used in Maine, and the State has been on an aggressive plan to reduce its emissions, so it is unlikely that incineration will be a viable option for biosolids management in the foreseeable future. The commenter also notes that as investigative efforts remain underway to determine the best technologies for PFAS substances treatment, pressing questions remain such as what level treatment needs to deliver and how smaller POTWs with limited land capacity can make treatment modifications that require land space they do not have. Additionally, policy and permitting standards are lacking. The commenter further notes that efforts are underway to identify solutions and that to date, estimated costs to implement just enhanced drying techniques to reduce the overall volume of biosolids being sent to landfills can be millions of dollars at each POTW. The commenter emphasizes collaboration with the Maine DEP and notes that as more data becomes available through studies, the commenter and their association would be happy to share that information with the EPA. [0316-MeWEA]

A commenter expressed concern that the EPA has not fully or reliably considered the foreseeable indirect costs of the Proposed Rule upon drinking water and wastewater utilities. EPA, state cleanup agencies, and private parties may bring cost recovery and contribution actions against other PRPs under CERCLA Sections 107 and 113 and under analogous state statutes.14 The commenter asserts that even if EPA itself does not intend to seek CERCLA remediation costs from water and wastewater agencies, other entities can – and often do – bring public agencies into protracted CERCLA litigation that should be fully considered in EPA's indirect costs assessment.

The commenter notes that drinking water and wastewater utilities will face the threat of CERCLA liability even if they lawfully store, transport, and treat water containing PFAS, and lawfully dispose of PFAS retained in biosolids resulting from water treatment. An increase in cost recovery claims, contribution claims, and cleanup and abatement orders against drinking water and wastewater utilities arising from the investigation and cleanup of offsite disposal facilities and other facilities under federal or state oversight where a release of PFAS has allegedly occurred, even if such claims lack merit, would force drinking water and wastewater utilities to incur significant costs in the form of legal fees, expert consultant fees, insurance premiums, and employee time.

The commenter is further concerned that indirect costs to drinking water and wastewater utilities have been underappreciated regardless of whether EPA ultimately applies a quantitative or qualitative analysis. EPA determined it would be "impractical" and "not feasible" to quantify the indirect effects of the Proposed Rule, largely because EPA says it lacks "robust information" regarding the number of PFAS-impacted sites potentially affected, the cleanup standards that would be applied, and the development and availability of treatment and disposal technologies.

The commenter states that uncertainties around these topics could be reduced if the EA is updated to account for EPA's available data sources. For example, the EA makes no reference to

EPA's large database of CERCLA cleanup enforcement history data that could provide useful quantitative benchmarking. A quantitative analysis could be informed by a review of cleanup costs incurred and recovered from PRPs at sites impacted by "emerging contaminants" before and after their eventual listing as CERCLA hazardous substances. The EA also fails to leverage available EPA and other public agency loan information that would reduce cost uncertainties. For example, in August 2021, EPA granted a \$131 million Water Infrastructure Finance and Innovation Act (WIFIA) loan to the Orange County Water District to fund approximately half of the anticipated \$267 million up-front project costs for its PFAS Facilities Treatment Project. The commenter also points out that a more robust review of federal and state loan and grant program information may provide further insights.

The commenter also notes that the EPA could also supplement a quantitative analysis with available and relevant public data. Recent studies and other resources regarding where PFAS have been and are expected to be found in the environment are publicly available and would help EPA assess the number of sites that could be impacted by the Proposed Rule. The EA could derive additional information about the number of potentially impacted sites from the large number of lawsuits that have already been filed stating common law claims relating to PFAS. For example, there are so many lawsuits regarding the use of aqueous film-forming foam (AFFF) and PFAS contamination (more than 1800 cases) that the Judicial Panel on Multi-District Litigation consolidated these cases and created Multidistrict Litigation (MDL) set in the United States District Court for the District of South Carolina.

The commenter notes that if EPA limits itself to a qualitative analysis of indirect effects, that review could be improved. The commenter and its members expect PFAS cleanup costs to be significant based upon instances where drinking water and wastewater utilities have incurred "arranger" liability under CERCLA and state equivalent laws at multiparty landfill cleanups where cleanup has been ongoing for decades. The commenter also asserts that the EA also fails to mention the potential for the Proposed Rule to exacerbate liabilities and litigation defense costs associated with toxic tort litigation. For these reasons, the commenter requests that EPA supplement its EA to more carefully consider the potential indirect costs of the Proposed Rule. [0561-WUWC]

A commenter stated that detecting PFAS in a water system can lead to severe and costly operational impacts, such as: (1) Taking groundwater wells out of service and relying on other alternative water supplies while establishing treatment systems for PFAS. Hazardous substance designation may increase the cost of disposing of the filter materials that these systems use; (2) Beneficial use of recycled water may be negatively impacted for direct use customers, and for groundwater recharge for indirect potable reuse, worsening the already precarious situation and reducing the already limited water supplies, especially during drought periods; (3) Biosolids management costs may increase due to PFAS liability concerns adversely affecting the ability to land apply, and further reducing the limited biosolids alternative use and disposal options. [0455-Inland Empire Utilities Agency (IEUA)]

A commenter notes that the Proposed Rule could cause many drinking water and wastewater utilities to adopt inefficient capital upgrades and accelerate research and development costs simply to preserve CERCLA liability defenses. The commenter points out that the EA states that the "direct benefits" of the Proposed Rule include incentivizing "better waste management practices for facilities handling PFOA or PFOS in an effort to avoid releases of these substances into the environment." The EA further suggests that the Proposed Rule "may also result in

increased research and development (R&D) expenditures to ensure the effective removal of PFOA and PFOS" while further noting "it is uncertain how those wastewater treatment plants needing to treat high levels of PFOA and PFOS would remove them from wastewater treatment sludge." The commenter states that the EPA should equally recognize the drawbacks these incentives will create for drinking water and wastewater utilities by forcing inefficient allocation of drinking water and wastewater utilities' resources. The commenter notes that the ratepayers will feel the impact of these inefficient uses of resources. [0561-WUWC]

The commenter explains that normally, drinking water and wastewater utilities plan capital upgrades to treatment facilities in response to regulatory actions adopting primary and secondary water quality standards, such as under the federal and state Safe Drinking Water Acts (SDWAs). While EPA and some states have adopted health advisories, notification levels (NLs), and response levels (RLs) for PFOA and PFOS in drinking water, national primary drinking water standards (MCLs) have not yet been developed. Future adoption of MCLs for PFOA and PFOS would be expected to identify numeric treatment objectives and/or treatment techniques following normal SDWA rulemaking procedures that give due consideration to health risk assessment, exposure analysis, feasibility analysis that considers best available treatment technologies (BAT), and implementation experience. [0561-WUWC]

The commenter asserts that drinking water and wastewater utilities' capital planning has already been challenged by EPA's decision earlier this year to release interim updated health advisories for PFOA and PFOS at 0.004 parts per trillion (ppt) and 0.02 ppt, respectively -- more than 10 to 100 times lower than the resolution of current analytical methods. The interim health advisories for PFOA and PFOS replace the 2016 health advisory set at 70 ppt either individually or collectively. As EPA acknowledges in the Proposed Rule, the interim updated health advisory levels of 0.004 ppt for PFOA and 0.02 ppt for PFOS "are below the levels at which analytical methods can measure these PFAS in drinking water." Drinking water and wastewater utilities are already facing significant uncertainty about how to determine when PFOA and PFOS are present in their water supplies when the health advisory levels are below the detection limit. Listing under CERCLA will greatly add to these uncertainties, and the commenter notes that they would like to work directly with EPA to discuss ways to avoid or lessen this impact. [0561-WUWC]

The commenter also notes that neither the Proposed Rule nor the EA acknowledges the risk that drinking water and wastewater utilities will need to accelerate capital upgrades to assert liability defenses in multiparty liability disputes. For example, drinking water and wastewater utilities may face cleanup liability claims under CERCLA sections 107 and 113 for which the "third party defense" would apply, but to assert the defense, drinking water and wastewater utilities would have to demonstrate they exercised "due care" with respect to the contamination. The commenter is concerned to the extent the EA and Proposed Rule suggest drinking water and wastewater utilities fail to exercise due care by waiting for SDWA standard-setting processes to conduct R&D and authorize capital upgrades. Instead, drinking water and wastewater utilities exhibit due care through their compliance with applicable federal, state, and local laws governing the lawful pumping, storage, treatment, and disposal of water and treatment wastes containing PFOA and PFOS. [0561-WUWC]

The commenter states that the EPA should revise the EA to consider more carefully the indirect effects of the Proposed Rule with respect to the acceleration of capital upgrades and R&D expenditures. The commenter also asserts that beyond this rulemaking, EPA should also exercise its authority to adopt new enforcement guidance and clarify existing guidance such that, until

EPA adopts national primary water quality standards for PFOA and PFOS, drinking water and wastewater utilities' compliance with applicable laws governing pumping, storage, treatment and disposal of PFOA and PFOS-containing water and treatment wastes is sufficient to establish the "due care" element of applicable liability defenses. The commenter also asserts that the EPA should take the added time necessary to fully consider and address the consequences of the Proposed Rule on drinking water and wastewater utilities. WUWC pledges its support to help EPA do so in a timely and efficient manner. [0561-WUWC]

A commenter acknowledged the concern raised in response to the Agency's proposal about the impact the proposal could have on landfill operations and cost to the public. The commenter referenced a May 10th letter to Congressional leadership that estimated capital costs to implement leachate pretreatment at a moderate-sized landfill to the extent necessary to reduce PFAS significantly range from \$2 million to \$7 million, with nationwide costs totaling \$966 million to \$6.279 billion per year. The commenter further notes that newer estimates for the cost of PFAS management have increased to upwards of \$8.2 billion per year for municipal solid waste landfills alone, not including true destruction of PFAS. The commenter points out that this is a large cost and undertaking for currently specified technologies such as Granular Activated Carbon, that merely remove PFAS from sources such as landfill leachate and require additional disposal techniques that move PFAS around in the environment but do not remove them from the environment or destroy them. As an alternative, the commenter recommends and seeks to inform the EPA that there are, in fact, cost-effective and sustainable approaches to destroy PFAS in landfills. As an example, the commenter notes the ability to destroy PFAS in landfill leachate with no required pre-treatment or additional disposal steps for less than \$0.10 per gallon. [0536-*Aclarity*

Response

EPA does not agree with the commenter(s) that designation of PFOA and PFOS as CERCLA hazardous substances will impose a significant cost burden on state and/or local governments that provide drinking water treatment, wastewater treatment, solid waste management, or airport services. Efforts to address PFAS in these sectors, and the associated costs of those efforts, are already underway in the absence of the proposed designation of PFOA and PFOS as CERCLA hazardous substances. As the commenter indicates with its example of EPA's \$131 million loan to the Orange County Water District for PFAS treatment, investments to address PFOA and PFOS in the wastewater sector are already being made, prior to EPA's proposed designation of PFOA and PFOS as CERCLA hazardous substances. In addition, the designation would not affect drinking water standards. Similarly, no PFAS are currently listed, or being proposed to be listed, as hazardous wastes under RCRA, and the designation of PFOA and PFOS as CERCLA hazardous substances does not require waste (e.g., biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills.

EPA does not agree with the commenter that designation of PFOA and PFOS as CERCLA hazardous substances will lead to significant cost impacts for landfill operations. Efforts to address PFAS in landfills, and the associated costs of those efforts, are already underway in the absence of the proposed designation of PFOA and PFOS as CERCLA hazardous substances. Additionally, the proposed rule itself will not require landfill site cleanups or impose the estimated PFAS-related costs on all landfills. In addition, EPA disagrees that the estimates of

PFAS management costs for municipal solid waste landfills provided by the commenter are generalizable to the proposed rule. The May 10th letter to Congressional leaderships (*Letter from the Waste & Recycling Association and the Solid Waste Association of North America. May 10th, 2022.*) concludes that the increased costs associated with PFAS management for municipal solid waste landfills could total \$966 million to \$6.279 billion per year. This assumes that all landfills would realize capital costs to implement leachate pretreatment, for 30,000 to 40,000 gallons per day of leachate, of \$2 to \$7 million. The letter merely states that most landfills do not employ leachate pretreatment and assumes that all landfills would incur these costs. But the proposed designation of PFOA and PFOS as CERCLA hazardous substances would not impose any requirements related to leachate pretreatment, so it is unclear based on the comments how these costs would be incurred as the result of this action.

The Agency recognizes that certain stakeholders are concerned about CERCLA liability resulting from the designation of PFOA and PFOS as hazardous substances. The only direct impact to the public 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 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 federal government broad discretion as to whether or how to respond to a release. EPA has used both statutory protections and enforcement discretion policies to ensure equitable results when possible. CERCLA also provides statutory provisions for exemptions from and affirmative defenses against liability. For those reasons, EPA cannot assess with reasonable certainty what litigation or liability outcomes may 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 designations.

EPA intends to focus its CERCLA enforcement efforts on those who significantly contribute to the release of PFAS into the environment, such as major manufacturers and users of manufactured PFAS, federal facilities that are significant sources of PFAS, and other industrial parties, and drinking water utilities are not among those sources of PFOA and PFOS. This approach will hold parties accountable for their actions, by ensuring that they assume responsibility for remediation efforts and prevent any future releases. This is consistent with EPA's polluter pays approach to cleanup under CERCLA. See Comment 4.F.3 (*Designation will shift cleanup costs from responsible parties to communities and public utility ratepayers and impose considerable liability on entities in a variety of sectors*) for additional details.

With respect to wastewater utilities, data available to EPA suggests that CERCLA hazardous substances other than PFOA and PFOS are present in water sources across the country and in the influent that passes through sewage treatment plants. See EPA's November 3rd, 2016 Memorandum "Best Practices Memorandum for NPDES Pretreatment Coordination to Address Toxic and Hazardous Chemical Discharges to POTWs"

(https://www.epa.gov/sites/default/files/2016-11/documents/memobestpractices_npdes-pretreatment-r.pdf). Relatedly, sewage sludge and biosolids can contain CERCLA hazardous substances in the baseline. Absent the designation of PFOA and PFOS as hazardous substances,

these facilities may face some CERCLA liability risk, particularly for substances regulated under 40 CFR Part 503, Standards for the Use or Disposal of Sewage Sludge. See supra-Section 4.F.4 (Liability Can Arise Without A Site Being Listed On the NPL). Given the varied CERCLA hazardous substances that have always been in biosolids and sewage sludge, EPA believes that significant litigation against producers, users and disposers of those materials would have occurred already if it was going to due to the presence of those other hazardous substances. EPA thus believes the concern that a barrage of new litigation will occur based on the designation of PFOA and PFOA is unrealistic.

A commenter expressed concerns about EPA sequencing its' actions forcing entities like POTWs to continuously reevaluate their wastewater and residuals disposal options based solely on the virtually unquantifiable indirect effects of EPA's proposed designation under CERCLA, without the benefit of specific scientific analysis. EPA believes this is a CERCLA program concern that exists even absent an new hazardous substance designation. That is, wastewater utilities already presumably have these obligations as a result of CERCLA requirements and with the current 800 Hazardous Substances that are already designated under CERCLA. Although EPA is designating new hazardous substances, utilities' obligations under environmental law have not changed and the CERCLA statutory requirements have been around for approximately 40 years. The commenters do not claim, nor can they, that PFOA and PFOS are the only CERCLA hazardous substances present in sewage sludge and biosolids, so it is unclear why these claims of changed circumstances are being raised with respect to PFOA and PFOS.

The comments regarding water sampling methods and EPA's drinking water health advisories are outside of the scope of this rulemaking. EPA agrees with the commenter that typically drinking "water utilities plan capital upgrades to treatment facilities in response to regulatory actions adopting primary and secondary water quality standards under the federal and state Safe Drinking Water Acts (SDWAs)." Under the Safe Drinking Water Act (SDWA), EPA is utilizing its authority to set enforceable maximum contaminant levels (MCLs) for six PFAS, including PFOA and PFOS, to limit concentrations of these contaminants in public drinking water supplies. Please see EPA's PFAS National Primary Drinking Water Regulation (NPDWR). The NPDWR will reduce the uncertainty capital upgrades water systems will need to make to comply with the NPDWR.

The comments regarding the costs associated with taking wells offline or installing treatment to remove PFAS from drinking water are also outside of the scope of the CERLCA rulemaking. Those costs have been or will be contemplated in their respective regulatory actions. EPA is contemplating these costs as part of its action to develop the National Primary Drinking Water Regulation for PFOA and PFOS. If finalized as proposed, community water systems and nontransient, noncommunity water systems would be subject to EPA's National Primary Drinking Water Regulations for PFAS. Potable recycled water that is delivered from a regulated public water system will also have to meet all federal and state PFOA and PFOS regulatory limits as part of state and/or federal drinking water requirements.

Additionally, in December 2022, EPA issued a memo to proactively use its Clean Water Act permitting authorities to reduce discharges of PFAS at the source and to obtain more comprehensive monitoring information on potential sources of PFAS. The memo will help minimize PFAS pollution in surface water as EPA works to set effluent guidelines, develop analytical methods, and issue water quality criteria for PFAS. This memo applies to Clean Water Act programs EPA oversees; EPA plans to issue a subsequent memo that provides guidance to

state permitting authorities. See Comment 4.G.2 ("Biosolids-Related (including Pulp and Paper)") for additional discussion of biosolids.

EPA does not agree with the commenter(s) that designation of PFOA and PFOS as CERCLA hazardous substances will lead to significant cost impacts for small businesses. The proposed rule EA demonstrated that the rule would not result in a significant impact to a substantial number of small entities. Consistent with long-standing EPA policy on implementation of the Regulatory Flexibility Act, the proposed rule economic assessment considered small entity impacts related to the direct cost impacts of the rule, which are limited to costs associated with the reporting of PFOA/PFOS releases.

The rule does not require monitoring and analysis specifically. Due to the phase out of PFOA and PFOS by many former users, EPA anticipates that any entities engaged in the handling of PFOA or PFOS in such quantities as the RQ, in the absence of the rule, would be aware of that and so new monitoring/analysis costs are presumed to be negligible.

Regarding R&D, EPA's Office of Research and Development (ORD) is conducting ongoing research on the effectiveness of different disposal methods. Additionally, EPA believes the rule may indirectly result in increased R&D expenditures to develop and improve methods, approaches, tools, and technologies for addressing PFOA/PFOS contamination. See RIA Section 5.1.2.5 ("Research and Development") for further detail.

Input provided by commenters regarding federal funding to state and local governments to address PFAS and other emerging contaminants is outside the scope of this rulemaking.

With regard to unintended consequences of regulatory actions, EPA has made tremendous progress in implementing EPA's PFAS Strategic Roadmap, working cross-Agency to mitigate potential unintended consequences of regulatory actions. Read about key EPA Actions to Address PFAS (https://www.epa.gov/pfas/key-epa-actions-address-pfas).

6.C.6 The EPA fails to consider the costs and adverse economic impacts to airports related to the proposed designation. In particular, EPA's proposed rule would impact ongoing airport infrastructure development and delay safety-critical projects.

A commenter asserts that the 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 points out that many of the "indirect" costs claimed by EPA are in fact "direct" costs. The commenter further notes that EPA characterizes its list of indirect effects as providing "meaningful" benefits, yet as to indirect costs – which the commenter believes are substantial, running into the hundreds of millions or even billions of dollars.

The commenter states that the limited economic analyses that the EPA performed to support the Proposal is flawed and its analysis about airports is particularly deficient. As the analysis notes itself, key information is missing such as the sites that need response activities, cleanup standards that need to be met, and the technologies and associated costs for remediating sites. The commenter states that these are direct and important costs for airports. Just the investigative process – without the remediation planning, and much less the remediation work – at one California airport has cost nearly \$1 million. Given that there are approximately 450 airports in the US with Part 139 certificates, the investigative process alone for the nation's airports will cost in the range of \$500 million.

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. The commenter cites the following two examples in particular: (1) The EPA listing annual revenues for aviation operations, which appears to presume airports somehow profit from these revenues. However, almost all U.S. commercial service airports and many general aviation airports are owned and operated by public agencies and operated on a non-profit basis. The aeronautical revenues collected by these airports are used to operate, maintain, and enhance airport infrastructure and meet the air transportation needs of the travelling public, air cargo shippers, and the general aviation and business aviation community; (2) The EPA appears to mischaracterize and misuse aviation data. For example, the footnote in the economic analysis identifying Lake Havasu City Airport as a "large" airport is simply wrong. Lake Havasu City airport is a general aviation airport serving small personal and corporate aircraft.

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. There are a range of costs for disposal of AFFF concentrate, acquiring new fluorine-free firefighting foam concentrate, decontaminating existing AFFF vehicles and systems, potentially replacing systems or equipment on these ARFF vehicles, training firefighters, and replacing personal protective equipment. Again, this assumes that an effective method for decontamination can be identified. If replacement of AFFF vehicles were required, transition costs would easily exceed \$3 billion by our estimation and a significantly longer timeline would be needed.

EPA's proposed rule would have a variety of other non-economic impacts on the airport industry beyond cleanup costs and impeding the ability for airports to transition to a new fluorine-free firefighting agent. First, the significant costs associated with EPA's proposed rule would negatively impact the ability for airports to complete other much-needed infrastructure projects, including delaying safety critical projects. In a report released in September, FAA found that approximately \$62.4 billion is needed over the next 5 years for about 18,700 airport development projects and noted that the needs are expected to substantially increase over the next few years. (Federal Aviation Administration, National Plan of Integrated Airport Systems (NPIAS) 2023-2027, at 1–2 (2022)) The estimate includes \$22 billion for rehabilitation or reconstruction of airport facilities, runways, taxiways, and aprons; \$17 billion for terminal improvements; \$12.4 billion to bring airports into compliance with existing design standards; and \$1.9 billion for other safety-related projects; among other needs. We would note that this estimate is just for projects eligible for funding under the AIP and BIL programs. The total infrastructure and capital development needs are much higher; one industry estimate places the amount at approximately \$115 billion. Second, designating PFOA and PFOS as hazardous substances would exacerbate issues that airports are already experiencing with planned and ongoing infrastructure projects. Under BIL, Congress made \$20 billion available to airports over five years for a range of infrastructure improvements and terminal development projects, and some airports have found it difficult to use their share of funding or proceed with other construction projects in a timely manner because of PFAS-related issues. These airports reported challenges with managing soil during project implementation because of regulatory uncertainty on soil action levels, the lack of cost-effective options for managing and disposing of potentially contaminated soil, and concerns with landfill capacity, especially if PFOA and PFOS are designated as hazardous. As noted, EPA has failed to produce any guidance on disposal or destruction of PFAS and PFAS-containing materials. Like AFFF and PFAS-containing rinsate, a hazardous substance designation would make it even more challenging to manage soil during construction projects, increasing costs and

delaying projects that are needed to improve safety and benefit the traveling public. [0424-ACI-NA; 0555 - AAAE]

Some commenters noted that EPA's economic assessment omitted many indirect costs that the aviation industry might incur, and that EPA attributed this to unknown factors, such as the types of contamination and the number of affected sites. However, commenters believed that existing data could be used to estimate the range of indirect costs. On the other hand, they raised objections to the proposed rule change because there are no FAA and DOD-approved alternative PFAS-free AFFF, making it impossible to estimate transition costs.

In addition, commenters expressed concerns about costs associated with efforts to decontaminate or replace stormwater conveyance, discharge, and filtration systems. One mentioned that there are no effective decontamination methods and therefore systems may have to be decommissioned and replaced. If this is necessary, there would be additional costs due to operational disruptions.

Another commenter provided the following examples of the costs that are unique to the aviation industry. The commenter noted that the Proposed Rule may effectively precipitate significant changes to the aviation industry's fire protection infrastructure, and the costs associated with such changes have not been addressed in EPA's EA. Typically, AFFF is stored in tanks at a secured location and on an impervious surface to prevent any release from affecting soils or groundwater. When a fire starts at an airport hangar, terminal, fuel storage facility, or maintenance facility, the AFFF is blended with water and pumped through a complex and extensive system of piping before it is applied to the target equipment or area.

The commenter pointed out that when the AFFF and water mixture is used, the piping and other equipment, which at many airports can equate to thousands of feet of conduit and hard surface square footage, may retain residuals PFAS. The commenter referenced that the EPA recently presented a webinar describing the challenges of decontaminating aviation firefighting equipment, and noting how, even after substantial cleaning efforts, PFAS can "rebound" due to its origination in the desorbing layer of the pipe. This results in PFAS concentrations increasing over time even after cleaning, which presents a substantial challenge for the aviation industry's ability to decontaminate existing firefighting equipment. The commenter asserted that currently, there is no comprehensive framework in place for evaluating the environmental impact of decontamination compared to the costs of replacing components and systems. EPA's recent webinar noted that DOD estimated the costs of replacing their 4,600 AFFF delivery systems at \$2.1 billion. The commenter asserted that this statistic, which was not incorporated or addressed in EPA's EA, further underscores EPA's failure to assess similar costs to the aviation industry. The commenter stated that the Proposed Rule could result in the decommissioning of this equipment, and its removal and disposal at off-airport locations. The disposal of such a substantial amount of equipment as an unintended consequence of the Proposed Rule is contrary to EPA's waste management or minimization goals. The commenter requested that EPA complete the research necessary to determine the best methods for the destruction and disposal of PFAS-based AFFF and PFAS containing equipment, and then finalize the guidance on such methods prior to finalizing the Proposed Rule.

The commenter further stated while the costs to dispose of equipment and materials potentially contaminated with PFOA or PFOS are substantial, there may be an even greater cost for the aviation industry to replace it with new infrastructure and systems to deliver AFFF that is PFAS-

free. The commenter asserted that the substantial disruption to airline operations associated with the retrofitting of hangar and fuel farm fire systems has not been assessed by EPA. The commenter also asserted that the EPA has not comprehensively assessed the costs to dispose of equipment, nor the cost to install new equipment at airports. The commenter states that such costs and effort are yet another reason for EPA to withdraw the Proposed Rule or, if EPA moves forward with this rulemaking, exercise its enforcement discretion with respect to the aviation industry when enforcing the final version of the Proposed Rule. The commenter supported transitioning to PFAS-free AFFF, but the timing for this requirement must be coordinated with (a) the availability of an FAA and DOD-approved alternative that is equally as protective of public safety as AFFF that contains PFAS, (b) EPA's completion of a robust cost-benefit analysis of the transition that accounts for relevant costs as described above, and (c) AFFF disposal options that will not negatively impact the environment.

Another commenter also asserted that without the federal government first addressing the fundamental issues regarding liability on innocent parties such as commercial airports and without cost-effective technical remedial solutions, using the blunt tool that is CERCLA will leave these fundamental issues for the courts to decide. The commenter asserts that these issues are better left for the federal agency with the expertise to work out. EPA should take the time to do so. There is no harm in doing so, because the sites that are of significant concern can be addressed under existing tools. There is no reason that EPA needs to proceed with this Proposal now. Doing so is an ineffective and inefficient way to address PFOA and PFOS-contaminated sites and will lead to the many costly repercussions. The commenter urges that EPA not finalize the Proposal at this time.

Another commenter noted that since most Florida airports are located next to surface waters, addressing regulatory response for PFOS and PFOA may mean retrofitting stormwater conveyance and discharge systems and installing, as of today, non-existent and unproven largesize filtration systems on conveyance canals with O&M costs in perpetuity. Any response addressing surface water or ecological impacts must also consider contributions by other, and unrelated to aviation operations, sources such as non-point sources and as proven recently, rainfall. The commenter also noted that airports are required to use AFFF containing low levels of PFOA and PFOS, so releases, or being the recipients of PFOS and PFOA-containing wastes, could trigger a CERCLA Superfund designation or potentially be named as a potential responsible party. The long process of CERCLA remediation (often decades long), could mean that these public entities will have to bear high direct and indirect costs for soil and groundwater to reach a health-based groundwater standard without any assurances that the remedial goal will actually be achieved. The commenter also noted that it is unclear in what cases will the CERLA reopener clause be applied by the EPA or State agencies to CERCLA and non-CERCLA sites that may have been delisted, granted a No Further Action, or where remediation was long considered complete. The reopener provision of federal and state-lead settlement agreements is broad, enforceable, and would be authorized by the hazardous substance designation. Therefore, public, and private entities may be saddled with unplanned and exorbitant costs to address this issue. The commenter asserted that airports should not be financially liable for the impacts of historical AFFF usage because the FAA has required airports to use AFFF (containing PFAS) at their facilities for decades.

The commenter further pointed out that they engaged with experts to conduct an economic analysis and estimate of potential cleanup costs at airports, and the findings and initial estimate

conservatively show that costs of at least \$2.6 billion to \$35.6 billion could be incurred at the 3,250 airports within the FAA's NPIAS should EPA move forward. The commenter pointed out that the analysis was based on the number of NPIAS airports identified in the FAA's NPIAS report from 2020. The commenter further noted that most of the estimated costs would be incurred at the 519 Part 139 certificated airports that support commercial air carrier operations. However, the financial impact at any single airport caused by the designation of PFOA and PFOS as hazardous substances would vary widely and depend on a range of factors.

The commenter also noted that the experts first developed reasonable estimates for a range of costs that could be incurred at airports because of EPA's proposed designation and the additional authorities that would be available to the agency for ordering cleanup and the ability of private parties to pursue cost recovery for cleanup activities. The commenter stated that the litany of costs that may be incurred generally fell within three distinct categories: administrative actions, investigation and remedial response actions, and mitigation actions.

The commenter explained that the experts then developed multiple estimates for each type of cost based on different risk factors, including the extent of AFFF usage (from minimal to extensive) and potential contamination; and site-specific variables such as the size, location, and geography of the airport. The analysis and model allowed the commenter to estimate that at least \$2.6 billion to \$35.6 billion could be incurred at airports in cleanup and associated costs due to the hazardous substance designation. The commenter clarified that this includes the need at certain airports to demonstrate there are no PFAS concerns at their site in response to public reaction to such designation. The commenter noted that they also believe the actual costs could be higher than this estimated range because of additional cost drivers that were not considered, such as the uncertainty and infancy of existing remediation technologies, the lack of cleanup standards, and the lack of effective options for disposing and destroying PFAS and AFFF products.

The commenter further clarified that each of the 3,254 airports included in the estimate will not require response and remediation actions and/or incur each type of cost identified. The commenter expressed that they appreciate the significant uncertainty associated with estimating potential cleanup and mitigation costs that may need to be incurred because each airport is different in its size, geography, historical AFFF usage, and overall risk profile. The commenter referenced that as EPA stated, the existence of PFOA or PFOS detections or historical use at a site does not necessarily imply that further evaluation is needed or would result in a determination that a response action is warranted (See EPA Economic Assessment, at 51). The commenter then asserted that their experts were still able to model a range of potential outcomes and evaluate reasonable best-case and worst-case scenarios based on data that currently exists. [0411/A4A; 0424-ACI-NA; 0555-AAAE; 0461/Lee County Port Authority]

Response

EPA does not agree with the commenter(s) that the EA issued with the proposed rule was insufficient. As it developed the EA, EPA followed its own Guidelines for Preparing Economic Analysis and OMB's Circular A-4 which provides guidance to Federal agencies on developing regulatory analyses to assure compliance with related E.O.s. Prior to approving the EA for the proposed rule, OMB reviewed it to ensure that the methods applied in the analysis were methodologically sound and that the analysis met the requirements articulated in those related executive orders and in Circular A-4. OMB's review also provided assurance that the EA

provided the public with adequate information to understand the rule's impacts. Thus, the proposed rule EA was sufficient for Federal agency rulemaking. However, EPA took substantive effort to develop quantified estimates for certain potential impacts to the best of the Agency's ability. Building on the information presented in the proposed rule EA, the RIA accompanying this final rule includes expanded analyses of direct and indirect costs and benefits relative to the analysis developed for the proposed rule, to better inform the public (See Preamble to Final Rule Section IV.C ("CERCLA section 102(a) and Cost Considerations."). The final RIA addresses financial, health, and environmental impacts on citizens, businesses, and industries. It includes quantitative analysis of indirect costs and benefits associated with potential enforcement actions that may follow promulgation of the rule and potential cost transfer impacts associated with cleanups and removals. The RIA also evaluates impacts related to liability and litigation that may arise after designation. Please see RIA Chapters 4 and 5 for more information about EPA's methodologies and discussion of direct and indirect costs, benefits, and transfers. Based on its analysis, which included a consideration of uncertainties, EPA determined that designation is warranted. See Section VI ("The totality of the circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted."). See also Comment 2.B.1 ("Consideration of Cost and 102(a)"). EPA also requested comment on costs and benefits (e.g., whether indirect costs and benefits should be considered for the final rule). 87 FR at 54423. EPA received a number of comments relevant to direct and indirect costs and benefits and, among other things, asserted that EPA must consider costs and benefits in designation decisions pursuant to CERCLA section 102(a). In the final rule, EPA exercised its discretion to conduct an additional totality of the circumstances analysis. As part of that analysis, 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 accompanying this final rule. Based on that "totality of the circumstances" analysis, EPA concluded that designation is warranted because the advantages of designation outweigh the disadvantages See Preamble Section VI.C.

EPA disagrees with the commenter's assertions that EPA did not properly characterize direct and indirect impacts. According to EPA's Guidelines for Preparing Economic Analyses (published in 2010 and updated in 2016), "direct costs are those which fall directly on regulated entities as the result of the imposition of a regulation." The only direct impact to the public 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 or other response action under CERCLA. Such actions occur only after EPA determines that response is necessary to protect human health and the environment. Prior to EPA reviewing the available data for each site after learning of a release, it is not possible to determine the number of sites where response action may be necessary, the specifications of the response, or the associated costs and benefits. See RTC Section 6.A.2.

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⁹ 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.

Regarding the commenters comment on the use of airport revenues in the EA for the proposed rule, EPA used these data (and the revenue data for other industries) to inform the assessment of potential small entity impacts relative to small entity revenues. The proposed rule EA did not assume that these revenues are an indicator of profits.

With respect to the commenter's assertion that EPA's identification of the Havasu City Airport is in error, the United Nations source used in the economic assessment for the proposed rule ("The Humanitarian Data Exchange: Airports in the United States of America") identifies this airport as large according to the criteria used by the United Nations.

EPA notes the input provided by the commenter on the investigation costs incurred by an airport in California. The Agency does not agree that these costs are indicative of potential investigative costs associated with the designation of PFOA and PFOS as CERCLA hazardous substances. The proposal does not include requirements for site investigation and given that the investigation costs described by the commenter were incurred in the absence of the proposed designation, similar or related costs at other airports of concern would be expected to occur in the absence of the rule as well.

EPA notes the information provided by commenter(s) on potential PFAS cleanup costs at airports and the costs to replace AFFF delivery systems. However, EPA disagrees that the designation would lead to a significant increase in costs for airports. The aviation industry is already in the process of transitioning away from PFOA- and PFOS-containing AFFF to other types of firefighting foam that do not contain PFAS or use other types of PFAS. The costs associated with this transition are not attributable to the proposed designation of PFOA and PFOS as CERCLA hazardous substances. Available information suggests that little PFOA- or PFOS-containing AFFF remains in service (See Chapter 2 of the RIA; Fire Fighting Foam Coalition, Inc., "Estimated Inventory of PFOS-based Aqueous Film Forming Foam (AFFF)," July 13, 2011; Annunziato et al. (2020). Chemical Characterization of a Legacy Aqueous Film-Forming Foam Sample and Developmental Toxicity in Zebrafish (Danio rerio). Environmental Health Perspectives, Vol. 128(9). Accessed at: https://doi.org/10.1289/EHP6470; Wang, Z; Cousins, I; Scheringer, M; Hungerbuehler, K. (2015). Hazard assessment of fluorinated alternatives to long-chain perfluoroalkyl acids (PFAAs) and their precursors: Status quo, ongoing challenges and possible solutions. Environmental International, Vol. 75,172-179, Accessed at: https://doi.org/10.1016/j.envint.2014.11.013). Once this transition is complete and PFOA- and PFOS-containing AFFF is no longer present 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. While the transition to fluorine-free foam is still in process, a major milestone in the transition to AFFF that is free from PFOA and PFOS occurred in 2017. In 2017, DoD published a new MILSPEC, MIL-PRF-24385F(SH) w/AMENDMENT 2, concerning AFFF. The new MILSPEC stated that PFOA and PFOS must be below the limit of quantitation, which at the time was 800 ppb, in the concentrate. To reach the Reportable Quantity of PFOA or PFOS of 1 pound using the 2017 MILSPEC, 2.5 million gallons of AFFF would need to be released. It is very unlikely that that much foam would be needed to fight a fire in a 24-hour period, and no training exercise would use that much foam. Further, the residual amounts of PFOA and PFOS in certain apparatus' that the commenter describes is unlikely to cause a release of 1 lb. or more of PFOA or PFOS, therefore it is unlikely such residuals would cause release reporting. See RIA Section 2.2.7 (Other Federal Efforts Related to PFAS).

Moreover, the designation will incentivize potentially affected entities to minimize response costs. Potentially affected entities may engage in R&D activities that reduce the costs of assessing and addressing PFOA/PFOS contamination and managing PFOA/PFOS-contaminated waste materials. For example, DoD's SERDP and ESTCP have funded research on PFAS for several years. The goals of this research include (but are not limited to) improving analytical methods and AFFF site characterization and developing and validating *in situ* and *ex situ* PFAS treatment technologies. See RIA Section 5.2.4.9 (R&D Benefits).

Additionally, EPA acknowledges the estimated cost provided by the commenter(s) for AFFF cleanup. The cleanups reflected in these estimates, however, are not anticipated to be required as a result of the designation of PFOA and PFOS as hazardous substances under CERCLA. Instead, these cleanups described by the commenter(s) are already occurring in the baseline. In addition, the basis for these cost values is unclear; the commenter notes that "each of the 3,254 airports included in the estimate will not require response and remediation actions and/or incur each type." As explained in the Preamble to the Final Rule Section I (Executive Summary), EPA does not intend to pursue entities where equitable factors do not support CERCLA responsibility. As EPA states in the FY 2024-2027 National Enforcement and Compliance Initiates (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 " The NECI also clarifies that "OECA 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 OECA exercises CERCLA enforcement discretion in other areas." For more information about CERCLA's liability framework, including how designation supports the "Polluter Pays" principle, see Preamble to the Final Rule Section VI (The totality of the circumstances confirms that designation of PFOA and PFOS as CERCLA hazardous substance is warranted). For enforcement and liability information, see preamble to the Final Rule Section I (Executive Summary) and Final Rule Section II.E.7 (What Enforcement Discretion is available when exercising CERCLA authority).

Finally, while commenters provided many hypothetical costs to airports, the commenters did not provide any data or information to support those potential costs. Further, the commenters did not provide data that would have assisted EPA in evaluating the potential liability of the various airports across the country, even though it would be expected that airports have records of related useful information. For example, commenters could have provided information on actual use of AFFF containing PFOA or PFOS at airports across the country and the concentration of PFOA and PFOS in the AFFF used at the various airports. Commenters could also have potentially provided information on the number of fires and training exercises that occur or have occurred at the various airports across the country. This type of information may have allowed EPA to provide a more certain assessment of the potential direct reporting costs and allowed the Agency to better assess the potential indirect impacts on airports. As it stands, EPA does not believe that the level of PFOA and PFOS contamination at most airports will pose the same potential for exposure associated with locations that used PFOA and PFOS in manufacturing and industrial activities, and the Agency plans to focus its enforcement efforts on such manufacturing and industrial sites. This final designation also does not require airports to take any immediate action, but only requires airports to report future releases of PFOA and PFOS at or above the RQ. The designation also does not require airports to stop using AFFF containing PFOA and PFOS, although such efforts are underway in the absence of this designation under FAA guidance and/or regulation. EPA may have been able to estimate the potential for future releases

at or above the RQ, or commenters could have submitted that information, but the commenters did not provide EPA with information about the concentration of PFOA and PFOS to calculate how much AFFF would have to be used before the RO is reached.

For all these reasons, EPA is taking final action to designation PFOA and PFOS despite the comments concerning airports, and does not expect there to be significant adverse effects from designation placed on airports.

6.C.7 The EPA needs to consider indirect costs to local fire departments as the Proposal may increase these.

A few commenters noted that considering fire departments to be Potentially Responsible Parties could severely affect their ability to protect communities. Further, they noted that departments will have to incur the cost of replacing equipment and facility infrastructure since it is not possible to fully clean them, unless EPA can provide guidance on how they can be decontaminated and cleaned. Commenters expressed specific concerns related to volunteer fire departments and suggested EPA use the Small Business Regulatory Enforcement Fairness Act to assess effects. Finally, one commenter provided six recommendations for how EPA might establish a national strategy for replacing hazardous firefighting foam.

A commenter noted that remediation of sites where AFFF was used is critical in preventing future exposures of firefighters. However, the commenter is concerned that under the proposed rule, fire departments and other fire service entities may be considered Potentially Responsible Parties (PRPs) and as such, would be forced to shoulder the financial burdens of properly remediating sites where their activities may have included the use or storage of AFFF. This would be devastating to fire department budgets and could threaten departments' abilities to protect their communities. Fire departments today are stretched thin. They are operating on minimal budgets while being asked to respond to more calls than ever for fire, hazardous materials, medical emergencies, and more. The commenter further noted that fire departments often operate on limited budgets and must stretch every dollar to ensure sufficient staffing levels, functional fire and EMS vehicles, and conduct ongoing training to respond to emerging dangers such as electric vehicle fires and public health emergencies such as the COVID-19 pandemic. Additionally, many volunteer fire departments are 501(c) organizations that operate as an instrumentality of their local governments, often relying on community fundraisers for their operating budgets. The commenter expressed appreciation for the EPA's focus on protecting communities noting that the fire departments work every day to respond to emergencies in their communities and protect residents' lives and properties. However, they expressed concern for fire department operations by placing untenable financial burdens on them that are associated with the needed remediation projects in sites where AFFF was used and stored. One commenter noted that utilizing other statutory remedies to fund these needed remediation projects will ensure these carcinogenic chemicals do not cause future incidences of cancer while preserving fire departments' budgets to allow them to maintain their day-to-day emergency response and mitigation responsibilities. [0446-Congressional Fire Services Institute; 0250-Foam Exposure Committee]

Another commenter noted that no fire department can adequately contain AFFF. The fire service knows a hazardous materials site cannot be addressed until the contamination source is stopped. The commenter recommends the complete stop of using AFFF and removing it as soon as practicable. Fire apparatus, hoses, fittings, nozzles and all other equipment are contaminated with

PFOA and PFOS. They will need to be completely replaced. As the Department of Defense and others have noted, there is not a method to successfully fully "clean" PFAS from equipment.3 To replace a fire truck can cost from \$250,000 up to \$750,000. At FAA certified airports, the total cost of an ARFF, for example, a Rosenbauer Panther 6X6 ARFF truck cost \$763,352.4 "There are approximately 14,400 private-use (closed to the public) and 5,000 public-use (open to the public) airports, heliports, and seaplane bases. Approximately 3,300 of these public-use facilities are included in the National Plan of Integrated Airport Systems (NPIAS)." Every year of delay will increase costs. The commenter also noted that the fluorine-free replacement firefighting foam products will also need to be purchased by fire departments.

A commenter also noted that fire departments would need to know what qualifies a PFAS-contaminated area as being "decontaminated" and what are the standards for decontamination. For example, fire departments "train as they fight" and have used AFFF and other PFAS firefighting foams during training exercises in the past. Both fire stations and fire training facilities could be contaminated with PFAS substances, along with fire apparatus. The commenter was concerned that the costs of removing buildings and soil contaminated by PFAS could be exorbitant and it is unclear what to do with the contaminated soil and building materials. In addition, there is an approximately two-year delay in replacing fire apparatus due to the supply chain shortage and the cost of fire apparatus increased by as much as 25 percent. So, the cost of removing all fire apparatus, soil, and buildings contaminated by PFAS would rise into possibly billions of dollars.

The commenter noted that these concerns are being tested here the Town of East Hampton, New York, sued its volunteer fire department about potential PFAS water contamination caused by the storage of AFFF in barrels on fire department property. The fire department may be forced to pay \$100,000 every two years to maintain a carbon filtration system in wells contaminated with PFAS.5 This expense would be hard for many fire departments to afford.

Further, the commenter noted that almost two-thirds of the nation's fire departments are all-volunteer fire departments, which rely upon donations and community fundraisers to fund their operations. The cost of notification, placarding, operational costs, and decontamination caused by this rule would be prohibitive for many of them. The commenter asserted that an analysis would show that the cost of this EPA designation would have a significant economic impact on a substantial number of small volunteer fire departments. The commenter encourages the EPA to use the review process created by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to better determine how this rule would affect local volunteer fire departments.

The commenter also stated that other indirect costs of the EPA's designation of PFOA and PFOS as hazardous substances may concern personnel. Once AFFF and other PFAS foams are declared as "hazardous substances," fire departments will need guidance on what to do in the cases of firefighter exposure to AFFF and the other PFAS foams. For example, there is no presumptive disability for cancer for federal firefighters. Over the course of their careers, many federal firefighters have been exposed to AFFF and come down with cancer. Once the EPA declares PFOA and PFOS to be hazardous substances will firefighters be able to claim workers compensation or disability due to exposure to an EPA-declared "hazardous substance."

The commenter thanked the EPA for working to prevent further contamination of the nation's land and waterways from PFAS chemicals like PFOA and PFOS. Over the years, firefighters have had to use AFFF and other firefighting foams containing PFAS to comply with federal

requirements and the NFPA's voluntary consensus standards. We are concerned about the effect that the large exposure to AFFF and other firefighting foams containing PFAS have had on both firefighters' and the public's health and safety. However, the commenter stated their belief that there needs to be a comprehensive national strategy for replacing firefighting foam containing PFAS and helping fire departments decontaminate their facilities. As such, the commenter requested that the EPA consider the following recommendations:

- 1) Delay implementation of draft regulation until a comprehensive PFAS plan for fire departments can be developed. The commenter noted that there is a lot of uncertainty about how the EPA designation of PFOS and PFOA will affect local fire departments. There will be direct effects on fire department operations, such as possibly having to placard fire apparatus. Also, there will be large indirect costs to clean up fire departments with PFAS contamination. Because of the federal government's role in mandating the use of AFFF and other PFAS-containing firefighting foams, the commenter would ask for federal assistance in developing guidelines for decontaminating fire department facilities and paying for the cost of decontamination.
- 2) Extend the exemption in 42 U.S.C. § 9607 (d)(2) to include training for response to an emergency release of a hazardous substance and include exemption to include self-incorporated volunteer fire departments, airport fire departments, federal and military fire departments, fire districts, and industrial fire brigades. Because of the replacement to MIL-PRF-24385 has not been released and there will be a delay in the full-scale adoption of PFAS-free foam, fire departments will have to continue to use it to fight fires. As stated above, self-incorporated volunteer fire departments, airport fire departments, federal and military fire departments, and industrial fire brigades act as instrumentalities of local government when responding to fires by agreement with the local government to be the first-due response agency or through mutual aid agreements and should be treated equally with local municipal fire departments. In addition, fire departments are reducing their use of AFFF and other PFAS-containing firefighting foams in training, but there will continue to be some use as fire departments "train as they fight."
- 3) Conduct a SBREFA review of the effects of the EPA designation on small volunteer fire departments. Without the exemption requested, small self-incorporated volunteer fire departments will have to meet the direct operational costs of the EPA designation as well as the substantial indirect costs of decontaminating their property. Considering that almost two-thirds of the fire service is all-volunteer fire departments, we are concerned that a significant number of small fire departments will have to bear the brunt of these substantial costs.
- 4) Develop guidance for PFAS decontamination. To prevent confusion and uncertainty, the commenter requested that the EPA develop guidance for decontaminating fire stations, fire apparatus, training centers, and other fire facilities.
- 5) Develop guidance for previous PFAS exposures. Firefighters have been using AFFF and other PFAS-containing foams for decades, because they were assured of its safety. Now, considering the prevalence of cancer in the fire service, there is concern that previous PFAS exposures may endanger the health of firefighters. This situation creates questions about the need to monitor the health of firefighters that have been exposed to PFAS and how to mitigate the health effects of these exposures. [0530 International Association of Fire Chiefs (IAFC)]

Response

EPA notes the information provided by the commenter(s) on potential PFAS clean-up costs to fire departments related to AFFF. However, EPA disagrees that the designation of PFOA and PFOS as CERCLA hazardous substances would lead to a significant increase in costs for fire departments. The transition away from AFFF to other types of firefighting foam that do not contain PFAS was already underway in the absence of the rule. 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, EPA expects no or minimal releases from fire department operations. In the interim, any direct costs incurred by fire departments 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. Since the only rule requirement is reporting, costs to clean or replace previously contaminated equipment are not a direct result of CERCLA designation.

EPA does not agree with the commenter(s) that designation of PFOA and PFOS as CERCLA hazardous substances will lead to significant cost impacts for small businesses. The proposed rule economic assessment demonstrated that the rule would not result in a significant impact to a substantial number of small entities. Consistent with long-standing EPA policy on implementation of the Regulatory Flexibility Act, the proposed rule economic assessment considered small entity impacts related to the direct cost impacts of the rule, which are limited to costs associated with the reporting of PFOA/PFOS releases.] This analysis of small entity impacts looked at 88 different industries, including the Fire Protection industry (NAICS Code 922160). See RIA Section 3.2 (Entities and Industries Potentially Affected by the Final Rule) and RIA Section 6.2 (Small Entity Analysis) for further detail.

As explained in the Preamble to the Final Rule Section I (*Executive Summary*), EPA does not intend to pursue entities where equitable factors do not support CERCLA responsibility. As EPA states in the FY 2024-2027 National Enforcement and Compliance Initiates (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 . . ." The NECI also clarifies that "OECA 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 OECA exercises CERCLA enforcement discretion in other areas." For more information about CERCLA's liability framework, including how designation supports the "Polluter Pays" principle, see Preamble to the Final Rule Section VI (*The totality of the circumstances confirms that designation of PFOA and PFOS as CERCLA hazardous substance is warranted*). For enforcement and liability information, see preamble to the Final Rule Section I (*Executive Summary*) and Final Rule Section II.E.7 (*What Enforcement Discretion is available when exercising CERCLA authority*).

EPA does not agree with the commenter's requests to delay the rulemaking. Circular A-4 states the following: "When the uncertainty is due to a lack of data, you might consider deferring the decision." Science has demonstrated that PFOA and PFOS may present a substantial danger to human health, welfare, and the environment when released and, if not addressed, these substances will continue to migrate, further exacerbating exposure risk and potential cleanup costs. These findings not only demonstrate why delaying CERCLA designation would be harmful, but also show that EPA's justification for designation is not based on incomplete or asymmetric information. See RIA Section 1.2 (*Need for Regulatory Action*) and Preamble to

Final Rule Section VI (*The totality of the circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted.*) for further details.

Finally, while commenters provided many hypothetical costs to fire stations, the commenters did not provide any data or information to support those claims of potential costs. Further, the commenters did not provide data that would have assisted EPA in evaluating the potential liability of the various fire stations across the country, even though they would be in the best position to provide such information. For example, commenters could have provided information on the number of fires and training exercises where AFFF containing PFOA and PFOS were used and the concentration of PFOA and PFOS in the AFFF. This type of information may have allowed EPA to provide a more concrete assessment of the potential direct impacts on fire stations as well as allowed the Agency to better evaluate potential indirect impacts. As it stands, EPA does not believe that the level of PFOA and PFOS contamination at fire stations will pose the same potential for exposure associated with locations that used PFOA and PFOS in manufacturing and industrial activities, and the Agency plans to focus its enforcement efforts on such manufacturing and industrial sites. As noted, this final designation also does not require fire stations to take any immediate action, but only requires entities to report future releases of PFOA and PFOS at or above the RQ. The designation also does not require fire stations to stop using AFFF containing PFOA and PFOS or to stop using equipment that was previously in service when PFOS and PFOS containing AFFF was used. EPA may have been able to estimate the potential for releases at or above the RO, or commenters could have submitted that information, but the commenters did not provide EPA with information about the concentration of PFOA and PFOS to calculate how much AFFF would have to be used before the RO is reached.

For these reasons, and as explained fully in the Preamble to the final rule, EPA declines to create exceptions for certain uses of PFOA and/or PFOS in this rulemaking. See Preamble to the Final Rule Section VII.A.3. (Authority to Create Exclusions from the Designation).

6.C.8 The EPA's Rulemaking will have significant implications and liabilities for businesses, consumers, and governments.

A number of commenters were concerned that the proposed rule change would impose significant costs on companies and communities, including landowners and other persons, businesses, and local governments. They cited a U.S. Chamber of Commerce estimate that the clean-up costs for existing non-federal national priority sites would exceed \$17.4 billion. They urged EPA to conduct a full RIA that includes model-based or simulated cost estimates. Commenters noted EPA's expectation that enforcement discretion will mitigate unintended consequences of the proposed designation; however, they mentioned that EPA had not provided information on how such discretion could be applied and that such discretion would offer no protection from private litigation.

The commenters suggested that CERCLA is complex and presents uncertainties that would be exacerbated by designating PFOS and PFOA as hazardous substances. Examples mentioned include (1) health and environmental thresholds for PFOS/PEOA that are not yet finalized by EPA, (2) the unknown number of affected sites, (3) lack of investigation at known sites, (4) site-specific factors (e.g., overlap of initial hazardous substances with PFOS/PFOA contamination) and (5) unclear PFOS/PFOA contamination goals. Commenters mentioned additional concerns associated with potential outcomes of the proposed rule change: (1) costs resulting from joint-

and-several liability findings, (2) assessments and inspections resulting in new NPL listings, and (3) flaws in the EPA proposal that would lead to litigation and adverse effects on the parties involved.

A commenter asserted that the costs and impacts of CERCLA designation would be enormous. The commenter also asserted that EPA has failed to adequately assess the major costs and impacts for companies and communities – as well as landowners, local governments, and other persons and entities – that would arise from CERCLA designation. The commenter referenced the U.S. Chamber of Commerce analysis of non-federal Superfund site cleanup modeled annual costs of \$700 million to \$800 million. The commenter asserted that a designation would also unleash massive potential liability for a host of public and private entities under CERCLA's joint and several liability scheme. This may significantly delay real estate transactions by private companies, in particular potential investments into brownfield sites with the goal of remediating the property for reuse.

The commenter further asserted that the rulemaking cost estimates are expected to be much higher as private party costs at Superfund sites are just one element of the total costs borne by communities from a proposed hazardous substance designation. The commenter's analysis and findings—developed with the help of a consulting firm with deep expertise in economic and environmental modeling—were based on existing, publicly available EPA and state sources. A significant and detailed effort was undertaken with publicly available information in a solid scientific framework to ensure a sound approach and reproducible results. The commenter noted that this work centered on three assumptions: 1) the numbers of affected National Priorities List sites; 2) the typical full cost of each CERCLA cleanup phase; and 3) the incremental costs that each Potentially Responsible Party will incur to address PFOA. The commenter noted that CERCLA authorizes the use of various enforcement tools to require PRPs such as private businesses, recycling and waste management companies, and governments to cleanup contaminated sites. The commenter further noted that the EPA has some existing authority to address pollutants or contaminants like PFOA and PFOS found at existing CERCLA sites that present an imminent danger to the public health or welfare. The commenter asserted that designating PFOS/PFOA as hazardous substances would create significant uncertainty regarding estimated cleanup costs for private entities. The commenter further noted that the uncertainty is driven in large part because designation would trigger new assessment and inspection, including sites with completed cleanups, and likely resulting in new NPL listings. The result is that PRPs at existing and new sites with PFOS/PFOA contamination would incur both direct cleanup costs and indirect transactional costs associated with the cleanup. The commenter noted that the EPA's indirect costs cover the costs of administering the Superfund program that cannot be attributable to any specific site.

This commenter described that they had engaged third party experts in environmental and economic modeling to estimate total private party costs for addressing PFOS/PFOA contamination at Superfund sites. The commenter pointed out that CERCLA cleanup is already a complex process, and is further complicated by site specific variables, the inherent complexity of PFOS/PFOA, and EPA metrics guidance presently under review at the Agency. The commenter specified that these factors include (1) Difficulty in determining the scope of affected sites because PFOA/PFAS contamination remains mostly uncharacterized; (2) Human health and

environmental thresholds for PFOS/PFOA are not yet finalized by EPA; (3) Specific NPL sites require remediation, but particular remedial actions are unknown and unclear because investigation has not yet begun; substances designation would impose on the U.S. economy – significant additional costs are expected to be incurred by (a) federal agencies that own and operate sites containing PFOS/PFOA and (b) municipalities responsible for community water systems, landfills, and publicly-owned treatment works, as well as at potential state and local brownfield sites; (4) Size, complexity, and on-site specific factors such as the progress made in addressing the initial hazardous substance(s), and the overlap of PFOS/ PFOA contamination; and (5) A lack of clear PFOS/PFOA contamination goals for different cleanup pathways and receptors. The commenter further asserted that additional uncertainty is created by pending and potential state-level action to regulate PFAS and federal and state-level environmental agency action to update disposal polices that would increase cleanup costs. The decades-long process of CERCLA remediation makes it further challenging to estimate costs today, when many remediation phases will not be implemented for another five or more years. The commenter pointed out that this complexity does not prevent a reasonable economic analysis now with the information available, as there are known economic impacts that will flow as a foreseeable consequence of a PFOS/PFOA listing.

The commenter pointed out that their analysis results show that annualized costs would have annual economic effects greater than \$100 million that necessitates the development of a regulatory impact analysis and should also be designated as "major" under the Congressional Review Act, the Unfunded Mandates Reform Act, and Executive Order 12866 (EO 12866, Congressional Review Act, and UMRA all impose additional cost-benefit analysis requirements on agencies when the costs (or benefits) are greater than \$100 million/year). However, the commenter noted that in the past, the EPA has asserted that the costs associated with designating PFOS/PFOA as hazardous would not have an annual effect, either costs or benefits, on the economy of \$100 million, which is the threshold beyond which regulations are considered "economically significant" and subject to more thorough analysis and internal review. By not designating the rule as economically significant, the agency would be avoiding the responsibility of undertaking a formal regulatory impact analysis (RIA) of PFAS cleanup costs triggered by a CERCLA designation. The commenter asserted that this agency determination would be surprising given the potential for responsible private parties, not counting the federal government (particularly the Department of Defense (DoD)), to face major cleanup liabilities at a broad range of PFAS sites. In order to ascertain a reasonable estimate of potential private cleanup costs triggered by a CERCLA designation, the commenter's third-party experts conducted economic modeling and analysis of financial liabilities associated with cleanup of PFOS/PFOA sites.

The commenter reported that the results of the model illustrate the likely significant cost of PFOS/PFOA cleanup at nonfederal Superfund sites. However, there is some uncertainty around the model's estimates. A top-down modeling approach was used in the absence of site-specific data due to the fact that PFOS/PFOA are not currently designated as hazardous substances under CERCLA, and that no sites have completed cleanups. The commenter asserted that the EPA should develop simulated PFOS/PFOA cleanup costs for existing NPL sites for the regulated community's review and input. The commenter pointed out that their Monte Carlo model illustrates that PRP costs for PFOS/PFOA cleanup will be significant. Mean estimates for existing NPL sites alone are present value \$17.4 billion (90% prediction interval equaling \$10 billion to \$27.2 billion) using a 3% discount rate and \$9.8 billion (90% prediction interval equaling \$5.9 billion to \$15 billion) using a 7% discount rate. Uncertainty in these estimates

notwithstanding, CERCLA cleanup costs are but a single component of total costs, which include long-term operations and maintenance programming and monitoring, that the CERCLA designation for PFOS/PFOA imposes on the private sector and communities across the nation. The commenter further asserted that prior to proposing any designation, the EPA should comply with its statutory and Executive Order requirements to conduct a cost-benefit analysis of the proposed action and possible alternatives.

This commenter urged EPA to develop simulated PFOS/PFOA cleanups for a set of existing NPL sites with different attributes that influence costs. The following are provided as an example by the commenter, site type, size, pathways, media, number, and type of initial COCs, degree of overlap with initial COCs, geographic locations, proximate environmental and human receptors, PFOS/PFOA concentrations, preliminary remediation goals. The commenter further noted that the EPA's simulation should consider the effectiveness of alternative cleanup technologies and the implications of future regulation and policy relating to PFAS waste management and disposal.

Another commenter asserts that the EPA ignores the remediation costs that would result directly from the proposed action. There are also operational costs that would arise, such as training and certifications and additional layers of complexity added to project coordination; none of which are accounted for in the Agency's analysis. Designation would also directly impact scheduling and coordination—adding layers of complexity and cost on construction sites.

Another commenter asserted that EPA should withdraw the proposed designation of PFOS and PFOA as CERCLA hazardous substances. The commenter supports accelerating responsible cleanups and believes that it is important to have strong, science-based regulations that are protective of public health and the environment. However, the commenter asserted that designation under CERCLA Section 102(a) is the wrong legal tool to achieve appropriate remediation for these chemicals. The commenter noted that it would be expensive, overreaching, and unworkable. The commenter noted that the EPA has not conducted a comprehensive regulatory impact analysis to fully evaluate the costs of this proposal. Without such an analysis, EPA has not given stakeholders sufficient information about the impacts to of the proposal. The commenter also noted that EPA has indicated that it intends to use enforcement discretion to minimize the unintended consequences of the proposed designation, but has not provided information on what those consequences would be and the Agency's clear policy to avoid them. Without this information, stakeholders cannot assess the potential impacts on their company/industry/sector. The commenter also points out that the EPA's use of its enforcement discretion cannot shield parties from private litigation under CERCLA. The commenter cites a recent publication by Salvatore et al. in Environmental Science and Technology Letters that estimates that more than 57,000 sites may be contaminated with PFOA and PFOS and may require remediation, yet EPA's limited economic analysis has not assessed those impacts or the specific impacts on small business and public entities. The commenters also notes that contrary to EPA's assertion, cleanups under CERCLA's joint and several liability scheme will prolong achieving timely cleanup of PFOA and PFOS contamination at significant sites and implicate thousands of sites unnecessarily. The commenter supports EPA's intention to clean up sites contaminated with PFOA and PFOS to protect public health, but believes those efforts must be based on the use of the best available science and on an accurate understanding of risk and other practical considerations, including technical and economic feasibility.

Lastly, another commenter stated that the EPA should work with the Small Business Administration's Office of Advocacy to convene a Small Business Regulatory Enforcement Fairness Act panel to ensure appropriate public engagement concerning the impacts on small entities. [0405/US Chamber of Commerce; 0404-A1- US Chamber of Commerce et al.,; 0387/Pennsylvania Chamber of Business and Industry et al.; 0239/ US Chamber of Commerce; 0418/AGC; 0808/NASF]

Response

EPA disagrees with the commenter(s) assertion that designation under CERCLA Section 102(a) is the wrong legal tool to achieve appropriate remediation of PFOA and PFOS contamination. 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[.]" See Preamble Section IV (*Legal Authority*).

EPA disagrees with the comments that a more detailed evaluation of direct costs is necessary, and that cleanup costs would be considered direct. According to EPA's Guidelines for Preparing Economic Analyses (published in 2010 and updated in 2016), "direct costs are those which fall directly on regulated entities as the result of the imposition of a regulation." The only direct impact to the public 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. A designation alone does not require the EPA to take response actions, does not require any response action by a private party, and does not determine liability for hazardous substance release response costs. Response actions are contingent, discretionary, and site-specific decisions made after a hazardous substance release or threatened release. They are contingent upon a series of separate discretionary actions and meeting certain statutory and regulatory requirements. Building on the information presented in the proposed rule EA, the RIA accompanying this final rule includes expanded analyses of direct and indirect costs, transfers, and benefits relative to the analysis developed for the proposed rule, to better inform the public. See Preamble to Final Rule Section IV.C (CERCLA section 102(a) and Cost Considerations.). See RTC 6.A.1.

EPA disagrees with the comments that the Chamber of Commerce 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. See RTC 6.A.2.

EPA disagrees with the commenters that the proposed designation of PFOA and PFOS as CERCLA hazardous substances will lead to significant increases in litigation, significant legal uncertainty, and the delay of real estate transactions. EPA notes that PFOA and PFOS are rarely, if ever, the sole contaminants at affected sites. Thus, any litigation or delays in real estate transactions for a given site are likely to be co-contaminated with substances already designated as hazardous under CERCLA. See the Preamble to the Final Rule Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way) and Section VI.B.3. (Potential litigation costs are uncertain, but CERCLA litigation is not expected to exponentially increase as a result of designation). Also see RTC 6.A.6. No comments provided data supporting a conclusion that PFOA and PFOS will be the only

hazardous substances that pose unacceptable risks supporting sited being listing on the NPL and EPA does not believe that many, if any, sites will be listed solely due to PFOA and PFOS contamination.

EPA acknowledges the commenters' reference to the Salvatore et al. publication on PFAS contamination. EPA notes that not all 57,000 sites included in the study were identified as containing PFAS. The paper uses a presumptive contamination approach and identifies these sites as having a relatively high likelihood of containing PFAS given they fall into the following categories: (1) AFFF discharge sites, (2) certain industrial facilities, or (3) sites related to PFAS-containing waste. Further, the paper does not provide an indication of the level of contamination at each of the sites, the types of individual PFAS that might be present at a given site, or the site-specific risks associated with that contamination. Even if all 57,000 sites contain PFOA and PFOS contamination, it is almost certain that most will not require remediation under CERCLA (e.g. a single use to put out a small fire, the deposition of such substances at landfills, OTHERS?). Also, to the extent that these sites have transitioned away from the use/production of PFOA and PFOS, the likelihood of future releases is low. See preamble to the Final Rule Section I (*Executive Summary*) and Final Rule Section II.E.7 (*What Enforcement Discretion is available when exercising CERCLA authority*).

In addition, EPA does not agree with the commenter(s) that the annualized costs of the final rule will have direct annual economic effects greater than \$100 million. This action imposes no direct 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. See RTC 6.A.1.

6.C.9 The EPA needs to address and prepare for cost implications for state programs.

A commenter stated the need to address and prepare for cost implications for state programs. When PFOA and PFOS are designated as hazardous substances under CERCLA, grants to States across EPA's portfolio should include additional funding to address known and unknown PFOA and PFOS impacts and associated costs. EPA must meet the potential widespread prevalence of these compounds with appropriate funding increases and not pass these costs down to the states. EPA should revise Superfund Cooperative Agreements to include PFOA and PFOS in the initial steps of the Superfund process, as well as reassessment of listed Superfund sites. Likewise, EPA should seek increased appropriations for state Brownfields program grants.

The commenter noted that when PFOA and PFOS are designated as hazardous substances under CERCLA, these chemicals would meet the definition of regulated substances for underground storage tanks in New Mexico. Any tanks in New Mexico that meet the definition of a regulated underground storage tank that contain PFOA and PFOS would then be covered under New Mexico's Petroleum Storage Tank regulations. This will increase the scope of regulatory activities, which will require additional funding to properly ensure protection of human health and the environment. Additionally, the commenter requested that the EPA provide states funding and flexibility to address PFAS. [0393 - New Mexico Environment Department (NMED)]

Response

The allocation of federal funds to states and localities is outside the scope of this rulemaking.

EPA acknowledges that CERCLA grant programs are an integral part of funding for state partners. States may use Superfund cooperative agreements for a range of pre-remedial (e.g., site assessments) activities. EPA encourages states to work with their EPA regional colleagues to

discuss state interest in leading work, and the availability of Superfund cooperative agreements to fund work throughout the Superfund process. EPA consistently evaluates the impact of emerging contaminants and will continue to use its existing prioritization practices to address PFOA and PFOS. EPA has considered that there may be an increased burden placed upon state response programs if additional brownfields cleanups become necessary as a result of identifying PFOA and PFAS constituents as hazardous substances. Whenever appropriate opportunities arise, EPA makes every effort to inform Congress of the important role that state and tribal response programs play in overseeing the safe and effective cleanup of brownfields sites and the need to adequately fund the Agency's CERCLA 128(a) allocation program for state and tribal programs.

Under CERCLA section 128(a), EPA has the authority to allocate, on a non-competitive basis, funding to support State and Tribal response programs. The issue is that Congress provides limited funding for this authority and EPA does not oversee the cleanup of brownfields sites. EPA's Brownfields Program provides direct funding, through several grants, for brownfields assessment, cleanup, revolving loans, environmental job training, technical assistance, training, and research. To facilitate the leveraging of public resources, EPA's Brownfields Program collaborates with other EPA programs, other federal partners, and state agencies to identify and make available resources that can be used for brownfield activities. Additionally, EPA Brownfields program provides Technical Assistance Programs, such as the Targeted Brownfields Assessments and Technical Assistance to Brownfields, that provide environmental assessments and technical assistance to communities through these programs. However, EPA notes that decisions regarding future brownfield grant and loan funds will be made independently from the final designation. See RTC 4.G.6.1.

EPA acknowledges that it is possible that some previously unregulated USTs could be subject to regulation if PFOA and PFAS are listed as CERCLA hazardous substances. However, EPA expects the number of tanks to be small and does not believe there will be significant impacts to UST programs. Commenters did not provide any data to support a contrary conclusion.

6.D Direct and Indirect Benefits

6.D.1 The designation of PFOA and PFOA as hazardous substances will accelerate the cleanup of contaminated sites.

A commenter agrees that the designation of PFOA and PFOS as hazardous substances will speed cleanup of contaminated sites even though CERCLA already authorizes cleanup of these substances as a pollutant or contaminant. Before initiating cleanup of a pollutant or contaminant that is not designated as hazardous at a site, EPA must take the time to document that the substance poses an imminent and substantial danger to public health or welfare. The commenter states that the EPA can initiate cleanup immediately for a substance designated as hazardous since this documentation of danger has already been completed. The commenter also notes that designation also speeds cleanup by making private funding available in place of limited federal funding. While EPA cannot require a private party to pay for or conduct the cleanup of a pollutant or a contaminant, the designation of PFOA and PFOS as hazardous substances gives EPA the authority to compel cleanup by the polluters and, where such parties refuse to take such action, the authority to enforce such actions. The designation also gives EPA the authority to recover its cleanup costs when it performs the work itself and provides responsible parties who

are cleaning up PFOA and PFOS authority to collect contributions from other responsible parties. The commenter is certain this long-awaited rule will accelerate cleanups nationwide and urge EPA to finalize this rule as soon as possible. [0365-EPN]

Response

EPA agrees with the commenter that the designation of PFOA and PFOS as hazardous substances will speed cleanup of contaminated sites. After designation, agencies will be able to respond to a release or threatened release without first determining if the 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) (CERCLA Section 104(a)(1)), allowing for action sooner. The designation also enables additional Fund-lead removal actions to address immediate risks. Once a chemical is designated as a hazardous substance, EPA can compel PRPs to investigate and cleanup contamination in certain cases and may recover response costs where EPA takes Fund-lead actions.

6.D.2 The hazardous substance designation will provide public benefits and cost savings.

A commenter asserts that the hazardous substance designation will provide critical public benefits and cost savings. The comment similarly notes that the hazardous substance designation will also create significant public health benefits and costs savings. The commenter referenced that earlier this year, leading experts quantified the estimated disease burden and related economic costs due to legacy PFAS exposure at \$5.52 billion to \$62.6 billion in annual costs. By remediating these legacy exposures, CERCLA cleanups can reduce this disease burden. The commenter also asserted that these actions would reduce exposures to PFOA and PFOS and will also reduce PFOA and PFOS in blood levels, decreasing health risks. [0552-EWG]

Response

EPA agrees with the commenter that the designation will lead to public health benefits and that it may lead to cost savings. In addition, EPA believes that resources spent on cleanup will substantially reduce the hazards posed by exposure to PFOA and PFOS, providing significant health benefits (particularly to sensitive populations). See RIA Chapter 5 (*Indirect Costs*, *Benefits, and Transfers*). EPA has expanded its analysis of indirect benefits in the final rule economic analysis relative to the proposed rule assessment to include health benefits related to reduced incidence of cardiovascular disease, birthweight impacts, and renal cell carcinoma under a range of scenarios. See RTC 6.A.1. The Agency has also considered the findings of the Obsekov et al. study referenced by the commenter in the final rule RIA.

6.D.3 It is premature to comment on R&D-related benefits.

A commenter noted that EPA requests comment on any R&D-related benefits that may result from the Proposed Rule. The commenter stated that it is too premature to provide full comment on this question. The commenter asserted that depending on the treatment technology that is ultimately implemented, there is a possibility that drying technology may reduce volume of biosolids. However, the value of this volume reduction may be offset by emissions and energy usage. [0316-MeWEA]

Response

EPA disagrees that it is necessarily premature for commenters to provide input on the potential R&D-related benefits of the rule. Commenters familiar with existing technologies to remediate

PFOA and/or PFOS or technological options at various stages of development could potentially provide insight into the degree to which the rule might indirectly lead to improvements to existing technologies (i.e., improve their effectiveness or reduce their costs) or accelerate the development of PFOA/PFOS remediation strategies that are not yet widely used.

6.D.4 The proposal makes the unsupported assertion that the designation will encourage better management of chemicals and will produce public health benefits but does not explain those benefits.

A commenter points out that the EPA identifies the regulatory requirement to report a release of one pound of PFOA or PFOS, if those chemicals become CERCLA hazardous substances, as a particular benefit of the proposed rulemaking. The commenter also states that it appears to be unlikely that EPA would ever receive many release reports of releases of one pound of PFOA or PFOS, as when those chemicals are present in the parts per trillion level (or even the part per billion level) the quantity of material that would have to be released to exceed the one-pound threshold in a 24-hour period would be enormous.

The commenter states that the proposal makes the unsupported assertion that the CERCLA designation of PFOA and PFOS will encourage better management of these chemicals. The commenter also notes that the proposal fails to explain how this better management will happen, it fails to comprehensively address how PFOA and PFOS contaminated materials should be managed and disposed. The proposal further fails to explain how the CERCLA designation will work with the ever-growing patchwork of state requirements that address the management of PFOA and PFOS contaminated materials.

The commenter further states that the proposal claims that the CERCLA designation will produce "meaningful" public health benefits but does not explain what those benefits would be or how CERCLA designation would create those benefits. While the proposal references significant progress in reducing PFOA and PFOS concentrations in blood levels of the general public (which has corresponded with the ceasing of the manufacture and distribution of PFOA and PFOS), it does not explain how CERCLA designation will contribute to further reduction in blood levels. The commenter also states that this proposal may cut against its intended goal in unexpected ways. For example, treating wastewater and drinking water to reduce or eliminate PFAS seems to be one of the approaches most likely to reduce background levels of PFAS contamination in the environment, providing the PFAS extracted from wastewater and drinking water can either be destroyed or managed in a permanent way. If the CERCLA designation of PFOA and PFOS makes it more expensive to treat wastewater and drinking water, it will ultimately slow down the treatment of water and the rate of removal of the background levels of PFAS. Unfortunately, this will require considerable resources and could equate to an additional tax on water. The commenter also states that EPA's existing CERCLA removal authorities allows EPA to immediately address drinking water sources and reduce the acute risk of increased PFOA and PFOS exposure for the people using those sources of drinking water. [0341-AFBF]

Response:

Although PFOA and PFOS are not produced domestically by the companies participating in the 2010/2015 PFOA Stewardship Program, PFOA and PFOS may still be produced domestically by non-participating companies. These substances or their products may still be used by many facilities. EPA's Toxic Release Inventory Program (TRI) report 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 may be on-going uses of these substances which indicate there may be potential releases, accidental or intentional, of these substances. Further, because PFOA and PFOS have been in production since the 1940s, EPA believes that there may be many sites with hazardous levels of PFOA and PFOS. EPA needs to evaluate the historic releases at sites where PFOA and PFOS were manufactured and used in industrial processes to determine the level of contamination and whether it poses a current or potential hazard because the contamination is persistent and mobile.

With this designation, the reporting and notification requirements will enable EPA to become aware and exercise its authorities more quickly whenever a release does occur. See the Preamble to the Final Rule Sections I (*Executive Summary*), III.B. (*PFOA and PFOS Production and Use*) and VII.G. (*Phase-out and PFOA Stewardship Program*).

EPA disagrees with the commenter that the designation will not lead to improvements in the management of PFOA and PFOS materials. A potential direct benefit from the designation's reporting requirement is better waste management and/or treatment by facilities handling PFOA or PFOS. Greater transparency provided by release reporting can lead to fewer releases to the environment and thus to health benefits associated with avoided exposure. Several studies cited in the EA of the proposed rule have shown that increased transparency regarding environmental releases is associated with reductions in releases. For example, focusing on the Toxics Release Inventory (TRI), Konar and Cohen (2000) found that disclosure requirements led to the most significant reductions in releases among firms that were most visible to the public. See the following studies: Konar and Cohen, *Information as Regulation: the Effect of Community Right to Know Laws on Toxic Emissions*, 1997; Konar and Cohen, *Why do Firms Pollute (and Reduce) Toxics Emissions*? 2000; and Khanna et al., *Toxics Release Information: A Policy Tool for Environmental Protection*, 1998.

Regarding state requirements, EPA acknowledges that current state requirements vary and continue to evolve. State requirements do not affect the direct costs of the final rule, nor the sites affected by the rule, but they will ultimately affect indirect response costs, benefits, and potential transfers. For example, in cases where a state undertakes cleanup for PFOA or PFOS contamination, this reduces the need for EPA to address such contamination. See RIA Chapter 5.

EPA acknowledges the commenter statements about EPA's description of the final rule's public health benefits. In the final rule economic assessment, EPA has expanded its assessment of indirect benefits to include illustrative quantified health benefit estimates related to reduced incidence of cardiovascular disease, birthweight impacts, and renal cell carcinoma under a range of scenarios. See RIA Section 3.5 (*Quantitative Analysis of Benefits Associated with Baseline Response to PFOA/PFOS Contamination at NPL Sites*) and RIA Section 5.2 (*Indirect Benefits*).

EPA agrees with the comment that EPA's existing CERCLA removal authorities allows EPA to immediately address drinking water sources to reduce acute risks of PFOA and PFOS exposure [at NPL sites?]. However, EPA also notes that the final rule will improve EPA's awareness of PFOA and PFOS releases, enabling the Agency to address contamination before there is an acute risk. The final rule will also improve EPA's authority to address PFOS and PFOA contamination in a timelier manner. See RTC 6.D.1.

EPA does not agree with the commenter that the designation will hinder water treatment or efforts to remove background levels of PFAS in wastewater and drinking water. Furthermore, when, how, and why the water sector would remove PFAS from drinking water and whether they

dispose of it in a hazardous waste site 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. Commenters provided no data on these issues to support their comments. EPA also disagrees with the comment that stated the CERLCA rulemaking will increase the costs associated with managing drinking water treatment residuals. No PFAS are currently listed, or being proposed to be listed, as hazardous wastes under RCRA, and the designation of PFOA and PFOS as CERCLA hazardous substances does not require waste (e.g. biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills.

Under the Safe Drinking Water Act (SDWA), EPA is utilizing its authority to set enforceable maximum contaminant levels (MCLs) for six PFAS, including PFOA and PFOS, to limit concentrations of these contaminants in public drinking water supplies. See EPA's PFAS National Primary Drinking Water Regulation. Additionally, according to the Interstate Technology and Regulatory Council, thirty states have developed standards and guidance threshold values for PFAS in drinking water and ground water. See *Interstate Technology Regulatory Council, Technical Resources for Addressing Environmental Releases of Per- and Polyfluoroalkyl Substances (PFAS), PFAS Water and Soil Regulatory and Guidance Values Table, October 2022.* Updated threshold values and expansion of existing standards and guidance to cover other PFAS chemicals continue to be planned, developed, and updated across these states and others. See RIA Sections 2.2.3 (*EPA Actions under the Safe Drinking Water Act (SDWA)*) and 2.3 (*State Baseline Regulations Affecting PFOA and PFOS*). For these reasons, the costs to address drinking water are not attributable to this rule and, instead, this rule is consistent with other Federal, state and local actions to address PFOA and PFOS contamination.

6.D.5 The Proposed Rule will not have the benefits that the EPA claims.

A commenter asserted that the EPA fails to quantify the benefits this action purports to achieve and inadequately demonstrates the value of any benefits to the Proposed Rule. The commenter further asserted that the Proposed Rule is unlikely to lead to the "speedier cleanups" proclaimed by EPA and is unnecessary to gather useful information on PFOA and PFOS occurrence. The commenter pointed out that the EPA can and has already used CERCLA and other existing authority to address its stated PFAS goals. As the Agency itself recognizes, "EPA has used existing authority and continues to address PFAS releases under the SDWA, TSCA, RCRA, and CERCLA. The commenter points out that the EPA has addressed PFAS in 16 cases using enforcement tools under these regulations and noted that the federal government has already developed and is continuing to develop regulations that will allow it to address releases of PFOA and PFOS that it believes may pose a danger to human health or the environment. The commenter asserts that the tools at EPA's disposal, as well as those in development, can provide EPA with the authority it needs to address PFOA and PFOS releases, and mitigate any benefit allegedly provided by the Proposed Rule.

The commenter further noted that as explained that the weight of scientific evidence does not clearly identify human health and environmental effects of PFOA and PFOS to substantiate a hazardous substance designation. The commenter asserted that this may explain EPA's reluctance to quantify the purported health and environmental benefits. The commenter further asserts that the EPA should (and must, under EO 12866 and OMB Circular A-4) conduct a

thorough RIA and consider alternative methods to fulfill its goals regarding PFOA and PFOS that would be more economically efficient and appropriate. The commenter notes that the EPA's failures to quantify the likely costs and purported benefits of this rule are especially egregious when viewed in light of the fact that the EPA failed to genuinely consider alternative actions to achieve the same goals. The commenter encourages the EPA to conduct a full RIA (as is required by EO 12866), which involves quantification of costs and benefits as well as a genuine consideration of reasonable alternative actions.

Another commenter asserted the following concerning benefits:

- More comprehensive understanding of the number and location of sites with future releases of PFOA and PFOS which meet or exceed the RQ: This benefit will not be realized from the proposed rule and, to the extent the benefit is needed, existing law already requires the information be reported. If there are very few anticipated releases, and no or negligible impacts from the HTMA requirement, and given the existing TRI requirement, it is hard to imagine what would be the benefit from "improved quality of information providing a more comprehensive understanding of the number and location of PFOA and PFOS releases meeting or exceeding the RQ" and what or how "greater transparency" would result.65 Reporting what is expected to be negligible releases of PFOA and PFOS will not improve information, and TRI data is available. In fact, EPA concedes that detection and measurement and reporting would already be done for TRI.
- Enable more efficient decision in the marketplace for nearby properties: This benefit is not likely to be realized. Again, information regarding releases, in fact more comprehensive information, is available through the TRI. To the extent EPA is maintaining this would be a benefit from the indirect costs, for those properties near existing NPL sites and former or active industrial facilities, the property market can be expected to have already adjusted. In general, this proposal would have a broad and chilling effect on property transactions and redevelopment given the current uncertainty of the science, the ubiquity of PFOA and PFOS in the environment, and the anticipated extremely low cleanup criteria.
- Reduce uncertainty in capital markets: The opposite of this claimed benefit would result. The study EPA relies on in the Economic Assessment to make this claim concludes that significant uncertainty in a firm's Superfund liabilities could reduce its market value. Given the current uncertainty surrounding PFAS, it is unsupportable to maintain that listing PFOA and PFOS will provide any certainty in liability. To the contrary, given the ubiquity and only developing science related to PFOA and PFOS, one can expect that this designation would cause corresponding great uncertainty in capital markets.
- Better waste management practices: This benefit will occur, indeed has already occurred, without a CERCLA designation. There is already plenty of incentive regulatory and otherwise for entities to manage PFAS appropriately. Further, releases are already reported through the TRI so any benefit would already be manifest. Indeed, the examples cited for this proposition in the Economic Assessment are related to TRI reporting.
- Speed of cleanups: This benefit will not be realized. Entities that release PFOA or PFOS are already required to respond promptly to releases. With respect to NPL sites, as discussed below, this designation will slow down cleanups of PFOA and PFOS as well as other site contaminants. With regard to new sites, these sites will be subject to the

- plodding pace of the Superfund process being overseen by an agency that will surely be overwhelmed by the impact of the proposal if finalized.
- Cost savings by having private parties do work: This benefit would result if EPA exercises its authority under other statutory authority. In addition, as described below, overall costs can expect to increase, particularly transaction costs at sites where PFOA or PFOS contamination is unrelated to site activities.
- Increased R&D expenditure: This benefit can be expected to continue regardless of the proposed rule. PFAS R&D is already very active, with DoD leading the way. DoD's funding for R&D (spent and committed) is approximately \$290M. Designation is not needed to encourage R&D expenditure. Inexplicably, EPA says the need for R&D is uncertain. Plainly, R&D is needed on many aspects related to PFAS and is already being undertaken by private and public entities. [0345-3M; 0391- Superfund Settlements Project (SSP)]

Response

EPA disagrees with the commenter's assertion that the weight of evidence does not clearly identify human health and environmental effects of PFOA and PFOS to substantiate a hazardous substance designation. While EPA acknowledges that the science regarding PFOA and PFOS human health and environmental effects is still evolving, a significant body of scientific evidence shows that PFOA and PFOS are persistent and mobile in the environment, and that exposure to PFOA and PFOS may lead to a variety of adverse human health effects. The weight of scientific evidence presented in EPA's 2016 Health Effects Support Documents for PFOA and PFOS and supporting documents for the Regulatory Determination process as well as ATSDR's 2021 Toxicological Profile of PFAS support the conclusion that exposure to PFOA and PFOS can lead to a variety of adverse human health effects.

Building on the information presented in the proposed rule EA, the RIA accompanying this final rule includes an expanded analyses of direct and indirect costs and benefits relative to the analysis developed for the proposed rule, to better inform the public. See Preamble to Final Rule Section IV.C (CERCLA section 102(a) and Cost Considerations.). Also see RTC 6.A.1.

EPA disagrees with the commenter(s) that the rule is unlikely to lead to speedier cleanups. Due to the notifications required under the proposal, EPA and states are likely to become aware of PFOA and PFOS releases more quickly than they would otherwise. Although EPA can already address PFAS under a number of statutory authorities, the Agency must first be aware of PFOA and PFOS at a site before it can exercise any of those authorities to address PFOA/PFOS contamination. The notification requirements in the final rule would enable EPA to become aware and exercise its authorities more quickly. Further, in many cases EPA will no longer have to make an imminent and substantial endangerment (ISE) finding for each individual site with potential risk before taking action to mitigate or eliminate relative risk. ISE findings take considerable time and programmatic resources and therefore eliminating this burden is expected to improve timely response. In addition, the designation will allow EPA to require PRPs to start evaluating sites where PFOA and PFOS were manufactured or used in the industrial process to determine whether the contamination warrants a response. This authority to address the many historic releases of PFOA and PFOS is critical to limiting the current and potential future harm from these persistent and mobile substances.

EPA disagrees with the commenter('s) assertion that the rule is unlikely to lead to benefits related to research and development (R&D). Although the commenter is correct that there is already much ongoing R&D on methods for addressing PFAS, these efforts do not preclude additional R&D. The incentive to conduct or fund R&D related to PFAS remediation will be stronger if sites with contamination may require cleanup in the future. See RIA Section 5.2.4.9 (R&D Benefits).

EPA disagrees with the commenter(s') assertion that the rule will not result in benefits associated with a more comprehensive understanding of the number and location of sites with future releases of PFOA and PFOS meeting or exceeding the RQ. Knowledge of the number and location of releases allows EPA to better understand the exposure risks faced by different populations (e.g., in the event that releases occur near sources of drinking water or other potential exposure pathways). The commenter maintains that such information is already collected through TRI reporting, but the existing TRI reporting threshold for PFAS, including PFOA and PFOS is 100 pounds which is significantly higher than the threshold of 1 pound associated with the CERCLA designation. See RIA Section 4.2 (*Direct Benefits*).

EPA also disagrees with the commenter(s') assertion that the rule will not enable more efficient decision-making in property transactions. Better information about contaminants present at a site will enable potential buyers to make more informed decisions about potential property values. Because data in the TRI are based on a reporting threshold of 100 pounds rather than the 1-pound threshold included in the final rule, reporting conducted under the final rule would provide information on releases not reflected in the TRI. Moreover, there is an established literature on the impact on nearby home values of contaminated sites and site cleanup. See RIA Section 5.2.3 (Hedonic Property Value Analyses of Contaminated Site Cleanups).

EPA disagrees with the comments claiming that the rule will not increase efficiency in capital markets. Capital markets function more efficiently when more information is available on the potential liabilities associated with individual investments. The notifications required under the final CERCLA hazardous substance designation for PFOA/PFOS would provide such information to capital market participants. See RIA Section 4.2 (*Direct Benefits*).

EPA agrees with the comments that the rule may lead to cost savings by increasing the likelihood that private parties will conduct cleanups rather than the federal government where EPA exercises its authority under CERCLA. EPA notes that this benefit may also be realized if notification of PFOA/PFOS releases pursuant to the final rule leads to cleanups under authorities other than CERCLA, including state cleanup programs. See RIA Section 5.2.4.1 (*Potential Benefits Associated with Cost Transfers*).

EPA disagrees with the commenter that the designation will not lead to improvements in the management of PFOA and PFOS. See RTC 6.D.4.

6.E Uncertainties Regarding Indirect Impacts on Response Activities

6.E.1 Information and comment exist that may allow EPA to estimate incremental costs associated with this rule.

To obtain information and comment that may allow EPA to estimate incremental indirect costs associated with this rule and because of the ubiquity of PFAS substances, a commenter encouraged EPA to undergo a wide stakeholder engagement and research process that further

examines indirect costs associated with this rule. The commenter's POTWs are experiencing multiple, cascading indirect and unintended cost impacts because of PFAS legislation – costs that are causing biosolids management challenges for which there are no or extremely limited options. The commenter agreed that "treatment and disposal technologies for PFOA and PFOS are changing, and the associated costs of implementing these technologies vary significantly based on geographic location, partly due to treatment costs and access to treatment and disposal facilities." [0316-Maine Water Environment Association (MeWEA)]

Response

EPA underwent a wide stakeholder engagement and research process prior to taking final action to designate PFOA and PFOS. EPA held a number of meetings to listen to state agencies and stakeholders' concerns and words of support. EPA held meetings with organizations representing agriculture, drinking water and wastewater utilities, industry, state environmental agencies, environmental and environmental justice organizations and others. EPA also hosted a national tribal informational webinar on September 7, 2022, to explain the action and answer questions. See RTC 8 A. Further, under the Administrative Procedure Act, "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." Following the publication of the proposed rule in the Federal Register, EPA provided a 60-day period for public comments on the proposed rule and held public hearings.

EPA does not agree with the comment that designation of PFOA and PFOS as CERCLA hazardous substances will impose a cost burden on wastewater treatment facilities. The commenters' concerns about costs to these facilities are not costs that arise from designation. Efforts to address PFAS in this sector, and the associated costs of those efforts, are already underway in the absence of the proposed designation of PFOA and PFOS as CERCLA hazardous substances. Additionally, EPA also refers the commenter(s) to the Agency's December 5, 2022, Memorandum "Addressing PFAS Discharges in NPDES Permits and Through the Pretreatment Program and Monitoring Programs." The memorandum recommends guidance for states to use the most current sampling and analysis methods in their NPDES programs to identify known or suspected sources of PFAS and to take steps using their pretreatment and permitting authorities, such as imposing technology-based limits, on sources of PFAS releases. The memorandum also includes new recommendations relating to biosolids monitoring, permit limits, and coordination across relevant state agencies. EPA expects the NPDES actions described in this memo to significantly reduce PFAS in wastewater treatment plant influent, which will reduce PFAS in wastewater treatment sludge. Further, the designation does not require waste (e.g., biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any particular type of landfill. See RTC 6.A.3.

6.E.2 Commenters noted uncertainties regarding the potential sites affected by the proposed rule.

A commenter stated that the statute requires EPA consider all relevant impacts when it determines where a direct listing under CERCLA is appropriate. EPA must make these determinations before making a direct listing. EPA accounts for only one direct impact – the reporting obligations for releases of PFOA and PFOS. However, among other impacts, the final rule would also: (1) Expand regulatory authority for EPA and other entities to require cleanup without demonstrating any imminent and substantial endangerment or other risk thresholds; (2)

Lead to designation of new CERCLA Superfund sites where PFOA and PFOS contamination is present and create CERCLA cleanup obligations even where sites are not ultimately "listed" as NPL sites; (3) Lead to new investigations and remediation requirements at preexisting Superfund sites; (4) Allow EPA, Tribes, or state environmental agencies to "reopen" sites where remediation has already been completed in order to require the remediation of PFOA and PFOS; (5) Allow agencies to raise concerns and create uncertainty about sites with pending agency determinations under CERCLA and other statutes, and settlement agreements already in place related to historic releases; and (6) Impose liability and risks of liability, as well as related burdens associated with the uncertainty of liability, on numerous property owners and past users of PFAS. [0523-Western States Petroleum Association (WSPA)]

A commenter stated that Minnesota's Superfund program is currently having discussion with EPA regarding: (1) Will, and if so how will, the 5-year review process under CERCLA change? For example, will previously selected remedies and records of decision be re-opened to consider PFAS? If so, will this initiative be led at the federal level and under what timeframe? Can the state participate in these evaluations (if completed)? (2) What is EPA's plan for assessing PFAS risks at previously delisted NPL sites? (3) What process and metrics will EPA use for determining the need to incorporate PFAS into active NPL sites? For NPL sites designated as federal-lead, in what timeframe will EPA be able to collect PFAS data and respond to releases or threatened releases? (4) If the proposed rule is implemented, will the EPA removal program be fully enabled to respond in situations where actual or eminent human health risks from PFAS are identified? (5) Will EPA investigate and establish indoor air standards for PFAS? If so, has EPA determined that traditional mitigation and testing methods or technologies be sufficient to manage PFAS vapors? [0374-Minnesota Pollution Control Agency (MPCA)]

A commenter stated that the Oil and Gas industry is managing remaining stocks of legacy C8 foams, moving toward C6 foams, and supporting research and other processes to identify effective fluorine-free foams. The proposed rule fails to acknowledge how and why PFAScontaining AFFF foams are used in our industry, particularly to protect the lives of first responders, workers, and the public, as well as the environment and fails to acknowledge that firefighting capacity is critical to ensuring stable operation for the entire oil and gas industry, which as part of the energy sector, is designated critical infrastructure by the Cybersecurity and Infrastructure Security Agency under Presidential Policy Directive 21.20 Critical infrastructure are those "assets, systems, and networks, whether physical or virtual, ... considered so vital to the United States that their incapacitation or destruction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof." 21 The energy industry's transition to ethanol blended fuels requires a heightened degree of flammable liquids risk management (including firefighting foam) as the ethanol blending component is more hydrophilic (e.g., has different physical properties) than other kinds of fuels. To secure America's future (including renewable biofuel production expansion), the energy industry must have effective firefighting capabilities to meet the elevated fire risk. Also, EPA should note that oil and gas facilities are supported by local government firefighting and commercially retained firefighters, and that they are also impacted by transition needs. The commenter stated that the Agency must consider either appropriate exclusions for life-saving firefighting operations or tailored modifications to the hazardous substance designation that delay the reporting obligations and liability related to the use of fluorine foams for an adequate transition period from the time an effective substitute is identified through transition time (i.e.,3 to 5 years at a minimum). [0419-The American Petroleum Institute (API), the American Fuel &

Petrochemical Manufacturers (AFPM), the Alaska Oil and Gas Association (AOGA), the Louisiana MidContinent Oil and Gas Association (LMOGA), the New Mexico Oil and Gas Association (NMOGA), The Petroleum Alliance of Oklahoma (PAO), the Petroleum Association of Wyoming (PAW), and the Utah Petroleum Association (UPA) (collectively, "the Associations")]

Response

EPA disagrees that the EA issued with the proposal required more detailed evaluation of direct costs. According to EPA's Guidelines for Preparing Economic Analyses (published in 2010 and updated in 2016), "direct costs are those which fall directly on regulated entities as the result of the imposition of a regulation." The only direct impact to the public 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. EPA provided, in the economic assessment, an estimated low and high range of potential reporting requirement frequencies and associated direct costs.

Building on the information presented in the proposed rule EA, the RIA accompanying this final rule includes expanded analyses of direct/indirect costs, transfers, and benefits relative to the analysis developed for the proposed rule (See Preamble to Final Rule Section IV.C (CERCLA section 102(a) and Cost Considerations.). The final RIA addresses economic, health, and environmental impacts on citizens, businesses, and industries. It includes quantitative analyses of indirect costs and benefits associated with potential enforcement actions that may follow promulgation of the rule and potential cost transfer impacts associated with cleanups and removals. The comments assert that existing NPL sites are likely to have some PFOA/PFOS present. The final rule RIA addresses this by estimating potential indirect remediation costs to sites currently on the NPL, proposed for addition to the NPL, and deleted from the NPL. The RIA also evaluates impacts related to liability and litigation that may arise after designation. Please see RIA Chapters 4 and 5 for more information about EPA's methodologies and discussion of direct and indirect costs, benefits, and transfers. See also Comment 2.B.1 (Consideration of Cost and 102(a)). EPA also requested comment on costs and benefits (e.g., whether indirect costs and benefits should be considered for the final rule). 87 FR at 54423. EPA received a number of comments relevant to direct and indirect costs and benefits and, among other things, asserted that EPA must consider costs and benefits in designation decisions pursuant to CERCLA section 102(a). In the final rule, EPA exercised its discretion to conduct an additional totality of the circumstances analysis. As part of that analysis, 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 ¹⁰ accompanying this final rule. Based on that "totality of the circumstances" analysis, EPA concluded that designation is warranted because the advantages of designation outweigh the disadvantages See Preamble Section VI.C. (The totality of the circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted).

¹⁰ 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 in its presentation of net benefits. This analysis is silent on whether designation is warranted and is a neutral analysis of benefits and costs that may result from designation.

EPA agrees that the designation of PFOA and PFOS as hazardous substances will expand regulatory authority for EPA and other entities to require cleanup without demonstrating any imminent and substantial endangerment or other risk thresholds. After designation, agencies will be able to respond to a release or threatened release without first determining if the 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), allowing for action sooner. The designation also enables additional Fund-lead removal actions to address immediate risks. Once a chemical is designated as a hazardous substance, EPA can compel PRPs to investigate and cleanup contamination where there may be an imminent and substantial endangerment and recover response costs where EPA takes Fund-lead actions.

EPA disagrees that designating PFOA and PFOS as hazardous substances will result in new CERCLA Superfund sites due to the presence of PFOA and PFOS, or the creation of CERCLA cleanup obligations even for sites not ultimately listed as NPL sites. EPA does not expect the number of sites on the NPL to substantially increase after designation. EPA already has the authority to add 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. Designation does not automatically make sites eligible for placement on the NPL because of the presence of PFOA and PFOS. 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. Additionally, 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, and EPA does not expect the rate at which annual additions to the NPL occur to increase as a result of this rule. 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, liability, or requirements for the site. 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 Superfund sites as NPL sites. See Preamble to the Final Rule Section VII.E.

EPA also disagrees that the designation could result in new investigations and remediation requirements at preexisting Superfund sites or the reopening of sites where remediation has already been completed. PFOA or PFOS detections or use at a site does not imply that response action is necessary. Response actions, which include investigations of hazardous substance releases and determining if removal or remedial action is necessary, are contingent, discretionary, and site-specific. Hazardous substance designation under section 102(a) of CERCLA does not lead automatically to any response actions. EPA prioritizes the highest-risk sites under CERCLA (and that listing process is open to public comment); the process for selecting remedies includes public notice and comment; and cost considerations, among other important factors such as protectiveness, are part of CERCLA's site-specific cleanup approach. The designation 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 and not systematically to all existing non-federal NPL sites. See Preamble Section VII.I.4.a.

See Preamble to the Final Rule Section VII.E. (*National Priorities List (NPL) Sites – Existing and Future Contamination*). For additional details regarding reopening Superfund sites based on the presence of PFOA and PFOS, see RTC 4.D.2.

Regarding the uncertainty concerns, EPA notes that there is a certain degree of unpredictability associated with any CERCLA designation. The unpredictability associated with this designation is no different than any past CERCLA designation. As with other designations, the resulting costs and economic effects depend on the number of future releases, the level of response deemed necessary by EPA to address those releases, and the extent of existing contamination that may result in enforcement action.

EPA understands that designation may lead to some liability associated with PFOA and PFOS releases. However, after a consideration, EPA determined that designation should not disrupt CERCLA's liability framework and that CERCLA will continue to operate as it has for decades. A significant benefit of listing PFOA and PFOS as CERCLA hazardous substance will be EPA's ability to require manufacturers and parties that use PFOA and/or PFOS in industrial processes to clean up PFOA and/or PFOS contamination that was released into the environment many years ago. EPA's CERCLA enforcement efforts help increase the number of sites that get cleaned up and preserve the Superfund Trust Fund for CERCLA cleanups where there are not any financially viable, liable parties. In general, in enforcement matters, the facts, circumstances, and equities of a case help dictate which parties the Agency will pursue. CERCLA also includes a number of statutory protections that may limit liability and discourage litigation (e.g., the provision for settlements with "de minimis" or minor parties, CERCLA section 122(g)). Moreover, EPA has well-established enforcement discretion policies that have historically and continue to give EPA needed flexibility to offer liability protections to parties when circumstances warrant (e.g., innocent landowners, de micromis parties, owners of residential property at or near Superfund sites, and contiguous property owners). EPA's CERCLA enforcement policies help the Agency focus on sites that pose the most risk and PRPs who have contributed significantly to contamination and prioritize such sites for enforcement. Consistent with CERCLA's objectives, EPA will focus on holding accountable those parties that have played a significant role in releasing or exacerbating the spread of PFAS into the environment, such as those who have manufactured PFAS or used PFAS in the manufacturing process, and other industrial parties. EPA will seek to hold these parties accountable for their actions, ensuring that they assume responsibility for remediation efforts and prevent any future releases. This is consistent with EPA's "polluter pays" approach to cleanup under CERCLA. See the Preamble to the Final Rule Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way) and Section VI.B.3. (Potential litigation costs are uncertain, but CERCLA litigation is not expected to exponentially increase as a result of designation).

Regarding implementation questions 1 - 3, please see RTC. 4.D.2. Designation does not alter the remedial process and will not impact EPA's process for evaluating and selecting, if necessary,

remedies at current and future NPL sites or the five-year review process. Designation enables earlier and more EPA response work by diversifying EPA's options—response work can now be conducted by EPA or a PRP, which should help alleviate EPA resource constraints if it could only conduct response work with its own resources. Indoor air standards and testing methods and technologies are outside the scope of this rule.

As shown in Section II.C. (*Does this Action Apply to Me?*) of the Preamble to the Final Rule, the oil and gas extraction industry is included in the list of entities that may be potentially affected by the final rule. Similarly, Chapter 3 of the final rule RIA, which discusses downstream users of PFOA/PFOS products, identifies surfactants as an associated product historically containing PFOA/PFOS for oil and gas extraction facilities. However, designation does not impose any regulatory requirements on any specific facilities or entities. EPA's analysis does use NAICS codes to identify those groups which may be potentially affected by the final rule but does not quantitively assess costs to all entities within a given NAICS category since the rule does not impose regulatory requirements on them. See RIA Section 3.2 (*Entities and Industries Potentially Affected by the Rule*) for further details. For commenter calls for exclusions for AFFF use or delays in reporting notifications, please refer to RTC 4.G.3.

6.E.3 Commenters noted significant uncertainties regarding the development of standards and technologies for the cleanup, handling, and disposal and/or destruction of PFOA and PFOS.

A commenter recapped that in 2019 OLEM released draft recommendations for PFOA and PFOS preliminary groundwater remediation goals (PRGs) of 70 ppt for groundwater that is a current or potential drinking water source, based on the 2016 Lifetime Health Advisories (LHAs) developed by the Water Office. More recently, OLEM revised the regional screening level (RSL) for PFOA and PFOS in tap water to 60 ppt and 40 ppt respectively when present individually and 6 and 4 ppt when present together 65 based on an ATSDR analysis. 66 Based on 2021 draft assessments, in June 2022, the Water Office issued interim LHAs of 0.004 ppt for PFOA and 0.020 ppt for PFOA. Despite SAB concerns with the assessments the Water Office has not indicated plans to revise the interim LHAs. The Water Office has indicated that it will promulgate drinking water standards for PFOA and PFOS by the end of 2023 thereby creating a national cleanup target at NPL, state-led, and private sites. [0421-American Chemistry Council (ACC)]

Some commenters stated that there are significant uncertainties regarding the development of standards and technologies for the cleanup, handling, and disposal and/or destruction of PFOA and PFOS and that there is the technical obstacle to achieve remediation to health-based concentrations below the reporting limits of EPA validated test methods and/or the capability of existing treatment technologies and what is technically and economically feasible. A few of these commenters described hypothetical scenarios to underscore the overall prematurity that in theory, where the interim health advisory limits are so low that, a property that receives incidental stormwater runoff from an adjacent site contaminated with PFOA and PFOS or a property that waters its lawn using potable water that contains trace levels of these chemicals could become Superfund sites. Another one of the commenters stated that even trace detections of PFOA and PFOS may impact operational and maintenance and construction activities such as soil excavation, groundwater dewatering or using "clean fill" may become problematic. One commenter asserted that, based on recent communications from the Agency, it appears that future cleanup targets for PFOA and PFOS may be set at the minimum detection level for the

substances using EPA's validated analytical methods. If then analytical methods continue to improve, the targets for cleanup will likely drop as the detection limit is lowered and as a consequence, PRPs would have no way of knowing if existing PFOA and PFOS levels are below those EPA will deem to be sufficiently protective - meaning that their duty for cleanup would conceivably never end. [0369-Hillsborough County Aviation Authority (HCAA) and Tampa International Airport, 0421-American Chemistry Council (ACC), 0512-Stericycle, 0387-Pennsylvania Chamber of Business and Industry et al, 0362-GATX Corp, 0493-Protecting Our Water, Environment, and Ratepayers Coalition (POWER!), [0482-Metropolitan Water District of Southern California, 0563-Union Tank Car (UTLX)]

Other commenters asserted that EPA's designation will cause essentially every industry sector, governmental agency, small business, and others that own real estate with detectable PFOA/PFOS to become subject to CERCLA liability. Commenters asserted that establishing PFOA and PFOS as CERCLA listed chemicals before establishing MCLs and RCRA concentration thresholds poses challenges and costs that have not been adequately considered, evaluated, and quantified. [0419- The American Petroleum Institute (API), the American Fuel & Petrochemical Manufacturers (AFPM), the Alaska Oil and Gas Association (AOGA), the Louisiana MidContinent Oil and Gas Association (LMOGA), the New Mexico Oil and Gas Association (NMOGA), The Petroleum Alliance of Oklahoma (PAO), the Petroleum Association of Wyoming (PAW), and the Utah Petroleum Association (UPA) (collectively, "the Associations"), 0298-South Dakota Department of Agriculture and Natural Resources, 0362-GATX Corp, 0369-Hillsborough County Aviation Authority (HCAA) Tampa International Airport]

Another commenter asserts that uncertainties can be controlled and minimized through GAP analysis and collection of the missing data. The commenter also states that EPA should consider international solutions, as other nations have longer experience with treatment of PFAS chemicals. [0438-City of Aurora]

Response

Comments suggesting EPA revise LHAs for PFOA and PFOS, to create a national cleanup target at NPL, state-led, and private sites are outside the scope of the final rule. A hazardous substance designation under CERCLA does not set standards nor produce limits that can be enforced, inspected and sampled. For more information regarding LHAs and SAB review, see RTC Section 3.B. (*Not in Support of EPA's Proposed Finding that PFOA and PFOS May Present a Substantial Danger*). Additionally, there is no prerequisite that drinking water standards or health advisories must be available before designating a hazardous substance under CERCLA. With respect to drinking water standards, less than 100 of the over 800 currently listed CERLA hazardous substances have drinking water standards (https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulation-table) so it is clear that a drinking water standard is not a prerequisite to designation. Moreover, EPA HAs primarily serve as information to drinking water systems and officials responsible for protecting public health when emergency spills or other contamination situations occur. They are non-enforceable, but they can help inform setting CERCLA cleanup levels.

EPA disagrees with the comments claiming that designation of PFOA and PFOS as CERCLA hazardous substances is premature. EPA disputes the commenters' assertion that designation under CERCLA is inappropriate due to significant uncertainties in the development of regulatory

standards for PFOA and PFOS. In fact, 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 and considers cost. See Preamble to the Final Rule Section V (*PFOA and PFOS may present a substantial danger to the public health or welfare or the environment, when released into the environment*), and Section VII.B.1 (*Comments suggesting that other authorities are better suited to address PFAS contamination*). Additionally, EPA disagrees that, at present, there is an absence of federal and state standards, requirements, or other criteria that allows EPA to respond effectively to PFOA and PFOS releases. See the Preamble to the Final Rule Section VII.B.1. (Comments suggesting that other authorities are better suited to address PFAS contamination).

EPA also disagrees with the comments to the extent they suggest the Agency should not designate because there are insufficient methods to treat, destruct and dispose of PFOA and PFOA. Specifically, EPA does not agree that it is necessary to identify specific control and cleanup technologies in order to designate PFOA and PFOS as hazardous substances under CERCLA, the only criteria needed is that EPA finds that PFOA and PFOS "may present substantial danger to the public health or welfare or the environment" when released into the environment." Notwithstanding, as noted in RTC 4.E.1-5, there are currently methods available to address PFOA and PFOS contamination and the Agency and other parties continue to work to improve those methods. See Preamble to the Final Rule Section VII.H (*Managing PFOA and PFOS Contaminated Waste*) and RTC Section 4.E.2.

EPA understands that designation may lead to some liability associated with PFOA and PFOS releases. However, after a consideration of the comments and careful analysis, EPA determined that designation should not disrupt CERCLA's liability framework and that CERCLA will continue to operate as it has for decades. Designation does not automatically confer liability, nor does it alter CERCLA's statutory or regulatory framework for liability. Additionally, CERCLA includes a number of statutory protections that may limit liability and discourage litigation (e.g., the provision for settlements with "de minimis" or minor parties, CERCLA section 122(g)). Moreover, EPA has well-established enforcement discretion policies that have historically and continue to give EPA needed flexibility to offer liability protections to parties when circumstances warrant (e.g., innocent landowners, de micromis parties, owners of residential property at or near Superfund sites, and contiguous property owners). EPA's CERCLA enforcement policies help the Agency focus on sites that pose the most risk and PRPs who have contributed significantly to contamination and prioritize such sites for enforcement. Consistent with CERCLA's objectives, EPA will focus on holding accountable those parties that have played a significant role in releasing or exacerbating the spread of PFAS into the environment, such as those who have manufactured PFAS or used PFAS in the manufacturing process, and other industrial parties. EPA will seek to hold these parties accountable for their actions, ensuring that they assume responsibility for remediation efforts and prevent any future releases. This is consistent with EPA's "polluter pays" approach to cleanup under CERCLA. See the Preamble to the Final Rule Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination and concluded that CERCLA would still function in a rational way) and Section VI.B.3. (Potential litigation costs are uncertain, but CERCLA litigation is not expected to exponentially increase as a result of designation). For enforcement and liability information, see Preamble to the Final Rule Section I (Executive Summary) and Final Rule Section II.E.7 (What Enforcement Discretion is available when exercising CERCLA authority).

Regarding the commenter's suggestion to control and minimize uncertainties through GAP analysis and collection of missing data, the final rule RIA analysis is consistent with guidance in OMB, Circular A-4, on how to address and account for uncertainty. See Preamble to Final Rule Section VI (*The totality of the circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted.*). For both costs and benefits in the final rule RIA, EPA has developed estimates under a range of scenarios designed to reflect uncertainty in several key parameters affecting indirect costs and benefits. For costs, this includes the use of three different cost premiums and the calculation of high- and low-end removal cost estimates. For benefits, this includes presenting a range of benefits based on different PFOA/PFOS concentration reductions and different assumptions regarding the baseline occurrence of PFOA/PFOS in private drinking water wells. Probability distributions derived from observational data, as would be required for Monte Carlo and similar uncertainty analyses, are not available.

EPA has considered the international solutions from other nations with longer experience with treatment of PFAS chemicals. PFOA and PFOS hazardous substance designation would be consistent with and supportive of many other actions taken by EPA, other Federal agencies, states, Tribal nations and international bodies. These entities have set PFOA and PFOS benchmarks and standards and have undertaken PFOA- and PFOS-based regulatory activities and enforcement actions.

6.E.4 Commenters disagree with EPA's proposition that the uncertainties are too great to conduct a robust analysis.

Many commenters disagree with EPA's proposition that the uncertainties are too great to conduct a robust analysis and stated that EPA 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. Per a US Chamber of Commerce analysis, costs are estimated to conservatively be between \$800 million and \$1.1 billion 11 (annualized over 30 years) at non-federal CERCLA sites not including other locations that may have PFAS contamination, such as DOD testing facilities, airports, and landfills not currently listed on the NPL The analysis demonstrates both that it is possible to make such estimates in the face of the uncertainties EPA identifies, and that the likely cost impacts are massive and will outweigh the marginal benefits of this proposal. The expected costs will increase substantially once EPA establishes drinking water standards for PFOA and PFOS in 2023 as the number of affected sites, and the cost per site, increase. 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. Annualized private party cleanup costs at existing non-federal sites could cost \$700-\$900 million annually. 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. [0410-Wyoming Department of Environmental Quality (WDEQ), 0419-The American Petroleum Institute (API), the American Fuel & Petrochemical Manufacturers (AFPM), the Alaska Oil and Gas Association (AOGA), the Louisiana MidContinent Oil and Gas Association (LMOGA), the New Mexico Oil and Gas Association (NMOGA), The Petroleum Alliance of Oklahoma (PAO), the Petroleum Association of Wyoming (PAW), and the Utah Petroleum Association (UPA) (collectively, "the

Associations"), 0421-A2 American Chemistry Council, 0325-Oak Ridge National Laboratory (ORNL), 0569-US Chamber of Commerce Coalition of Companies and Trade Associations

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. Consistent with recommendations in Circular A-4, the Agency should delay any decision to finalize this rulemaking until it obtains sufficient data. Uncertainty analysis should also be used to characterize the cost to cleanup community water systems, an effort with direct relevance to the Strategic Roadmap. Recent published research indicates that groundwater across the eastern USA has been shown to contain more than trace amounts of PFAS. [0421-A2 American Chemistry Council]

Response

EPA disagrees that the EA issued with the proposal required more detailed evaluation of direct costs and that it was inconsistent with Circular A-4. According to EPA's Guidelines for Preparing Economic Analyses (published in 2010 and updated in 2016), "direct costs are those which fall directly on regulated entities as the result of the imposition of a regulation." The only direct impact to the public 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. EPA provided, in the economic assessment, an estimated low and high range of potential reporting requirement frequencies and associated direct costs.

EPA also disagrees that the EA issued with the proposal required more detailed evaluation of indirect costs and benefits. Neither a release nor a report of a release automatically triggers cleanup or other response action under CERCLA. Such actions occur only after EPA makes a determination that response is necessary to protect human health and the environment. Prior to EPA reviewing the available data for each site after learning of a release, it is not possible to determine the number of sites where response action may be necessary, the specifications of the response, or the associated costs and benefits.

Building on the information presented in the proposed rule EA, the RIA accompanying this final rule includes an expanded analyses of direct/indirect costs and benefits relative to the analysis developed for the proposed rule, to better inform the public of potential direct and indirect costs and benefits. See Preamble to Final Rule Section IV.C (*CERCLA section 102(a) and Cost Considerations*). The final RIA addresses financial, health, and environmental impacts on citizens, businesses, and industries. It includes quantitative analysis of indirect costs and benefits associated with potential enforcement actions that may follow promulgation of the rule and potential cost transfer impacts associated with cleanups and removals. The RIA also evaluates impacts related to liability and litigation that may arise after designation. Please see RIA Chapters 4 and 5 for more information about EPA's methodologies and discussion of direct and indirect costs, benefits, and transfers.

Based on its analysis, which included a consideration of uncertainties, EPA determined that designation is warranted. Further, science has demonstrated that PFOA and PFOS may present a substantial danger to human health, welfare, and the environment when released and, if not addressed, these substances will continue to migrate, further exacerbating exposure risk and

potential cleanup costs. See Section VI (*The totality of the circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted.*). See also RTC 2.B.1 (*Consideration of Cost and 102(a)*). EPA also requested comment on costs and benefits (e.g., whether indirect costs and benefits should be considered for the final rule). 87 FR at 54423. EPA received a number of comments relevant to direct and indirect costs and benefits and, among other things, asserted that EPA must consider costs and benefits in designation decisions pursuant to CERCLA section 102(a). In the final rule, EPA exercised its discretion to conduct an additional totality of the circumstances analysis. As part of that analysis, 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 Analysis¹¹ accompanying this final rule. Based on that "totality of the circumstances" analysis, EPA concluded that designation is warranted because the advantages of designation outweigh the disadvantages See Preamble to the Final Rule Section VI.C.

This final rule RIA analysis is also consistent with guidance in OMB Circular A-4, on how to address and account for uncertainty. See Preamble to Final Rule Section VI (*The totality of the circumstances confirms that designation of PFOA and PFOS as hazardous substances is warranted*). For both costs and benefits in the final rule EIA, EPA has developed estimates under a range of scenarios designed to reflect uncertainty in several key parameters affecting indirect costs and benefits. For costs, this includes the use of three different cost premiums and the calculation of high- and low-end removal cost estimates. For benefits, this includes presenting a rage of benefits based on different PFOA/PFOS concentration reductions and different assumptions regarding the baseline occurrence of PFOA/PFOS in private drinking water wells. Probability distributions derived from observational data, as would be required for Monte Carlo and similar uncertainty analyses, are not available.

Additionally, see RTC 6.A.8 (*The EPA should use publicly available information to estimate the number reportable releases and associated costs*) for a discussion of the data gathered and assessed by EPA, as well as an explanation of why they were not sufficient for quantifying certain costs.

EPA disagrees that the Chamber of Commerce cost analysis provides a reasonable representation of potential costs associated with designation of PFOA and PFOS as hazardous substances. See Comment 6.A.2 (*EPA needs to consider the actual costs associated with the Proposed Rule*) for a discussion of how the Chamber of Commerce cost analysis is based on several unfounded or inaccurate assumptions that lead to the overestimation of costs.

EPA agrees that Department of Defense (DoD)'s experience with PFAS provides some insight into the investigation, laboratory analysis, treatment and costs associated with the designation of PFOA and PFOS as CERCLA hazardous substances. EPA included discussion on DoD's experience regarding PFAS efforts, including its extensive research and development, within Chapter 2.2.7 of the RIA. EPA also addressed the cost information from the DoD's PFAS response efforts within Chapter 5.1.6 of the RIA accompanying the final rule. However, EPA

¹¹ 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 in its presentation of net benefits. This analysis is silent on whether designation is warranted and is a neutral analysis of benefits and costs that may result from designation.

disagrees with the commenter's assertion for EPA to use DoD's cost data as the basis for estimating costs likely to result from the designation. See RTC 6.A.2 (*EPA needs to consider the actual costs associated with the Proposed Rule*) for further discussion on how DoD's cost information from ongoing remediation work is not representative of costs associated with non-federal CERCLA sites.

EPA notes the comments reference to the finding from the study, *Perfluoroalkyl and* Polyfluoroalkyl Substances in Groundwater Used as a Source of Drinking Water in the Eastern United States, by McMahon PB et al. (2022) indicating that groundwater across the eastern USA has been shown to contain more than trace amounts of PFAS. 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. In the case of drinking water utilities, EPA's 2024 PFAS National Primary Drinking Water Regulation (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. Therefore, EPA disagrees with the commenter(s) that uncertainty analysis should be used to characterize the cleanup cost of community water systems as part of the analysis for the designation of PFOA and PFOS as CERCLA hazardous substances as those are not costs that arise from the designation. For more information on costs to public utilities, see the Preamble to the Final Rule Section VII.I.1 (Liability and Costs to Public Utilities).

6.E.5 EPA needs to not only account for benefits of the proposed rule but also must account for impacts in addition to reporting.

A commenter asserted that despite not accounting for it as a cost or impact of the proposal, EPA accounts for the benefit. While required reporting of PFOA and PFOS releases may improve the speed and design of any subsequent cleanups (both privately and publicly funded) and may also lead to an incremental increase in the number of contaminated sites identified, assessed, and remediated, EPA should not avoid accounting for the impacts of the rule by dismissing such impacts as "indirect" or as "costs" that EPA says it must not take into account, especially when these impacts actually form the very justification for what EPA is proposing. As EPA acknowledges, there are very significant impacts, in addition to reporting, that EPA says are benefits. Because EPA frames these impacts as benefits for a rational rule, EPA must also account for the consequences these impacts have where they impose burdens. Another commenter noted that many states have already implemented their own regulations to limit the amount of PFAS in drinking water, meaning some utilities are already required to remove it from source waters, and subsequently dispose of it. As EPA prepares to propose its own NPDWR for PFOA and PFOA, EPA should recognize that the water sector will be legally required to remove PFAS from drinking water and dispose of media in a hazardous waste site - thereby forcing local ratepayers to cover the cleanup bill after they already paid to remove the PFAS from their source water. EPA should consider how these two rulemakings affect each other and work to prevent costs of removal, disposal, and potential liabilities, from falling to ratepayers. [0523-Western States Petroleum Association (WSPA), 0537-Association of Metropolitan Water Agencies (AMWA)

Response

EPA disagrees with the comments asserting that the EA for the proposed rule did not sufficiently address benefits and costs of the proposed designation. EPA followed its own Guidelines for Preparing Economic Analysis and OMB's Circular A-4 which provides guidance to Federal agencies on developing regulatory analyses to assure compliance with related E.O.s. OMB reviewed the EA to ensure it provided the public with adequate information to understand the rule's impacts prior to proposal.

EPA agrees with the commenters that the required reporting of PFOA and PFOS releases may improve the speed and design of any subsequent cleanups (both privately and publicly funded) and may also lead to an incremental increase in the number of contaminated sites identified, assessed, and remediated. See RTC 1.A. (General Support for the Rule) and RTC 6.D.1 (The designation of PFOA and PFOS as hazardous substances will accelerate the cleanup of contaminated sites). However, EPA disagrees with the commenter's assertion that EPA avoids accounting for the impacts of the rule by dismissing impacts as "indirect" or as "costs" that EPA says it must not take into account. According to EPA's Guidelines for Preparing Economic Analyses (published in 2010 and updated in 2016), "direct costs are those which fall directly on regulated entities as the result of the imposition of a regulation." The only direct impact to the public 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 or other response action under CERCLA. Such actions occur only after EPA makes a determination that response is necessary to protect human health and the environment and are therefore considered indirect. EPA also disagrees that the EA issued with the proposal required more detailed evaluation of indirect costs. Neither a release nor a report of a release automatically triggers cleanup or other response action under CERCLA. Such actions occur only after EPA makes a determination that response is necessary to protect human health and the environment. Prior to EPA reviewing the available data for each site after learning of a release, it is not possible to determine the number of sites where response action may be necessary, the specifications of the response, or the associated costs and benefits.

Building on the information presented in the proposed rule EA, the RIA accompanying this final rule includes an expanded analyses of direct/indirect costs and benefits relative to the analysis developed for the proposed rule, to better inform the public of potential direct and indirect costs and benefits. See Preamble to Final Rule Section IV.C (CERCLA section 102(a) and Cost Considerations.). The final RIA addresses financial, health, and environmental impacts on citizens, businesses, and industries. It includes quantitative analysis of indirect costs and benefits associated with potential enforcement actions that may follow promulgation of the rule and potential cost transfer impacts associated with cleanups and removals. This includes estimating the indirect costs of remediation that may occur at sites currently on the NPL, proposed for addition to the NPL, and deleted from the NPL, as well as sites that may be proposed and added to the NPL in the future. The RIA also evaluates impacts related to liability and litigation that may arise after designation. Please see RIA Chapters 4 and 5 for more information about EPA's methodologies and discussion of direct and indirect costs, benefits, and transfers.

EPA disagrees that it did not account for consequences of the rule's impact where they impose burdens. A hazardous substance designation under section 102(a) of CERCLA does not lead automatically to any response actions or confer liability. See Preamble to the Final Rule Section VI for an analysis of direct and indirect potential outcomes that may arise after designation.

Additionally, EPA does not agree with the comment that designation of PFOA and PFOS as CERCLA hazardous substances will lead to significant implementation, management, and operations costs for drinking water and wastewater utilities Efforts to address PFAS in drinking water and wastewater treatment, and the associated costs of those efforts, are already underway and unrelated to designation. For more information on liability and costs to public utilities, see Preamble to the Final Rule Section VII.I.1 (*Liability and Costs to Public Utilities*) and RTC 6.C.5 (*The EPA should consider a variety of indirect costs for municipalities and public utilities*).

EPA disagrees with the commenters that "the water sector will be legally required to remove PFAS from drinking water and dispose of media in a hazardous waste site." No PFAS are currently listed, or being proposed to be listed, as hazardous wastes under RCRA, and the designation of PFOA and PFOS as CERCLA hazardous substances does not require waste (e.g. biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills.

EPA understands that designation may lead to some liability associated with PFOA and PFOS releases. However, after a careful analysis, EPA determined that designation should not disrupt CERCLA's liability framework and that CERCLA will continue to operate as it has for decades. For more information about CERCLA and "polluter pays" see Preamble to the Final Rule Section VI.C (Results of Totality of the Circumstances Analysis), and Preamble to the Final Rule Section VI.B.2 (EPA evaluated whether designation would create hardship for parties that did not contribute significantly to contamination, such as landfills and nearby residents, and concluded that CERCLA would still function in a rational way).

Additionally, for the relationship between the CERCLA designation and NPDWR for PFAS rulemakings, EPA is not looking to target drinking water utilities in the Agency's CERCLA PFAS enforcement strategy. Instead, EPA intends to focus its CERCLA enforcement efforts on those who significantly contribute to the release of PFAS into the environment, such as major manufacturers and users of manufactured PFAS, federal facilities that are significant sources of PFAS, and other industrial parties. EPA will seek to hold these parties accountable for their actions, ensuring that they assume responsibility for remediation efforts and prevent any future releases. This is consistent with EPA's polluter pays approach to cleanup under CERCLA. See Comment 4.F-3 (Designation will shift cleanup costs from responsible parties to communities and public utility ratepayers and impose considerable liability on entities in a variety of sectors) for additional details.

7. Statutory and Executive Order Review

7.A Executive Order 12866: Regulatory Planning and Review

Several commenters contend that EPA violated E.O. 12866, E.O. 13563 and OMB Circular A-4 by failing to provide a regulatory impact analysis of the designation. Other commenters also claim that the economic assessment accompanying the proposed designation was insufficient for failing to consider the potential financial impact of the action on utilities. One commenter claimed that pursuant to E.O. 12866, EPA must consider more suitable alternatives that would address concerns regarding PFOA and PFOS. To this point, the commenter asserted that there are other initiatives that would be both more productive and targeted to secure the objectives of the designation. The commenter also called upon EPA to work with the airport community to conduct research on remediation technologies and options for the disposal and destruction of PFAS and PFAS-containing products such as AFFF; update and provide guidance on cost-effective options for the disposal and destruction of PFAS and PFAS-containing products such as AFFF; and improve the coordination with FAA and DOD to ensure that airports have the guidance and resources they need to more smoothly transition away from AFFF to a fluorine-free firefighting agent.

Some commenters identified several deficiencies in the content of the proposed rule: (1) EPA had not identified a problem that needs to be addressed via CERCLA, (2) there was no defined baseline describing what the situation would look like if no action were taken, (3) the relationship between designation of the hazardous substances and enforcement of the rule was not clear, and (4) alternative approaches were not considered.

Other commenters noted that the Office of Management and Budget (OMB) identified the proposed designation as "economically significant," because the cost of the designation exceeds \$100 million. Relatedly, these commenters argued that EPA should not proceed with the proposed designation in light of OMB's identification of the rulemaking as "economically significant" because the Agency has not adequately estimated the costs of the rulemaking, including: (1) the potential costs to solid waste and wastewater utilities associated with CERCLA litigation; (2) the cost to such entities of remediating facilities contaminated with PFOA and PFOS; and (3) disposal requirements of PFOA and PFOS-laden filtration media or biosolids. One commenter also argued that OMB's classification of the rulemaking as "economically significant" reflects EPA's alleged inability to quantify the number of sites that may be contaminated or what the costs (direct and/or indirect) of remediation would be at those sites. Additionally, a commenter claims that EPA misapprehended the costs of reporting associated with this designation; specifically, the commenter asserted that EPA failed to account for the cost of preparing a report and the frequency of doing so. Another commenter argued that EPA should have identified the proposed designation as a "significant regulatory action" under E.O. 12866 because of the purported significant monetary impact of the designation on the economy. Finally, one commenter stated that the designation is subject to the Congressional Review Act (CRA) for having an annual effect on the economy of more than \$100 million. [0555-AAAE, 0474/MFBF, 0497-Orange Co FL, 0508-WEF, 0556/ISRI, 0569-US Chamber of Commerce Coalition]

Response

EPA disagrees with the comment that the Agency's decision not to conduct a regulatory impact analysis (RIA) for the proposed rule creates a justiciable issue. As an initial matter, E.O. 12866 expressly states that compliance/noncompliance with the EO is not judicially reviewable and that the Order is intended only to improve internal management of the Federal Government. *See e.g.* E.O. 12866, Sec. 10. Judicial Review (stating "[n]othing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person."). ¹² OMB Circular A-4 implements Section 6(a)(3)(c) of Executive Order 12866 concerning economic analysis and it is similarly unenforceable outside the Federal government.

In this case, while OMB concluded that the proposal was economically significant, OMB also determined that the EA conducted for the proposed designation was sufficient and it did not require EPA to provide further economic analysis for the proposed rule. However, at the time of proposal, EPA agreed to conduct further economic analysis consistent with E.O. 12866 guidelines for economically significant rules for the final action. The Agency followed up on this commitment and conducted additional analyses for the final designation including consideration of regulatory alternatives, explained further below. For these reasons, EPA disagrees with the comments that imply EPA cannot proceed with this final action because of alleged noncompliance with E.O. 12866, E.O. 13563, and OMB Circular A-4.

EPA does not agree with the commenter(s) that the EA issued with the proposed rule was insufficient. As it developed the EA, EPA followed its own Guidelines for Preparing Economic Analysis and OMB's Circular A-4 which provides guidance to Federal agencies on developing regulatory analyses to assure compliance with related E.O.s and statutory requirements. Prior to approving release of the proposed rule and the associated EA, OMB reviewed both documents to ensure that the methods applied in the analysis were methodologically sound and that the EA met the requirements articulated in those related executive orders and in Circular A-4. OMB's review also provided assurance that the EA provided the public with adequate information to understand the rule's potential impacts. Thus, the proposed rule EA was sufficient for Federal agency rulemaking.

Additionally, the final rule RIA includes consideration of two alternatives to the final rule – one more stringent regulatory alternative and one less stringent regulatory alternative. See RIA Appendix ("Potential Regulatory Alternatives") for a description and analysis of these alternatives.

To the comment regarding cooperation with the airport community, as discussed in the PFAS Strategic Roadmap, EPA has committed to working with a wide range of partners to address the risks posed by PFOA and PFOS, including stakeholders in the aviation industry.

¹² Section 7.d of E.O. 13563 has a similar provision addressing judicial review: "(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person."

The Agency disagrees with the comment that EPA has not considered the potential impact of the designation on solid waste or wastewater treatment utilities. In fact, the EA explicitly identified these entities as industries that may potentially be affected by the final rule. For further discussion of this issue see RTC 6.A.1.-3. and Chapters 4 and 5 of the RIA.

EPA acknowledges that this action is a "significant regulatory action", as defined under section 3(f)(1) of E.O. 12866, as amended by Executive Order 14094. However, the Agency's RIA indicates that the final rule is projected to result in aggregate annual social direct costs of approximately \$0 under the lower bound scenario, and approximately \$1.5 million under the upper bound scenario. See Chapter 4 of the RIA. And, while one commenter argues that the cost of reporting is more significant than allowed for by EPA, the Agency disagrees; Chapter 4 of the RIA estimates that the total reporting costs per release under CERCLA and EPCRA requirements are \$2,658 and the number of release incidents per year is 0 to 614.

EPA recognizes that the Congressional Review Act generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register.

7.B Regulatory Flexibility Act

Multiple commenters argued that EPA failed to comply with the Regulatory Flexibility Act (RFA) because the Agency improperly certified that the designation does not need to go through the Small Business Regulatory Enforcement Fairness Act (SBREFA) process.

One commenter argued that EPA's position that the action will not have a significant economic impact on a substantial number of small entities under the RFA is flawed because EPA has not estimated how many small entities will be expected to report and how many reportable releases could be attributed to them. Several commenters argued that the Agency failed to consider the impact of designation on a range of small entities, including certain utilities, small governmental jurisdictions, landowners, construction companies, and bulk liquid terminal operator facilities.

Several commenters also argued that EPA's certification that the designation will not have a significant economic impact on a substantial number of small entities under the RFA is flawed because the Agency failed to properly characterize the scope of certain impacts on small business and public entities. Here, several commenters argue that EPA's small entity analysis did not consider or consider fully certain costs associated with: (1) reporting requirements; (2) cost estimates based on DoD's experience with PFOA and PFOS cleanups; (3) cleanup obligations and litigation costs associated with potential CERCLA liability; (4) management of PFOA or PFOS-containing wastes; and (5) an increase in the cost to purchase property associated with requirements under CERCLA section 101(35)(B) of CERCLA to conduct all appropriate inquiries.

One commenter expressed concern regarding the adverse impact of the designation on bulk liquid terminal operators' commercial property values. The commenter argued that the fair market value of a property that may be potentially classified as a Superfund site is significantly reduced due to decreased demand for the property by potential purchasers that are concerned with potential CERCLA liability exposure. The commenter also argued that EPA failed to

consider the costs that the bulk liquid terminal industry may incur to replace and dispose their storage, piping, nozzles, and other equipment through which AFFF passed to avoid further contamination.

Finally, one commenter stated that EPA has the sole authority to determine whether a private party can be released from liability based on its determination of the party's compliance with the NCP. Accordingly, the commenter claimed that the Agency is required to measure the litigation-related impacts of the rule and determine whether those impacts are significant for a substantial number of small entities. [0421-A2 American Chemistry Council; 0523-WSPA; 0569-US Chamber of Commerce Coalition, 0418- Associated General Contractors of America (AGC), 0418-ACG; 0387-A1. Pennsylvania Chamber of Business and Industry et al.; 0371-A1- The State Chamber of Oklahoma and the Environmental Federation of Oklahoma, 0460-ILTA, 0341/AFBF, 0485/MI Farm Bureau, 0311-MWWA, 0410/WDEQ, 0811-SBA Office of Advocacy, 0543-AWWA, 0548/NAM, 0565/USWAG]

Response:

EPA has determined that this action will not have a significant economic impact on a substantial number of small entities under the RFA. Accordingly, convening a SBREFA panel was not required for the proposed rule and it is unnecessary for the final rule.

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. EPA's RIA determined that the expected annual notification costs of the rule do not exceed one percent or three percent of annual revenues for the typical small entity subject to the designation. Although the number of small entities experiencing a burden from the final rule is uncertain and will depend on the number of reportable releases from small entities on an annual basis, EPA estimates that up to 614 reportable releases will meet the RQ threshold each year. However, the Agency has concluded that it is highly unlikely that all 614 reportable releases would be made by small entities, therefore the designation will not result in a significant impact to a substantial number of small entities. See Chapters 4 and 6 of the RIA.

The Agency disagrees with the commenters' stance that EPA failed to properly consider the costs associated with reporting because it did not consider the impact of reporting requirements on certain small government entities. EPA evaluated the notification costs of the rule for small government entities in the RIA and concluded that the final rule will not result in a significant impact to a substantial number of small government entities. See Chapter 6.2 of the RIA.

EPA also disagrees with the commenter's suggestion that the Agency use cost data for Department of Defense (DoD) PFAS response efforts as the basis for estimating costs likely to result from the designation. Data for DoD sites (i.e., military installations, facilities of the National Guard, and Formerly Used Defense Sites in the United States) would not be representative of costs associated with private 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.

EPA further disagrees with the commenters that it failed to comply with the RFA because it did not consider costs to small entities associated with CERCLA liability and remediation, including entities such as airport services, construction companies, landowners, and state and/or local governments that provide drinking water treatment, wastewater treatment, and solid waste management, because designation does not automatically confer liability, nor does it alter CERCLA's statutory or regulatory framework for liability. Further, response actions are contingent, discretionary, and site-specific decisions made after a hazardous substance release or threatened release. Moreover, while the precise magnitude of litigation-related costs associated with the final rule is uncertain, EPA does not expect these costs to be significant based on the way CERCLA's primary causes of action—cost recovery and contribution—operate to resolve liability. Private party CERCLA cost recovery actions are limited to relief associated with certain costs and damages. Most notably relief is permitted for response costs only, which is limited to costs incurred consistent with the NCP, which includes a consideration of cost in the remedy selection process. See Chapter 5 of the RIA.

The Agency disagrees that the designation will increase costs associated with PFOA or PFOS-related waste management. Designation has no direct impact on landfill operations. With the exception of certain release reporting and notification requirements, the designation does not impose any regulatory requirements on any specific facilities, including landfills. Designation also does not require EPA or any other person to even test, much less take response actions. Any future response actions are determined on a site-specific basis.

EPA disagrees that the Agency's small entity analysis is defective for failing to consider a potential increase in the cost of conducting AAI in accordance with CERCLA section 101(35)(B) of CERCLA. AAI requirements generally apply to parties seeking to claim protection from CERCLA liability as an innocent landowner, contiguous property owner or bona fide prospective purchaser. Also, parties who receive grants under EPA's Brownfields Program must comply with the AAI rule when using grant funds to assess or characterize properties. The designation, however, does not require any party to seek a particular exemption from liability, nor does it mandate that any entity seek grant funding from the Agency.

EPA disagrees with the commenter's assertion that the designation will have an adverse impact on the property values of bulk liquid terminal operator facilities. In fact, a 2016 study by Taylor, Phaneuf, and Liu in the Journal of Urban Economics ("Disentangling Property Value Impacts of Environmental Contamination from Locally Undesirable Land Uses: Implications for Measuring Post Cleanup Stigma") found that remediation of a contaminated site (including NPL sites) increases property values by as much as five percent. EPA also demonstrated that Superfund cleanups positively impact economic activity at re-used properties. Based on an analysis for remediated sites in 2022, EPA found that businesses located at re-used Superfund sites generate approximately \$74.1 billion in annual revenues, supporting 236,802 jobs and \$18.6 billion in annual labor income. The Agency also disagrees with the commenter that designation of PFOA and PFOS as CERCLA hazardous substances will require certain operational changes by the bulk liquid operator terminal industry. The most significant direct effects of the designation pertain to release reporting requirements under CERCLA sections 103 and 111(g) and section 304 of EPCRA.

EPA disagrees with the commenter's characterization of the Agency's role in determining CERCLA liability. In fact, the D.C. Circuit has held that, in enacting CERCLA, Congress reserved resolution of liability issues to the judiciary, not the Agency. *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."). And, as discussed above, the Agency does not expect litigation-related costs to increase significantly as a result of designation.

7.C Unfunded Mandates Reform Act

Multiple commenters argued that the designation is subject to the requirements of the Unfunded Mandates Reform Act (UMRA) because it imposes an unfunded mandate of more than \$100 million on state, local, and tribal governments, or the private sector. Specifically, these commenters claimed that the designation constitutes an unfunded mandate because it will require significant modifications to waste management operations and result in additional cost burdens in the form of litigation and remediation costs that will, in turn, impose a heavy economic burden on municipalities. Other commenters also argued that EPA's position that the action does not contain an unfunded mandate runs counter to OMB's conclusion that the designation is "economically significant." Finally, several commenters argued that EPA failed to consider alternatives of the proposed action and to select the least costly option or to provide a rationale for not choosing the least costly option, in violation of UMRA.

[0405-A1- US Chamber of Commerce, 0529-August Co, 0434- City of Manhattan KS, 0403- Town of Purcellville, 0400-Town of Windsor, 0349/Broome, 0448-City of Thousand Oaks, 0451- Harford Co, 0489-Shelby Co, 321/Tillamook County Board, 0514/Wasatch, 0315-City of Tallahassee, 0565/USWAG; 0543-AWWA; 0495/PFAS Regulatory Coalition, 0438-City of Aurora, 0310 (NEWWA), 0311 (MWWA), 0395 (MWRA), 0464 (JEA), 0521 (WMWD), 0545 (FSAWWA)]

Response

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, as the designation 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. 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, and none of the commenters provided data indicating they are likely to have reportable releases of PFOA and PFOS nor have they shown that any prior releases are likely to pose a hazard to human health or the environment such that clean-up costs might be incurred. Findings of EPA's regulatory cost analysis (see Chapter 4 of the RIA) indicate that the final rule is projected to result in aggregate annual social direct costs of approximately \$0 under the lower bound scenario, and approximately \$1.5 million under the upper bound scenario.

EPA also disagrees with the commenter's assertion that OMB's designation of the rule as "economically significant" has any bearing on whether the rule is subject to UMRA. Although OMB designated this final rulemaking as an economically significant action pursuant to E.O. 12866, an economic significance determination does not relate to direct impacts/costs but, rather, to OMB's assessment of cost transfers. In the absence of direct costs that trigger UMRA, this

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.

EPA's decision not to include alternatives in the proposed rule does not create a justiciable flaw in the rule. In response to comments and consistent with RIA requirements, EPA has considered a less stringent option and a more stringent option for the final rule. The less stringent option would have delayed the compliance date of the reporting requirement by six months (approximately 180 days) after publication of the final rule in the Federal Register. In comparison, the final rule will go into effect 60 days following publication in the Federal Register. The more stringent option would have added to the requirements in the final rule by requiring a follow-up written release report within 30 days of any release that requires notification under 40 CFR 302.6, to the appropriate EPA Regional Office. For further discussion of the costs and benefits of the alternative options, and how they differ from the final rule, see the Appendix to the RIA.

7.D Executive Order 13132: Federalism Analysis

Multiple commenters expressed concern regarding EPA's compliance with E.O. 13132. Specifically, these commenters argued that EPA failed to engage in a federalism consultation process in accordance with the requirements of E.O. 13132 to obtain the input of state and local governments regarding the proposed designation.

[0529-Augusta Co; 0431-City of Lexington; 0434-City of Manhattan KS; 0448-City of Thousand Oaks; 0451-Harford Co; 0489-Shelby Co; 0321/Tillamook Co Board; 0403-Town of Purvcellville; 0400-Town of Windsor; 0506/Conference of Mayors; 0524/Worcester, 0399/Coalition for Renewable Energy, 0394/Broome, 0514/Wasatch, 0347-Brevard Co]

Response

EPA disagrees with the commenters' claim that it failed to comply with E.O. 13132, which requires the Agency to develop an accountable process to ensure "meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" are defined in the E.O. to include regulations that 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." Under E.O. 13132, an agency may not issue a regulation with federalism implications that imposes substantial direct compliance costs and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by state and local governments or the agency consults with state and local governments early in the process of developing the regulation.

EPA analyzed this proposed rule in accordance with the principles and criteria contained in E.O. 13132. EPA determined that the proposed rule would not have substantial direct effects on the states, on the relationship between the Federal government and the states, or on the distribution of power and responsibilities among the various levels of government. Additionally, EPA has determined that this final designation will not have federalism implications that impose substantial direct compliance costs on state and local governments. Accordingly, the consultation requirement of E.O. 13132 does not apply.

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

One commenter argued that EPA incorrectly determined that the designation does not qualify as a "significant energy action" under E.O. 13211. Specifically, the commenter stated that the rule will result in significant direct and indirect consequences for bulk liquid terminal operators, including: (1) reallocation of capital toward acquiring alternative fire suppressant systems; (2) decontaminating, reengineering, retrofitting, or replacing and disposing of all PFAS-contaminated equipment; and (3) training employees on the appropriate application of alternative foams and new equipment. The commenter also argued that the designation will significantly increase bulk liquid terminal operators' indirect costs due to potential CERCLA liability exposure (e.g., costs of cleanup, litigation, compliance, etc.). The commenter then argued that increased costs could create sufficient market pressures to shut down bulk liquid terminals, thereby negatively impacting the distribution of energy in the U.S. market, the actual distribution of energy, and the price paid by consumers. [0460-ILTA]

Response:

EPA disagrees with the commenter; this designation is not subject to E.O. 13211 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. The most significant direct impact of designation is the requirement for facilities to report releases of PFOA and PFOS that occur after designation. Designation alone does not automatically confer liability nor does it alter CERCLA's statutory or regulatory framework for liability. EPA understands that, historically, liquid terminals have used AFFF containing C-8 PFAS (e.g., PFOS) for fire control. This type of AFFF has been replaced by other AFFF formulations containing different types of PFAS or AFFF formulations that are PFAS-free. Because alternatives to C-8 AFFF are widely available, tested, and employed the impacts to terminals is not expected to be significant. See RTC 4.G.3 for additional discussion on AFFF.

7.F Executive Order 12898: Impacts on Minority and Low-Income Populations

Multiple commenters asserted that PFAS pollution is particularly concerning for low-income communities and communities that face historically disproportionate exposure to pollution and the cumulative adverse health effects of multiple co-occurring contaminants Several commenters also stated that EPA's proposed designation aligns with the Agency's commitment to advance environmental justice by addressing historical contamination and deterring on-going releases of these toxic chemicals into the environment.

Multiple commenters challenged EPA's conclusion in the proposed designation that it could not determine if the proposal would disproportionally affect environmental justice communities, particularly given the Agency's finding in the proposed designation that manufacturing and large airport facilities are often surrounded by low-income and minority populations.

One commenter asserted that CERCLA section 102(a) gives EPA the authority to designate additional substances as substances and, to protect public health, urged EPA to designate PFOA and PFOS as hazardous substances. Several commenters requested that EPA consider cost as part

of its decision to designate the chemicals as hazardous substances and conduct a cost-benefit analysis to understand whether the designation burdens minority and low-income populations.

Another commenter urged EPA to move quickly to protect communities from PFOA and PFOS and stated that the rulemaking and other actions underway by EPA are necessary to ensure federal, state, tribal and local governments have the regulatory tools and resources needed to protect human health and the environment. The commenter also encouraged EPA to lead the way for states, tribes and local governments through the provision of strong risk communication resources and tools.

A commenter called upon EPA to consider faster implementation of the regulation, arguing that doing so would reduce toxic exposure and alleviate the burden of cleanup costs. This commenter also requested that EPA consider updating its Hazardous Ranking System and prioritizing funding to eliminate the backlog of remedial construction projects and begin cleanup on additional Superfund remediation projects.

Another commenter stated that a source of exposure that is often overlooked is PFAS present in fast food packaging. The commenter asserted that fast food chains actively and persistently market their products in Black and Hispanic neighborhoods and argued that food wrapping facilitates the migration of PFAS into food, resulting in exposure to toxic contamination. The commenter also claimed that consumers discard empty packaging into trash cans where it may end up in landfills or incinerated, leading to PFAS—related contamination of multiple environmental media.

One commenter expressed interest and support for EPA PFAS testing in Indian country. Specifically, the commenter recommended sampling in surface and ground water sources and expressed the point that sampling results would be beneficial for tribes, villages and rancherias, by allowing individuals and communities to act proactively to mitigate exposures.

Another commenter argued that the proposed designation does not match the urgency of the problem and called upon EPA to ensure that PFOA and PFOS wastes are not transferred to marginalized communities who live near incinerators, landfills and injections wells. Multiple commenters also urged EPA to conduct an environmental justice evaluation consistent with E.O. 12898 to examine the impact of the proposed rule on minority, low-income, and indigenous populations; specifically, these commenters claimed that the designation will negatively impact such groups by increasing water and sewer rates, intensifying the use of hazardous waste management facilities and potentially producing climate change effects. Several commenters suggested that EPA target its enforcement efforts on producers and industrial users of PFOA and PFOS rather than passive consumers. [0306/EWG, 0393/NMED; 0501/Vermont PFAS/Military Poisons Coalition; 0567/WE ACT; 0326/ National Tribal Water Council (NTWC), 0363- Paso Water Utilities, 0571-Anonymous; 0537-AMWA; 0348-BGMU; 0773-Livingston; 0438-City of Aurora; 0276-DCWA/City of Vancouver; 0475-NARUC; 0389-Town of Ledgeview; 0480-NWRA-SWANA; 0439 (Sunnyvale), 459 (GFL); 0543-AWWA, 0310 (NEWWA), 0311 (MWWA), 0395 (MWRA), 0438 (Aurora), 0464 (JEA), 0521 (WMWD), 0545 (FSAWWA), 0432-Columbus; 0401- Village of Ashwaubenon]

Response

EPA acknowledges 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 environmental justice (EJ) concerns. EPA believes that this action is likely to reduce existing disproportionate and adverse human health or environmental effects on communities with EJ concerns as specified in E.O. 12898. See the Preamble to the Final Rule Section IX.J. EPA has also issued an RIA that qualitatively considers the possible impact of the rule on populations and locations relevant to E.O. 12898. See the Preamble to the Final Rule Sections VI.A.2 and IX.J as well as Section 6.3 of the RIA.

The Agency agrees with the comment that this action is necessary to address the urgent challenge of PFOA and PFOS contamination in the environment. And, to the extent the commenter expresses concerns regarding the transfer of waste to incinerators, landfills and injections wells situated near marginalized communities, EPA will continue to develop the data and tools needed to identify and protect overburdened communities and vulnerable populations that may be disproportionately impacted by PFOA or PFOS contamination.

EPA agrees with the comment that CERCLA section 102(a) gives EPA the authority to designate PFOA and PFOS as hazardous substances. EPA also reiterates that it considered the available scientific and technical information, along with the advantages and disadvantages of designation, including costs and benefits, and concluded this analysis supports the conclusion that designation is warranted. See the Preamble to the Final Rule Section IV.A. (CERCLA section 102(a) Designation Considerations), IV.C., (CERCLA Section 102(a) and Cost Considerations), VII.A.1. (Consideration of Cost and Section 102(a)).

EPA disagrees with the comment that an accelerated implementation of this rulemaking is necessary, but notes that this rulemaking, among other environmental and public health issues related to PFAS, are Agency priorities. Finalization of the rulemaking will trigger the applicability of release reporting requirements under CERCLA sections 103 and 111(g), and EPCRA section 304. The Agency also notes that designation does not change the Hazard Ranking System, which is EPA's primary tool for evaluating releases to determine NPL eligibility. See the Preamble to the Final Rule Section VII.E (National Priorities List (NPL) Sites - Existing and Future Contamination).

EPA acknowledges the comment regarding PFAS-contamination in fast food packaging. Food consumption represents an important pathway of PFAS exposure, and EPA agrees that food can be contaminated through food packaging made with PFOA and PFOS.

The comment requesting sampling of specific sites is outside the scope of this rulemaking and no response is required.

EPA disagrees with the comment that the designation will result in increased costs to water utilities and/or ratepayers. 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. CERCLA, however, 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. Further, designation does not alter CERCLA's liability framework. Designation does not expand the definition of "potentially responsible parties" nor does it amend, change, or curtail existing statutory limitations on liability. Liability determinations are site-specific and designation does not determine liability. EPA expects to continue to operate as it has for decades to equitably resolve who should pay. See Preamble to the Final Rule Section VI.B and Section VII.J.

EPA acknowledges that removing PFOA and PFOS from drinking water may increase disposal costs for some systems, but those costs are evaluated as part of the development of the PFAS National Primary Drinking Water regulation (EPA-HQ-OW-2022-0114, March 29, 2023, 88 FR 18638). These costs are beyond the scope of this CERCLA regulatory action. EPA also does not expect spent drinking water treatment residuals containing PFOA or PFOS to be released into the environment at or above the reportable quantity as a part of standard residuals management practices used by water systems. Furthermore, when, how, and why the water sector would remove PFOA or PFOS from drinking water and whether they dispose of it is complex and will depend on the volume and concentration of PFOA or PFOS captured, availability of disposal sites, decisions made at individual public water systems, and state and federal regulatory actions and enforcement actions. Relatedly, EPA also disagrees with the commenters' premise that the designation will result in certain waste management practices that result in negative climate change impacts. The designation of PFOA and PFOS as CERCLA hazardous substances does not require waste to be treated in any particular fashion, nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills.

EPA acknowledges the commenters request that the Agency focus its enforcement efforts on certain industrial producers and users of PFAS. EPA intends to develop a policy, consistent with existing limitations built in to CERCLA's existing liability framework and existing enforcement discretion policies, that explains EPA's priorities for enforcement in the context of PFOA and PFOS releases. See Section VI.C. of the Preamble to the Final Rule. See also FY 2024-2027 National Enforcement and Compliance Initiatives.

8. Miscellaneous Comments

8.A Need for Stakeholder Engagement

One commenter emphasized the need for responsible parties and other stakeholders to collaborate to ensure compliance, mitigation of risk of exposure, and transparency. The commenter also noted the need for public engagement to ensure that communities have access to information and participatory decision-making events, so that communities can determine the next steps for protecting their human health.

Another commenter stated that the Federal Register notice for the proposed rulemaking noted that tribal consultation was unnecessary. The commenter appreciated that the proposed rulemaking was subsequently amended to incorporate tribal consultation. The commenter emphasized that any rulemakings that could potentially impact tribal subsistence resources in any way is an issue that requires tribal consultation.

A commenter urged EPA to delay the designation to allow the Agency to consider multiple perspectives from a variety of stakeholder communities. The commenter noted that the addition of other perspectives would be particularly helpful in informing the development of EPA's guidance regarding the disposal of PFOA and PFOS.

Multiple commenters recommended interagency collaboration at the federal level to advance progress on a comprehensive, nationwide action plan or response framework for addressing PFAS contamination, including both short- and long-term solutions. One of these commenters specified that EPA should collaborate with the CDC, FDA, and USDA. Similarly, another commenter specified the need for EPA to collaborate with the DoD and States to identify PFAS challenges and propose recommendations to improve cleanups at U.S. DoD facilities and state national guard bases. One commenter specified that EPA should collaborate with clean water communities, internal offices, and States to develop PFAS strategies that avoid putting local clean water utilities in untenable positions for management and treating biosolids, stormwater, and wastewater, while another focused solely on States. Several commenters recommended establishing an interagency collaboration with states to support mitigation and responses efforts as they relate to PFOA and PFOS. Commenters also noted that those collaborations should establish a universal response framework that supports States ability to respond to PFOA and PFOS while minimizing impacts on interstate commerce and protecting the environment and human health. [0567/WE ACT, 0326 - NTWC, 0269 - HLF, 0547 - ME DACF, 0506 -Conference of Mayors, 0234-ILTA, 0473 – MESERB, 0393 – NMED, 0328 – FL WEA, 0547 – ME DACF, 0298 – SD DANR1

Response

EPA encourages meaningful community participation during Superfund cleanups to ensure communities have a voice throughout the decision-making process. To learn more about community involvement at Superfund sites please visit the Agency's website at: https://www.epa.gov/superfund/superfund-community-involvement.

EPA disagrees with the commenter's characterization of the Agency's position in the proposed rulemaking regarding tribal consultation. Although EPA noted that the proposed rulemaking did not have Tribal implications as specified in E.O. 13175, the Agency also explicitly stated that—

consistent with EPA's *Policy on Consultation with Tribal Nations*—it intended to consult with and request comments from tribal officials regarding the designation. EPA subsequently offered consultation, but the Agency did not receive any requests for government-to-government consultation regarding this rulemaking effort. EPA nevertheless hosted a national tribal information webinar (which did not constitute consultation) on September 7, 2022, to explain the action and answer any questions.

EPA declines to adopt the commenter's recommendation that it delay the designation. PFOA and PFOS are persistent in the environment and highly mobile, further delay increases the extent of contamination, potentially increasing both the number of individuals exposed to these substances and the costs associated with cleanup. For further discussion regarding the Agency's understanding of the current state of science on techniques and treatments that may be used to destroy or dispose of PFAS and PFAS-containing materials, see the Preamble to the Final Rule Section VII.H. (*Managing PFOA and PFOS Contaminated Waste*); see also infra RTC Section 4.E.2.

EPA acknowledges the commenters' request to coordinate PFAS-related regulatory efforts at a federal level. As discussed in the PFAS Strategic Roadmap, EPA has committed to working with a wide range of partners to address the risks posed by PFOA and PFOS, including other federal agencies, state and Tribal regulators, scientists, industry, public health officials, and communities living with PFOA and PFOS contamination.

8.B Regulate PFAS as a Class

Several commenters asserted that EPA should not regulate PFAS as a class. These commenters argued that EPA has recognized that there are a significant number of different PFAS chemistries with "varying effects and toxicity levels." The commenters highlighted the use of different PFAS chemistries for applications in medical devices and renewable energy and claimed that classifying all PFAS chemistries together could result in severe disruptions in vital industries. Instead, the commenters recommended that EPA adopt a measured approach to future PFAS regulation which balances high value/low risk PFAS against low value/high risk PFAS.

Multiple commenters urged EPA to develop a common definition of PFAS as a broad class to address community exposure to a mixture of different PFAS. These commenters argued that regulation of PFAS as a broad class would be more efficient and protective that addressing each substance individually. One commenter stated that regulating PFAS as a class according to common characteristics, rather than individually, will provide federal and state regulators greater enforcement and regulatory authority when considering the development of drinking water, groundwater, and soil standards. Additionally, this commenter claimed that regulation as a class would further federal and state efforts to compel responsible parties to investigate and remediate contamination nationwide, especially when private wells and public water systems are impacted.

One commenter noted that there is already a precedent for regulating groups of related chemicals at the federal and state level, observing that EPA has previously regulated groups of related chemicals due to common health risks. Several commenters asserted that the designation should encompass other specific types of PFAS, including GenX and PFBS. To support the designation of additional PFAS as CERCLA hazardous substances, another commenter also stated that three types of PFAS (PFHxS, PFOA, and PFOS) are already regulated by New Mexico as toxic

pollutants pursuant to the State's Water Quality Act. One commenter argued that industries will switch their formulations to use other types of PFAS if PFAS are not regulated as a class.

Several commenters expressed concern that PFAS precursors can be converted to PFAS in the environment, requiring a more comprehensive regulatory approach (i.e., regulating the entire class of PFAS). Other commenters noted that PFAS precursors can degrade into PFOA and PFOS, specifically and argued that precursors pose a "substantial danger to the public health or welfare of the environment" under CERCLA section 102(a).

Multiple commenters called upon EPA to follow through on its commitment to issue an advanced notice of proposed rulemaking (ANPRM) seeking comments and data on designating additional PFAS for hazardous substance designation. A few of these commenters further stated that for PFAS in which there is an authoritative assessment (i.e., ATSDR Toxicity Assessment, EPA Health Advisory Level, or IRIS Assessment) showing "a substantial danger to the public health or welfare or the environment," an ANPRM is unnecessary with one commenter noting that it would unduly delay the designation. Instead, this commenter argued that EPA should issue a proposed rulemaking designating those PFAS as hazardous substances. [0479 - NACS, NATSO, SIGMA; 0326 – NTWC, 0571 – Anonymous, 0710 – Citizen, 0501 – Vermont PFAS/Military Poisons Coalition, 0806 – BACWA, 0467 – NCHR; 0264 – Endocrine Society, 0463 - Little Hocking Water Assoc, 0503 - NPCC, 0519 - WV Rivers, 0301 - GLPAN, 0306 - Mass Comments by EWG, 0552 – EWG, 0564 - U.S. PIRG, 0458 – Earthjustice, 0428 – CARE, 0366 – EHP, 0810 – EDF, 0273 – LLSF CAG, 0452 - Defend Our Health, 0566 - University of Arizona, 0393 – NMED, 0382 - NC Conservation, 0414 - Attorney Generals of the States of NY]

Response

On April 13, 2023, EPA issued an ANPRM seeking input and data regarding potential future hazardous substance designations of categories of PFAS and the Agency is still evaluating the feedback it received. *See* the Preamble to the Final Rule Section VII.F. (*Regulate PFAS as a Class*); *see also Addressing PFAS in the Environment*, 88 Fed. Reg. 22399 (Apr. 13, 2023).

8.C Need for Advances in Science and Technology and More Research

Some commenters stated that clear guidance is needed on detection, destruction, disposal, management, and remediation of PFAS contaminated media (i.e., biosolids, brine concentrations, influent, etc.). These commenters argued that the designation of PFOA and PFOS as hazardous substances could be a significant burden without such guidance and/or source control to prevent PFAS from entering the environment. Similarly, other commenters urged EPA to continue and expand research on technologies for destruction/disposal, drinking water and wastewater treatment, and remediation for different environmental media (including landfill leachate). Two commenters specifically underscored support in identifying cost-effective technologies. One commenter noted that the significant gaps in scientific record and technology could lead to significant negative consequences for water utilities and corresponding communities. Several commenters called for affordable and reliable sampling and analytical methods to ensure local and state agencies, as well as utilities, can meet regulatory requirements.

One commenter underscored that public agencies have limited control over the amount of these substances they receive. The commenter claimed that, to date, EPA has not leveraged available resources to reduce the flow of PFAS; specifically, the commenter asserted that EPA has not

implemented source control measures to limit the ongoing introduction of these chemicals into the environment, set effluent limits to control industrial PFAS discharges into waterways, or set pretreatment standards that clean water agencies can implement to limit industrial discharges to their systems.

One commenter expressed specific concern regarding the delays and supply shortages of granular activated carbon (GAC) and claimed that this issue could be further exacerbated by the designation. This commenter urged EPA to research alternatives to GAC that are more practical and sustainable.

A few commenters suggested EPA invest in research to identify alternatives to PFAS for specific use cases. These commenters also called for the development of chemical alternatives assessments for functional uses of PFAS in processes and products through the EPA Safer Choice Program, or other credible third-party research organizations, to ensure the availability of safer chemical or non-chemical alternatives. Another commenter also requested: (1) support for the development of fluorine-free foam, including certification and testing; (2) communication and research to further understand the effects of PFAS from biosolids applications; and (3) initiatives to focus on consumption/food safety. A few commenters stated that there are gaps in the current suite of analytical methods that preclude a proper investigation and remediation of PFOA and PFOS contamination and likewise prevent potentially responsible parties from assessing their potential liability and therefore advocated for timely development of additional cost-effective analytical methods for a large range of PFAS in all media. These commenters stated that robust and accurate methods for detecting PFAS in the environment are essential for implementing remedies, evaluating treatments, and supporting effective regulation. However, the commenters noted that there are currently no multi-laboratory-validated methods published other than those for drinking water.

Another commenter stated that EPA's proposed rule would require testing parties to adhere to an inordinately expensive variety of testing standards. A few commenters identified scientific and technological data gaps that could significantly affect facility/utility operations. These commenters stated that there are currently no cost-effective techniques available to treat or remove PFOA or PFOS from the drinking water, landfill leachate, and wastewater managed by passive receiver facilities. Similarly, another commenter noted that technology required to reduce PFOA and PFOS in biosolids is not readily available and argued that wastewater utilities will face significant burdens without funding and technological advancements. A few other commenters supported continued collection of scientific research and survey data to better understand the risks associated with the land application of biosolids; additionally, commenter encouraged EPA to continue its dialogue with stakeholders to gather insight about unintended consequences of limiting land applications of biosolids through the proposed designation. One of these commenters underscored that limiting land applications of biosolids would require other means of disposal that are less environmentally beneficial and greater cost to ratepayers. Another commenter specifically requested standards for PFAS in biosolids, compost, and industrial byproducts that are suitable for land application. [0554 - DC Water, 0471 - Loudoun Water, 0352 -Clark County, 0269 - HLF, 0562 - NBC, 0340 - ASTSWMO, 0468 - NGWA, 0485 - MI Farm Bureau, 0473 - MESERB, 0393 - NMED, 0547 - ME DACF, 0463 - Little Hocking, 0225 -Anonymous, 0485 - MI Farm Bureau, 0393 - NMED, 0375 - MSD, 0322 - Environmental Compliance Manager, 0363 – EPWater, 0370 – OR ACWA, 0341-American Farm Bureau

Federation, 0396-Michigan Water Environment Association, 0559/RuttenKern, 0344 - APWA et al., 0394 - OSEE, ODEQ, 0485 - MI Bureau, 0482 - Monterey, 0509 - TDEC, 0470 - MEG]

Response

EPA acknowledges that the science on treating, destroying, and disposing of PFAS continues to evolve. For further discussion of the Agency's understanding of the current state of science on techniques and treatments that may be used to destroy or dispose of PFAS and PFAS-containing materials, see the Preamble to the Final Rule Section VII.H. (*Managing PFOA and PFOS Contaminated Waste*); see also infra RTC 4.E.

EPA disagrees with the commenter's position regarding testing; this final designation under CERCLA does not require any testing. See RTC 4.A.6. Regarding the availability of analytical methods, EPA recognizes that robust, accurate methods for detecting and measuring PFAS in air, land, and water are essential for understanding which PFAS are in the environment and how much are present. For further discussion, see RTC 3.C.7. (Uncertainties regarding cleanup, D&D, standardization of testing).

EPA disagrees with the commenter's stance regarding the Agency's efforts to reduce PFAS contamination. In fact, EPA is pursuing a comprehensive approach to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment. For further discussion of this effort see the PFAS Strategic Roadmap, available at: https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf. The commenter's concerns regarding the availability and generation of granular activated carbon are outside the scope of this rulemaking. Additionally, the commenter's recommendations regarding the development of PFAS alternatives is outside the scope of this rulemaking.

EPA disagrees with the commenter's position that the designation will necessitate adoption of certain testing standards. See the Preamble to the Final Rule Section VII.D.1. (Effects of Designation, Section 1 Reporting and Notification Requirements). EPA also notes that the designation does not create any unique requirements for water treatment facilities, nor does EPA intend to focus enforcement activities on these facilities.

With respect to the commenter's concerns regarding biosolids use, disposal, and potential risks, see RTC 4.G.2.

For information about pretreatment standards and the Agency's December 5, 2022, Memorandum "Addressing PFAS Discharges in NPDES Permits and Through the Pretreatment Program and Monitoring Programs," *see* RTC 4.E.1-1.

With respect to the commenter's suggesting that EPA invest in research to identify alternatives to PFAS for specific use cases, see RTC 3.C.5. (Disparity Between Assessments), 4.G.3. (Airports/Aviation/Transportation/Firefighting), and 4.E. (Impacts on Managing Waste Streams and Identification).

8.D Call for Source Control

Multiple commenters called upon the federal government to continue to support the phase-out of PFAS both domestically and internationally and to reduce PFOA and PFOS entry into the U.S.

marketplace. These commenters supported limiting the domestic production and use of PFAS substances in commercial and consumer products (i.e., carpet, cooking pans, cosmetic products, food packaging, stain- and weather resistant clothing, etc.). Several commenters also argued that EPA should prevent or minimize the use of PFOA/PFOS in consumer products (or use other source controls) and address subsequent contamination rather than trying to regulate after the fact.

Another commenter argued that use of PFOA/PFOS in all manufactured goods and industrial processes should be outlawed, without exception. Similarly, one commenter urged EPA to proactively prevent the importation, manufacture, and use of PFOA and PFOS so that products containing PFOA and PFOS are not continually used then discharged or disposed through municipal solid waste and recycling collection, where the materials are then deemed "hazardous." A commenter also suggested that EPA impose a mandate on PFAS products requiring annual reporting, fees, replacement of PFAS with safer alternatives, and source reduction. Another commenter called for a label requirement for all products containing PFAS.

Some commenters stated that PFOA/PFOS cannot be removed through existing wastewater treatment processes and can persist in biosolids, reuse water, and treated effluent. One commenter stated that those who manufacture PFOA/PFOS should be responsible for any needed remediation, and ultimately the elimination, from uses that pose a threat to the environment. Several commenters urged EPA to refocus its enforcement efforts away from water and wastewater agencies. One of these commenters specifically noted that by implementing source control measures to control industrial discharges and limiting the ongoing introduction of PFOA and PFOS into the environment, EPA could promote the "polluter pays" concept rather than "punish" wastewater treatment facilities. Another commenter encouraged EPA to work with water and wastewater industry representatives to address PFOA/PFOS to address the impact of these substances on the clean water industry. Finally, one commenter stressed that if EPA and other Federal agencies continue to permit products with harmful PFAS to be imported, created, and used in the United States, public utilities will continue to be passive receivers of additional harmful PFAS substances within their systems.

Other commenters asserted that manufacturing sources are unlikely to be substantial contributors to PFOA or PFOS-related contamination, except in limited circumstances, because PFOA and PFOS manufacture and use in products have been largely phased out in the United States. Several commenters also stated that internal studies had demonstrated that household, not industry products serve as a major source of PFAS to POTWs, particularly in California.

[0355 - LASAN, 0538 - NACWA, 0470 - MEG, 0527 - Metro, 0730 - Citizen, 0563 - UTLX, 0362 - GATX, 0315 - City of Tallahassee, 0370 - OR ACWA, 0449 - Weatherford, 0318 - MMSD, 0396 - MWEA, 0276 - DCWA/City of Vancouver, 0360 - GLWA, 0328 - FWEA, 0399 - Coalition for Renewable Energy, 0367 - ECDSM, 0328 - FWEA, 0298 - SD DANR, 0473 - MESERB, 0784 - Citizen, 0394 - OSEE/ODEQ, 0462 - LA Sanitation, 0477 - CRROPS, 0806 - BACWA, 0809 - OC San, 0557 - SWACO, 0538-NACWA, 0493-POWER!]

Response

EPA acknowledges the commenters request for the federal government to support the phase-out of PFAS both domestically and internationally and to reduce PFOA and PFOS entry into the U.S. marketplace. To deliver on EPA's commitment to help reduce the potential risks to the public from PFOA and PFOS, the Agency has undertaken a multi-pronged effort across a range of environmental media and EPA program offices to protect people and the environment from these substances. To read more about the range of regulatory actions EPA has undertaken to address PFAS substances in manufacturing and consumer products, see the Preamble to the Final Rule Section III.C. (*PFAS Strategic Roadmap*) and visit EPA's website at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas.

The commenter's requests regarding specific source control methods, including prohibitions on importation and manufacturing of PFAS-containing products designed for commercial/residential use, as well as end-of-life product management, are outside the scope of this rule and no response is required. Likewise, the commenter's request with respect to labeling requirements falls outside the scope of this rule and no response is required.

To the extent the commenter urges EPA to focus its enforcement efforts specifically on PFOA and PFOS manufacturers, the Agency notes that it intends to develop a policy, consistent with existing limitations built in to CERCLA's existing liability framework and existing enforcement discretion policies, that explains EPA's priorities for enforcement in the context of PFOA and PFOS releases. *See* the Preamble to the Final Rule Section I. (*Executive Summary*); *see also* FY 2024-2027 National Enforcement and Compliance Initiatives.

EPA disagrees with the commenters' that the Agency should focus its efforts on the regulation of PFOA and PFOS in consumer products in lieu of designation of these substances under section 102(a) of CERCLA; CERCLA designation is necessary to adequately tackle the threat posed by PFOA and PFOS contamination to communities across the country. *See* the Preamble to the Final Rule Section I. (*Executive Summary*). EPA agrees with the commenter that many companies have successfully phased out of the use of PFOA and PFOS. In 2006, EPA invited eight companies within the PFAS industry to join in a stewardship program to commit to reducing PFOA from facility emissions and product content by 95 percent no later than 2010, and to work toward eliminating PFOA from emissions and product content no later than 2015. Each of the eight companies has met the stewardship program goals and has further committed to work toward a global phaseout of PFOA and related chemicals, both for U.S. operations and for the company's global business. *See* the Preamble to the Final Rule Sections III.C. (*PFAS Strategic Roadmap*) and III.B. (*PFOA and PFOS Production and Use*). However, the phaseout is not industry-wide and it does not address the historic release of PFOA and PFAS.

8.E Extension of Comments Period

Many commenters requested an extension of the public comment period of 60-days, 90-days, or for an unspecified period to provide the public with an additional amount of time to evaluate and provide input on the impacts of the proposed designation and economic assessment.

Response

EPA disagrees with the commenters' assertion that the 60-day comment period was insufficient. *See* RTC 2-A-1.

Appendix Commenter Name/Affiliation & Docket ID

Commenter ID	Commenter Name/Affiliation
0225	Anonymous
0226	Katherine Dillman
0227	Jade Hart
0228	Sadie Williams
0229	lan Fraser
0230	Sean Whiting
0231	Lynn Masters
	National Waste & Recycling Association (NWRA) and
0232	Solid Waste Association of North America(SWANA)
0233	Anonymous
0234	International Liquid Terminals Association (ILTA)
0235	Association of California Water Agencies (ACWA)
0236	Katrina Matheson
0237	William Fergusson
0238	Harry and Regina Nizer
0239	U.S. Chamber of Commerce et al.
0240	National Association of Clean Water Agencies (NACWA) et al.
0241	Celine M. (no surname provided)
	American Petroleum Institute (API),
	American Fuel & Petrochemical Manufacturers (AFPM) and
0242	International Liquid Terminals Association (ILTA)
0243	American Farm Bureau Federation et al.
0244	Savannah River Nuclear Solutions, LLC
0245	National League of Cities et al.
0246	Superfund Settlements Project (SSP)
0247	Olivia Hernandez
0249	PFAS Regulatory Coalition
0250	Foam Exposure Committee
0251	Savannah River Nuclear Solutions, LLC (SRNS)
0252	National Association of Chemical Distributors (NACD)
0253	Interested Parties for Hazardous Materials Transportation (IP's)
0254	Cailey Ennis
0255	Layla VanPool
0256	Aisha Mares
0257	Chelsea McKee
0258	Louise Mon
0259	Lisa Geary
0260	Richard Schoonover
0261	Mical Woldemichael

0262 Keirsten Mcpheeters 0263 International Dairy Foods Association (IDAF) and National Milk Producers Federation (NM 0264 **Endocrine Society** 0265 William Harms 0266 Matas Webb 0267 Monika Pettersen 0268 **Anonymous** 0269 Hispanic Leadership Fund (HLF) 0270 Elizabeth Cunningham Jim Scullion 0271 0272 Sebastian Valverde 0273 Lowry Landfill Superfund Site Citizens Advisory Group (LLSF Site CAG) 0274 **Nathaniel Sivin** 0275 Jimmy Watson 0276 Discovery Clean Water Alliance 0277 Erika Vadopalas 0278 **Tiffany Langston** Samantha Nathan 0279 0280 Marcy Signorelli 0281 Mason Montante 0282 Meg Ruby 0283 Amilia Thibodeaux 0284 **Kevin Roldos** 0285 Frank Wanda 0286 Jean Cameron 0287 Stefny Wallingford Jolie Jacobus 0288 0289 Lorene Waybrant 0290 **Anonymous** Maggie Poulos 0291 0292 Mary Frasson Kylie Ford 0293 0294 Debra Ann Hunter 0295 Juliana Anderson 0296 Allenna Wilson 0297 Citizens for Safe Water Around Badger (CSWAB) 0298 South Dakota Department of Agriculture and Natural Resources 0299 City of Thornton, CO CropLife America and Responsible Industry for a Sound Environment (RISE) 0300 0301 Great Lakes PFAS Action Network (GLPAN) National Ground Water Association (NGWA) 0302 0303 Clermont County Water Resources Department 0304 Water & Health Advisory Council

Nicole Palaschak

0305

0306	Mass Comment Campaign sponsored by Environmental Working Group et al
0307	Elsinore Valley Municipal Water District (EVMWD)
0308	Town of Peshtigo, WI
0309	South Essex Sewerage District (SESD), MA
0310	New England Water Works Association (NEWWA)
	,
0311	Massachusetts Water Works Association (MWWA)
0312	Florida Farm Bureau Federation
0313	American Public Works Association (APWA)
0314	Maine Water Utilities Association (MWUA)
0315	City of Tallahassee, Florida
0316	Maine Water Environment Association (MeWEA)
0317	Wisconsin Conservation Voters
0318	Madison Metropolitan Sewerage District (MMSD), WI
0319	Bristol Bay Native Association (BBNA)
0320	Mass Comment Comment Campaign sponsored by National Wildlife Federation (NWF)
0321	Tillamook County, OR
0322	Valerie Leone
0323	Environmental Protection Network (EPN)
0324	Evelyn Sellers
0325	Oak Ridge National Laboratory (ORNL)
0326	National Tribal Water Council (NTWC)
0327	Taylor Hatridge
0328	Florida Water Environment Association (FWEA) Utility Council et al.
0329	Mass Comment Campaign sponsoring organization unknown
0330	Mass Comment Campaign sponsoring organization unknown
0331	Mass Comment Campaign sponsoring organization unknown
0332	Mass Comment Campaign sponsored by League of Conservation Voters
0333	Mass Comment Campaign sponsoring organization unknown
0334	Mass Comment Campaign sponsoring organization unknown
0335	Mass Comment Campaign Sponsored by North Carolina Conservation Network
	Mass Comment Campaign Sponsored by
0336	U.S. PIRG Education Fund & Environment America Research & Policy Center
0337	Mass Comment Campaign Sponsored by Halt the Harm Network
0338	Alison Heins
0339	Association of State Drinking Water Administrators (ASDWA)
0340	Association of State and Territorial Solid Waste Management Officials (ASTSWMO)
0341	American Farm Bureau Federation (AFBF)
0342	Association of Environmental Authorities (AEA)
0343	Advantek Waste Management Services LLC
0344	American Public Works Association (APWA) et al.
0345	3M Company
0346	California Association of Sanitation Agencies (CASA)
0347	Brevard County, FL. Board of County Commissioners
0348	Bowling Green Municipal Utilities (BGMU)

0349	Broome County Division of Solid Waste Management
0350	City of Henderson, Nevada
0351	City of Saint Charles, MO. Department of Public Works
0352	Clark County Water Reclamation District
0353	Connecticut Water Works Association (CWWA)
0354	City of Roseville, CA
0355	City of Los Angeles Sanitation and Environment (LASAN)
0356	Connecticut Council of Small Towns (COST)
0357	Hampton Roads Sanitation District (HRSD)
0358	Georgia Farm Bureau (GFB)
0359	Greater Cincinnati Water Works (GCWW)
0360	Great Lakes Water Authority (GLWA)
0361	Hazardous Waste Management Program
0362	GATX Corp.
0363	El Paso Water Utilities
0364	Des Moines Metropolitan Wastewater Reclamation Authority (WRA)
0365	Environmental Protection Network (EPN)
0366	Environmental Health Project (EHP)
0367	Erie County Division of Sewerage Management (ECDSM)
0368	Electric Power Supply Association (EPSA)
0369	Hillsborough County Aviation Authority (HCAA) Tampa International Airport
0370	Oregon Association of Clean Water Agencies (ACWA)
0371	The State Chamber of Oklahoma and the Environmental Federation of Oklahoma
0372	NEW Water
0373	Milwaukee Metropolitan Sewerage District (MMSD)
0374	Minnesota Pollution Control Agency (MPCA)
0375	Metropolitan St. Louis Sewer District (MSD)
0376	Kent County, MI. Department of Public Works
0377	Massachusetts Department of Environmental Protection (MassDEP)
0378	Metropolitan Sewer District of Greater Cincinnati (MSD)
0379	Stafford County Department of Utilities
0380	Little Blue Valley Sewer District
0381	King County Department of Natural Resources and Parks (DNRP)
0382	NC Conservation Network et al.
0383	Northwest Biosolids Association et al.
0384	Jurupa Community Services District (JCSD)
0385	New York Section of the American Water Works Association (NYSAWWA) et al.
0386	Renewable Water Resources (ReWa)
0387	Pennsylvania Chamber of Business and Industry et al.
0388	Suffolk County Water Authority (SCWA)
0389	Town of Ledgeview and Ledgeview Sanitary District No.2
0390	National Milk Producers Federation (NMPF)
0390	Superfund Settlements Project (SSP)
0391	National Association of Water Companies (NAWC)
UJJZ	ivational Association of viater companies (IVAVIC)

0393	New Mexico Environment Department (NMED)
	Oklahoma Secretary of Energy and Environment and
0394	Oklahoma Department of Environmental Quality
0395	Massachusetts Water Resources Authority (MWRA)
0396	Michigan Water Environment Association (MWEA)
0397	Massachusetts Water Resources Authority (MWRA) Advisory Board
0398	Pennsylvania Department of Environmental Protection
0399	Local Government Coalition for Renewable Energy
0400	Town of Windsor, VA
0401	Village of Ashwaubenon
0402	Wyoming Farm Bureau Federation
0403	Town of Purcellville, VA
0404	U.S. Chamber of Commerce et al.
0405	U.S. Chamber of Commerce
0406	Wastewater Advisory Committee (WAC)
0407	Water Coalition Against PFAS
0408	W. L. Gore & Associates
0409	Santa Clara Valley Water District
0410	Wyoming Department of Environmental Quality (WDEQ)
0411	Airlines for America (A4A)
0412	Oklahoma Farm Bureau (OKFB)
0413	Association of California Water Agencies (ACWA)
0414	Attorneys General of the States of New York, et al.
0415	Association of Missouri Cleanwater Agencies (AMCA)
0416	Alexandria Renew Enterprises
0417	Aircraft Rescue & Fire Fighting Working Group Inc.
0418	Associated General Contractors of America (AGC)
0419	American Petroleum Institute (API) et al.
0420	American Water Works Association Connecticut Section (CT AWWA)
0421	American Chemistry Council (ACC)
0422	Alabama Water and Wastewater Institute (AWWI)
0423	American Forest & Paper Association (AF&PA)
0424	Airports Council International - North America (ACI-NA)
0425	Cascade Water Alliance
0426	California Department of Toxic Substances Control (DTSC)
0427	City of Auburn, Alabama
0428	Citizens Against Ruining the Environment (CARE)
0429	City of Fort Worth, TX
	City of Elyria, Ohio Wastewater Pollution Control Plant and
0430	Municipal Separate Storm Sewer System (MS4)
0431	City of Lexington, VA.
0432	City of Columbus OH, Department of Public Utilities (CDPU)
0433	City of Redmond, WA
0434	City of Manhattan, Kansas
- · · ·	and an interminational intermedia

0435 City of Columbus, Indiana 0436 City of Manhattan 0437 City of Dubuque 0438 City of Aurora Water 0439 City of Sunnyvale California 0440 Consumer Action for a Strong Economy 0441 Clean Streams, Rivers and Lakes 0442 Cooper Kohlman 0443 City of Tampa Water and Wastewater Departments Dairy Producers of New Mexico (DPNM) 0444 0445 Colorado Farm Bureau (CFB) 0446 Congressional Fire Services Institute et al. 0447 Coalition of Recyclers of Residual Organics by Practitioners of Sustainability (CRROPS) 0448 City of Thousand Oaks, CA 0449 City of Weatherford, Texas Ezraterra, LLC 0450 0451 Harford County Maryland **Defend Our Health** 0452 0453 Illinois Association of Wastewater Agencies (IAWA) 0454 Illinois Farm Bureau (IFB) 0455 Inland Empire Utilities Agency (IEUA) 0456 Florida Airports Council (FAC) 0457 Genesee County Drain Commissioner's Division of Water and Waste Services (GCDCWWS 0458 Earthjustice et al. 0459 **GFL** Environmental 0460 International Liquid Terminals Association (ILTA) 0461 Lee County Port Authority 0462 Los Angeles County Sanitation Districts 0463 Little Hocking Water Association 0464 JEA 0465 Johnson County Wastewater (JCW) 0466 Lone Star Chapter, Solid Waste Association of North America, Incorporated (TxSWANA) National Center for Health Research 0467 0468 National Ground Water Association (NGWA) 0469 North Carolina Farm Bureau Federation (NCFB) 0470 Municipal Environmental Group (MEG) - Wastewater Division 0471 Loudoun Water 0472 New York Farm Bureau (NYFB) 0473 Minnesota Environmental Science and Economic Review Board (MESERB) 0474 Mississippi Farm Bureau Federation (MFBF) National Association of Regulatory Utility Commissioners (NARUC) 0475 0476 Michigan Manufacturers Association (MMA) 0477 Louisiana Chemical Association (LCA) 0478 **New York City**

0479	National Association of Convenience Stores (NACS), NATSO and SIGMA National Waste & Recycling Association (NWRA) and
0480	Solid Waste Association of North America (SWANA)
0481	New Mexico Farm and Livestock Bureau (NMF&LB)
0482	Metropolitan Water District of Southern California
0483	Monterey One Water
0484	National Association of Chemical Distributors (NACD)
0485	Michigan Farm Bureau
0486	San Francisco Fire Department
0487	Purdue University
0488	South Central Connecticut Regional Water Authority (RWA)
0489	Shelby County, Alabama
0490	Pennsylvania Municipal Authorities Association (PMAA)
0491	Orange County Water District (OCWD
0492	South Carolina Water Quality Association (SCWQA)
0493	Protecting Our Water, Environment, and Ratepayers Coalition (POWER!)
0494	Save Our Water (S.O.H2O)
0495	PFAS Regulatory Coalition
0496	Northeast Ohio Regional Sewer District (NEORSD)
0497	Orange County, Florida
0498	Santa Clarita Valley Water Agency (SCV Water)
0499	Rachael Wilfong and Daren Bakst
0500	Utility Solid Waste Activities Group (USWAG)
0501	Vermont PFAS/Military Poisons Coalition
0502	United Steelworkers (USW or Steelworkers)
0503	The National PFAS Contamination Coalition (NPCC)
0504	Virginia Biosolids Council (VBC)
0505	Virginia Association of Municipal Wastewater Agencies, Inc. (VAMWA)
0506	U.S. Conference of Mayors et al.
0507	Wasatch Front Water Quality Council
0508	Water Environment Federation (WEF)
0509	Tennessee Department of Environment and Conservation (TDEC)
	Water Environment Association of Texas (WEAT) and
0510	Texas Association of Clean Water Agencies (TACWA)
0511	WateReuse Association
0512	Stericycle, Inc.
0513	Trinity River Authority of Texas
0514	Wasatch Integrated Waste Management District
0515	Upper Blackstone Clean Water
0516	Water Replenishment District of Southern California (WRD)
0517	Wessler Engineering, Inc.
0518	Wet Weather Partnership (WWP)
0519	West Virginia Rivers Coalition
0520	Wisconsin Paper Council (WPC)

0524	Maria a Maria a Maria District
0521	Western Municipal Water District
0522	Wisconsin Manufacturers & Commerce (WMC)
0523	Western States Petroleum Association (WSPA)
0524	Worcester County, Maryland - Department of Public Works
0525	Consumer Choice Center
	North Carolina National Association for the
	Advancement of Colored People (NC NAACP)
	Environmental Justice Committee;
0526	Charlotte Mecklenburg Climate Justice and Green Workforce Development
0527	Metro Water Recovery
0528	National Special Districts Coalition (NSDC)
0529	Augusta County Service Authority (ACSA)
0530	International Association of Fire Chiefs (IAFC)
0531	East Bay Municipal Utility District (EBMUD)
0532	Be The Change – Colorado
0533	Horsham Water & Sewer Authority
0534	Kansas Department of Health and Environment (KDHE)
0535	Maine Rural Water Association (MRWA)
0536	Aclarity, Inc.
0537	Association of Metropolitan Water Agencies (AMWA)
0538	National Association of Clean Water Agencies (NACWA)
0539	North Carolina Water Quality Association (NCWQA)
0540	Pennsylvania Farm Bureau (PFB)
0541	Great Lakes Water Authority (GLWA) MI
0542	CropLife America (CLA) and RISE (Responsible Industry for a Sound Environment)
0543	American Water Works Association (AWWA)
0544	American Water Works Association
0545	Florida Section of the American Water Works Association (FSAWWA)
0546	Arizona Farm Bureau Federation
0547	Maine Department of Agriculture, Conservation and Forestry (DACF)
0548	National Association of Manufacturers (NAM)
0549	California Farm Bureau
0550	Delaware Solid Waste Authority (DSWA)
0551	Cross-Cutting Issues Group (CCIG)
0552	Environmental Working Group (EWG)
0553	National Air Transportation Association (NATA)
0554	District of Columbia Water and Sewer Authority
0555	American Association of Airport Executives (AAAE)
0556	Institute of Scrap Recycling Industries, Inc. (ISRI)
0557	Solid Waste Authority of Central Ohio (SWACO)
0558	South Dakota Farm Bureau Federation
0559	RuttenKern LLC
0560	Public Health - Seattle and King County (PHSKC)
0561	Western Urban Water Coalition (WUWC)

The Narragansett Bay Commission (NBC)

Union Tank Car (UTLX)

U.S. PIRG Education Fund & Environment America

0565 Utility Solid Waste Activities Group (USWAG)

0566 Natural Resource Use & Management Clinic at the University of Arizona

0567 WE ACT for Environmental Justice (WE ACT)

Water and Wastewater Equipment Manufacturers Association (WWEMA)
 U.S. Chamber of Commerce Coalition of Companies and Trade Associations

0570 Donald Payne, Jr.

0571 Anonymous 0572 Brooke Lindsey 0573 Nick McLelland

0574 Elias Baez

0575 Nicholas Littlejohn0576 George E. Robertson

0577 Shaina Oliver 0578 **Anonymous** 0579 Pamela Grieser 0580 Tria Shaffer 0581 Patricia Rowell 0582 Vanya Wright 0583 Suzanne Hume 0584 **Garrett Cottier**

O585 Jonathan (no surname provided)

0586 Andrea Funez
0587 Anonymous
0588 Betty Hanacek
0589 Richard Ramirez
0590 Gracie Layman
0591 John Smith
0592 Anonymous

0593 Nicholas DeGuzman

0594 **Anonymous** 0595 Joseph Minor 0596 **Anonymous** 0597 James Klein 0598 Bud Hoekstra 0599 **Brant Hinrichs** 0600 Sandy Dillon 0601 Jill Seiden

0602 Janet Grossman

0603 Karen Lee 0604 Karen Rapp 0605 Julie Unruh

0606 Regula Hess 0607 Mimi Foust 0608 Nancy Campbell 0609 Catherine Carter 0610 **Chris Jenkins** 0611 Stephen Snell 0612 Nancy Cadet 0613 S. A. Linden 0614 **Edward Simpson** 0615 **Buck Schall** 0616 **David Williams** 0617 Bruce Hlodnicki 0618 Francelle Carapetyan

0619 Lisa Wentland
0620 Rich Elam
0621 Mark Pezzati
0622 John Commerford

0623 Pat Janiga 0624 Lori Paul

0625 Peter Lauterbach
0626 Charles Schmalz
0627 John Savlove
0628 Barry Fass-Holmes
0629 Martin Westerman
0630 Jaclyn Kimball
0631 Hans-Werner Reiser

0631 Hans-Werner Reise
0632 Barbara Gottlieb

0633 I. Alexakos

0634 Nicole Lewandowski

0635 Debra Dunson 0636 Maureen Kilroy 0637 Susan Curry 0638 **Edward Janusz** 0639 Debora McCreedy 0640 **Dwight Johnson** 0641 Marc Huysmans 0642 Darcy Johnson 0643 Cindy Black 0644 Jean Naples 0645 Jean Naples 0646 Jean Naples 0647 Matthew Lykken Barbara Smith-Moran 0648

0649 Chloe Fessler

0650 Cynthia Hudley 0651 Carolyn Turner 0652 Zachariah Love 0653 Yvonne Monroe 0654 Lisa Buckingham 0655 Margaret Barrett 0656 Kathleen Gonzalez Felicito Guerrero 0657 0658 Susan Kline 0659 **Hugh Caton** 0660 Karen Caton 0661 Gay Goodman 0662 Carol Gibson-Kish 0663 **Anonymous** 0664 William Dawson 0665 Gina Griffith

0666 Charlotte Fremaux

Anonymous 0667 0668 **Elvia Fontes** 0669 **Dina Andrews** 0670 **Todd Cochran** 0671 **Doris Cellarius** 0672 Paula Hunt 0673 Leslie Edwards 0674 John Rossbach 0675 Skyla Spearman 0676 Amelia Walker 0677 Karen Ganey 0678 Karen Ganey 0679 Alayna Zang 0680 Julia Tuttle 0681 Marion Settle 0682 **Ann Bunting**

0683 Anonymous
0684 M. Carolyn Bemis
0685 Hannah MacLaren
0686 Mark Barone
0687 Diane Desemberg
0688 Barry Fass-Holmes

0689 Joe Hiss
0690 Chris Eaton
0691 Joseph Alvarado
0692 Jean Naples
0693 Mark Junker

0694	Anonymous
0695	H. Parker
0696	Robert Long
0697	Marlene Liskay
0698	Christine Bruce
0699	Carolyn Lawler
0700	Debby Patten
0701	Jessie Zerick
0702	Valerie Lockard
0703	Elizabeth Enright
0704	Anonymous
0705	Michael Ciocci
0706	Leslie Shanley
0707	Anna Schwendinger
0708	Anonymous
0709	Hannah Starnes
0710	Charlie Weaver
0711	Todd Snyder
0712	Anonymous

0714 Meagan McEachern

Anonymous

0713

0715 **Anonymous** 0716 Jessica Gibson 0717 **Taylor Lowe** 0718 Anonymous 0719 Jenna Rethman 0720 **Beth Jones** 0721 Olivia Freiberg 0722 Kai Szostak 0723 Robert Bowen 0724 Anonymous 0725 Alicia Pride 0726 **Todd Snyder** 0727 **Judy Klevins** 0728 Constance Hartke

0729 Birgit Sharp 0730 John Holmes

0731 Stacey DiMaria 0732 M. Gilges

0733 Aileen Curfman
0734 David Thurston
0735 Doug Barker
0736 Carey Cling
0737 Derrick Porter

0738	Anandi Breen
0739	Lucinda Snow
0740	Christiana Walford
0741	Don Lipmanson
0742	Richard Johnson
0743	Katie DeVan
0744	T Joseph Young
0745	Anonymous
0746	Kathy Bernthal
0747	Larry Roettger
0748	Jeremy Ehrlich
0749	Anonymous
0750	Sasha Slayton
0751	Alan Miller
0752	Patricia Guthrie
0753	Henry Frank
0754	Anonymous
0755	Joyce Caracci
0756	K. Christopher
0757	Nila Cogan
0758	William Gawne
0759	Ceri Jensen
0760	Anonymous
0761	Lyle Courtsal
0762	Charles Campbell
0763	Ella Bradley
0764	Sandra Weiss
0765	Lawrence Rosin
0766	Patti Clancy
0767	David Addison
0768	John Derek
0769	Romalda Allsup
0770	John Derek
0771	Dave Kisor
0772	Gary Sack
0773	Sandra Livingston
0774	James Boylan
0775	Margaret Christoffer
0776	Deanna Levanti
0777	Emma Miniscalco
0778	Suzanne Hume
0779	Bruce Hlodnicki
0780	Veronica Jones

Richard Mezzavilla

0782 Peter Gordon 0783 Donna Staton

0784 Sonia Skakich-Scrima

0785 Jeffery Moser0786 Effie Katsanos0787 Karen Kimbrel

0788 Eamon HolmesHolmes

Larry Nelson 0789 0790 **Christopher Lish** 0791 **Deborah Calvert** 0792 **Travis Murray** 0793 Paula Smolen 0794 **Brenda Martinez** 0795 Lindsay Klees 0796 Catherine Dodd 0797 J. D. Ruybal 0798 **Anonymous** 0799 Erin Albright 0800 **Anonymous** 0801 Victoria Wright

O802 Alyssa R. (no surname provided)

0804 South Platte Renew0805 US Composting Council

0806 Bay Area Clean Water Agencies (BACWA)

0807 American Water Works Association, California-Nevada Section

0808 National Association for Surface Finishing 0809 Orange County Sanitation District (OC San)

0810 Environmental Defense Fund (EDF)

0811 U.S. Small Business Administration (SBA) Office of Advocacy

0812 Wisconsin Department of Natural Resources (WDNR)

O813 City of Worcester Department of Public Works & Parks (DPWP)
West Virginia Municipal Water Quality Association (WVMWQA)

0815 Daikin America, Inc. (DAI)

0816 Tom Martin 0817 Grace Terry

0821 Mass Comment Campaign sponsoring organization unknown

0822 Krissa Dutton-Schandelmaier

0823 Barbara Katusha 0824 John J. Dziak

0825 Timothy Armstrong

0826 Debra Graves

0827 Lee Ann Landstrom