April 8, 2024

Via Electronic Filing

Mr. Narendra Chaudhari
Office of Resource Conservation and Recovery
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Comments of the U.S. Chamber of Commerce's Coalition of Companies, Trade Associations, and Other Stakeholders on the U.S. Environmental Protection Agency's Proposed Rule, Listing of Specific PFAS as Hazardous Constituents (EPA-HQ-OLEM-2023-0278) (Feb. 8, 2024)

Dear Mr. Chaudhari:

The Coalition appreciates the opportunity to provide these comments on the U.S. Environmental Protection Agency's (EPA's or Agency's) proposed rule on "Listing of Specific PFAS as Hazardous Constituents" (Proposed Rule or Listing Rule).[1]

The Coalition represents downstream product manufacturers and users of PFAS chemistries[2] and manufacturers and users of other emerging contaminants that are subject to, or could be subject to, Corrective Action under the Resource Conservation and Recovery Act (RCRA) through their operation of RCRA-permitted treatment, storage, and disposal facilities (TSDFs) and interim status facilities. The Coalition also includes previous manufacturers and processors and businesses in other areas of the value chain potentially impacted by the proposal. The Coalition is composed of a wide cross-section of trade associations and industries, including aerospace, automotive, construction, electronics, energy, mining, health care, telecommunications, and textiles, and other community stakeholders, including first responder services, water and wastewater utilities, and waste management facilities. The Coalition also represents other businesses that could potentially be subject to Corrective Action under RCRA.

The Coalition continues to support the safe management and disposal of PFAS chemistries and other emerging contaminants across the value chain. We support the responsible cleanup of these chemistries, consistent with the best science and appropriate consideration of risk and the protection of human health and the environment in communities across our nation. As we have described before, PFAS chemistries are varied in structure and demonstrate a wide variety of physical and chemical properties.[3] In addition, they have diverse biological properties, including

[1] 89 Fed. Reg. 8,606 (Feb. 8, 2024).
[2] In the Proposed Rule, when referring to an individual PFAS, EPA notes that the agency is also referring to its salts and branched and linear structural isomers. While we do not endorse an approach that treats all salts and isomers the same, when we refer to an individual PFAS in these comments, to be consistent with EPA's approach, EPA should interpret the comment as also applying to the salts and branched and linear structural isomers of the PFAS.
[3] *See* Comments of the U.S. Chamber of Commerce Coalition of Companies and Trade Associations on Advanced Notice of Proposed Rulemaking, Addressing Per- and Polyfluoroalkyl (PFAS) in the Environment, 88 Fed. Reg. 22,399 (Apr. 13, 2023) (submitted Aug. 11, 2023).

different toxicological modes of action, as well as different precursors, salts, isomers, and degradants. In the Proposed Rule, EPA focuses on nine PFAS (perfluorooctanoic acid (PFOA), perfluorooctanesulfonic acid (PFOS), perfluorobutanesulfonic acid (PFBS), hexafluoropropylene oxidedimer acid (HFPO–DA), perfluorononanoic acid (PFNA), perfluorohexanesulfonic acid (PFHxS), perfluorodecanoic acid (PFDA), perfluorohexanoic acid (PFHxA), and perfluorobutanoic acid (PFBA)) and also proposes to include their isomers and salts as hazardous constituents listed under 40 CFR Part 261 Appendix VIII. As we described in previous comments,[4] this broad approach is problematic because some of the isomers and salts that are included in the Proposed Rule cannot be detected and measured by current analytical methods.

The Coalition supports accelerating the cleanup of select PFAS in the environment, such as by utilizing EPA's authority under RCRA Section 7003 as a viable alternative to joint and several liability regimes under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Businesses are actively collaborating with federal agencies and local and state government stakeholders to ensure an effective and balanced approach to addressing PFAS-related concerns. However, as described in the comments below, there are essential steps that EPA must take before adding additional chemicals, including the nine PFAS addressed in the Proposed Rule, to Appendix VIII. The comments below describe the Coalition's specific concerns with the Listing Rule, including the following:

- This Proposed Rule would represent only the second time in RCRA's history that EPA has listed substances as hazardous constituents on Appendix VIII without a corresponding listing of hazardous waste on Appendix VII. EPA must develop clear criteria to determine whether an Appendix VIII listing is warranted before utilizing Appendix VIII in this unusual way to address individual new and emerging contaminants.

- The scientific record for the PFAS selected is insufficient to support listing these PFAS on Appendix VIII.

- EPA's approach of including all salts and isomers of each of the nine PFAS is overly broad.

- EPA's economic analysis is insufficient and does not support the listing of these nine PFAS.

- The significant cost of listing the selected PFAS is far greater than the benefits.

- EPA should not proceed to a full hazardous waste listing for any of the nine PFAS on the basis of their listing on Appendix VIII if this Proposed Rule is finalized.

I. Overview of Relevant Statutory and Regulatory History

The Resource Conservation and Recovery Act,[5] passed in 1976, amended the Solid Waste Disposal Act of 1965 to address issues with municipal and industrial waste. RCRA gave EPA

[4] *Id*.
[5] Pub. L. No. 94-580, 90 Stat. 2795 (1976) (codified at 42 U.S.C. § 6901 *et seq.*).

new authorities under a number of legal programs, including the solid waste program under Subtitle D and the hazardous waste program under Subtitle C. The hazardous waste program, which governs the regulations at issue in this rulemaking, gives EPA the authority to regulate hazardous waste "cradle to grave," including generation, transportation, treatment, storage, and disposal. Most states have been authorized to implement the RCRA hazardous waste program. Major amendments to RCRA over time include the Solid Waste Disposal Amendments of 1980, which exempted certain wastes from Subtitle C; the Hazardous and Solid Waste Amendments of 1984 (HSWA), which expanded the hazardous waste program; and the 1986 amendments, which enabled EPA to address programs addressing underground storage tanks.

RCRA directs EPA to "develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste."[6] In 1980, EPA promulgated regulations at 40 C.F.R. Part 261 setting forth procedures and criteria for identification and listing of hazardous waste and establishing the list of hazardous constituents under Appendix VIII to Part 261.[7] Those regulations provide 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."[8] Importantly, the 1980 rulemaking emphasized that, in order for a study to provide a basis for listing in Appendix VIII, that study must be "reputable."[9] According to EPA, the purpose of Appendix VIII is to capture a broad universe of chemicals of concern under RCRA.[10] Once a chemical has been listed under Appendix VIII, EPA then determines whether it should be considered for inclusion in a hazardous waste listing.[11] The regulations provide three potential pathways through which a substance can be listed as a hazardous waste under Appendix VII to Part 261.[12] One of these pathways provides that a substance shall be listed as hazardous waste if it "contains any of the toxic constituents listed on appendix VIII," and "the Administrator concludes," based on an analysis of eleven enumerated factors, "that the waste is capable of posing a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported or disposed of, or otherwise managed."[13]

In addition to providing a potential basis for hazardous waste listing, listing a substance on Appendix VIII subjects that substance to Corrective Action under Section 3004(u) of RCRA.[14] Section 3004(u), which was added to RCRA through the Hazardous and Solid Waste Amendments of 1984, provides that EPA "shall require[] corrective action for all releases of

[6] 42 U.S.C. § 6921(a).
[7] 45 Fed. Reg. 33,066 (May 19, 1980).
[8] 40 C.F.R. § 261.11(a).
[9] 45 Fed. Reg. at 33,107.
[10] 52 Fed. Reg. 25,942, 25,942 (July 9, 1987).
[11] 40 C.F.R. § 261.11(a).
[12] *Id*.
[13] 40 C.F.R. § 261.11(a)(3).
[14] There are a number of other references to Appendix VIII in the RCRA regulations and, accordingly, additional potential impacts of the Proposed Rule. *See, e.g.*, 40 C.F.R. § 261.2(d) (referencing Appendix VIII listing as a factor in determining whether materials are solid wastes when recycled); *id.* § 261.3(a)(2)(v) (providing criteria for rebutting the presumption that used oil is hazardous waste, including a showing that used oil does not contain significant concentrations of Appendix VIII constituents); *id.* § 264.340(d) (providing that a TSDF that burns waste may be exempted from certain regulatory requirements if the waste contains insignificant concentration of Appendix VIII constituents).

hazardous waste ***or constituents*** from any solid waste management unit at a treatment, storage, or disposal facility seeking a permit under this subchapter" (emphasis added).[15] This provision brings substances listed on Appendix VIII within the scope of RCRA Corrective Action.[16] EPA has periodically updated Appendix VIII since it was initially promulgated in 1980. A full list of EPA's prior actions adding substances to Appendix VIII to Part 261 follows below. Of these actions, only one—a rulemaking in 1994—consisted of a listing of hazardous substances on Appendix VIII without a corresponding listing of hazardous waste on Appendix VII.

- In 1989, EPA listed as hazardous waste two categories of substances from the production of certain chlorinated aliphatic hydrocarbons by free radical catalyzed processes (F024 and F025). It also added two related compounds, chloroprene and allyl chloride, to Appendix VIII.[17]

- In 1990, EPA listed as hazardous waste certain wastes generated from wood preserving processes that use either chlorophenolic, creosote, and/or inorganic preservatives (F032, F034, and F035). The Agency also added two related compounds, benzo(k)fluoranthene and heptachlorodibenzofurans, to Appendix VIII.[18]

- In 1994, EPA – after reviewing public comments to a proposed rule – elected not to list wastes generated from chlorophenolic formulations in wood surface protection processes as hazardous waste as it had proposed. In the same rulemaking, it added four chemicals to Appendix VIII: potassium pentachlorophenate, sodium pentachlorophenate, 2,3,4,6-tetrachlorophenol potassium salt, and 2,3,4,6-tetrachlorophenol sodium salt.[19] This appears to be the only instance in which EPA has added substances to Appendix VIII without simultaneously listing the related hazardous waste category on Appendix VII. In that instance, EPA had initially proposed to list the substances as hazardous waste at certain concentrations. It ultimately decided not to proceed with that listing because chlorophenolic formulations were no longer being produced in the United States, and the risk to human health and the environment is shown to tail off quickly because they quickly diminish to concentrations of near zero. However, EPA acknowledged that a number of the constituents of concern that are present in waste generated from wood surface production processes, which use chlorophenolic formulations, did not appear on Appendix VIII. So, EPA proceeded with the listing on Appendix VIII despite declining to list the broader categories as hazardous waste in certain concentrations.

- In 1995, EPA listed as hazardous waste six wastes generated during the production of carbamate chemicals (K156 – K161), and added 58 substances to Appendix VIII, several of which formed the basis of the hazardous waste listings. It also added the same 58

[15] 42 U.S.C. § 6924(u).
[16] *See* comments submitted by the U.S. Chamber of commerce et al, on EPA's Proposed Rule, Definition of Hazardous Waste Applicable to Corrective Action for Releases From Solid Waste Management Units, 89 Fed. Reg. 8,598 (Feb. 8, 2024) (submitted Mar. 26, 2024), available at: https://www.regulations.gov/comment/EPA-HQ-OLEM-2023-0085-0077.
[17] 54 Fed. Reg. 50,968 (Dec. 11, 1989).
[18] 55 Fed. Reg. 50,450 (Dec. 6, 1990).
[19] 59 Fed. Reg. 458 (Jan. 4, 1994).

substances to 40 C.F.R. 261.33 which lists substances that are considered "hazardous [wastes] when discarded."[20]

- In 1998, EPA added 2,4,6-tribromophenol to both its list of hazardous wastes under Appendix VII and its list of hazardous constituents under Appendix VIII.[21]

- In 2000, EPA listed as hazardous wastes two wastes generated by the chlorinated aliphatics industry (K174 and K175) and added two related chemicals to Appendix VIII: octachlorodibenzo-p-dioxin and octachlorodibenzofuran.[22]

- In 2005, EPA listed as hazardous wastes seven nonwastewater constituents generated from the production of certain dyes, pigments, and FD&C colorants (K181) and at the same time listed five of those substances on Appendix VIII: o-anisidine, p-cresidine, 2,4-dimethylaniline, 1,2-phenylenediamine, and 1,3-phenylenediamine.[23]

II. It Is Critical That EPA Develop Clear Criteria To Determine Whether Appendix VIII Listing Is Warranted.

As described above, listing a substance on Appendix VIII has two main effects. First, listing a substance on Appendix VIII brings that substance within the scope of RCRA Corrective Action. Second, listing a substance on Appendix VIII provides a partial basis upon which EPA can list the substance as hazardous waste. Listing a substance on Appendix VIII accordingly has the potential both to create broad cleanup obligations and to lead to future cradle-to-grave regulation of that substance.

As a general matter, the Coalition does not object to EPA's updating of Appendix VIII as a means to bring additional substances within the scope of RCRA Corrective Action, even though that vehicle has not generally been used in the past. Listing a new substance on Appendix VIII is an action that requires notice-and-comment rulemaking and, if done appropriately, should therefore provide an appropriate opportunity for stakeholders to review and engage with the technical analysis underlying EPA's decision-making. Unfortunately, given the current absence of well-defined criteria for listing a substance on Appendix VIII, EPA provided scant information about its analysis, making it impossible for the regulated community to meaningfully engage. Given the potentially significant effects of Appendix VIII listing, and to ensure consistency in listing determinations, EPA should develop clear criteria for determining whether Appendix VIII listing is warranted.

Part 261 provides that, in order to list a substance on Appendix VIII, EPA must find that a substance has "been shown in scientific studies to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms."[24] In the Proposed Rule, EPA states that these criteria "do not require a finalized toxicity assessment, or exhaustive search and evaluation of all

[20] 60 Fed. Reg. 7,824 (Feb. 9, 1995).
[21] 63 Fed. Reg. 24,596 (May 4, 1998).
[22] 65 Fed. Reg. 67,068 (Nov. 8, 2000).
[23] 70 Fed. Reg. 9,138 (Feb. 24, 2005).
[24] 40 C.F.R. § 261.11(a)(3).

published scientific studies for the substance, or a final toxicity value."[25] This standard is much too vague and undefined. If all EPA must do is find that "scientific studies have shown one or more of the criteria effects for the substances," (i.e. toxic, carcinogenic, mutagenic, or teratogenic effects), then regulated entities are deprived of an opportunity to engage meaningfully with EPA's decision, including by presenting evidence from studies showing different results, because EPA's threshold for finding a substance meets the criteria set forth in Section 261.11 is unacceptably low. Indeed, as currently articulated by EPA, the standard for listing a substance on Appendix VIII is to identify a single study that may not even have been subject to peer-review that shows a health effect in any life form. Under this approach, every chemical on earth has the potential to be listed on Appendix VIII, which is not consistent with RCRA or EPA's regulatory authority. Following the approach in the Proposed Rule, EPA would arguably have the ability to list even water or salt on Appendix VIII, as studies exist that show these chemistries can be toxic.[26]

The Coalition recognizes that, when it was initially promulgated in 1980, Appendix VIII was purposefully constructed as a broad list. This is because, at the time, "[t]he principal purpose of the list [was] to define a universe of chemicals of concern. Wastes would be matched against the list to see if they contained any chemicals from this universe. If so, they would be considered for listing as 'hazardous.'"[27] In a 1987 rulemaking, EPA stated that "the Appendix VIII list is actually a composite of several other lists" and "includes chemicals identified as priority pollutants under the Clean Water Act, chemicals identified by the Department of Transportation as hazardous to transport," and other chemicals from existing EPA and NIOSH registries.[28] As such, the chemicals were not individually evaluated, but rather added in large groups due to their presence on other existing lists. EPA explained that this broad approach did not present problems in the hazardous waste listing context because there were other criteria, in addition to Appendix VIII listing, that EPA was required to consider before listing a substance as hazardous waste.[29]

In the 44 years since Appendix VIII was initially promulgated, EPA has rarely made changes to it. As detailed in Part I above, EPA has added substances to Appendix VIII on only seven occasions. And it has added substances to Appendix VIII without a corresponding listing of hazardous wastes on only one occasion in 1994.[30] Whereas EPA initially used Appendix VIII to capture broad groups of potentially hazardous chemicals, this Proposed Rule represents an almost completely novel use of the provision to add individual emerging contaminants to Appendix VIII without considering their potential addition to Appendix VII as hazardous wastes. EPA must develop clear guidance and criteria for Appendix VIII listings, so that it adequately considers risk when regulating a new or emerging contaminant before that substance is subjected to the Corrective Action program and available to serve as a basis for hazardous waste listing.

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[25] 89 Fed. Reg. at 8,612.
[26] See for example Farrell, D.J. and Bower, L., *Fatal water intoxication*, J Clin Pathol. 2003 Oct; 56(10): 803–804, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1770067; and Methany, N.A. and Krierger, M.M., *Salt Toxicity: A Systematic Review and Case Reports*, J Emerg Nurs. 2020 Jul;46(4):428-439; available at: https://pubmed.ncbi.nlm.nih.gov/32340735.
[27] 52 Fed. Reg. 25,942, 25,942 (July 9, 1987).
[28] *Id.*
[29] *See id.*
[30] 59 Fed. Reg. 458 (Jan. 4, 1994); 70 Fed. Reg. 9,138 (Feb. 24, 2005).

In 1980, rigorous approaches for evaluating scientific evidence were quite different than they are today.[31] Now, with the benefit of several decades' worth of scientific developments since the initiation of the Appendix VIII list, EPA must take those developments into account as it starts to use Appendix VIII in a new way. EPA must provide guidance for a hazardous constituent listing that is commensurate with modern available methods for assessing toxicity and risk. Today, characterizing the hazards of a chemical requires a robust multi-step scientific process. For instance, in 2022, EPA's Office of Research and Development (ORD) completed development of the ORD Staff Handbook for Developing IRIS Assessments (IRIS Handbook).[32] The IRIS Handbook was developed in response to recommendations from the National Academies of Sciences, Engineering, and Medicine (NASEM), which identified persistent problems in EPA's approach to hazard assessment and recommended that EPA develop a new, more uniform, approach that would ensure transparency and consider the weight of the evidence when evaluating scientific studies.[33] The IRIS Handbook provides an evidence-based approach for hazard identification that involves scoping, problem formulation, development of a systematic review protocol, literature searching, literature screening, study evaluation, evidence synthesis, and evidence evaluation. These concepts are often referred to as "systematic review" and "weight of the scientific evidence."

Years of funding from the federal government, as well as from the private sector, has led to an overwhelming amount of scientific information regarding existing chemical toxicity. Systematic review and weight of the scientific evidence approaches are necessary in order to evaluate scientific information in a transparent and reproducible manner. As EPA acknowledges in the Proposed Rule, interpreting epidemiology data and toxicological responses is an ongoing challenge.[34]

Since Appendix VIII was developed, the only time there was an Appendix VIII listing separate from a full hazardous waste listing was in 1994.[35] As scientific approaches have significantly advanced since 1994, and the circumstances supporting that addition differ greatly from the reasons underlying this proposal, before EPA adds additional chemicals to Appendix VIII, as it proposes to do here, it must develop clear criteria and guidance for these listings.

The criteria EPA must develop should take into account the recommendations from NASEM and Congress that have led to the incorporation of systematic review and weight of the scientific evidence approaches into best practices throughout EPA. In developing the necessary criteria and guidance, EPA must also determine whether health effects in humans would be treated as equal to a health effect in "any life form." In addition, the criteria should consider the scientific requirements described in the Office of Management and Budget (OMB) Information Quality Guidelines and the EPA Information Quality Guidelines,[36] as well as the requirements of EPA's

[31] 45 Fed. Reg. 33,066, 33,132 (May 19, 1980).
[32] The 2022 IRIS Handbook is available at: https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=356370#tab-3.
[33] National Academies of Sciences, Engineering, and Medicine, *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde (2011)*, available at: https://www.ncbi.nlm.nih.gov/books/NBK208227.
[34] 89 Fed. Reg. at 8,613.
[35] 59 Fed. Reg. 458 (Jan. 4, 1994).
[36] *See* EPA, Information Quality Guidelines, available at https://www.epa.gov/quality/information-quality-guidelines-iqgs.

Peer Review Handbook.[37] Robust external peer review of the scientific evidence should be required before any chemical is listed on Appendix VIII.

III. Currently, There Is an Inadequate Scientific Basis To Conclude That Any of the Nine PFAS Satisfy the Standard for Listing in Appendix VIII.

Because each PFAS compound is unique, as we described above and in previous comments,[38] EPA has taken the correct approach by seeking to list individual PFAS chemistries. However, EPA's approach of including all salts and isomers of each of the nine PFAS is too broad. As the Coalition described in previous comments,[39] not all isomers and salts for the nine PFAS have been identified, and, for some that have been identified, validated detection methods do not exist. EPA previously acknowledged concerns about including chemicals in Appendix VIII that lack analytical standards and measurement methods.[40] Thus, it is premature for EPA to include all isomers and salts in any listing.

In the sections below, we describe the state of the science for each of the nine PFAS that EPA proposes to list in Appendix VIII. As is described below, EPA has not conducted sufficiently robust, transparent, and peer reviewed weight of the scientific evidence evaluations to justify listing any of these compounds on Appendix VIII. Criteria and guidance are needed to inform a listing in Appendix VIII, and, as we describe, none of the individual PFAS meet the most basic criteria that should be required for an Appendix VIII listing.

A. PFOA and PFOS

EPA's justification for listing PFOA and PFOS includes some of the same science it cited in the SDWA national primary drinking water regulation proposed rule. EPA received many public comments, including comments from EPA's Science Advisory Board (SAB), on EPA's proposed approach for deriving a maximum contaminant level Goal (MCLG) for both PFOA and PFOS. Unfortunately, instead of substantively addressing public and peer review comments and making robust revisions to the scientific documents, EPA did not make necessary significant changes when it developed and released the updated draft toxicity assessments for PFOA and PFOS to support a national primary drinking water regulation under the Safe Drinking Water Act. As described in the Coalition comments to EPA on the proposed drinking water regulation, the peer review process was inappropriately truncated, peer reviewers did not have adequate expertise as required by EPA's own policies, and robust peer review principles were not followed.[41] These flaws in the process compromised the scientific review. As described in the Coalition comments

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[37] U.S. EPA, Peer Review Handbook (2015), available at: https://www.epa.gov/sites/default/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.

[38] *See* Comments of the U.S. Chamber of Commerce Coalition of Companies and Trade Associations on Advanced Notice of Proposed Rulemaking, Addressing Per- and Polyfluoroalkyl (PFAS) in the Environment, 88 Fed. Reg. 22,399 (Apr. 13, 2023) (submitted Aug. 11, 2023).

[39] *Id*.

[40] *See* 52 Fed. Reg. 25,942 (July 9, 1987) (promulgating a core list of substances for which groundwater screening would be required, based on the recognition that screening could not be conducted for all substances listed on Appendix VIII due to the lack of available methods).

[41] Chamber of Commerce and Coalition, Comments on EPA's PFAS National Primary Drinking Water Regulation Rulemaking Preliminary Regulatory Determination and Proposed Rule, 88 Fed. Reg. 18,638 (Mar. 29, 2023) (submitted May 30, 2023), available at: https://www.regulations.gov/comment/EPA-HQ-OW-2022-0114-1713.

on the proposed drinking water regulation, a full review of all the available evidence, including epidemiological, clinical, and toxicological evidence, shows that an association with PFOA and PFOS with the health effects referenced is not supported.[42] EPA's findings in the proposed drinking water regulation are not consistent with "best available public health information" because EPA did not consider all the available information. EPA must develop a consistent and transparent approach to evaluate the weight of the scientific evidence.

To support an Appendix VIII listing for PFOA and PFOS, EPA also cites individual journal publications, the 2021 Agency For Toxic Substances and Disease Registry (ATSDR) Toxicological Review for Perfluoroalkyls (ATSDR Toxicological Review), and the 2016 Office of Water Health Effects Support Documents for PFOA and PFOS. EPA also notes that the science was also reviewed by the SAB, as described above. This evidence does not provide an appropriate basis for Appendix VIII listing.

First, individual journal articles do not present a weight of the scientific evidence evaluation. For each of the endpoints that EPA points to as showing an effect in a journal publication, it is easy to find a similarly robust study that does not support an association with the same effect. Singular reliance on a single set of epidemiological data or rodent data is inadequate for an Appendix VIII listing. If it were adequate, as noted above, Appendix VIII would be rendered meaningless, as potentially every chemical could meet this low standard and be added to the Appendix.

Second, reliance on the ATSDR Toxicological Review is inadequate. While this document presents a weight of the scientific evidence evaluation, it did not follow best practices for conducting a systematic review of the evidence, and it did not undergo a robust peer review process. Considering the complexity of evaluating twelve individual PFAS, ATSDR should have followed best practices for systematic review, including by releasing a problem formulation document and a protocol to inform the review. ATSDR did not include any of these steps in its review because the Toxicological Review was not intended to be a robust systematic review of the available evidence. In fact, ATSDR itself stated that "[t]he profile is not intended to be an exhaustive document."[43] Additionally, ATSDR conducted a letter peer review, which is inconsistent with EPA's own best practices for the peer review of influential or highly influential scientific information.[44] For instance, as described by ATSDR, the peer reviewers were not provided with any of the public comments before the review.[45] EPA's Peer Review Handbook recognizes that a letter review is appropriate when a work product is "not controversial" and also

[42] *Id*.
[43] ATSDR, Toxicological Profile for Perfluoroalklys (May 2021), available at: https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf.
[44] As described in EPA's Peer Review Handbook, the term "influential scientific information" means scientific information the Agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private-sector decisions. Scientific information that supports a regulatory listing, such as a listing in Appendix VIII, would at a minimum be considered influential scientific information which must meet requisite peer review standards.
[45] ATSDR, Peer Review Agenda for the Toxicological Profile for Perfluoroalkyls (PFAS), available at: https://www.atsdr.cdc.gov/sites/peer_review/tox_profile_perfluoroalkyls.html.

recognizes that, for highly influential scientific assessments, a panel review is preferable.[46] Thus, while ATSDR conducted a weight of the scientific evidence evaluation, the peer review was inadequate, and important elements of a systematic review were completely absent.

Third, the 2016 Office of Water Health Effects Support Documents for PFOA and PFOS does not represent the best available scientific information. These documents include information only through 2015 and do not include consideration of the last nine years of additional scientific research. Importantly, a search on PubMed, the National Institutes of Health database of biomedical literature, shows that, from 2016 through February 2024, over 1,900 journal publications discussing PFOA and PFOS were published.[47] Reliance on a 2016 review for an Appendix VIII listing in 2024 is inadequate.

Finally, while it is not clear that EPA is relying on the updated draft toxicity assessments for PFOA and PFOS that were developed to support a national primary drinking water regulation under the Safe Drinking Water Act, the Proposed Rule does mention these documents. As described above, these documents do not represent the best available science and are still draft documents. It would be inappropriate for EPA to rely upon them for an Appendix VIII listing.

B. PFHxA and PFBA

For PFHxA and PFBA, the Proposed Rule relies on individual journal articles, an IRIS assessment for each chemistry, and the ATSDR Toxicological Profile. Importantly, for both of these chemistries, EPA acknowledges that the human data supporting possible associations "are sparse and overall insufficient on their own to draw conclusions regarding adverse health effects."[48]

As described above, in addition to relying on a sparse human database, there are concerns with relying on individual journal articles and the ATSDR Toxicological Review. EPA also relies on IRIS assessments for PFHxA and PFBA. The peer reviews for these assessments were conducted by external contractors, not an EPA panel such as the SAB, which operates under the auspices of the Federal Advisory Committee Act (FACA). EPA's peer review bulletin notes that SAB peer reviews are more robust than contractor-run peer review and are therefore more appropriate for highly visible and controversial environmental issues.[49] For example, the SAB strives to reach consensus in all its reports because its final product is meant to be a consensus advisory report.

[46] U.S. EPA, Peer Review Handbook, 4th edition, 2015, at pages 55-57, available at: https://www.epa.gov/sites/default/files/2015-10/documents/epa_peer_review_handbook_4th_edition_october_2015.pdf.
[47] *See* National Library of Medicine, PubMed, available at https://pubmed.ncbi.nlm.nih.gov/?term=PFOA+PFOS&filter=years.2016-2024&sort=date.
[48] 89 Fed. Reg. at 8,615.
[49] U.S. EPA, Peer Review Handbook, 4th edition, 2015, at pages 66, available at: https://www.epa.gov/sites/default/files/2015-10/documents/epa_peer_review_handbook_4th_edition_october_2015.pdf.

However, in the contractor run peer reviews for PFHxA and PFBA, there was no effort to reach consensus.[50] This compromises the integrity of the peer review.

C. PFBS

For PFBS, the Proposed Rule relies solely on individual studies that are described in EPA's Human Health Toxicity Values for PFBS (HHTV Assessment).[51] An HHTV Assessment is an assessment completed by EPA's Office of Research and Development (ORD) but is not conducted under the auspices of the IRIS program. An HHTV assessment undergoes a less rigorous peer review process which includes only an external letter review, which, like a contractor-run review, does not seek consensus. It is considered to be a fit-for-purpose assessment that can be completed more quickly than an IRIS assessment due to the limitations of the available database.[52] HHTV assessments are used when the Agency does not plan to issue a regulation for a chemical.[53] It is not an appropriate assessment for making an Appendix VIII listing determination.

As described in the HHTV for PFBS, the human studies on PFBS are of low confidence.[54] Instead, EPA relies on thyroid effects in rodent studies, but notes that the human study data do not inform the potential for thyroid effects in humans. In addition, the Proposed Rule acknowledges that the available evidence does not support a clear association with PFBS exposure for most of the outcomes evaluated in animal studies.[55] Finally, while EPA did not rely on the ATSDR Toxicological Profile for PFBS, it is important to note that the ATSDR Toxicological Profile was unable to quantify a minimal risk level for PFBS due to insufficient data to quantify an adverse effect.[56] The weight of the scientific evidence, as described in EPA's HHTV Assessment for PFBS, does not support a listing on Appendix VIII.

D. HFPO–DA

For HFPO-DA, the Proposed Rule relies on a Human Health Toxicity Value developed by the EPA Office of Water (OW). In this OW assessment, EPA relied on data provided to EPA pursuant to a consent order.[57] EPA's reliance on this OW assessment to justify listing HFPO-DA on Appendix VIII is flawed for numerous reasons.

The OW assessment contains significant deviations from standard EPA toxicity assessment methods and is not supported by the weight of scientific evidence. The OW assessment used a

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[50] See meeting materials provided by EPA which describe the contractor run process, available at: https://iris.epa.gov/Document/&deid=353986#materials and https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=350051#.
[51] 89 Fed. Reg. at 8,613.
[52] As described by Maureen Gwinn, EPA's Science Advisor at the Society of Toxicology Meeting, Mar. 11, 2024.
[53] *See* EPA's fact sheet for PFBS available at: https://www.epa.gov/chemical-research/learn-about-human-health-toxicity-assessment-pfbs.
[54] EPA, *Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate*, 2021, available at: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=350888.
[55] 89 Fed. Reg. at 8,613.
[56] ATSDR Peer Review Agenda for the Toxicological Profile for Perfluoroalkyls (PFAS), available at: https://www.atsdr.cdc.gov/sites/peer_review/tox_profile_perfluoroalkyls.html.
[57] 89 Fed. Reg. at 8,614.

new toxicological endpoint—a "constellation of liver effects"—that is unprecedented and misapplies scientific criteria in determining whether observed effects are in fact adverse effects in the context of a human health risk assessment. The OW assessment also uses inappropriate and significantly inflated uncertainty factors that are inconsistent with EPA's own guidance and practice in other toxicity assessments. Furthermore, the process EPA undertook to develop the OW assessment was procedurally flawed, as it did not undergo any external peer review or public comment. The OW assessment was met with a legal challenge shortly after its June 2022 release that is ongoing.[58] Last, the regulated community continues to provide OW with new peer-reviewed scientific publications that are related to OW's toxicity assessment of HFPO-DA that must be taken into account as part of the Proposed Rule.[59]

Therefore, it would be inappropriate for EPA to rely on this OW assessment document to inform an Appendix VIII listing because the most basic public comment and peer review criteria have not been met and EPA did not comply with standard EPA toxicity assessment methods during its development.

[58] The Chemours Company FC, LLC v. United States Environmental Protection Agency, No. 22-2287 (3d. Cir.).

[59] A recent submission to OW included the following studies: Rogers JM, Heintz MM, Thompson CM, Haws LC. A putative adverse outcome network for neonatal mortality and lower birth weight in rodents: Applicability to per- and polyfluoroalkyl substances and relevance to human health. Birth Defects Res. 2023 Jun 15;115(11):1011-1062. doi: 10.1002/bdr2.2185. Epub 2023 May 23. PMID: 37219003; Heintz MM, Haws LC, Klaunig JE, Cullen JM, Thompson CM. Assessment of the mode of action underlying development of liver lesions in mice following oral exposure to HFPO-DA and relevance to humans. Toxicol Sci. 2023 Mar 20;192(1):15-29. doi: 10.1093/toxsci/kfad004. PMID: 36629480; PMCID: PMC10025879; Thompson CM, Heintz MM, Wolf JC, Cheru R, Haws LC, Cullen JM. Assessment of Mouse Liver Histopathology Following Exposure to HFPO-DA With Emphasis on Understanding Mechanisms of Hepatocellular Death. Toxicol Pathol. 2023 Jan;51(1-2):4-14. doi: 10.1177/01926233231159078. Epub 2023 Mar 29. PMID: 36987989; PMCID: PMC10278389; Heintz MM, Chappell GA, Thompson CM, Haws LC. Evaluation of Transcriptomic Responses in Livers of Mice Exposed to the Short-Chain PFAS Compound HFPO-DA. Front Toxicol. 2022 Jun 27;4:937168. doi: 10.3389/ftox.2022.937168. PMID: 35832492; PMCID: PMC9271854; Lea IA, Pham LL, Antonijevic T, Thompson C, Borghoff SJ. Assessment of the applicability of the threshold of toxicological concern for per- and polyfluoroalkyl substances. Regul Toxicol Pharmacol. 2022 Aug;133:105190. doi:10.1016/j.yrtph.2022.105190. Epub 2022 Jun 1. PMID: 35662637.

E. PFNA

For PFNA, the Proposed Rule relies on the ATSDR Toxicological Profile and individual journal articles. There are no EPA assessments of PFNA toxicity. As described above, both of these types of evidence are inadequate to support an Appendix VIII listing. The weakness of the database is seen in EPA's description of PFNA toxicity in the Proposed Rule. For instance, when considering immune effects, the Proposed Rule notes that, while some studies found associations, other studies reported inverse associations or no associations.[60] Public comment, peer review, and robust systematic reviews that evaluate the weight of the scientific evidence, for each endpoint, and consider epidemiological, clinical, and toxicological data, are necessary minimum criteria for an Appendix VIII listing and the data cited for listing PFNA do not meet these criteria.

F. PFHxS

For PFHxS, the data relied upon in the Proposed Rule are similar to the data for PFNA, with one difference. The Proposed Rule relies upon the ATSDR Toxicological Profile, individual journal articles, and also a draft EPA IRIS assessment. The draft IRIS assessment underwent an external contractor-run peer review, and no peer review report is available at this point in time. Thus, these data do not meet minimum criteria that should be necessary for an Appendix VIII listing.

G. PFDA

For PFDA, the Proposed Rule relies on the ATSDR Toxicological Profile, a draft IRIS assessment, and individual journal articles. As described above, none of these evidence streams are sufficient to justify an Appendix VIII listing. In addition, for PFDA, the ATSDR Toxicological Profile was unable to quantify a minimal risk level due to insufficient data to quantify an adverse effect.[61]

IV. The Cost of Listing These Substances Is Likely Far Greater Than the Benefits.

A. EPA is not precluded from considering costs in hazardous constituent listing under RCRA Section 3001.

In addition to failing to consider the weight of the scientific evidence, EPA in the Proposed Rule inappropriately fails to consider costs. As an initial matter, EPA errs when it asserts that it is not permitted to consider cost when deciding whether to list a substance in Appendix VIII. EPA claims in the Proposed Rule that, under its Section 3001 authority, cost is not a "required or permissible factor" to consider because cost has no "bearing or relevance" on the criteria for listing a substance in Appendix VIII.[62] EPA further claims that cost may not be considered in identifying hazardous constituents under Section 3004(u), which authorizes the identification of hazardous constituents subject to Corrective Action.[63] While the statutory criteria and EPA's

[60] 89 Fed. Reg. at 8,614.
[61] ATSDR Peer Review Agenda for the Toxicological Profile for Perfluoroalkyls (PFAS), available at: https://www.atsdr.cdc.gov/sites/peer_review/tox_profile_perfluoroalkyls.html.
[62] 89 Fed. Reg. at 8,611.
[63] 89 Fed. Reg. at 8,611–12.

implementing regulations do not mandate the consideration of costs, they certainly do not prohibit the consideration of costs in determining whether a substance should be listed in Appendix VIII.

EPA itself acknowledges its authority to consider cost in developing standards under RCRA. Its 1980 rulemaking stated that, while "EPA may not consider cost burden upon industry in choosing the level of its standards" under RCRA, it may "take cost considerations in account in order to select the most effective regulation among various alternatives that meet the statutory requirement of being 'necessary to protect human health and the environment.'"[64] Since EPA is not precluded from evaluating cost in order to select the most effective regulation, and it is possible that less stringent alternatives could achieve the desired aim of protecting human health and the environment, the Coalition urges EPA to consider the cost of implementing these Appendix VIII listings in relation to the benefit. The U.S. Supreme Court has consistently held that, absent statutory text to the contrary, agencies should consider the costs and benefits of their actions. As the dissenting Justices in *Michigan v. EPA* emphasized, "[c]ost is almost always a relevant—and usually, a highly important—factor in regulation. Unless Congress provides otherwise, an agency acts unreasonably in establishing 'a standard-setting process that ignore[s] economic considerations.' … ([A]bsent contrary indication from Congress) an agency must take costs into account in some manner before imposing significant regulatory burdens."[65] Section 3001 of RCRA does not expressly preclude EPA from considering costs in making determinations regarding listing hazardous constituents or hazardous wastes; therefore, those considerations must be taken into account.

In the Proposed Rule, EPA refers to the scope of the proposal as "limited" and repeatedly refers to the direct costs of the rule as "negligible." Although substantial indirect (or secondary) costs are presented in the economic analysis,[66] EPA does not treat them as meaningful when discussing the impacts of the proposal. Instead, EPA focuses solely on the direct costs and ignores the indirect costs. This is contrary to relevant executive orders and the Office of Management and Budget's (OMB) guidance on regulatory analysis. EPA's Guidelines for Preparing Economic Analysis is clear that indirect costs must be considered.[67] These guidelines refer to Executive Order 12866, stating: "EO 12866 specifies that an assessment of the costs of a regulation should include '***any adverse effects*** on the efficient functioning of the economy and private sector (including productivity, employment, and competitiveness)' ***in addition to compliance costs***." (emphasis added).[68] The Guidelines recommend that "[a]nalysts should take care to think through potential secondary or indirect effects of the policy options as well, as these

[64] Hazardous Waste Management System: Identification and Listing of Hazardous Waste, 45 Fed. Reg. 33,084, 33,089 (May 19, 1980).
[65] *Michigan v. EPA*, 576 U.S. 743, 769 (2015) (Kagan, J., dissenting); *compare id.* at 752–53 (opinion of the Court) ("Agencies have long treated cost as a centrally relevant factor when deciding whether to regulate. Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions."); *id.* at 747, 760 (holding that EPA interpreted provision of Clean Air Act unreasonably when EPA deemed cost irrelevant to its decision whether to regulate hazardous air pollutants).
[66] EPA, Economic Assessment of the Potential Costs, Benefits, and Other Impacts of the Proposed Rulemaking to List Specific PFAS as RCRA Hazardous Constituents (Jan. 2024), available at: https://www.regulations.gov/document/EPA-HQ-OLEM-2023-0278-0179 ("Economic Analysis")
[67] EPA, Guidelines for Preparing Economic Analyses (updated May 2014), available at: https://www.epa.gov/sites/default/files/2017-08/documents/ee-0568-50.pdf.
[68] *Id*. at 8-7.

may prove to be important."[69] Additionally, OMB provides guidance to all federal agencies on regulatory analysis in Circular A-4.[70] This circular, which was recently updated in 2023, refers to the additional costs of a regulation as indirect or ancillary costs or countervailing risks and states that efforts should be made to quantify and monetize these effects.[71] Furthermore, Circular A-4 recognizes that the "inappropriate omission" of costs should be avoided.[72]

EPA's omission of all discussion of these costs in the Proposed Rule preamble must be corrected, and EPA must consider the complete monetary impacts of listing the nine PFAS, including the indirect costs. In addition, as described below, EPA's analysis in the Economic Analysis underestimates costs and overestimates benefits. As such, EPA must take into consideration that the costs of the Proposed Rule far exceed the public health benefits.

B. EPA underestimates important indirect costs.

There is no question that there will be additional costs, on a facility-specific basis, if EPA lists nine PFAS chemicals as hazardous constituents. EPA admits this in the Economic Analysis,[73] but assumes that the number of facilities that initiate Corrective Action will be consistent with the historical rate. This assumption is unsupported and likely underestimates costs. Although EPA recognizes that costs will be incurred when permits are renewed, and that there may also be additional costs for facilities that are already subject to Corrective Action, EPA likely underestimates those costs.[74] Notably, EPA recognizes that the additional costs of listing PFAS chemicals would impact all phases of the Corrective Action program, including the performance of a RCRA Facility Assessment (RFA), the completion of the more detailed RCRA Facility Investigation (RFI), the development of a Corrective Measures Study (CMS), taking interim actions, and Corrective Measures Implementation (CMI) (i.e., implementation of the appropriate remedy).[75] Recognizing the uncertainties in predicting these costs, EPA uses hypothetical scenarios to evaluate potential cost increases of 2%, 5%, and 10% relative to a baseline for TSDFs subject to Corrective Action. EPA has not justified excluding costs greater than 10%, and there are many reasons why these costs may be greater.

For instance, EPA arbitrarily assumes that the cost for each initial RFA that is in Corrective Action will be 15 percent of the low end of RFI costs.[76] EPA provides no data to support this assumption. Also, based on historical data, EPA assumes that only 42% of the RFIs are followed by CMI.[77] Because EPA is publicly characterizing PFAS as an emerging contaminant of concern, and because EPA has suggested extremely low cleanup levels in the context of other EPA rulemakings (see for instance EPA's proposed rule to regulate PFAS under the Safe Drinking Water Act), it is highly likely that more than 42% of RFIs would be followed by some type of Corrective Action measure. This assumption alone leads to an underestimate of over

[69] *Id*. at 7-3.
[70] Office of Management and Budget, Circular No. A-4 (Nov. 9, 2023), https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf.
[71] *Id*. at 40.
[72] *Id*.
[73] Economic Analysis at 10.
[74] *Id*. at 11, 101.
[75] *Id*. at 11.
[76] *Id*. at 102.
[77] *Id*.

$1,000,000 for just the very large facilities.[78] Further, given the broad occurrence of PFAS in the environment, PFAS may be present even when unrelated to facility operations. If this Proposal is finalized, those PFAS may become the subject of corrective action, imposing additional costs on facilities that do not use these substances through their operations.

EPA's underestimation of costs is compounded by its assumption that some corrective measures used for PFAS contamination of soil or groundwater would likely already be applied for other hazardous constituents. Additionally, EPA assumes that PFAS in soil and groundwater is co-located with other contaminants that are being addressed by remediation and does not consider that the occurrence of PFAS may differ from other constituents, thus requiring different remedial treatment and new remediation infrastructure at a potentially greater cost. For example, EPA suggests that granular activated carbon (GAC) may already be applied at facilities to remediate groundwater contamination involving other hazardous constituents, but it provides no data to support or quantify this assumption. EPA suggests that remediation of PFAS contaminants might only increase the pace of GAC replacement. It does not consider that many facilities may need to switch to GAC to remediate PFAS, and that this would lead to additional and new infrastructure costs. EPA has not sufficiently considered these costs. The Economic Analysis describes some private and Department of Defense costs to remediate PFAS and notes that remediation, including using GAC systems, has cost upwards of $2.5 million to $8.2 million per facility.[79] However, despite recognizing there are greater than 25 "very large" TSDFs that may need to undergo Corrective Action, EPA caps the hypothetical cost scenario at only a 10% increase, seemingly paying no attention to the infrastructure costs at facilities that may need to put in place programs to remediate PFAS.

EPA has not considered the costs of disposing of spent GAC and resin. There are also potential costs to the environment of using GAC that are not accounted for by EPA. For example, a recent study from Maine found that PFAS mitigation using GAC may actually increase greenhouse gas emissions in the state: "greenhouse gas emissions for water treatment to bring PFAS down to the current interim standard are substantial, raising the footprint of an average user by 6.7–18 percent."[80] The report explains that GAC is sourced either directly from coal or generated by high-temperature treatment of biomass, and in some states (like Maine), there are no GAC manufacturers, so it must be transported by freight.[81] The report discusses that GAC would be an "add-on" to many water treatment systems because it is not effective for typical drinking water contaminants like arsenic; thus, "[t]hese factors combined may mean substantial GHG emissions."[82] In addition, EPA has not finalized its Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing

[78] *See* Exhibit 4-9 in the Economic Analysis. EPA assumes that only 25 of the very large facilities undergo corrective measures. If EPA assumed that all facilities took corrective measures, this value would be over $1.7 million for just the very large facilities, assuming a 10% cost increase.
[79] Economic Analysis at 4.3.1 and 4.3.2.
[80] Benjamin McAlexander, "Estimated Greenhouse Gas Emissions from EPAS Treatment of Maine Drinking Water," Maine Policy Review, Vol. 31 at 41 (2022), available at https://digitalcommons.library.umaine.edu/mpr/vol31/iss1/4.
[81] *Id*. at 42.
[82] *Id*.

Perfluoroalkyl and Polyfluoroalkyl Substances.[83] This delay calls into question EPA's acceptance of long-standing disposal methods and the limited capacity of existing TSDFs to receive PFAS waste.

EPA also recognizes that "[p]otential associated costs may be incurred by TSDFs that are already in Corrective Action as well as TSDFs not currently in Corrective Action."[84] EPA considers the costs to TSDFs that have already completed Corrective Action but may need to be reopened to address a specific PFAS release. For the analysis of those facilities that have completed Corrective Action and may need to be reopened, EPA underestimates costs because it again inappropriately assumes that only 42% of the facilities that conduct RFIs will perform a CMS.[85] As discussed earlier in these comments, it is likely that a much greater percentage of facilities with PFAS that conduct RFIs will likely perform a CMS. And the analysis does not consider the impacts of facilities that are currently in Corrective Action but may need to reconsider or change planned corrective measures that are under consideration due to the need to potentially address PFAS.

C. EPA overestimates indirect benefits.

EPA's analysis of potential monetized benefits stemming from the indirect impacts of PFAS remediation are scaled from EPA's proposed PFAS National Primary Drinking Water Regulation (NPDWR). These benefits are overestimated for many reasons. First, EPA quantified benefits related to the PFOA and PFOS health effects purported to be related to renal cancer, birth weight impacts, and cardiovascular disease (CVD). In particular, EPA quantified reductions in medical costs and mortality associated with PFAS decreases. As described in detail in the Coalition comments on the NPDWR,[86] EPA's benefits analysis is quantitatively flawed because it is not grounded in science. Importantly, even though EPA overestimates the quantified benefits, EPA's analysis itself indicates that the quantified benefits are much lower than the quantified indirect costs.[87]

To evaluate CVD, EPA quantifies benefits for PFOA and PFOS by evaluating total cholesterol and high-density lipoprotein cholesterol (HDLC). However, in the NPDWR, in table 42, EPA clearly notes that for HDLC the "[e]vidence of the relationship between the PFAS compound and the health outcome is not conclusive."[88] Based on EPA's own evaluation, it is not likely that these benefits will accrue, and this endpoint should not have been quantified. Similarly, EPA's justification for relying on birth weight as a critical adverse developmental effect for PFOA and

[83] *See* U.S. EPA, Interim Guidance on Destroying and Disposing of Certain PFAS and PFAS-Containing Materials That Are Not Consumer Products, available at: https://www.epa.gov/pfas/interim-guidance-destroying-and-disposing-certain-pfas-and-pfas-containing-materials-are-not.
[84] Economic Analysis at 87.
[85] *Id*. at 106.
[86] Chamber of Commerce and Coalition, Comments on EPA's PFAS National Primary Drinking Water Regulation Rulemaking Preliminary Regulatory Determination and Proposed Rule, 88 Fed. Reg. 18,638 (Mar. 29, 2023) (submitted May 30, 2023), available at: https://www.regulations.gov/comment/EPA-HQ-OW-2022-0114-1713.
[87] The Economic Analysis estimates indirect costs to be between $5,000,000 and $21,500,000 and estimates indirect benefits to be between $266,000 and $12,200,000. *See* EPA, Economic Assessment of the Potential Costs, Benefits, and Other Impacts of the Proposed Rulemaking to List Specific PFAS as RCRA Hazardous Constituents (Jan. 2024), at 21, 25, available at: https://www.regulations.gov/document/EPA-HQ-OLEM-2023-0278-0179.
[88] 88 Fed. Reg. at 18,704 n.5.

PFOS is also not supported by the body of scientific literature as a whole. The studies upon which EPA relied to justify a relationship did not consider confounding by other chemical and non-chemical stressors, including by other PFAS. While EPA in the NPDWR acknowledges uncertainties in the science and concerns with the studies used, it did not address the concerns and continued to inappropriately use these studies to support quantitative analysis. As presented in Table 6-50 of EPA's economic analysis for the NPDWR, there are significant limitations and uncertainties in the analysis of birth weight benefits.[89] Additionally, as we describe in our comments on the NPDWR, and as even EPA recognizes, the epidemiological evidence does not support a causal association between PFOA and renal cancer.[90] Yet EPA quantified benefits of reducing renal cell carcinoma and relied upon a study with which the external peer reviewers expressed concerns due to an outlier in the data.[91]

In addition to overestimating quantified benefits, EPA notes there are also unquantified benefits to human health due to PFAS reductions through Corrective Action. EPA does not identify these health benefits and notes that "they did not have adequate information for monetization."[92] However, in the NPDWR, non-quantified health benefits are discussed, and many of these benefits, including benefits related to the hepatic system, endocrine outcomes, and musculoskeletal system, are highly speculative and are not supported by the weight of the scientific evidence.[93] In the NPDWR, EPA describes many of these benefits as "possible" or "potential" benefits, but neither the existing record in the NPDWR nor this Proposed Rule includes information to support these benefits as being "likely" to accrue.

D. EPA's small entity analysis lacks sufficient clarity.

While EPA presents a small entity analysis, as required by the Regulatory Flexibility Act (RFA), EPA's analysis is inadequate. Though EPA recognizes that 612 facilities (47% of all TSDFs) may be considered small entities,[94] EPA conducts a break-even analysis looking at only 75 small entities. Unfortunately, this analysis cannot be subject to public comment because it is not sufficiently transparent. EPA uses an incremental cost value of $54,900, as is shown in Exhibit 6-3 in the Economic Analysis, but it does not explain how this number was derived.[95] Without further clarity, the public is unable to determine whether EPA has correctly analyzed the impacts on small entities.

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[89] *See* U.S. EPA *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances*, 2023, at 6-113 to 6-116.

[90] Chamber of Commerce and Coalition, Comments on EPA's PFAS National Primary Drinking Water Regulation Rulemaking Preliminary Regulatory Determination and Proposed Rule, 88 Fed. Reg. 18,638 (Mar. 29, 2023) (submitted May 30, 2023), available at: https://www.regulations.gov/comment/EPA-HQ-OW-2022-0114-1713.

[91] *Id.*

[92] *See* U.S. EPA *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances*, 2023, at 130.

[93] *See* discussion in the Chamber of Commerce and Coalition, Comments on EPA's PFAS National Primary Drinking Water Regulation Rulemaking Preliminary Regulatory Determination and Proposed Rule, 88 Fed. Reg. 18,638 (Mar. 29, 2023) (submitted May 30, 2023), available at: https://www.regulations.gov/comment/EPA-HQ-OW-2022-0114-1713.

[94] Economic Analysis at 141.

[95] *Id.* In footnote 183 of the Economic Analysis, EPA provides a discussion of the estimate, but this discussion does not allow a reader to reproduce the analysis. In particular, the footnote refers to a value of $86,200, which is not presented in Exhibit 6-3, nor is it discussed anywhere else in the Economic Analysis.

V. The Coalition Strongly Opposes Proceeding to a Full Hazardous Waste Listing for Any of the Nine PFAS.

Under the criteria codified at 40 C.F.R. § 261.11, a hazardous constituent listing is a precursor to a hazardous waste listing. This is because, under one of the available pathways for listing hazardous waste provided in Part 261, EPA must evaluate solid wastes containing any of the toxic constituents listed in Appendix VIII. The Proposed Rule explicitly states that "a hazardous constituent listing is a step toward a potential hazardous waste listing," and, "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 hazardous waste."[96] EPA further explains that it "will continue to evaluate available data to determine whether a future regulatory action to list certain PFAS, or waste containing such PFAS, as a regulatory hazardous waste is appropriate."[97]

If EPA were to take the next step of listing one or more of these PFAS as hazardous waste, it would subject those substances to cradle-to-grave regulation under RCRA, a much broader set of requirements than for substances listed as hazardous constituents.

Listing these nine substances as hazardous wastes would affect not only TSDFs and interim status facilities, but also handlers of PFAS and PFAS-containing products across the lifecycle of the substances, including generators and transporters. Generators in particular would face increased costs related to transporting and disposing of PFAS-containing waste in hazardous waste landfills. Because EPA is not currently proposing to list any of the nine PFAS at issue as hazardous waste, the Coalition has not prepared a detailed analysis of such costs for the purpose of these comments. The Coalition notes, however, that a full hazardous waste listing for any of these nine PFAS would impose substantial costs on a broad universe of corporate entities without providing any clear benefit to human health or the environment. As detailed above, the weight of the scientific evidence does not support Appendix VIII listing for any of the nine PFAS, let alone a full hazardous waste listing.

The Coalition is equally concerned about impacts under other statutory regimes if EPA proceeds to a full hazardous waste listing. CERCLA defines "hazardous substances" in part as "any hazardous waste having the characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act [42 U.S.C. § 6921]."[98] Therefore, if EPA eventually lists any of these nine PFAS as hazardous wastes, they would automatically be treated as hazardous substances under CERCLA, triggering liability for cleanup costs from releases or threatened releases of those substances.

As detailed in prior comments, the Coalition opposes the designation of PFAS as hazardous substances under CERCLA. Listing any of these nine PFAS as hazardous wastes under RCRA would result in a hazardous substance designation under CERCLA, potentially bringing millions of landowners around the country under CERCLA jurisdiction and possibly prompting the reopening of thousands of CERCLA sites. While EPA may use its enforcement discretion to avoid bringing actions against landowners with small amounts of PFAS contamination, these persons could still face potential liability through contribution and cost recovery actions by third

[96] 89 Fed. Reg. at 8,609.
[97] *Id.*
[98] 42 U.S.C. § 9601(14).

parties. Designating PFAS as hazardous substances under CERCLA will slow down the already multi-year, often multi-decade, Superfund site cleanup process at existing sites (which involves site assessment, remedial investigation, feasibility study, remedial design, and remedial action). Further, listing under CERCLA would affect every real estate transaction for properties where the relevant PFAS are potentially present. The widespread presence of these substances may present significant challenges for buyers attempting to qualify for CERCLA's limited exemptions, exclusions, and defenses.[99]

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In summary, the Coalition opposes EPA's Proposed Rule to list nine PFAS as hazardous constituents in Appendix VIII to 40 C.F.R. Part 261 in light of the undefined criteria for listing and the inadequacy of EPA's scientific basis for listing these substances. The Coalition urges EPA to develop clear procedures and criteria for listing hazardous constituents in Appendix VIII prior to proposing to list new and emerging contaminants, such as PFAS chemistries, as hazardous constituents.

As a final matter, the Coalition disagrees with EPA's position on when the Proposed Rule, if finalized, would take effect in authorized states. EPA states that it "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 . . . ."[100] As a result, EPA states that "EPA would implement the new rule as applied to corrective action in all States until those States become authorized for the new rule."[101]

That reading of EPA's statutory authority is incorrect. RCRA Section 3006(g) provides that any RCRA rule "which is imposed" pursuant to the 1984 HSWA amendments to RCRA shall take effect in states that have been authorized by EPA to administer the affected RCRA program at the same time they take effect in unauthorized states. That means that rules "that are imposed pursuant to statutory authority that was in place prior to enactment of HSWA" in 1984, in contrast, are non-HSWA rules.[102] By necessary implication, those rules do not take effect in authorized and unauthorized states simultaneously. Section 3001, which was part of the original RCRA, directs EPA to identify and list hazardous wastes by considering, in part, the hazardous constituents in the waste.[103] The corrective action provisions—Sections 3004(u), 3004(v), and 3008(h)—however, were enacted as part of the 1984 HSWA amendments, and do not authorize

[99] For example, regarding the de micromis exemption, the person must have transported or arranged for the disposal of some of the hazardous substance at a given facility on the National Priorities List before April 1, 2001. *See* 42 U.S.C. § 9607(o)(1)(B). Regarding the contiguous properties exemption, the person cannot have caused, contributed to, or consented to the disposal of the hazardous substances on the person's property and is not potentially liable for response costs at another facility. *See* 42 U.S.C. § 9607(q)(1)(A)(i), (ii)(I). Regarding the bona fide prospective purchaser exemption, the person must prove that no disposal of hazard substances at the facility occurred after the person acquired the facility. *See* 42 U.S.C. § 9601(40)(B)(i). Regarding the limited exclusion for state and local governments, they cannot have caused or contributed to the release or threatened release of a hazardous substance from the facility. *See* 42 U.S.C. § 9601(20)(D).
[100] 89 Fed. Reg. at 8,616.
[101] *Id.*
[102] U.S. EPA, State Consolidated RCRA Authorization Manual, OSWER Direction 9540.00-9.
[103] 42 U.S.C. § 6921.

EPA to list hazardous wastes or constituents. Here, EPA has undertaken to list hazardous constituents in Appendix VIII, as it is authorized to do under Section 3004, and thus, the proposed rule, if finalized, would not be "imposed" pursuant to HSWA. That the listing has the effect of adding hazardous constituents for corrective action (under Sections 3004(u), 3004(v), and 3008(h)) does not transform the proposed rule into one "imposed" pursuant to the 1984 HSWA amendments. Thus, as a rule not "imposed" pursuant to HSWA, the proposed rule, if finalized, would become effective on the effective date only in non-authorized states. In authorized states, the final rule would become effective, and enforceable, only after the state adopts it and receives EPA authorization.

Sincerely,

Aerospace Industries Association
Alliance for Chemical Distribution
American Chemistry Council
American Coatings Association
American Fuel and Petrochemical Manufacturers
American Petroleum Institute
Council of Industrial Boiler Owners
Fuel Cell & Hydrogen Energy Association
National Asphalt Pavement Association
National Association for Surface Finishing
National Council of Textile Organizations
National Mining Association
National Oilseed Processors Association
PRINTING United Alliance
RCRA Corrective Action Project
Superfund Settlements Project
The Fertilizer Institute
The Meat Institute
TRSA - The Linen, Uniform and Facility Services Association
U.S. Chamber of Commerce

Cc: Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management, EPA