



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 261 and 271

[EPA-HQ-OLEM-2023-0278; FRL-9248-01-OLEM]

RIN 2050-AH26

Listing of Specific PFAS as Hazardous Constituents

AGENCY: Environmental Protection Agency (EPA)

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is proposing to amend its regulation under the Resource Conservation and Recovery Act (RCRA) by adding nine specific per- and polyfluoroalkyl substances (PFAS), their salts, and their structural isomers, to its list of hazardous constituents. These nine PFAS are perfluorooctanoic acid (PFOA), perfluorooctanesulfonic acid (PFOS), perfluorobutanesulfonic acid (PFBS), hexafluoropropylene oxide-dimer acid (HFPO-DA or GenX), perfluorononanoic acid (PFNA), perfluorohexanesulfonic acid (PFHxS), perfluorodecanoic acid (PFDA), perfluorohexanoic acid (PFHxA), and perfluorobutanoic acid (PFBA). EPA's criteria for listing substances as hazardous constituents under RCRA require that they have been shown in scientific studies to have toxic, carcinogenic, mutagenic, or teratogenic effects on humans or other life forms. EPA reviewed and evaluated key toxicity and epidemiological studies and assessments for the nine PFAS to determine whether the available data for these PFAS meet the Agency's criteria for listing substances as hazardous constituents under RCRA. Based on EPA's evaluation, the above nine PFAS, their salts, and their structural isomers meet the criteria for being listed as RCRA hazardous constituents. As a result of this proposed rule, if finalized, when corrective action requirements are imposed at a facility, these PFAS would be among the hazardous constituents expressly identified for consideration in RCRA facility assessments and, where necessary,

further investigation and cleanup through the RCRA corrective action process at RCRA treatment, storage, and disposal facilities.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-OLEM-2023-0278, by any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov> (our preferred method).

Follow the online instructions for submitting comments.

- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, OLEM Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

- *Hand Delivery or Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m. - 4:30 p.m., Monday – Friday (except Federal Holidays).

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

FOR FURTHER INFORMATION CONTACT: Narendra Chaudhari, Office of Resource Conservation and Recovery (5304T), Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460; telephone number 202-566-0495; email address: Chaudhari.narendra@epa.gov.

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List of Abbreviations and Acronyms

The following list is for reference only and is not exhaustive:

AFFF	Aqueous film-forming foam
ATSDR	Agency for Toxic Substances and Disease Registry
CDC	Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations

ECF	Electrochemical fluorination
EJ	Environmental justice
EPA	Environmental Protection Agency
FR	<i>Federal Register</i>
GenX	Processing aid technology that includes Hexafluoropropylene Oxide-Dimer acid and its ammonium salt
HFPO-DA	Hexafluoropropylene Oxide-Dimer acid
HSWA	Hazardous and Solid Waste Amendments of 1984
mg/kg	milligram per kilogram
mg/kg/day	milligram per kilogram per day
NAICS	North American Industrial Classification System
OMB	Office of Management and Budget
PBI	Proprietary Business Information
PFAS	Per- and polyfluoroalkyl substances
PFBA	Perfluorobutanoic acid
PFBS	Perfluorobutanesulfonic acid
PFDA	Perfluorodecanoic acid
PFHxA	Perfluorohexanoic acid
PFHxS	Perfluorohexanesulfonic acid
PFNA	Perfluorononanoic acid
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonic acid
RCRA	Resource Conservation and Recovery Act
RFA	Regulatory Flexibility Act
RfD	Reference dose
SWMU	Solid Waste Management Unit
TSDFs	Treatment, storage, and disposal facilities
UMRA	Unfunded Mandates Reform Act
U.S.	United States
U.S.C.	United States Code

I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA-HQ-OLEM-2023-0278, at <https://www.regulations.gov> (our preferred method), or the other methods identified in the ADDRESSES section. Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at <https://www.regulations.gov> any information you consider to be Proprietary Business Information (PBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish

to make. EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about PBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

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

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

II. General Information

A. Does this action apply to me?

The purpose of this proposed rulemaking is to add nine PFAS, their salts, and their structural isomers, to the list of hazardous constituents in 40 CFR part 261 Appendix VIII (Appendix VIII). Entities potentially affected by this action include hazardous waste treatment, storage, and disposal facilities (TSDFs) with solid waste management units (SWMUs) that have released or could release any of the PFAS proposed to be listed as RCRA hazardous constituents. EPA has identified 1,740 such facilities, which could be subject to additional corrective action requirements (pursuant to RCRA section 3004(u) and (v)) to address releases not already subject to corrective action pursuant to EPA's corrective action regulations.

The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide for readers to determine whether this action may affect them. For further details about the potentially affected universe of facilities, refer to Section 3.2 of the draft *Economic Assessment of the Potential Costs, Benefits, and Other Impacts of the Proposed Rulemaking to List Specific PFAS as RCRA Hazardous Constituents*

(Ref. 41), which can be found in the public docket for this action. Potentially affected entities may include:

Table II-1. Potentially Affected Entities

NAICS (3-Digits)	NAICS Description	Universe of Facilities	Facilities with Higher Likelihood of Handling PFAS
111	Crop Production	2	
115	Support Activities for Agriculture and Forestry	1	
211	Oil and Gas Extraction	2	1
213	Support Activities for Mining	2	
221	Utilities	25	1
233	Building, Developing, and General Contracting	1	
238	Specialty Trade Contractors	2	
311	Food Manufacturing	3	
312	Beverage and Tobacco Product Manufacturing	1	
313	Textile Mills	4	4
321	Wood Product Manufacturing	52	
322	Paper Manufacturing	3	1
323	Printing and Related Support Activities	1	
324	Petroleum and Coal Products Manufacturing	79	76
325	Chemical Manufacturing	335	278
326	Plastics and Rubber Products Manufacturing	14	9
327	Nonmetallic Mineral Product Manufacturing	23	9
331	Primary Metal Manufacturing	68	1
332	Fabricated Metal Product Manufacturing	68	28
333	Machinery Manufacturing	20	
334	Computer and Electronic Product Manufacturing	46	19
335	Electrical Equipment, Appliance, and Component Manufacturing	12	3
336	Transportation Equipment Manufacturing	64	
337	Furniture and Related Product Manufacturing	1	
339	Miscellaneous Manufacturing	14	2
422	Wholesale Trade, Nondurable Goods	6	
423	Merchant Wholesalers, Durable Goods	14	

NAICS (3-Digits)	NAICS Description	Universe of Facilities	Facilities with Higher Likelihood of Handling PFAS
424	Merchant Wholesalers, Nondurable Goods	38	38
447	Gasoline Stations	1	
454	Non-store Retailers	1	
481	Air Transportation	3	
482	Rail Transportation	4	
484	Truck Transportation	2	
486	Pipeline Transportation	4	
488	Support Activities for Transportation	11	1
493	Warehousing and Storage	22	
519	Other Information Services	1	
525	Funds, Trusts, and Other Financial Vehicles	3	
531	Real Estate	12	
532	Rental and Leasing Services	4	
541	Professional, Scientific, and Technical Services	39	
551	Management of Companies and Enterprises	2	
561	Administrative and Support Services	22	
562	Waste Management and Remediation Services	461	359
611	Educational Services	31	
621	Ambulatory Health Care Services	2	
622	Hospitals	3	
811	Repair and Maintenance	7	
813	Religious, Grantmaking, Civic, Professional, and Similar Organizations	2	
921	Executive, Legislative, and Other General Government Support	13	
922	Justice, Public Order, and Safety Activities	2	
924	Administration of Environmental Quality Programs	9	
925	Administration of Housing Programs, Urban Planning, and Community Development	1	
926	Administration of Economic Programs	3	
927	Space Research and Technology	5	
928	National Security and International Affairs	142	1
	Missing	27	
	Total	1,740	831
Notes:			

NAICS (3-Digits)	NAICS Description	Universe of Facilities	Facilities with Higher Likelihood of Handling PFAS
	1. This proposed rule only lists specific PFAS as hazardous constituents in 40 CFR part 261, Appendix VIII. EPA notes that listing these PFAS as RCRA hazardous constituents does not make them, or the wastes containing them, RCRA hazardous wastes.		

B. What action is the Agency taking?

This action is proposing to amend EPA's regulations under RCRA by listing the following nine PFAS (names given for acid forms below), their salts, and their structural isomers¹ as hazardous constituents in 40 CFR part 261 Appendix VIII:

1. *Perfluorooctanoic acid* (PFOA; CASRN 335-67-1). PFOA is an eight-carbon molecule with seven fully fluorinated carbon atoms and one carboxylic acid functional group. It has been used as a processing aid to produce fluoropolymers and has been found in cleaning agents, waxes, aqueous film-forming foam (AFFF), and other products.

2. *Perfluorooctanesulfonic acid* (PFOS; CASRN 1763-23-1). PFOS is a fully fluorinated eight-carbon molecule with one sulfonic acid functional group. It has been used in AFFF, in surface treatments of textiles to provide oil and water resistance, in metal plating, and other uses and industries.

3. *Perfluorobutanesulfonic acid* (PFBS; CASRN 375-73-5). PFBS is a fully fluorinated four-carbon molecule with one sulfonic acid group. It has been used as a replacement for PFOS and has been used in the manufacture of paints and cleaning agents, metal plating, AFFF, to provide oil and water resistance, and other uses and industries.

4. *Hexafluoropropylene oxide-dimer acid* (HFPO-DA or GenX; CASRN 13252-13-6). HFPO-DA is a six-carbon molecule consisting of five fully fluorinated carbon atoms, one ether functional group, and one carboxylic acid functional group. HFPO-DA is a chemical associated with GenX processing aid technology used to make fluoropolymers without the use of PFOA.

5. *Perfluorononanoic acid* (PFNA; CASRN 375-95-1). PFNA is a nine-carbon molecule with eight fully fluorinated carbon atoms and one carboxylic acid functional group. It has been used as a processing aid to produce fluoropolymers and has been used or found in metal plating, cleaning agents, waxes, AFFF, energetic materials, and other products.

¹ All references to PFOA, PFOS, PFBS, HFPO-DA (or GenX), PFNA, PFHxS, PFDA, PFHxA, and PFBA or to all nine PFAS in this notice are meant to include their salts and their linear and branched structural isomers, except where the notice expressly distinguishes the different forms. The CASRN for the linear acid version is given for reference. Linear and branched structural isomers maintain the carboxylic acid and sulfonic acid functional groups, respectively, but have different arrangements of the carbon atoms in the fluorinated carbon chain. The reference to HFPO-DA only applies to the specific structural isomer noted, including both enantiomers.

6. *Perfluorohexanesulfonic acid* (PFHxS; CASRN 355-46-4). PFHxS is a fully fluorinated six-carbon molecule with one sulfonic acid functional group. It has been used in AFFF, in surface treatments of textiles to provide oil and water resistance, in metal plating, and other uses and industries.

7. *Perfluorodecanoic acid* (PFDA; CASRN 335-76-2). PFDA is a ten-carbon molecule with nine fully fluorinated carbon atoms and a carboxylic acid functional group. It has been used as a processing aid to produce fluoropolymers and has been used or found in metal plating solutions, cleaning agents, waxes, AFFF, and other products.

8. *Perfluorohexanoic acid* (PFHxA; CASRN 307-24-4). PFHxA is a six-carbon molecule with five fully fluorinated carbon atoms and a carboxylic acid functional group. It has been used or found in metal plating solutions, cleaning agents, waxes, AFFF, and other products.

9. *Perfluorobutanoic acid* (PFBA; CASRN 375-22-4). PFBA is a four-carbon molecule with three fully fluorinated carbon atoms and one carboxylic acid functional group. It has been used or found in metal plating, cleaning agents, waxes, AFFF, energetic materials, and other products.

In addition, if finalized, this action would add this listing action, as it would apply for corrective action purposes, to Table 1 in 40 CFR 271.1. Table 1 in 40 CFR 271.1 identifies the Federal program requirements that are promulgated pursuant to HSWA and take effect in all States, regardless of their authorization status.

C. Why is the Agency taking this action?

EPA is proposing to list the nine PFAS, their salts, and their structural isomers as RCRA hazardous constituents because animal and epidemiological studies and assessments have shown that exposure to these PFAS have toxic and adverse effects in animals, humans, or both. The toxic and adverse effects include reproductive effects, developmental effects, increased risk of some cancers, reduced immune system response, and increased cholesterol levels (Refs. 1 and 2).

In addition, EPA has received three petitions requesting that the Agency take regulatory actions on PFAS under RCRA. The petitions were submitted by Public Employees for Environmental Responsibility (PEER), Environmental Law Clinic of University of California, Berkeley (UC Berkeley), and the Governor of New Mexico. PEER's petition, submitted on September 19, 2019, requested that EPA develop regulations for listing wastes containing PFAS (long-chain and short chain) as hazardous wastes under Subtitle C of RCRA to ensure the safe

management and disposal of these wastes (Ref. 3). UC Berkeley's petition, submitted on January 15, 2020, on behalf of six community and environmental advocacy groups from six different states (California, Alaska, North Carolina, Pennsylvania, Michigan, and Colorado), requested that EPA promulgate regulations listing wastes containing PFOA, PFOS, GenX chemicals (including HFPO-DA and its ammonium salt), or any combination of these, as hazardous wastes and that the RCRA hazardous waste listings for PFOA and PFOS wastes extend to cover the full chemical subclass of each (long-chain perfluoroalkyl carboxylates and sulfonates) (Ref. 4). The Governor of New Mexico's petition, submitted on June 23, 2021, incorporated the above two petitions by reference and requested a timely listing of PFAS, as a class of chemicals, as hazardous wastes under the RCRA Subtitle C regulations, or in the alternative, a listing of individual PFAS chemicals as hazardous wastes under the regulations (Ref. 5). EPA acted upon the Governor of New Mexico's petition with its October 26, 2021 letter (Ref. 6). EPA indicated in that letter that it would be initiating the rulemaking process for two rulemakings. This proposal, along with EPA's proposal titled *Definition of Hazardous Waste Applicable to Corrective Action for Releases from Solid Waste Management Units*, constitute initiation of those rulemakings.

EPA evaluated the information in the above three petitions in addition to the toxicity and health effects data available for PFAS and determined that the existing data for PFAS supports listing the nine PFAS, their salts, and their structural isomers at issue in this action as RCRA hazardous constituents in 40 CFR part 261 Appendix VIII (see section V for additional information).

A hazardous constituent listing is a step toward a potential hazardous waste listing. To list a waste as a RCRA hazardous waste under 40 CFR 261.11(a)(3), the Agency must show that the waste contains a hazardous constituent listed on Appendix VIII and determine that it is capable of posing a substantial hazard. This determination requires EPA to collect and carefully

consider information on the eleven regulatory factors specified in 40 CFR 261.11(a)(3)². If finalized, this hazardous constituent listing would form part of the basis for any future action the Agency may take to list these substances as a hazardous waste. EPA will continue to evaluate available data to determine whether a future regulatory action to list certain PFAS, or waste containing such PFAS, as regulatory hazardous waste is appropriate. In the meantime, based on the toxicity and human health effects data available and evaluated by EPA for each of the nine PFAS, EPA is moving forward with this regulatory action under RCRA to add the nine PFAS, their salts, and their structural isomers, as hazardous constituents in 40 CFR part 261 Appendix VIII.

Finally, EPA is proposing to designate these PFAS as hazardous constituents so that when corrective action requirements are imposed by program implementers these PFAS would be among the constituents expressly identified for consideration in RCRA facility assessments, and where necessary, further investigation and cleanup through the RCRA corrective action process at RCRA TSDFs.

D. Impacts of the Proposed Rule

EPA is proposing to list nine PFAS, their salts, and their structural isomers, as RCRA hazardous constituents in 40 CFR part 261 Appendix VIII. The Appendix VIII list of hazardous constituents does not by itself impose regulatory requirements. Rather, references to hazardous constituents are found in various sections of the Federal hazardous waste regulations in Parts 261, 264, 265, 268, and 270.

The principal impacts of this rule will be on the RCRA Corrective Action Program. EPA expects that the proposed rule, combined with the Agency's increased attention to addressing

² The eleven factors to be considered are: constituent toxicity, concentration, migration potential, persistence, degradation product potential, bioaccumulation potential, plausible management scenarios, waste quantity, damage cases, coverage by other regulatory programs, and other factors as may be appropriate.

risks associated with PFAS³, would facilitate and likely result in additional corrective action to address releases of specific PFAS listed as RCRA hazardous constituents. RCRA section 3004(u) requires that any permit issued to a TSDF after November 8, 1984 require corrective action for all releases of hazardous waste or hazardous constituents from solid waste management units at the facility. In the 1990 Subpart S proposed corrective action rule (see 55 FR 30798; July 27, 1990), EPA stated its view that the use of the phrase “hazardous waste or constituents” in section 3004(u) indicates that Congress was particularly concerned that the Agency use its corrective action authority to address hazardous constituents and stated that the term “hazardous constituents” in section 3004(u) means those constituents found in Appendix VIII.⁴ Thus, hazardous constituents listed on Appendix VIII are assessed for and addressed as part of the corrective action process as necessary to protect human health and the environment. As a result of this proposed rule, nine PFAS, their salts, and their structural isomers would be among the hazardous constituents expressly identified for consideration in RCRA facility assessments and, where necessary, further investigation and cleanup through the corrective action process⁵. Additional discussion of this topic can be found in the draft Economic Assessment (Ref. 41). Applicability of the rule in authorized states and effect on state authorization are discussed in Section VI of this preamble.

While various RCRA regulatory provisions, unrelated to corrective action, reference hazardous constituents, EPA expects that any impacts from those references would be negligible, as EPA expects that the processes and procedures currently in place to meet the requirements of these regulations would likely address PFAS as well as other constituents already on Appendix VIII. Furthermore, there are also a few references to hazardous constituents or Appendix VIII in

³ For example, see, PFAS Strategic Roadmap, EPA’s Commitment to Action 2021 – 2024, https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf

⁴ EPA, in addition, proposed to include constituents appearing in 40 CFR part 264 Appendix IX as hazardous constituents subject to corrective action. 55 FR at 30809.

⁵ A facility-specific administrative record would still be needed to support corrective action measures imposed on the basis of protection of human health or the environment.

other, non-RCRA, EPA regulations; EPA also believes the impacts from these regulations would be negligible.

The scope of this proposal is limited. Listing these PFAS as RCRA hazardous constituents does not make them, or the wastes containing them, RCRA hazardous wastes. Additionally, only facilities that are hazardous waste TSDFs are subject to RCRA corrective action. 42 U.S.C. 3004(u), (v). Therefore, EPA anticipates that, for example, a facility such as a publicly owned treatment works (POTW), would not be potentially affected by the RCRA corrective action requirements unless the facility is a hazardous waste TSDF. Finally, the domestic sewage exclusion in 40 CFR 261.4(a)(1), which excludes domestic sewage and any mixture of domestic sewage and other wastes that passes through a sewer system from being considered solid wastes (with some exceptions), applies to the POTW influent.

Similarly, solid waste disposal facilities, such as municipal waste, or construction and demolition landfills would not be potentially affected by the RCRA corrective action requirements unless such facilities also operate as hazardous waste TSDFs.

EPA solicits comment on the impacts of this rule on the RCRA Corrective Action Program and the interaction with other existing RCRA regulatory provisions including those non-corrective action provisions that reference hazardous constituents.

E. What are the incremental costs and benefits of this action?

EPA has evaluated the potential impacts and associated costs and benefits of this proposed rule. The draft Economic Assessment (EA) for this action, *Economic Assessment of the Potential Costs, Benefits, and Other Impacts of the Proposed Rulemaking to List Specific PFAS as RCRA Hazardous Constituents* (Ref. 41), is available in the docket for this action. If finalized, the quantifiable direct annual social cost of this proposed rule is estimated to be negligible, as EPA anticipates no significant direct impacts (see Sections II.A. and II.D. of this preamble).

However, listing the specific PFAS as RCRA hazardous constituents may have indirect, indeterminate impacts associated with potential increases in the speed, extent, and total number of corrective action activities at certain TSDFs to address PFAS releases. Such potential increases are dependent upon subsequent actions and numerous factors, including decisions made and implemented by the permitting authority regarding associated corrective actions at certain TSDFs.

RCRA Corrective Action Program implementers already have authority to require investigation and cleanup at RCRA TSDFs for substances not identified as hazardous constituents either through state cleanup regulations, or through the authority provided by section 270.32(b)(2), EPA's omnibus authority, and authorized state analogues. In addition, cleanup at TSDFs can also be required or conducted pursuant to CERCLA, such as ongoing DOD PFAS investigations and responses under CERCLA. EPA has also proposed to designate certain PFAS as CERCLA hazardous substances (see 87 FR 54415; September 6, 2022). It is uncertain how many investigative and response actions for releases of these nine PFAS, and their salts, and structural isomers, would occur under the authority of this rule that would not have occurred absent this rule under one of these other authorities.

While there are significant uncertainties about potential indirect impacts and the precise costs and benefits associated with corrective action are nonquantifiable due to these significant uncertainties, EPA provides hypothetical scenarios for how corrective action activity costs may increase for certain TSDFs as a result of addressing PFAS contamination. EPA also considers potential indirect benefits associated with corrective action, including avoided risk exposures, improved waste management practices, and improved quality of information about PFAS cleanup efforts. Other indirect effects may be experienced as a result of hastened investigative and cleanup activities that would otherwise be implemented pursuant to RCRA or other authorities which are not predicated upon a hazardous constituent determination. The full

discussion of direct and indirect impacts is presented in the EA, which can be found in the public docket. EPA requests comment on specific aspects of the EA; see EA sections 4.3.3.1, 4.3.3.2, and 5.3.4.5. EPA also solicits comment on whether the potential impacts of this rulemaking may be affected by the availability of other authorities that program implementers might rely on to satisfy corrective action requirements to address PFAS at RCRA facilities including other RCRA authorities such as omnibus permitting authority and RCRA section 7003, and CERCLA.

III. Legal Authority

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

EPA is proposing these regulations under the authority of sections 2002(a), 3001, and 3004 of the Solid Waste Disposal Act of 1965, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended, by the Hazardous and Solid Waste Amendments of 1984 (HSWA), among other amendments, 42 U.S.C. 6912(a), 6921, and 6924. These public laws combined are commonly referred to as the “Resource Conservation and Recovery Act” (RCRA) and will be referred to as such for the remainder of this notice.

RCRA was enacted to effectively manage hazardous and solid wastes and thereby protect human health and the environment. RCRA 2002(a) provides EPA the general authority to prescribe regulations to carry out the functions of RCRA. RCRA section 3001 provides EPA with the authority to promulgate criteria for identifying and listing hazardous waste, and to identify and list hazardous wastes based on those criteria.⁶ On May 19, 1980, EPA promulgated the initial list of hazardous constituents under this authority, which serve as part of the criteria for listing hazardous wastes⁷, 40 CFR part 261, Appendix VIII. EPA has amended Appendix VIII several times to list or delete hazardous constituents. The criteria for listing substances as

⁶ RCRA section 3001(a) and (b), 42 U.S.C. 6921(a), (b).

⁷ Hazardous Waste Management System: Identification and Listing of Hazardous Waste, 45 FR 33084, May 19, 1980.

RCRA hazardous constituents on Appendix VIII are specified under 40 CFR 261.11(a)(3). The criteria state that substances will be listed on Appendix VIII “only if they have been shown in scientific studies to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms.”

The 1984 Hazardous and Solid Waste Amendments (HSWA) to RCRA expanded EPA’s authority to address releases of hazardous waste and constituents at RCRA treatment, storage, and disposal facilities. This includes section 3004(u) and (v) of RCRA, which provides for corrective action requirements at permitted facilities. Section 3004(u) authorizes EPA to promulgate standards requiring corrective action for all releases of hazardous waste and hazardous constituents from solid waste management units at permitted hazardous waste treatment, storage, or disposal facilities regardless of the time at which waste was placed in the units.⁸ Section 3004(u) further mandates that permits require financial assurance for completion of corrective action.

Section 3004(v) directed EPA to require that corrective action be taken beyond facility boundaries where necessary to protect human health and the environment unless facility owners/operators demonstrate to the Agency's satisfaction that, despite their best efforts, they were unable to obtain the necessary permission to undertake off-site corrective action. 40 CFR 264.101 essentially codifies these RCRA section 3004(u) and (v) requirements. EPA has interpreted the hazardous constituents subject to corrective action as including those constituents identified in 40 CFR part 261 Appendix VIII and 40 CFR part 264 Appendix IX, 55 FR 30798, 30809 (July 27, 1990).

A significant part of EPA’s objective in proposing to add the new constituents to Appendix VIII is to ensure that releases of those substances can be effectively and efficiently

⁸ Section 3004(u) provides that “standards promulgated under this section shall require, and a permit issued. . . by the Administrator or a State shall require, corrective action for all releases of hazardous waste or constituents from any solid waste management unit ...regardless of the time at which waste was placed in such unit.”

considered and addressed through corrective action. In addition, the principal regulatory impact of this action would be to expand the scope of constituents subject to routine consideration in the corrective action process. Therefore, EPA is relying on its authority under RCRA section 3004(u) to propose listing these PFAS as hazardous constituents for the purposes of corrective action.

B. RCRA Sections 3001 and 3004(u) Preclude Consideration of Cost in Identifying Hazardous Constituents

In RCRA section 3001, Congress directed EPA to promulgate criteria for identifying the characteristics of hazardous waste and listing hazardous waste. Cost has no bearing on whether a material is hazardous, under the ordinary meaning of the word. Consistent with this ordinary meaning, Congress directed EPA to take into account “toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics.” RCRA section 3001(a); *see also*, RCRA section 3001(b) (“such as identified carcinogens, mutagens, or teratogens”). These statutory factors focus on various hazardous characteristics. Congress did not list cost as a required or permissible factor, and none of the Congressionally-listed statutory factors encompass a consideration of costs. This reflects the Agency’s longstanding position. *See*, Hazardous Waste Management System: Identification and Listing of Hazardous Waste, 45 FR 33084, 33089, May 19, 1980. Additionally, determining whether something is “toxic” or has any of the other identified characteristics described in section 3001 does not naturally lend itself to considerations of cost — that is, whether a substance is or is not toxic is determined by examining the properties of the substance at issue.

In carrying out this statutory obligation, EPA has promulgated regulatory criteria for adding constituents to Appendix VIII. Consistent with the health- and hazard- related factors identified in section 3001(a) and (b), these criteria (“toxic, carcinogenic, mutagenic or

teratogenic effects on humans or other life forms.”), 40 CFR 261.11(a)(3), do not include cost nor does cost have any bearing or relevance on them.

EPA interprets the RCRA section 3004(u) corrective action standard-setting authority as authorizing the identification of hazardous constituents subject to corrective action. Moreover, Congress identified Appendix VIII as the source for the hazardous constituents referenced in 3004(u). *See* H.R. REP. 98-198, 98th Cong., 1st Sess., pt. 1 at 60-61 (1983), reprinted in 1984 U.S.C.C.A.N. 5576, 5619-20. (“The term ‘hazardous constituent’ as used in this provision is intended to mean those constituents listed in Appendix VIII of the RCRA regulations.”). As discussed above, cost is not a relevant consideration under the ordinary meaning of “hazardous.” Thus, as under section 3001, cost may not be considered in identifying hazardous constituents under section 3004(u).

If finalized, this rule may have indirect, indeterminate costs and benefits associated with the speed, extent, and total number of corrective action activities at certain TSDFs to address these nine PFAS, their salts, and their structural isomers. EPA has presented cost and benefit information consistent with Executive Order 12866 in the EA for this rule, but these costs and benefits do not form any part of EPA’s decision to designate these PFAS substances as hazardous constituents.

IV. Background

A. What are PFAS?

Per- and polyfluoroalkyl substances, also known as PFAS, are a class of manufactured chemicals that have been widely used in many industrial and consumer products since the 1940s, and they are still being used today. PFAS have been or are currently being manufactured for a variety of different uses, ranging from adhesives, coatings for clothes and furniture, fire-fighting foam, and other uses. PFAS have been released into the environment during the manufacturing process and from various uses in industrial, commercial, and consumer settings.

PFAS have carbon chains with fluorine atoms attached to the carbons potentially linked to functional groups. Because the carbon-fluorine bond is the strongest known single carbon bond, these chemicals do not degrade readily in the environment (Ref. 7). However, some bigger molecules where a portion of the molecule has fluorinated carbons, known as precursors, can degrade or transform into other PFAS that are known to be toxic and are potentially mobile in the subsurface environment. For example, each of the nine PFAS that are the subject of this proposed rulemaking could be present as a result of degradation of a precursor. This proposed rulemaking applies to the PFAS identified in this action regardless of whether they exist as chemical substances on their own or result from degradation of precursors. There are thousands of different PFAS (<https://comptox.epa.gov/dashboard/chemical-lists/PFASMASTER>), some of which have been more widely used and studied than others. A growing body of scientific evidence shows that exposure to certain PFAS can adversely impact human health and other living things.

B. What has been learned from PFAS toxicity studies?

Certain PFAS, such as perfluorinated alkyl acids (e.g., PFOA, PFOS), are manufactured in both acid and salt forms. In aqueous environments, such as groundwater or the digestive system of humans and other animals, the acids and salts will dissociate into the ion form. Exposure to the salts or acid form of certain PFAS have been shown to lead to similar toxicity, as it has often been the salt form used in experimental animal toxicity studies.

PFAS may also be present in products and in the environment as mixtures of linear and branched isomers, depending on the methods by which they are manufactured. Most studies do not clearly state what isomers were used, but of those that do, a mixture of linear and branched isomers was generally used. Studies generally only state the material purity, but purity does not refer to isomeric mixture. As a result, it's not currently practicable to differentiate the toxicity of the individual isomers, including the linear isomer. Therefore, any reference in this proposal to

toxicity and health effects or listing of the nine PFAS as hazardous constituents on Appendix VIII includes the acids, salts, and structural isomers of the nine PFAS.

V. Review of the Available Toxicity and Health Effects Information for PFAS

A. PFAS Identified to have Sufficient Information to be Evaluated for Appendix VIII

Listing Criteria

EPA's evaluation of the available toxicity and health effects information for PFAS focused on PFAS that have final peer reviewed assessments and those with toxicity studies supporting ongoing assessments. The toxicity and health effects assessments that EPA is relying on for this proposal are those published by EPA and the Agency for Toxic Substances and Disease Registry (ATSDR).

The EPA published a final peer reviewed toxicity and health effects assessment for PFOA and PFOS in 2016 (Ref. 9 and 14). Updated, draft toxicity and health effects assessments for PFOA and PFOS were published in 2023 as part of EPA's proposed National Primary Drinking Water Regulation for specific PFAS (Ref. 10 and 11). In 2021, EPA published a final peer reviewed toxicity and health effects assessment for PFBS (Ref. 15) and for HFPO-DA (Ref. 16). EPA published final peer reviewed toxicity and health effects assessments for PFBA in 2022 (Ref. 17) and PFHxA in 2023 (Ref. 32). EPA published a draft toxicity and health effects assessment for PFDA in 2023 and sought public comment and external peer review (Ref. 31), the final peer review report has been published (Ref. 45). EPA's ongoing toxicity and health effects assessment process for PFDA is expected to be finalized in the near future. EPA also released a draft toxicity and health effects assessment for PFHxS in 2023 and sought public comment and external peer review (Ref. 44). EPA's ongoing toxicity and health effects assessment for PFNA is in progress. ATSDR, in their 2021 Toxicological Profile for Perfluoroalkyls, reviewed toxicity information for twelve PFAS including PFOA, PFOS, PFBS, PFBA, PFHxA, PFNA, PFDA, and PFHxS (Ref. 18). In this Profile ATSDR derived toxicity values for PFOA, PFOS, PFNA, and PFHxS.

Assessments conducted by EPA, ATSDR, and information published in scientific studies support the conclusion that PFOA, PFOS, PFBS, HFPO-DA, PFBA, PFNA, PFHxS, PFDA, and PFHxA warrant a hazardous constituent designation.

It should be noted that EPA's criteria for listing a substance as a hazardous constituent on Appendix VIII under 40 CFR 261.11(a)(3) do not require a finalized toxicity assessment, or exhaustive search and evaluation of all published scientific studies for the substance, or a final toxicity value. Rather, the criteria for listing substances on Appendix VIII only require that scientific studies have shown one or more of the criteria effects for the substances (i.e., toxic, carcinogenic, mutagenic or teratogenic effects).

The Agency's evaluation has determined that more than the required scientific information showing toxic, carcinogenic, mutagenic or teratogenic effects already exists to list the selected PFAS as RCRA hazardous constituents.

B. Summary of Toxicity and Health Effects Information for the Nine PFAS

Below are brief summaries of the toxicity and adverse health effects information for the nine PFAS from the final peer reviewed assessments or toxicity studies supporting ongoing assessments. Please see the list of references and docket for this proposed rule to completely examine these assessments and studies which form the basis of EPA's proposed conclusions that these PFAS, their salts, and their structural isomers meet the criteria for listing as RCRA hazardous constituents.

Interpreting epidemiology data for PFAS and determining the individual toxicological responses of each PFAS individually (or their interaction effects) is an ongoing challenge because multiple PFAS have been shown to induce similar adverse health effects (e.g., immune, developmental, hepatic, cardiovascular effects, cancer). This is a subject where the science is rapidly evolving.

1. PFOA

Human epidemiology data report associations between PFOA exposure and high cholesterol, increased liver enzymes and serum lipid levels, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, cancer (testicular and kidney), and decreases in birth weight (Refs. 9 and 18).

Oral animal studies of short-term subchronic and chronic duration are available in multiple species including monkeys, rats, and mice. These studies report developmental effects, liver toxicity including degenerative and necrotic effects, kidney toxicity, immune effects including impaired response to antigens, and cancer (liver, testicular, and pancreatic). Developmental effects observed in animals include decreased survival, delayed eye opening and reduced ossification, skeletal defects, altered puberty (delayed vaginal opening in females and accelerated puberty in males), and altered mammary gland development (Refs. 9 and 18).

There has been consistent evidence of associations between PFOA exposure and immunosuppression including reduced response to vaccines. Epidemiology studies have looked at the effects of exposure to several PFAS. In one study (Ref. 22), large datasets have been used to mutually adjust for concomitant PFAS exposures. Epidemiological studies have associated decreased vaccine response in children with elevated levels of PFOA in sera (Refs. 19, 20, 21, 22 and 40). Epidemiological studies have also indicated an increased risk of renal cell carcinoma with PFOA exposure (Refs. 42 and 43). An association with increased risk of ulcerative colitis has also been observed. The results of several mouse studies reported findings consistent with the epidemiological data suggesting that exposure to PFOA can result in immunosuppression (Ref. 18).⁹

2. PFOS

⁹ It is important to note that in March 2023, EPA proposed a National Primary Drinking Water Regulation for certain PFAS, including PFOA and PFOS (88 FR 18638; March 29, 2023). To support this rule, EPA developed and released updated draft toxicity assessments for PFOA and PFOS for public comment, to which EPA is currently responding (Refs. 10 and 11). The draft toxicity assessments underwent external peer review through EPA's Science Advisory Board PFAS Review Panel (Ref. 12), and EPA responded to the SAB's recommendations in the updated draft toxicity assessments (Ref. 13).

Epidemiology data report associations between PFOS exposure and high cholesterol, decreased vaccination response, and altered reproductive and developmental parameters including low birth weight. The strongest associations are related to serum lipids with increased total cholesterol and high-density lipoproteins (HDLs), and there are also associations with increases in serum enzymes and decreases in serum bilirubin (Refs. 14 and 18). There is suggestive epidemiological evidence for an association between serum PFOS and pregnancy-induced hypertension and/or pre-eclampsia (Ref. 18). Data also suggest a correlation between higher PFOS levels and decreases in female fecundity and fertility, in addition to decreased body weights in offspring, and other measures of postnatal growth (Ref. 14).

There is consistent evidence of immunotoxicity after PFOS exposure. There is evidence of an association between serum PFOS levels and decreased antibody responses to vaccines in children (Ref. 18). Epidemiology studies have looked at the effects of exposure to several PFAS. In one study (Ref. 22), large datasets have been used to mutually adjust for concomitant PFAS exposures. Epidemiological studies have indicated decreased vaccine response in children associated with elevated levels of PFOS in sera (Refs. 19, 20, 21, 22 and 40). Rodent studies have also shown immunotoxicity after PFOS exposure (Ref. 18).

Short-term and chronic exposure studies in animals consistently demonstrate increases in liver weight with co-occurring effects that include decreased cholesterol, hepatic steatosis, lower body weight, and liver histopathology (Ref. 14). Some degenerative and necrotic effects that are likely relevant to humans have been observed (Ref. 18). One and two generation toxicity studies also show decreased pup survival and body weights. Additionally, developmental neurotoxicity studies show increased motor activity and decreased habituation and increased escape latency in the water maze test following in utero and lactational exposure to PFOS. Gestational and lactational exposures were also associated with higher serum glucose levels and evidence of insulin resistance in adult offspring (Ref. 14).

3. PFBS

Asthma and serum cholesterol levels in humans were found to exhibit a statistically significant positive association with PFBS exposure. No studies have been identified that evaluate the association between PFBS exposure and potential cancer outcomes (Ref. 15).

The limited number of human studies examining oral PFBS exposure does not inform the potential for effects in thyroid, developing offspring, or the renal system (Ref. 15). Animal studies of repeated-dose PFBS exposure have been exclusively via the oral route, used the potassium salt of PFBS as the source exposure material, and have examined noncancer effects only. The available rat and mouse studies support identification of thyroid, developmental, and kidney endpoints as potential health effects following repeated exposures in utero and/or during adulthood. Thyroid effects in exposed adult rats and mice and in developing mice were primarily expressed through significant decreases in circulating levels of hormones such as thyroxine and triiodothyronine. In early developmental life stages in mice (e.g., newborn), decreases in thyroid hormones were accompanied by other effects indicative of delayed maturation or reproductive development (e.g., vaginal patency and eyes opening). Kidney weight and/or histopathological alterations (e.g., renal tubular and ductal epithelial hyperplasia) were observed in rats following short-term and subchronic oral exposures. Many of the kidney effects, however, occurred at higher doses than did the thyroid and developmental effects.

Animal studies have also evaluated other health outcomes, such as liver effects, reproductive parameters, lipid/lipoprotein homeostasis, and effects on the spleen and blood; however, the evidence currently available does not support a clear association with PFBS exposure and these outcomes (Ref. 15).

4. HFPO-DA (GenX)

Most of the available data for HFPO-DA and its ammonium salt (also known as GenX chemicals) were submitted to EPA by the manufacturer (DuPont/Chemours) under the Toxic Substances Control Act (TSCA), as required by TSCA reporting requirements (15 U.S.C. 2607.8(e)) or pursuant to a consent order (Ref. 23).

Oral toxicity studies for HFPO-DA and its ammonium salt were available for acute, short-term, subchronic, and chronic durations of exposure in rats and mice. These studies reported liver effects (increased relative liver weight, hepatocellular hypertrophy, single cell necrosis and apoptosis), kidney effects (increased relative kidney weight), immune effects (antibody suppression), developmental effects (increased early deliveries and delays in genital development), and tumorigenesis (liver and pancreatic tumors) (Ref. 16). Overall, the weight of the scientific evidence indicates the liver as a sensitive target for toxicity (meaning the liver is most susceptible to the toxic effects); however, the available data are inadequate to determine the mode of action for these effects.

EPA's Office of Water followed current EPA risk assessment guidance and recommendations to select points of departure from the available animal studies for RfD derivation to support risk characterization. EPA also conducted literature searches to identify publicly available peer-reviewed hazard studies on HFPO-DA and its ammonium salt. All laboratory animal studies containing dose-response information were evaluated for study quality using an approach consistent with the Office of Research and Development's Handbook for developing IRIS assessments (Ref. 25).

EPA selected an oral reproductive/developmental toxicity study in mice (Ref. 26) showing hepatotoxicity (i.e., cytoplasmic alterations, apoptosis, single-cell necrosis, and focal necrosis) as the critical study and effect, respectively. Selection of this effect (liver toxicity) is supported by the National Toxicology Program Pathology Working Group's conclusion that the dose response for the constellation of liver lesions observed following oral exposure to HFPO-DA and its ammonium salt represents an adverse (rather than adaptive) response. The National Toxicology Program Pathology Working Group's Final Report on the Pathology Peer Review of Liver Findings is Appendix D of EPA's Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3, Ref. 16). Further support for the selection of liver toxicity as a critical effect was obtained

from additional animal studies showing similar hazard outcomes (i.e., increased liver enzyme levels, histopathological lesions, and tumors) in both male and female mice and rats following various durations and levels of exposure (Ref. 16).

5. PFNA

The available epidemiological studies suggest associations between PFNA and several health outcomes including increases in serum hepatic enzymes, particularly alanine aminotransferase (Ref. 18). Numerous studies have evaluated the hepatic toxicity of PFNA. The observed effects are consistent with effects observed for other perfluoroalkyl acids such as PFOA including alterations in serum lipid levels (Ref. 18). An epidemiological study has also indicated increased risk of renal cell carcinoma with exposure to PFNA, especially within African-Americans (Ref. 43).

Some studies have found associations between serum PFNA and diphtheria and tetanus antibody levels. Grandjean and associates found a significant inverse association between diphtheria antibodies levels at age 5 and serum PFNA levels at age 5, but not for antibody levels at age 13 and PFNA levels at age 7 or 13. Some others also reported an inverse association between serum PFNA and diphtheria antibody levels in a small study of adults. An inverse association between maternal serum PFNA and rubella antibody levels was observed in children (Refs. 19, 20, 21, 22, and 24). Timmermann et al. found each 1 ng/mL increase in serum concentrations of PFNA was associated with decreases of 39% (95 % CI: -4-64 %) in diphtheria antibody concentrations (Ref. 40).

Animal studies have also shown detrimental health effects. Two weeks after a single administration of PFNA in mice, Kielsen et al. also observed a number of immunological alterations (Ref. 24). Two acute-duration studies have evaluated the reproductive toxicity of PFNA in male rats. PFNA exposure resulted in decreases in serum testosterone and increases in serum estradiol levels and morphological changes. These changes as well as others were suggestive of damage to the secretory function of the Sertoli cells. In mice administered PFNA

for 90 days, decreases in sperm motility, viability, and count and degenerative changes in the seminiferous tubules were observed. When the mice were mated with unexposed females, significant decreases in litter size were observed (Ref. 18).

Three studies were identified that examined the developmental toxicity of PFNA in laboratory animals. Full litter resorptions were observed in mice administered PFNA, and maternal weight loss was also observed. Decreases in postnatal survival were observed. Decreases in birth weight were observed in female offspring of rats. Postnatal growth was decreased in the offspring of mice, and the decreases in body weight persisted in the pups. Reductions in nephron endowment (number of functioning nephrons at birth) were observed in male rat pups. Delays in eye opening and decrease in pup body weight gain were observed in offspring of mice administered PFNA (Ref. 18).

6. PFHxS

The available epidemiological studies suggest associations between PFHxS and several health outcomes including decreased antibody response to vaccines in humans and increases in serum lipids, particularly total cholesterol and low-density lipoprotein (LDL) cholesterol, in animals (Ref. 18). EPA has released a draft assessment for PFHxS for public comment (Ref. 44).

Epidemiology studies have looked at the effects of exposure to several PFAS. In one study (Ref. 22), large datasets have been used to mutually adjust for concomitant PFAS exposures. Epidemiological studies have indicated decreased vaccine response in children associated with elevated levels of PFHxS in sera (Refs. 19, 20, 21, 22, and 40). Inverse associations were observed between tetanus antibody levels in 5- and 7-year-old children and PFHxS levels in maternal serum and in children at age 5. A study in 3-year-old children found an inverse association between maternal PFHxS levels and rubella antibody levels, but no association with influenza type B or tetanus antibody levels. In adolescents, serum PFHxS levels were also inversely associated with rubella antibody titers in a seropositive subcohort (Ref. 18).

Timmermann et al. found each 1 ng/mL increase in serum concentrations of PFHxS was associated with decreases of 78 % (95 % CI: 25-94 %) in diphtheria antibody concentrations.

Centrilobular hepatocellular hypertrophy was observed in rodents. Microvascular fatty changes were also observed. In male mice, dietary exposure to PFHxS in a western-type diet resulted in decreases in plasma triglyceride, total cholesterol, non-HDL cholesterol, and HDL cholesterol levels and decreases in the hepatic production of VLDL. Increases in liver weight and hepatic triglyceride levels were also observed (Ref. 18).

7. PFDA

PFDA has been associated with cardiovascular disease, immunological affects, and developmental affects. In this subsection, limited human and then animal evidence for potentially related health end points are discussed together for each end point. EPA has released a draft assessment for PFDA for public comment (Ref. 31).

In a study of NHANES participants, Huang et al. (Ref. 27) found an increased risk of any type of cardiovascular disease among participants with the highest serum PFDA levels when the statistical analyses adjusted for serum total protein levels and estimated glomerular filtration rate; however, no associations were found for specific types of cardiovascular disease. Death in female mice following administration of a single lethal dose of PFDA by gavage was associated with mural thrombosis of the left ventricle of the heart. Non-lethal doses did not cause gross or microscopic alterations in the heart, assessed 30 days after dosing, but significantly decreased relative heart weight. Significant decrease in mean corpuscular hemoglobin and mean corpuscular hemoglobin concentration were observed in rats administered PFDA for 28 days (Ref. 18).

Epidemiology studies have looked at the effects of exposure to several PFAS. In one study, large datasets have been used to mutually adjust for concomitant PFAS exposures.

Epidemiological studies have indicated decreased vaccine response in children associated with

elevated levels of PFDA in sera (Refs. 19, 20, 21, 22, and 40). Inverse associations were observed between serum PFDA levels at age 5 and tetanus antibody levels at ages 5 and 7 (Ref. 19) and serum PFDA levels at age 7 and antibody levels at age 13 (Ref. 20). Similarly, diphtheria antibody levels at age 13 were inversely associated with serum PFDA levels at age 7 years (Ref. 20). In adults, diphtheria antibody levels were inversely associated with serum PFDA levels, but there was no association for tetanus antibody levels.

In case-control studies, associations between asthma diagnosis and asthma severity were observed in children; associations with serum immunoglobulin E levels, absolute eosinophil counts, and eosinophil cationic protein levels were also observed. A case-control study in adolescents found significantly higher serum PFDA levels among the asthmatic cases (Ref. 18).

Lind et al. found an inverse association between maternal PFDA levels and anogenital distance in human girls, but not in boys (Ref. 28). An increase in fetal mortality was observed in mice exposed to PFDA, and PFDA was also associated with a marked decrease in fetal weight/litter, 100% incidence of variations in ossification of the braincase, decreases in maternal body weight, and maternal mortality (Ref. 18). Decreases in fetal body weight/litter in mice also were observed (Ref. 18).

8. PFHxA

Although some human epidemiological studies have examined possible associations between PFHxA exposure and several adverse health outcomes, they are sparse and overall insufficient on their own to draw conclusions regarding adverse health effects. Based primarily on animal studies, certain PFHxA exposure levels have led to hepatic, developmental, hematopoietic, and endocrine effects (Refs. 18 and 32).

In humans, an increased risk of cardiovascular disease (any type) was found in NHANES participants with higher serum PFHxA levels. A study of 70-year-old adults reported increases in the intima media thickness in the common carotid artery that was associated with serum PFHxA levels (Ref. 18). Several studies in rats have identified the hematological system as a target of

PFHxA toxicity. Decreases in red blood cell counts, hemoglobin levels, and/or hematocrit levels and increases in reticulocyte levels have been observed in rats administered PFHxA (Refs. 18 and 32).

Increases in liver weight, decreases in serum cholesterol levels, and centrilobular hepatocellular hypertrophy have been observed in rats administered PFHxA. In a chronic-duration study, gavage administration of PFHxA for 2 years resulted in increases in the incidence of hepatocellular necrosis in female rats. Decreases in triglyceride levels were observed in male rats (Ref. 18). Thus, the hepatic findings correlated with changes in clinical chemistry and necrosis (Ref. 32).

Administration of PFHxA resulted in decreases in fetal weight in rats (Ref. 30). Similarly, decreases in pup body weight were observed in the offspring of rats administered PFHxA for 70 days prior to mating, during mating, and throughout gestation and lactation (Refs. 18 and 30).

9. PFBA

Although several human epidemiological studies have examined possible associations between PFBA exposure and several adverse health outcomes, they are sparse and overall insufficient on their own to draw conclusions regarding toxic effects. Based primarily on animal studies, developmental, thyroid, and liver effects in humans are likely caused by PFBA exposure, given sufficient exposure conditions. In human studies, increases in the risk of hypertension in men and women, which was associated with serum PFBA levels, have been found. Systolic blood pressure levels were also associated with serum PFBA levels in men and women combined or in men only; no associations were found for diastolic blood pressure (Ref. 17).

Oral doses of PFBA for 90 days resulted in significant reductions in red blood cell counts, hemoglobin, and hematocrit, and an increase in red blood cell distribution width in male rats. This dose level also caused a reduction in mean corpuscular hemoglobin and reduced mean

corpuscular hemoglobin concentration in male rats. The lower hemoglobin and hematocrit observed in males were still detected at the end of a 3-week recovery period (Ref. 18).

PFBA intermediate-duration studies have consistently found increases in liver weight and histological alterations. Dosing rats with PFBA resulted in significant increases in absolute and relative liver weight and decreases in serum cholesterol and hepatocellular hypertrophy (Ref. 17 and 18).

Thyroid effects in adult exposed rats were expressed through decreases in free and total thyroxine (T4) and increased incidence of thyroid follicular hypertrophy and hyperplasia. Developmental effects in exposed animals were expressed as the loss of viable offspring (total litter resorption), and postnatal delays in postnatal developmental milestones: eye opening, vaginal opening, and preputial separation (Ref. 17).

C. EPA's proposed conclusions on whether the nine PFAS, their salts, and their structural isomers meet the criteria for listing on appendix VIII

The Agency's proposed conclusions are that the nine PFAS, their salts, and their structural isomers meet the criteria for listing as RCRA hazardous constituents on Appendix VIII because it has been shown through scientific studies referenced above that they have toxic effects on humans or other life forms.

The nine PFAS discussed in this proposed rule 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 blood), the acid and salt forms will dissociate to the ionic form. Further, toxicity studies on PFAS were often performed using the salt form. Thus, EPA is proposing to list both acid and salt forms of the nine PFAS on Appendix VIII.

Additionally, PFAS exist as linear and branched isomers, depending on the process used to manufacture them. For example, PFAS when manufactured through electrochemical

fluorination consist of an isomeric mixture that is approximately 70% linear isomers and 30% branched isomers. The linear and branched isomers have been found in environmental media and in human sera. Most animal toxicity studies using isomeric mixtures do not state the ratio of linear and branched isomers in the test material, and, therefore, it is not feasible to distinguish the toxicity of the individual isomers. However, in a few studies, including Lieder et al. (2009) for PFBS, George and Andersen (1986) for PFDA, Bijland et al. (2011) for PFHxS, Butenhoff et al. (2004), Lau et al. (2006), and Lou et al. (2009) for PFOA, and Ankley et al. (2004) for PFOS (Refs. 33 - 39), the authors stated that the PFAS test substance was not 100% linear, and thus any effects indicated in these studies can only be associated with the isomeric mixture of linear and branched and not specifically with linear isomers or branched isomers. Further, Loveless et al. (2006) compared the toxicity of linear ammonium PFOA, branched ammonium PFOA, and a mixture of linear and branched ammonium PFOA in rodents, and demonstrated that both linear and branched isomers exhibit similar types of toxicity (Ref. 29). While toxicity studies such as these are not available for all PFAS included in this proposal, EPA believes it is both reasonable and public health protective, based on the available toxicity data for isomeric mixtures, to list the structural isomers. Thus, EPA is proposing to also list the structural isomers for the nine PFAS on Appendix VIII.

VI. State Authorization

A. Applicability of the Rule in Authorized States

Under section 3006 of RCRA, 42 U.S.C. 6926, EPA may authorize a qualified State to administer and enforce a hazardous waste program within the State in lieu of the Federal program, and to issue and enforce permits in the State. Following authorization, EPA retains enforcement authority under sections 3008, 3013, and 7003 of RCRA, although authorized States have primary enforcement responsibility. The standards and requirements for State authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The Federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities in that State, since only the State was authorized to issue RCRA permits. When new, more stringent Federal requirements were promulgated, the State was obligated to enact equivalent authorities within specified timeframes. However, the new Federal requirements did not take effect in an authorized State until the State adopted the Federal requirements.

In contrast, under RCRA section 3006(g), (42 U.S.C. 6926(g)) (which was added by HSWA), new Federal requirements and prohibitions imposed, pursuant to HSWA authority, take effect in authorized States at the same time that they take effect in unauthorized States. Although authorized States are still required to update their hazardous waste programs to remain equivalent to the Federal program, EPA is directed by the statute to implement the requirements and prohibitions in authorized States, including the issuance of new permits implementing those new requirements, until EPA authorizes the State to do so.

Authorized States are required to modify their programs only when EPA promulgates Federal requirements that are more stringent or broader in scope than existing Federal requirements. RCRA section 3009 allows the States to impose standards more stringent than those in the Federal program. *See also* 40 CFR 271.1(i). If EPA promulgates a Federal requirement that is less stringent than an existing requirement, authorized States may, but are not required to, adopt the requirement regardless of whether it is a HSWA or non-HSWA requirement.

B. Effect on State Authorization

This rule is promulgated pursuant to both non-HSWA authority (RCRA section 3001) and HSWA authority (RCRA section 3004(u)). The changes to Appendix VIII proposed in this

rule are more stringent than the current Federal requirements because adding new substances to Appendix VIII expands the list of hazardous constituents that are subject to RCRA regulatory requirements. Therefore, States will be required to adopt and seek authorization for these changes. The Appendix VIII list of hazardous constituents does not by itself impose regulatory requirements. Rather, requirements to address hazardous constituents are found in various sections throughout the Federal hazardous waste regulations.

Today's proposal, if finalized, would add nine PFAS, their salts, and their structural isomers to Appendix VIII for all purposes except corrective action, pursuant to RCRA section 3001. Today's action would also add these substances to Appendix VIII for corrective action purposes and add this listing action, as it would apply to corrective action purposes, to Table 1 in 40 CFR 271.1, pursuant to RCRA section 3004(u). Given the dual nature of today's proposal, EPA would consider the final rule to be a non-HSWA rule promulgated under RCRA 3001 for all purposes except corrective action under RCRA 3004(u) and (v), and would consider the final rule to be a HSWA rule as applied to such corrective action (for example, as applied to the scope of hazardous constituents subject to corrective action under 40 CFR 264.101, the principal regulation implementing these provisions). Thus, the addition of the nine PFAS, their salts, and their structural isomers, as applied to RCRA section 3004(u) and (v) corrective action would become immediately effective in all States on the effective date (which would be provided in any final notice for the action); and EPA would implement the new rule as applied to corrective action in all States until those States become authorized for the new rule.

States with authorized RCRA programs may already include one or more of these PFAS on their lists of hazardous constituents, since RCRA contemplates that States may promulgate regulations which are more stringent than the Federal RCRA requirements. These State regulations have not been assessed against the Federal regulations proposed today to determine whether they meet the authorization requirements. Thus, such a State would not be authorized to implement these regulations as RCRA requirements until the State program provisions are

submitted to EPA and approved, pursuant to 40 CFR 271.21. Of course, States with existing regulations that are more stringent than or broader in scope than current Federal regulations may continue to administer and enforce their regulations as a matter of State law. In implementing the HSWA corrective action requirements, EPA will work with the States under agreements to avoid duplication of effort.

VII. Statutory and Executive Order Reviews

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

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is a “significant regulatory action” as defined in Executive Order 12866, as amended by Executive Order 14094. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to Executive Order 12866 review is available in the docket. The EPA prepared an analysis of the potential impacts associated with this action. This analysis, the draft *Economic Assessment of the Potential Costs, Benefits, and Other Impacts of the Proposed Rulemaking to List Specific PFAS as RCRA Hazardous Constituents* (Ref. 41), is available in the docket for this action.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, because it does not contain any information collection activities. Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601, *et seq.* EPA projects negligible direct impacts to regulated entities associated with the proposed rule (see Sections II.A. and II.D.). To the extent the proposed rule may result in indirect costs associated with corrective action, the small entity analysis in the draft Economic Assessment identifies 75 small entities that could be impacted.

Because the proposed rule estimates negligible costs associated with direct impacts, EPA concludes the proposed rule will not result in a significant economic impact for a substantial number of small entities. Additional details of the small entity analysis, including information about the broader universe of TSDFs, are presented in the draft *Economic Assessment of the Potential Costs, Benefits, And Other Impacts of the Proposed Rulemaking to List Specific PFAS as RCRA Hazardous Constituents* (Ref. 41), available in the public docket for this action.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments because direct costs are projected to be negligible.

E. Executive Order 13132: Federalism

This action does not have federalism implications based on EPA's policy for implementing E.O. 13132, entitled "Federalism." It will not have substantial direct effects on the States or localities based on EPA's intergovernmental cost threshold for the E.O. 13132 analysis; it will not preempt State or local law or substantially affect the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications as specified in Executive Order 13175 because it does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. There is only one facility on Tribal lands that EPA has identified that could be potentially affected by this rulemaking, and because the rule is not expected to result in substantial direct impacts (i.e., EPA anticipates negligible direct impacts) it is also not expected to result in adverse impacts on this tribal entity. Thus, Executive Order 13175 does not apply to this action.

However, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, the EPA intends to consult with and request comments from the affected tribe and other tribal officials that wish to consult with the Agency on this rulemaking.

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

Executive Order 13045 (62 FR 19885, April 23, 1997) directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because it is not “economically significant” as defined in Executive Order 12866, and because it does not concern an environmental health risk or safety risk. This action, which proposes to add nine PFAS, their salts, and their structural isomers as RCRA hazardous constituents, does not itself address environmental health or safety risks. Therefore, EPA does not believe there are disproportionate risks to children.

However, EPA’s 2021 Policy on Children’s Health applies to this action, which requires EPA to consider early life exposures and lifelong health consistently and explicitly in all human

health decisions.¹⁰ To the extent that the proposed rulemaking leads to the remediation of select PFAS, potential exposure to these PFAS is expected to be reduced for the population living in close proximity to these sites, including susceptible subpopulations such as workers and children. Additionally, to the extent that the proposed rule reduces exposure, a reduction in the risks of adverse health effects in children might be expected, as well as associated health care cost savings. The information that EPA used to evaluate the toxicity and health effects of these PFAS, which includes many studies that looked at effects during development and on children, is described above in the Section Summary of toxicity and health effects information for the nine PFAS and the supporting documents in the public docket for this action.

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

This action is not a “significant energy action” because it is not related to, or likely to have a significant adverse effect on, the supply, distribution, or use of energy. This action proposes to add nine PFAS, their salts, and structural isomers as RCRA hazardous constituents, and thus, does not involve the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations; Executive Order 14096: Revitalizing Our Nation’s Commitment to Environmental Justice for All

¹⁰ <https://www.epa.gov/system/files/documents/2021-10/2021-policy-on-childrens-health.pdf>.

Executive Order 14096 (88 FR 25251, Apr. 26, 2023) directs Federal agencies to advance the goal of environmental justice for all. This action builds upon and supplements the efforts of Executive Order 12898 (59 FR 7629, February 16, 1994) to address environmental justice.

The EPA believes that the human health or environmental conditions that exist prior to this action may result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with environmental justice concerns.

Several key demographic categories were analyzed relative to the universe of facilities potentially affected by the proposed rule. This proposed regulation identifies groundwater and surface water as potential sources of exposure for the identified PFAS. Due to uncertainty surrounding the location of PFAS releases, this analysis additionally considers a subset of the total universe of facilities which are associated with a potentially higher likelihood of handling PFAS, and where corrective action for PFAS may occur. These facilities are identified based on:

- A list of NAICS codes (at the 6-digit level) used by Salvatore et al. (2022) for identifying presumptive PFAS contamination across the U.S.¹¹
- EPA's proposed rule, 'Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances', identified industries (at the 6-digit NAICS level) historically associated with PFAS; therefore, TSDFs in these industries are also assumed to have higher likelihood of handling PFAS.
- The PFAS Analytical Tools page in EPA's Enforcement and Compliance History Online (ECHO) includes a list of industry sectors potentially associated with PFAS, defined by 6-digit NAICS.¹² Any permitted TSDFs within these industries are also assumed to have a higher likelihood of handling PFAS.

¹¹ See Salvatore et al., "Presumptive Contamination: A New Approach to PFAS Contamination Based on Likely Sources", *Environ Sci Technol Lett.* Vol. 9, Issue 11. November 8, 2022. Accessed at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9648201/>

¹² See United States Environmental Protection Agency, PFAS Analytical Tools, available at <https://echo.epa.gov/trends/pfas-tools>.

- If a TSDF in the regulatory universe reported any of the specific PFAS proposed for addition to 40 CFR part 261, Appendix VIII in the EPA’s Toxic Release Inventory (TRI),¹³ that facility is also assumed to have a higher likelihood of handling PFAS.

The sites identified as having potential association with PFAS make them a reasonable proxy for identifying where corrective action for these substances may be required and offer an associated surrounding demographic context. However, the spatial distribution and predicted risk factor of a PFAS release cannot be certain without further site-specific investigation into a facility’s waste handling capacity, proximity to population centers, and interconnectivity of local environmental resources.

The EPA believes that this action may indirectly reduce existing disproportionate and adverse effects on communities with environmental justice concerns. To the extent that the proposed rule leads to the remediation of releases for any of the nine PFAS, their salts, and their structural isomers that EPA proposes to list as RCRA hazardous constituents, health risks for populations living in close proximity to these sites (particularly populations that rely on private well water near these sites) may decline. As groundwater and surface water have been identified as potential exposure pathways of PFAS, the inclusion of private well usage rates in areas surrounding facilities known to use, produce, or release PFAS provides additional information about populations that may have a potentially higher likelihood of negative health outcomes from a PFAS release. In some cases, focusing the analysis solely on those potentially more vulnerable populations served by private wells reveals further demographic disparities compared to the total U.S. population served by private wells.

Details of the full analysis and findings are presented in the draft *Economic Assessment of the Potential Costs, Benefits, and Other Impacts of the Proposed Rulemaking to List Specific*

¹³ PFAS chemicals included in search: PFOS, PFOA, PFBS, HFPO-DA (GenX), PFNA, PFHxS, PFDA, PFHxA, and PFBA. Environmental Protection Agency, “Envirofacts: TRI Search”, December 2022. Accessed at: <https://www.epa.gov/enviro/tri-search>.

PFAS as RCRA Hazardous Constituents (Ref. 41), which can be found in the public docket for this action.

Better understanding the impacts of a PFAS release and the factors that determine the magnitude of effects on the surrounding human and natural environment will potentially become more apparent over time, allowing for improved information and a more robust analysis on any disproportionate and adverse outcomes experienced by populations with EJ concerns. This improved information would not increase risk for communities with EJ concerns and may improve the speed and design of remediation. The EPA is committed to minimizing and/or eliminating existing barriers and burdens that communities with EJ concerns may encounter related to accessing data and information associated with this rulemaking, if finalized. EPA seeks comment on strategies to improve access to associated data, which may become available in RCRA Info, for communities with environmental justice concerns.

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List of Subjects

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 271

Administrative practice and procedure, Confidential business information, Environmental protection, Hazardous materials transportation, Hazardous waste, Indians-lands, Intergovernmental relations, penalties, and Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons set out in the preamble, EPA proposes to amend title 40, chapter I of the Code of Federal Regulations as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

2. Appendix VIII to Part 261 is amended by adding in alphabetical order the following entries:

Appendix VIII to Part 261 – Hazardous Constituents

* * * * *

Common name	Chemical abstracts name	Chemical abstracts No.	Hazardous waste No.
HFPO-DA	Hexafluoropropylene oxide-dimer acid	13252-13-6	
HFPO-DA salts and enantiomers			
PFBA	Perfluorobutanoic acid	375-22-4	
PFBA salts and structural isomers			
PFBS	Perfluorobutanesulfonic acid	375-73-5	
PFBS salts and structural isomers			
PFDA	Perfluorodecanoic acid	335-76-2	
PFDA salts and structural isomers			
PFHxA	Perfluorohexanoic acid	307-24-4	
PFHxA salts and structural isomers			
PFHxS	Perfluorohexanesulfonic acid	355-46-4	
PFHxS salts and structural isomers			
PFNA	Perfluorononanoic acid	375-95-1	
PFNA salts and structural isomers			
PFOA	Perfluorooctanoic acid	335-67-1	
PFOA salts and structural isomers			
PFOS	Perfluorooctanesulfonic acid	1763-23-1	
PFOS salts and structural isomers			

PART 271—REQUIREMENTS FOR AUTHORIZATION OF STATE HAZARDOUS WASTE PROGRAMS

3. The authority citation for Part 271 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6926, and 6939g.

4. Section 271.1(j) is amended by adding the following entry to Table 1 in chronological order by date of publication to read as follows.

§ 271.1 Purpose and scope.

* * * * *

(j) * * *

Table 1.—Regulations Implementing the Hazardous and Solid Waste Amendments of 1984

Promulgation date	Title of regulation	Federal Register reference	Effective date
* * * * *			
[DATE OF PUBLICATION OF FINAL RULE]	Listing of certain PFAS ⁶	[FEDERAL REGISTER PAGE NUMBERS FOR FINAL RULE]	[EFFECTIVE DATE OF FINAL RULE]
* * * * *			

⁶ This listing implements HSWA only to the extent it applies to 40 CFR 264.101 and 270.14(d) and to 40 CFR Subpart S.