

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 302

[EPA-HQ-OLEM-2019-0341; FRL-10019-13-OLEM]

RIN 2050-AH09

Addressing PFOA and PFOS in the Environment: Potential Future Regulation Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is seeking comment on whether the Agency should consider using authorities other than those we have already used and, if so, what other authorities it might seek to exercise through rulemaking, to address environmental contamination by perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), including their salts and structural isomers. The Agency is seeking comments and data to assist in the consideration of potential development of future regulations pertaining to PFOA and PFOS under CERCLA and RCRA.

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

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

- *Federal eRulemaking Portal:* <https://www.regulations.gov/> (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:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

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. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via <https://www.regulations.gov/> or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. 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: For questions concerning this ANPRM, contact Michelle Schutz, Environmental Protection Agency, Office of Superfund Remediation and Technology Innovation, 1200 Pennsylvania Avenue NW, MC: 5204P, Washington, DC 20460; email address: Schutz.Michelle@epa.gov. For more information on this advance notice of proposed rulemaking please visit <https://www.epa.gov/pfas>.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Docket

EPA has established a docket for this action under Docket ID No. EPA-HQ-OLEM-2019-0341. All documents in the docket are listed in the <https://www.regulations.gov> index. Publicly available docket materials are available electronically at <https://www.regulations.gov>. EPA has temporarily suspended its Docket Center and Reading Room for public visitors, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via <https://www.regulations.gov/> as there may be a delay in processing mail and faxes. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at <https://www.epa.gov/dockets>.

B. Written comments

Submit your comments, identified by Docket ID No. EPA-HQ-OLEM-2019-0341, at <https://www.regulations.gov> (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) 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 CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

C. Submitting CBI

Do not submit information that you consider to be CBI electronically through <https://www.regulations.gov> or email. Send or deliver information identified as CBI to only the following address: OSRTI Document Control Officer, Mail Code 5204P, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; Attn: Docket ID No. EPA-HQ-OLEM-2019-0341.

Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD-ROM or disk that does not contain CBI, mark the outside of the disk or CD-ROM clearly that it does not contain CBI. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

II. General Information

A. Does this action apply to me?

Perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) are synthetic compounds that are resistant to environmental degradation and thus highly persistent in the

environment. They are part of a class of compounds known as per- and polyfluoroalkyl substances (PFAS). Since the 1940s, they have been used in hundreds of industrial applications, such as fire-fighting foam and metal plating, and consumer products such as carpeting, apparel, upholstery and food contact materials. Due to these widespread uses, PFAS have been detected in many media, including drinking water, ground water, landfill leachate, wastewater effluent, and dust.

Since EPA issued the PFAS Action Plan¹ on February 19, 2019, and annual plan update,² EPA has continued to act to address PFAS contamination in the environment. EPA has used its existing authorities (under the Safe Drinking Water Act, 42 U.S.C. 300f et seq., and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9601 et seq.) to address the occurrence of PFAS contamination. Since the issuance of the PFAS Action Plan, EPA has released and implemented the December 19, 2019 “Interim Recommendations for Addressing Groundwater Contaminated with Perfluorooctanoic Acid and Perfluorooctanesulfonate.” This guidance was based on the same health-based reference doses used to establish the 2016 EPA Health Advisories for PFOA and PFOS in drinking water. As of June 11, 2020, EPA identified 233 private and federal facility National Priorities List (NPL) sites with confirmed PFAS detections in ground water. Sampling results exceeded EPA’s health advisories of 70 ppt for PFOA and PFOS at 47 sites (15 private sites and 32 Federal Facility sites). For all of these instances where sources of drinking water exceeded EPA’s health advisory for PFOA or PFAS, either EPA or others have provided alternate drinking water supplies.

In the PFAS Action Plan, EPA reported that it was initiating the regulatory development process for designating PFOA and PFOS as hazardous substances. That work was initiated.

¹ http://www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf

² https://www.epa.gov/sites/production/files/2020-01/documents/pfas_action_plan_feb2020.pdf

However, in light of EPA’s success and experience in addressing PFAS in drinking water at levels above EPA’s current health advisory, EPA is reconsidering whether it should take any additional regulatory steps such as proposing to designate PFOA and PFOS as hazardous substances and, if so, what additional or alternate regulatory steps or authorities would be best suited and could be most appropriately tailored to address PFAS contamination in the environment. This notice seeks comment on the potential need for other regulatory steps and the benefits and the costs associated with such steps.

For example, if EPA decides to propose and finalizes a rulemaking to designate PFOA and PFOS, including their salts and structural isomers³, under CERCLA section 102(a), they will become hazardous substances for purposes of CERCLA section 101(14) (defining “hazardous substances”). If such a hazardous substance designation was made, it may affect the following: any person in charge of a vessel or an offshore or an onshore facility required under CERCLA section 103(a) to provide notification about a release; the owner and operator of a vessel or facility; 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; any person who by contract, agreement, or otherwise arranged for disposal or treatment, or arranged with a transporter with 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 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 or hazardous substance.

³ A list of PFOA and PFOS’ salts and structural isomers is available in the docket for the ANPRM.

Five broad categories of entities potentially affected if EPA proposes and finalizes a rulemaking to designate PFOA and PFOS, including their salts and structural isomers, as CERCLA hazardous substances include: (1) PFOA and PFOS manufacturers; (2) PFOA and PFOS processors; (3) manufacturers of products containing PFOA and PFOS; (4) downstream product manufacturers and users of PFOA and PFOS products; and (5) waste management and wastewater facilities. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include and are not limited to:

- Aviation operations (NAICS code 488119);
- Carpet manufacturers (NAICS code 314110)
- Car washes (NAICS code 811192);
- Chrome electroplating, anodizing, and etching services (NAICS code 322813);
- Coatings, paints, and varnish manufacturers (NAICS code 325510);
- Fire-fighting foam manufacturers (NAICS code 325998);
- Landfills (NAICS code 562212);
- Municipal fire departments and firefighting training centers (NAICS code 922160);
- Paper mills (NAICS codes 322121 and 322130);
- Petroleum refineries and terminals (NAICS codes 324110 and 424710);
- Photographic film manufacturers (NAICS code 352992);
- Polish, wax, and cleaning product manufacturers (NAICS code 325612);
- Polymer manufacturers (NAICS code 325211);

- Printing facilities where inks are used in photolithography (NAICS codes 323111 and 325910);
- Textile mills (textiles and upholstery) (NAICS codes 313210, 313220, 313230, 313240, and 313320);
- Wastewater treatment plants (NAICS code 221320).

If you have any questions regarding the applicability of such a potential rule to a particular entity, consult the EPA contacts listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the purpose of this notice?

EPA is seeking comments and data on potential options for addressing PFAS in the environment beyond its current authorities. EPA is seeking comments and data relevant to whether EPA should consider proposing to designate as hazardous substances under section 102(a) of CERCLA, PFOA and PFOS, including their salts and structural isomers, to assist in the potential development of future regulations pertaining to this designation, including the scope of impacts (benefits and costs) related to such an action. EPA is also seeking comments and data relevant to evaluating the nature and extent of potential sources of wastes containing PFOA and PFOS, as part of any scoping effort on listing particular wastes or chemicals as hazardous waste under subtitle C of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901 et seq.

By this notice, EPA is seeking public input on key issues at this preliminary stage to inform its thinking on any future proposed rulemaking. EPA is not reopening or otherwise proposing to modify any existing regulations through this ANPRM.

III. Background

In February 2019, the Agency published its PFAS Action Plan (www.epa.gov/pfas) announcing four actions it would take, including beginning the necessary steps to propose designating PFOA and PFOS as “hazardous substances” through one of the available statutory mechanisms identified in CERCLA. The Agency is requesting information through this ANPRM before determining whether to develop a proposed rule designating PFOA and PFOS as hazardous substances.

CERCLA establishes broad federal authority to respond to releases or substantial threats of releases of hazardous substances into the environment, or to releases or substantial threats of releases into the environment of any pollutant or contaminant, which may present an imminent and substantial danger to the public health and welfare. The term “hazardous substance” is defined in section 101(14) of CERCLA primarily by reference to other environmental statutes.

The EPA Administrator is authorized under CERCLA section 102(a) to promulgate regulations designating as a hazardous substance any elements, compounds, mixtures, solutions, or substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. Because EPA has not previously promulgated a regulation pursuant to its authority under CERCLA section 102(a), it has not had occasion prior to this action to express its view on the standard for designating hazardous substances. Consequently, the Agency is explaining its current interpretation of the authority under CERCLA 102(a) in this notice and is requesting comment on this interpretation.

EPA currently views its CERCLA 102(a) authority as follows. EPA interprets “may present” in the statutory language as indicating that Congress did not require certainty that the substance presents a substantial danger or require proof of actual harm. This is consistent with

EPA's reading of "may" in other similar provisions discussed below. EPA interprets the phrase "substantial danger" as requiring EPA to find that the substance, when released, may be significantly harmful in the degree of danger posed, regional or national in geographic scope, and more than fleeting in terms of time. To satisfy this standard, EPA's current interpretation of CERCLA section 102(a) would require the Agency to have a significant level of evidence that when released into the environment, PFOA and PFOS may present a substantial danger to the public health or welfare or the environment. Information that is best characterized as inconclusive, anecdotal or speculative would not be sufficient.

EPA currently interprets the text of CERCLA section 102(a) in this manner because of the nature of designation actions under this provision. The scope of CERCLA section 102(a) is not limited to any specific facility, person or event. Rather, it has a broad scope of applicability, which means that the designation process requires a comprehensive assessment of any candidate element, compound, mixture, solution, or substance based on, for example, information from a wide range of sources that could include local, tribal, state, federal and international governments, as well as academia and the private sector.

Other provisions of CERCLA contain similar, but not identical language and have been interpreted to require a lesser showing than that required by EPA's current interpretation of CERCLA section 102(a). Those provisions include:

- CERCLA section 101(24) defines "remedy" and "remedial action" as "those actions consistent with permanent remedy taken instead of or in addition to removal actions in the event of a release or threatened release of a hazardous substance into the environment, to prevent or minimize the release of hazardous substances so that they do not migrate to cause substantial danger to present or future public health or welfare or the environment." 42 U.S.C. 9601(24).

- CERCLA section 104 authorizes the government to take a response action “[w]henever . . . 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.” 42 U.S.C. 9604(a)(1)(B).

- CERCLA section 105 directs the national contingency plan to include “methods for evaluating, including analyses of relative cost, and remedying any releases or threats of releases from facilities which pose substantial danger to the public health or the environment.” 42 U.S.C. 9605(a)(2).

- CERCLA section 106 allows the federal government to seek judicial enforcement when “there may be an imminent and substantial endangerment to the public health or welfare or the environment because of an actual or threatened release of a hazardous substance from a facility.” 42 U.S.C. 9606(a).

- CERCLA section 128 allows the federal government to bring an enforcement action where a response action is being or was conducted in compliance with certain state programs if, among other things, “a release or threatened release may present an imminent and substantial endangerment to public health or welfare or the environment.” 42 U.S.C. 9628(b)(1)(B)(iii)(I).

The Agency’s current reading of CERCLA section 102(a) described in this notice is based on the specific language and purpose of section 102(a), and would not affect EPA’s interpretations of these other provisions. Indeed, the Supreme Court has held that statutory terms, even those that are defined in the statute, “may take on distinct characters from association with distinct statutory objects calling for different implementation strategies.” *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 320 (2014) (quoting *Environmental Defense v. Duke Energy Corp.*, 549 U.S. 561, 574 (2007)). See also *Idaho Conservation League v. Wheeler*, 930 F.3d 494, 503

(D.C. Cir. 2019) (quoting *Weaver v. U.S. Info. Agency*, 87 F.3d 1429, 1437 (D.C. Cir. 1996) (“[i]dentical words may have different meanings where ‘the subject-matter to which the words refer is not the same in the several places where they are used, or the conditions are different.’”). The other CERCLA provisions containing similar language are associated with different statutory objectives than EPA’s current understanding of CERCLA section 102(a). Those other provisions concern enforcement and response actions and apply to and require analyses of narrow, site-specific circumstances relevant to a particular facility or person, and to a specific event. As a result, the Agency conducts an assessment of the particular situation at each site when it invokes those other authorities. By contrast, under this interpretation, the statutory objectives associated with designating hazardous substances under CERCLA section 102(a) require a different implementation strategy because of its broad, national applicability and similarly broad, national analytical requirements.

The Resource Conservation and Recovery Act (RCRA) (42 U.S.C. 6901 *et seq.*) also contains provisions with similar language:

- RCRA section 7002 permits citizen suits “against any person . . . who has contributed or who is contributing to the past or present handling, storage, treatment, transportation, or disposal of any solid or hazardous waste which may present an imminent and substantial endangerment to health or the environment.” 42 U.S.C. 6972(a)(1)(B).

- RCRA section 7003 allows EPA to bring suit regarding the “handling, storage, treatment, transportation or disposal of any solid waste or hazardous waste [that] may present an imminent and substantial endangerment to health or the environment.” 42 U.S.C. 6973(a).

- RCRA 9003 permits EPA to take corrective action at an underground storage tank “where immediate action is necessary to respond to an imminent and substantial endangerment to human health or the environment.” 42 U.S.C. 9661b(h)(7)(B), (h)(11).

As with the similar CERCLA provisions, those RCRA provisions relate to site-specific enforcement and corrective action unlike EPA’s current reading of CERCLA section 102(a), which applies broadly and requires a national analysis. While the other similar provisions provide authority to undertake important actions, they are all limited in scope to site-specific situations unlike the national applicability of designations under CERCLA section 102(a). As a result, the thresholds for triggering these provisions differ despite the similarities in language.

EPA requests comment on this interpretation of CERCLA section 102(a).

Designation as a CERCLA hazardous substance can result in a reporting obligation if there is a release in an amount equal to or greater than the reportable quantity (RQ) for that substance within a 24-hour period. In addition, when federal agencies sell or transfer real property to any other person or entity, they must provide notice of the presence of hazardous substances in certain circumstances as required by CERCLA section 120(h).

Section 102(a) of CERCLA authorizes EPA to promulgate regulations establishing the RQ for any hazardous substance. Section 102(b) of CERCLA provides that, unless and until superseded by regulations, the RQ for any hazardous substance is one pound. Furthermore, if EPA later decides to propose to designate PFOA and PFOS as hazardous substances, the Agency recognizes that questions may arise about potential liability or enforcement. While such issues are speculative at this preliminary data collection point, EPA requests comments regarding such issues.

IV. What information is EPA seeking?

A. Addressing PFOA and PFOS in the environment

In this action, EPA is seeking additional information related to comprehensively exploring whether perfluorooctanoic acid (PFOA), CASRN 335-67-1 and perfluorooctanesulfonic acid (PFOS), CASRN 1763-23-1 present a substantial danger to human health, welfare or the environment that would warrant the designation of one or both of these substances as a CERCLA hazardous substance (or substances, as the case may be), to better inform a possible future rulemaking. The Agency is seeking input on the toxicity or hazard profile, chemical and physical properties, degradation kinetics, environmental prevalence, manufacturing and use, and regulatory and advisory statutes of PFOA and PFOS. This includes the salts (ammonium, sodium, potassium, etc.) and structural isomers of PFOA and PFOS. In particular, EPA is seeking the following information:

- Is the scientific understanding of the chemical and physical characteristics, toxicity and kinetics, food chain accumulation and mobility, manufacturing and use, and regulatory status at other federal agencies and states for PFOA and PFOS sufficiently documented in published scientific literature to enable EPA to make determinations regarding potential designation as a hazardous substance? If so, please provide supporting information and scientific literature citations.
- Please provide any information available to you that EPA should consider regarding the benefits and costs of a CERCLA hazardous substance designation for any of the above-mentioned compounds. Please provide specific citations and, if possible, any data for the applicable information.

- Which of the authorities listed in this draft ANPRM would be best suited for regulating PFAS in the immediate term and/or longer term? Please provide information in support of any recommended authorities and/or sequencing of authorities.

B. Addressing other PFAS found in the environment

The Agency recognizes that other PFAS have been found in the environment and may have properties similar to those of PFOA and PFOS including similar toxicity, physical and chemical properties, and resistance to degradation. The Agency is also soliciting specific information on the below listed PFAS and any other PFAS where similar information may be available with regards to toxicity, chemical and physical properties, degradation kinetics, environmental prevalence, manufacturing and use, and regulatory and advisory statuses. The following list is based on PFAS that have been found at Superfund National Priorities List sites; have information (such as noted above with respect to PFOA and PFOS); or are of potential interest to the Superfund program:

- Perfluorotetradecanoic acid (PFTetDA) CASRN 376-06-7
- Perfluorotridecanoic acid (PFTriDA) CASRN 72629-94-8
- Perfluorododecanoic acid (PFDoDA) CASRN 307-55-1
- Perfluoroundecanoic acid (PFUDA) CASRN 2058-94-8
- Perfluorodecanoic acid (PFDA) CASRN 335-76-2
- Perfluorononanoic acid (PFNA) CASRN 375-95-1
- Perfluoroheptanoic acid (PFHpA) CASRN 375-85-9
- Perfluorohexanoic acid (PFHxA) CASRN 307-24-4
- Perfluoropentanoic acid (PFPeA) CASRN 2706-90-3

- Perfluorobutanoic acid (PFBA) CASRN 375-22-4
- Perfluorodecanesulfonic acid (PFDS) CASRN 335-77-3
- Perfluorononanesulfonic acid (PFNS) CASRN 68259-12-1
- Perfluoroheptanesulfonic acid (PFHpS) CASRN 375-92-8
- Perfluorohexanesulfonic acid (PFHxS) CASRN 355-46-4
- Perfluoropentanesulfonic acid (PFPeS) CASRN 2706-91-4
- Perfluorobutanesulfonic acid (PFBS) CASRN 375-73-5
- Perfluorooctanesulfonamide (PFOSA) CASRN 754-91-6
- 2-(N-Ethylperfluorooctanesulfonamido)acetic acid (NEtFOSAA) CASRN 2991-50-6
- 2-(N-Methylperfluorooctanesulfonamido)acetic acid (NMeFOSAA) CASRN 2355-31-9
- Perfluoro(2-methyl-3-oxahexanoic) acid (HFPO-DA, commonly known as GenX) CASRN 13252-13-6
- Fluorotelomer sulphonic acid 8:2 (FtS 8:2) CASRN 39108-34-4
- Fluorotelomer sulphonic acid 6:2 (FtS 6:2) CASRN 27619-97-2
- Fluorotelomer sulphonic acid 4:2 (FtS 4:2) CASRN 757124-72-4

In particular, EPA is seeking the following information:

- Is the scientific understanding of the chemical and physical characteristics, toxicity and kinetics, food chain accumulation and mobility, manufacturing and use, and regulatory status at other federal agencies and states for any of the PFAS mentioned above or others not mentioned sufficiently documented in published scientific literature to enable EPA to make determinations regarding potential designation as a hazardous substance? If so, please provide supporting information and scientific literature citations.
- Please provide information about situations not described in this notice in which PFOA or PFOS contamination may be a concern. This may include additional affected entities and alternative authorities to use.
- Please provide any information available to you that EPA should consider regarding the benefits and costs of a hazardous substance designation for any of the above-mentioned compounds. Please provide specific citations for the applicable information.
- Please provide the above requested information on any additional PFAS the Agency should consider through this ANPRM.
- In considering other PFAS that might be appropriate to propose designating as hazardous substances, the EPA would be interested in information that would support designating groups, categories, or classes of PFAS. This could include homologs, those with the same chain length, or similar functional groups. For example, would certain structural similarities, or other characteristics provide scientific support for such an approach?

The Agency is also soliciting input regarding any information that will assist in comprehensively studying, and (if determined to be appropriate) identifying compounds that degrade in the environment by processes such as biodegradation, photolysis, and hydrolysis to form PFOA and/or PFOS. For clarification purposes, this request is not related to other terminal PFAS compounds that are not precursors of PFOA and PFOS, such as HFPO-DA or PFNA, but rather, is related to compounds such as certain fluorotelomer alcohols that will degrade to form PFOA or PFOS. EPA is soliciting input on the following topics:

- Is the scientific understanding of the degradation mechanisms of PFOA and PFOS precursors sufficiently developed and documented in published literature for EPA to make hazardous substance determinations regarding respective potential precursor compounds? If so, for which precursors is there a sufficient understanding of the degradation mechanisms?
- What factors, if any, regarding degradation time and environmental conditions (e.g., aqueous vs. arid, anaerobic vs. aerobic, available nutrients) should be considered in choosing the appropriate precursor compounds that could be proposed to be designated as hazardous substances?
- With respect to the preceding questions, EPA is requesting public input on the identification of specific names and Chemical Abstracts Service Registry Numbers (CASRN) of possible PFOA and PFOS precursor compounds.
- Given that standard analytical chemistry methods and commercially available chemical standards may not exist for measuring PFOA and PFOS precursors, how might PFOA and PFOS precursors be identified and quantitatively measured in environmental samples?

C. Reportable Quantity (RQ)

Under CERCLA, a hazardous substance is assigned an RQ. This is a level at which the federal government should be notified if a release of that substance occurs in the environment within a 24-hour period. Pursuant to CERCLA section 103, persons in charge of vessels or facilities must immediately report to the National Response Center releases of hazardous substances in an amount that meets or exceeds the RQ within a 24-hour period. Under section 102(a), EPA has authority to promulgate regulations establishing the RQ of a hazardous substance. Under CERCLA section 102(b), Congress established an initial RQ of one pound for any hazardous substance, until superseded by regulation.

In establishing RQs, EPA has evaluated the properties of hazardous substances (other than radionuclides) in a two-step process (48 FR 23561, May 25, 1983; 50 FR 13465-70, April 4, 1985):

Step 1: Primary Criteria

RQ adjustment begins with an evaluation of the intrinsic physical, chemical, and toxicological properties of each substance. These intrinsic properties called "primary criteria" are:

- Aquatic toxicity,
- Acute mammalian toxicity (oral, dermal, and inhalation),
- Ignitability,
- Reactivity,
- Chronic toxicity, and
- Potential carcinogenicity.

EPA ranks hazardous substances for each intrinsic property (except potential carcinogenicity) on a five-tier scale, associating a specific range of values on each scale with a particular RQ value, from one to 5,000 pounds. For hazardous substances evaluated for potential carcinogenicity, each substance is assigned a hazard ranking of "high," "medium," or "low," corresponding to RQ levels of 1, 10, and 100 pounds, respectively. Each substance receives several tentative RQ values based on its particular intrinsic properties. The lowest of all the tentative RQs becomes the "primary criteria RQ" for that substance.

Step 2: Secondary Criteria

After the primary criteria RQs are assigned, substances are further evaluated for their susceptibility to certain degradative processes, which are used as secondary adjustment criteria.

These natural degradative processes are:

- Biodegradation,
- Hydrolysis, and
- Photolysis (BHP).

In general, if a hazardous substance degrades relatively rapidly in the environment to a less hazardous form by one or more of the BHP processes, its primary criteria RQ is raised one level (e.g., from 1 lb to 10 lbs.). Conversely, if a hazardous substance degrades to a more hazardous product after its release, the original substance is assigned an RQ equal to the RQ for the more hazardous substance.

As such, EPA requests the following:

- Information (i.e., peer-reviewed scientific studies, research or monitoring data) for EPA to use in determining the appropriate RQ for PFOS, PFOA, and their salts and structural isomers based on the application of the RQ methodology.

D. RCRA Hazardous Waste Listing for PFOA and PFOS

Apart from EPA's authority to designate hazardous substances under section 102(a), CERCLA defines "hazardous substance" by referencing lists of substances established by other statutes. 42 U.S.C. 9601(14) including "any hazardous waste having the characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act" (also referred to as RCRA). Consequently, another possible approach for addressing PFOA and PFOS in the environment is one in which EPA lists particular wastes or chemicals as hazardous waste under RCRA subtitle C. Wastes listed as hazardous waste under RCRA become subject to the RCRA regulations - a "cradle-to-grave" management system from the point of generation through transportation to treatment and disposal at a RCRA facility. RCRA treatment, storage, and disposal facilities are subject to permits and corrective action.

EPA generally lists as hazardous waste either individual chemicals⁴ or wastes containing certain chemicals⁵ when they can be shown to "pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed." RCRA section 1004(5)(B), 42 U.S.C. 6903(5)(B). Therefore, apart from acutely hazardous waste⁶, EPA lists wastes as hazardous under the RCRA regulations based on

⁴ Individual chemicals listed as hazardous waste include discarded commercial chemical products (CCPs) that are unused product formulations where the listed chemical is the sole active ingredient. *See e.g.*, 40 CFR 261.33(f).

⁵ *See* 40 CFR 261.31 and 261.32, which list wastes from non-specific and specific sources, respectively. These listings are most often based on the presence of one or more hazardous constituents listed in 40 CFR part 261, Appendix VIII.

⁶ Acutely hazardous wastes are wastes or chemical constituents that are so toxic or so hazardous that they present an acute risk irrespective of how they are managed. *See* RCRA section 1004(5)(A) and 40 CFR 261.11(a)(2); also 40 CFR 261.33(e).

the criteria set out in 40 CFR 261.11(a)(3). Under this approach, EPA assesses these criteria through the use of risk assessments, as well as a consideration of other relevant factors. Most of the listing criteria are incorporated directly into the risk assessment, which EPA undertakes based on information it collects or otherwise obtains about the wastes being evaluated and how they are managed. Such information includes the toxicity and concentrations of chemical constituents of concern present in waste, waste quantities, the potential of chemical constituents in the waste to migrate in the environment, persistence, degradation, and bioaccumulation of the chemical constituents and any degradation products. How the waste is “otherwise managed” (from RCRA 1004(5)(B) and also 40 CFR 261.11(a)(3)), sometimes referred to as “plausible mismanagement” is also an important consideration. For example, for a new hazardous waste listing, EPA has typically focused its risk assessment modeling on existing waste management practices. EPA will also consider damage cases in its regulatory listing evaluation, where information exists that prior management of the waste under review has resulted in environmental harm. Regulatory actions by other agencies or programs are also considered when selecting which mismanagement scenarios to evaluate; for example, if a particular waste management practice is effectively prohibited by another federal statute or regulation, EPA may choose not to evaluate risks from that waste management practice as it is already prohibited.

EPA takes the resultant risk estimates and either issues a proposed rule to list the waste being evaluated or takes no further action if the data does not support listing. The Agency typically uses a “weight-of-evidence” approach in which calculated risk information is a key factor considered in making a listing decision. EPA is required to evaluate each of the listing criteria and considers estimates of risk posed by wastes containing chemical constituents that cause cancer (carcinogens), and chemical constituents that are non-carcinogens. EPA uses as an

initial level of concern one case in 100,000 for carcinogens, and/or a hazard quotient (HQ) of 1 for non-cancer health effects.⁷ A fuller explanation of EPA's approach to hazardous waste listing and risk is presented in the preamble to a proposed rulemaking from 1994.⁸ After reviewing public comment, EPA issues a final listing decision.

EPA would need to evaluate the nature and extent of potential sources of wastes containing PFOA and PFOS constituents, as part of any scoping effort on hazardous waste listing.⁹ Industrial, commercial, and municipal solid waste are all potential sources that contain these constituents. Wastes generated during site cleanups are also potential sources. When considering RCRA's "cradle-to-grave" regulatory framework as a way to prevent future contaminated sites, any new effort to identify candidate wastes to add to the regulatory list of hazardous wastes might reasonably consider newly-generated wastes with the potential to "pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed." RCRA section 1004(5)(B), 42 U.S.C. 6903(5)(B). Wastes listed as hazardous would no longer be allowed to be disposed in industrial solid waste or municipal landfills. Consumer wastes generally would not be affected, if a listing is focused on industrial wastes. In addition, household wastes are generally excluded from RCRA subtitle C.

PFOA and PFOS may be present as several different types of salts and structural isomers. To address this variation of chemical forms as well as the variety of waste streams that may be present, EPA may list classes or types of wastes if it has reason to believe that individual wastes

⁷ Hazard quotients are the ratio of the potential exposure to a substance and the level at which no adverse effects are expected (calculated as the exposure divided by the appropriate chronic or acute value).

⁸ See 59 FR at 66073 for further discussion of how human health risk is evaluated in making hazardous waste listing determinations.

⁹ This evaluation may involve the collection and analysis of information that differs to some extent from that relevant to a designation as a hazardous substance under CERCLA section 102(a).

within the class or type are typically or frequently hazardous. (40 CFR 261.11(b);45 FR 33107, May 19, 1980).

Through this ANPRM, EPA is soliciting input on the following:

- Should EPA seek to list particular PFOS- and PFOA-containing wastes as hazardous wastes under RCRA subtitle C regulations?
- Would such an action be most appropriate for individual compounds (e.g., specific isomers of PFOA or PFOS) or as a class of substances (e.g., a group of chemicals that may degrade to PFOA or PFOS)?
- Are there specific waste sources that should be the focus of any potential new waste listing under RCRA?
- Are there wastes containing other PFAS chemicals that EPA should consider regulating under RCRA?
- Are there specific examples of an “action taken by other governmental agencies or regulatory programs based on the health or environmental hazard posed by the waste or waste constituent” (40 CFR 261.11(a)(3)(x)) that EPA should consider if the Agency develops a hazardous waste listing?
- Are there specific examples of “other factors as may be appropriate” (40 CFR 261.11(a)(3)(xi)) that EPA should consider if the Agency develops a hazardous waste listing, such as contingent-management listing, or consideration of hazardous constituent concentrations?¹⁰

¹⁰ See for example listing descriptions for Hazardous Waste Codes K174 and K181 at 40 CFR §§ 261.32, and 261.32(b) and (c).

- If EPA were to regulate wastes containing PFAS chemicals as Toxicity Characteristic (TC) wastes, what information should EPA collect to determine appropriate hazardous constituent concentrations? What are some considerations for applying the analytical test method required for making TC determinations (i.e., the Toxicity Characteristic Leaching Procedure, or TCLP) to different waste matrices containing PFAS chemicals, such as manufacturing process wastes (e.g., sludges) and environmental media (e.g., groundwater, soil)?¹¹

EPA notes that it has received two rulemaking petitions requesting that EPA list certain PFAS-containing wastes as hazardous under RCRA. EPA emphasizes that this ANPRM does not constitute a proposed response to either petition. EPA continues to review the petitions, and there will be opportunity for public comment at a later date when EPA issues either a proposed rule or proposed denials as part of the rulemaking petition procedures in 40 CFR 260.20. EPA continues to review these petitions, but given the topic of this ANPRM, EPA is making these petitions available to the public in the docket associated with this notice in the spirit of transparency and welcomes any comment that might assist EPA in its ongoing review.

E. Effect of a New RCRA Hazardous Waste Listing

Upon the effective date of a hazardous waste listing, wastes meeting the listing description must be managed in accordance with applicable RCRA subtitle C regulatory requirements. Residuals from the treatment, storage, or disposal of the wastes listed as hazardous also are classified as hazardous wastes under subtitle C regulations pursuant to the “derived-from” rule (40 CFR 261.3(c)(2)(i)). Also, any mixture of a listed hazardous waste and a solid

¹¹ See references in Section VII of this ANPRM.

waste is itself generally defined as a hazardous waste under the RCRA regulations (40 CFR 261.3(a)(2)(iv), “the mixture rule”).

EPA must promulgate Land Disposal Restrictions (LDR) treatment standards within six months of the date of a final listing (RCRA section 3004(g)(4), (m)(1), 42 U.S.C. 6924(g)(4), (m)(1)). RCRA also requires EPA to set as these treatment standards “... levels or methods of treatment, if any, which substantially diminish the toxicity of the waste or substantially reduce the likelihood of migration of hazardous constituents from the waste so that short term and long term threats to human health and the environment are minimized.” RCRA section 3004(m)(1), 42 U.S.C. 6924(m)(1).

On December 22, 2020, EPA issued for public comment interim guidance on the destruction and disposal of PFAS and PFAS-containing materials from non-consumer products (85 FR 83554). This document generally describes the use of thermal treatment, landfill and underground injection technologies that, to varying degrees, may be effective in the destruction or disposal of PFAS and PFAS-containing materials.¹² Comments are due on or before February 22, 2021. EPA will consider and incorporate comments, as appropriate, into a revised document. EPA expects to review and revise the interim guidance, as appropriate, or at least once every 3 years. A separate docket has been established for this interim guidance EPA-HQ-OLEM-2020-0527 and comments on the guidance should be submitted there.

EPA evaluates whether adequate commercial capacity exists to manage a newly-listed waste under the LDR before the waste is restricted from further land disposal. EPA estimates the quantities of newly-listed hazardous waste and compares these to estimates of available

¹² <https://www.epa.gov/pfas/interim-guidance-destroying-and-disposing-certain-pfas-and-pfas-containing-materials-are-not>

commercial treatment capacity. If adequate capacity does not exist, RCRA section 3004(h)(2) authorizes EPA to grant a national capacity variance for the waste for up to two years or until adequate alternative treatment capacity becomes available, whichever is sooner.

Hazardous waste listings are also applicable to historically-disposed wastes that meet the new listings, as if they had been enacted at the time of disposal.¹³

Finally, when EPA lists a hazardous waste under RCRA, the waste becomes a hazardous substance pursuant to CERCLA 101(14). Under 40 CFR 302.6(a), any release of a hazardous substance in a quantity equal to or exceeding the reportable quantity in any 24-hour period must be reported. Under 40 CFR 302.6(b), if the quantity or quantities of all the hazardous constituent(s) are known, notification is required where the RQ or more of any hazardous constituent is released.

V. Request for Comment and Additional Information

EPA is seeking comment on all questions and topics described in this ANPRM, including questions and issues identified in section IV, and requests that you submit any other information, which may not be specifically mentioned in this notice, that you believe is important for EPA to consider in connection with these questions and topics. At the same time, EPA does not plan to consider comments that are beyond the scope of the questions and topics described in this ANPRM.

Instructions for providing written comments are provided under **ADDRESSES**, including how to submit any comments that contain CBI.

¹³ See 53 FR 31147-48, August 17, 1998.

VI. What are the next steps EPA will take?

EPA intends to carefully review all the comments and information received in response to this ANPRM. Once that review is completed, EPA would supplement the collected information, as appropriate, to determine whether a future rulemaking should address designating PFOA and PFOS as hazardous substances, whether additional PFAS compounds should be included in a future designation rulemaking and whether EPA should consider using a legal authority other than CERCLA section 102(a) to add PFOA, PFOS, or other PFAS compounds as hazardous substances under CERCLA. If the Agency proceeds with an NPRM, EPA would gather more information, including the information regarding the potential effects (benefits and costs), and the Agency will submit an information collection request to OMB.

VII. References

1. Public Employees for Environmental Responsibility. (2019) *Petition for Rulemaking Pursuant to Section 6974(a) of the Resource Conservation and Recovery Act concerning the Regulation of a Class of Wastes Containing Per- and Polyfluoroalkyl Substances.*

2. Berkeley Law, University of California, Environmental Law Clinic. (2020) *Petition for Rulemaking: RCRA Regulation of Wastes Containing Long-Chain PFAAs and GenX Chemicals.*

VIII. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821, January 21, 2011), this action was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket for this action. Because this action does not impose or propose any requirements, and instead seeks comments and suggestions for the Agency to consider in possibly developing a subsequent proposed rule, other statutory and Executive Order reviews

that apply to rulemaking do not apply to this action. Should EPA subsequently determine to pursue a rulemaking, EPA will address the statutes and Executive Order as applicable to the rulemaking.

Nevertheless, the Agency welcomes comments and/or information that would help the Agency to assess any of the following: the potential impact of a rule on small entities pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.); potential impacts on federal, state, or local governments pursuant to the Unfunded Mandates Reform Act ((UMRA) (2 U.S.C. 1531-1538); federalism implications pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, November 2, 1999); availability of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113; tribal implications pursuant to Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000); environmental health or safety effects on children pursuant to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997); energy effects pursuant to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001); Paperwork burdens pursuant to the Paperwork Reduction Act (PRA) (44 U.S.C. § 3501); or human health or environmental effects on minority or low-income populations pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). The Agency will

consider such comments during the development of any subsequent proposed rulemaking.

Andrew Wheeler,

Administrator.