December 9, 2024

The Honorable Michal Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: Environmental Protection Agency, Addition of Certain Per- and Polyfluoroalkyl Substances (PFAS) to the Toxics Release Inventory (TRI); Proposed Rule, 89 Fed. Reg. 81,776 (Oct. 8, 2024)

Dear Dr. Freedhoff:

The undersigned organizations appreciate the opportunity to comment on the U.S. Environmental Protection Agency's (EPA's) Proposed Rule, Addition of Certain Per- and Polyfluoroalkyl Substances (PFAS) to the Toxics Release Inventory (TRI) (Proposed Rule).[1] EPA is proposing to add 16 individually listed PFAS, and 15 PFAS categories, to the TRI list of chemicals subject to reporting under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Pollution Prevention Act (PPA). This Proposed Rule is part of EPA's "whole-of-government" approach to addressing PFAS as outlined in its 2021-2024 PFAS Strategic Roadmap.[2]

We are part of the U.S. Chamber of Commerce Coalition of Companies and Trade Associations (the Coalition), which represents manufacturers and processors of PFAS, downstream product manufacturers and users of PFAS products, previous manufacturers and processors, and businesses in other areas of the value chain across the broad economy potentially impacted by the Proposed Rule. The Coalition is composed of a wide cross-section of trade associations and industries, including aerospace, automotive, construction, electronics, energy, mining, health care, telecommunications, textiles, private recyclers, waste management facilities, and other community stakeholders, including first responder services, and water and wastewater utilities. The Coalition also represents businesses potentially subject to TRI reporting obligations for the proposed PFAS to be listed. The U.S. Chamber of Commerce is the largest business trade association in the world, representing more than 3 million companies of all sizes and sectors.

[1] 89 Fed. Reg. 81776 (Oct. 8, 2024).
[2] EPA, PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024, at 11, PFAS Strategic Roadmap: EPA's Commitments to Action 2021—2024 (stating as a key action to "enhance PFAS reporting under the Toxics Release Inventory").

Our organizations are concerned that EPA's proposal to list 16 individual PFAS and 15 categories of PFAS on the TRI:

- Fails to put forth a sufficient scientific record for listing required to meet EPCRA's standards for scientific evaluation.
- Inappropriately relies upon Provisional Peer-Reviewed Toxicity Values and EPA Transcriptomic Assessment Products for automatic TRI listing.
- Is not warranted under the National Defense Authorization Act (NDAA), which does not authorize an automatic listing of the proposed PFAS, nor does it authorize a sweeping designation of all PFAS listed on the TRI as "Chemicals of Special Concern."[3]
- Does not provide the scientific evidence to support an arbitrary 100-pound reporting threshold and removal of the *de minimis* exemption for supplier notifications.
- Will lead to miscommunication and misunderstanding regarding the risk of PFAS chemistries.
- Improperly proposes to list *categories* of PFAS, which is inconsistent with the NDAA's mandate.
- Is not supported by EPA's inadequate cost analysis.

For these and other reasons, we are concerned that the Proposed Rule, if finalized, would be deemed unsupported by record evidence, and otherwise arbitrary and capricious, in violation of the Administrative Procedure Act (APA).

The Coalition supports EPCRA's goal to provide the public, through the TRI program, with meaningful information about the risk of exposure to certain chemicals. The members of the Coalition are dedicated to promoting sustainability, environmental stewardship, and the safety of our companies' employees and the communities where we live and operate. However, it is important for EPA to fully evaluate the human health, environmental, economic, safety, legal, and other practical impacts of any potential regulatory requirement. We urge EPA to utilize appropriate processes and criteria to ensure that the proposed action is based on the best available science-based information and risk-based decision making to inform potential impacts to health and the environment. With this in mind, we are eager to work with EPA to protect human health and the environment through the risk-based approach contemplated under EPCRA.

[3] Comments of the U.S. Chamber of Commerce on Environmental Protection Agency Proposed Rule: *Changes to Reporting Requirements for Per- and Polyfluoroalkyl Substances and to Supplier Notifications for Chemicals of Special Concern; Community Right-to-Know Toxic Chemical Release Reporting*, 87 Fed. Reg. 74379 (Dec. 5, 2022) (submitted Feb. 3, 2023).

We urge EPA to consider these comments and to make appropriate modifications before listing of any PFAS chemistries to the TRI.

I. EPA Has Not Put Forth a Sufficient Scientific Record for Listing Under EPCRA, Which Requires a Science-Based Approach to the Listing of PFAS on the TRI

EPA's proposed listing for this group of PFAS substances and categories of substances fails to meet the standards for scientific evaluation required by EPCRA. Section 313(d)(2) of EPCRA requires that, for a chemical to be listed due to human health impacts, it must be "known to cause" or "reasonably anticipated to cause" certain health effects.[4] For chronic effects other than cancer, these effects must be "serious or irreversible."[5] For environmental endpoints, EPA must show "a significant adverse effect on the environment of sufficient seriousness" to justify listing.[6] The scientific evaluations that EPA relies upon to make determinations regarding a TRI listing for a chemical must meet basic requirements to be scientifically robust, to be considered reliable, and to sufficiently support EPA's finding that the EPCRA standard for listing chemicals under TRI has been met. Consistency with best practices, transparency and rigor must be hallmarks of evaluations for listing a chemical, and the approach used should include using systematic review methodologies to evaluate evidence.[7] Systematic review methods provide a structured, reproducible, and transparent approach for evaluating evidence from disparate scientific studies to inform a conclusion that is representative of the weight of the scientific evidence. For chemicals, a weight of the evidence approach is one in which evidence from animal, human, and mechanistic studies are evaluated and synthesized to draw an overall conclusion that weighs all the information to determine the likelihood of a hazard being associated with a particular chemical.[8] When weighing scientific information, one important factor is understanding the quality of each piece of evidence so that assessors can give appropriate weight to each item of relevant evidence.

When considering a chemical for a TRI listing, EPA must ensure that best practices are utilized, including a weight of the scientific evidence approach. And, consistent with best practices, EPA's analysis should undergo public comment and peer review to ensure that EPA has appropriately weighed and evaluated information. As described by EPA, "peer review has been fundamental in developing the sound and defensible scientific and technical work products that support Agency

[4] 42 U.S.C. § 11023(d)(2)(A)-(B).
[5] 42 U.S.C. § 11023(d)(2)(B).
[6] 42 U.S.C. § 11023(d)(2)(C).
[7] See for example EPA's requirements for risk evaluation under the Toxic Substances Control Act, 89 Fed. Reg. 37028 (May 3, 2024), available at: https://www.federalregister.gov/documents/2024/05/03/2024-09417/procedures-for-chemical-risk-evaluation-under-the-toxic-substances-control-act-tsca, and EPA's IRIS handbook, 2022, which requires systematic review, available at: https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=356370#tab-3.
[8] See for example EPA's discussion of weight of the evidence in EPA's *Guidance on Use of Weight of the Evidence When Evaluating the Human Carcinogenic Potential of Pesticides*, 2023, available at: https://www.epa.gov/system/files/documents/2023-06/2023%20CARC%20WoE%20Guidance.pdf.

decisions."[9] EPA has also recognized the importance of public comment, which provides important input to peer review and enhances the transparency of the peer review process.[10]

A. TRI Listing Support Documents Are Not of Sufficient Scientific Rigor to Support the Proposed Listings

The TRI listing support documents that EPA developed for this Proposed Rule do not meet scientific standards of reliance for TRI listings. As noted above, for health effects, EPA must show that the individual PFAS or PFAS category proposed to be listed is known or reasonably anticipated to cause cancer or other serious or irreversible effects. For environmental endpoints, EPA must show a significant adverse effect on the environment of sufficient seriousness to warrant reporting. And EPA should use a transparent and reproducible systematic review framework to evaluate all the available information. As part of these evaluations, EPA must consider the quality of the individual studies cited. The EPA TRI listing support documents are scientifically insufficient and do not provide sufficient evidence to establish that the criteria under EPCRA section 313(d)(2) have been met. In particular, the listing documents do not provide a weight of the scientific evidence review,[11] lack discussion of the quality of studies considered, and do not articulate why health effects are "serious or irreversible."[12] For environmental effects, the listing support documents do not explain why EPA finds the effects to be serious enough to warrant listing. In addition, while EPA says that the listing support documents were reviewed internally by at least three EPA scientists, this type of review does not comport with the requirements for external independent peer review.

Eleven individual PFAS and four categories of PFAS rely on TRI listing support documents. Because these documents do not meet basic requirements to ensure sufficient scientific rigor for regulatory use, these PFAS should not be listed. These PFAS include:

Individual PFAS:

1. 1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-(MeFBSA) (CASRN 68298–12–4) (Chronic Human Health)
2. 1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-(2- hydroxyethyl)-N-methyl-(MeFBSE) (CASRN 34454–97–2), (Chronic Human Health)

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[9] EPA Peer Review Handbook: 4th Edition, Executive Summary, available at: https://www.epa.gov/sites/default/files/2015-10/documents/october_19-20_2015_hsrb_meeting_-_final_agenda.pdf.

[10] EPA Peer Review Handbook: 4th Edition, available at: https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf.

[11] In the 1994 rulemaking, EPA conducted a thorough hazard assessment analysis and determined on the weight of the evidence whether there was sufficient evidence to establish that the candidate chemical met the statutory criteria for addition to EPCRA under section 313. U.S. EPA, *Addition of Certain Chemicals; Toxic Chemical Release Reporting; Community Right-to-Know*, 59 Fed. Reg. 61432, 61433 (Nov. 30, 1994).

[12] For example, the listing support document for 2-methylpentane (see https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0538-0470) has not explained why increased liver weight and changes in serum chemistry in rats would be known or reasonably anticipated to cause "serious or irreversible" effects in humans. Similarly, the listing document for PFDoA (see https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0538-0469) does not explain why elevated liver weights and potential alterations in lipid homeostasis and energy metabolism in rats would be known or reasonably anticipated to cause a "serious or irreversible" effects in humans.

3. Cyclopentene, 1,3,3,4,4,5,5- heptafluoro- (HFCPE) (CASRN 1892– 03–1) (Effect on the Environment)
4. Ethanesulfonamide, 1,1,2,2,2- pentafluoro-N-[(pentafluoroethyl) sulfonyl]-, lithium salt (CASRN 132843–44–8) (Chronic Human Health)
5. 6:2 Fluorotelomer alcohol (6:2 FTOH) (CASRN 647–42–7), (Chronic Human Health)
6. Pentane, 1,1,1,2,2,3,4,5,5,5- decafluoro-3-methoxy-4- (trifluoromethyl)- (CASRN 132182–92–4) (Chronic Human Health)
7. Perfluorotridecanoic acid (PFTrDA) (CASRN 72629–94–8) (Effect on the Environment)
8. Perfluoro(2-ethoxy-2-fluoroethoxy) acetic acid ammonium salt (EEA–NH4) (CASRN 908020–52–0) (Chronic Human Health)
9. 2-Propenoic acid, 2-[methyl[(nonafluorobutyl)sulfonyl]amino]ethylester (MeFBSEA) (CASRN 67584–55–8). (Chronic Human Health)
10. Triethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8- tri-deca-fluorooctyl)silane (CASRN 51851–37–7) (Chronic Human Health)
11. Trifluoro(trifluoromethyl) oxirane (HFPO) (CASRN 428–59–1), (Chronic Human Health)

PFAS Categories:

12. 9-Chlorohexadecafluoro-3-oxanone-1-sulfonic acid (9Cl-PF3ONS) (CASRN 756426–58–1), Salts, and Sulfonyl Halides Category
13. 11-Chloroeicosafluoro-3-oxaundecane-1-sulfonic acid (11Cl-Pf3OUdS) (CASRN 763051–92–9), Salts, and Sulfonyl Halides Category
14. Perfluorododecanoic acid (PFDoA) (CASRN 307–55–1)*, Salts, Acyl Halides, and Anhydride Category
15. Perfluoroundecanoic acid (PFUnA) (CASRN 2058–94–8), Salts, Acyl Halides, and Anhydride Category

B. ECOTOX Is Not of Sufficient Scientific Rigor to Support Proposed Listings

EPA also relies on the EPA ECOTOX Knowledgebase (ECOTOX) application to inform a proposed PFAS listing. ECOTOX is simply a web-based application that lets a user find information related to the aquatic, terrestrial, and wildlife effects of a chemical.[13] It is a compilation of data that is drawn from other databases, but it provides no weight of the evidence evaluation, and EPA's analysis of the data in ECOTOX has not undergone peer review or public comment. EPA inappropriately relies on ECOTOX for the proposed listing of one chemical, fulvestrant (CASRN 129453–61–8). EPA's justification for listing is based upon results from three individual journal articles that were identified through ECOTOX. Yet EPA provides no weight of the evidence review, presenting only the results from these three journal publications without mention of any other studies that may support or refute these results. A search of the ECOTOX database for fulvestrant yields 533 results.[14] While these results do not necessarily

[13] 89 Fed. Reg. at 81780.
[14] Search conducted Nov. 18, 2024 using "fulvestrant."

represent 533 individual studies, EPA has identified over 50 studies, and ECOTOX provides no way to synthesize, integrate, or weigh all of that data.[15] EPA provides no discussion regarding why the three studies discussed in the Proposed Rule are sufficiently reliable for regulatory purposes. In addition, there has been no opportunity for peer review or public comment on EPA's choice to rely on these three studies, and EPA provides no discussion of any of the other information available in ECOTOX for fulvestrant.

The evaluation EPA has provided is not sufficiently robust to show that fulvestrant is known to cause or can be reasonably anticipated to cause a significant adverse effect on the environment. Thus, fulvestrant should not be listed as proposed.

C. HAWC Is Not of Sufficient Scientific Rigor to Support Proposed Listings

EPA also relies on the EPA Health Assessment Workspace Collaborative (HAWC) for the listing of one PFAS category, 1H,1H, 2H, 2H-Perfluorooctane Sulfonic Acid (6:2 fluorotelomer sulfonic acid, 6:2 FTS) (CASRN 27619– 97–2), Salts, Sulfonyl Halides, and Anhydride Category. EPA has identified, by CAS number, six PFAS that would be part of this category. HAWC is another web-based application tool that allows EPA to assess chemicals and make findings publicly available; however, unlike ECOTOX, HAWC focuses on human health assessments. EPA has used HAWC to make publicly available a summary (also referred to as a systematic evidence map) of available epidemiology and animal data for approximately 150 PFAS. EPA relies on the data files created as part of the evaluation of the approximately 150 PFAS, as well as one journal article, to determine that the 6:2 FTS and members of this category cause serious or irreversible chronic effects. Yet EPA provides no weight of the evidence evaluation, and EPA has not sought public comment or peer review of this conclusion. The evaluation provided in the Proposed Rule, and supporting documentation, is not sufficient to support a listing for 6:2 FTS and members of this category.

D. Draft IRIS Values Are Not of Sufficient Scientific Rigor to Support Proposed Listings

Finally, EPA relies on draft IRIS values to support the listing of two PFAS categories, Perfluorohexanesulfonic acid (PFHxS) (CASRN 355–46–4), Salts, Sulfonyl Halides, and Anhydride Category and Perfluorononanoic acid (PFNA) (CASRN 375–95–1), Salts, Acyl Halides, and Anhydride Category. Because these values are drafts and have not completed the peer review and public comment processes, which includes providing responses to peer review and public comments, these two PFAS categories should not be listed.

In total, at minimum, 11 individual PFAS and 7 PFAS categories should not be listed as proposed because they do not meet the scientific standards necessary to justify that these PFAS chemicals

[15] *See* EPA supporting documentation "Fulvestrant casrn129453618 Ecotox-Aquatic-Export 20230816," available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0538-0049.

and categories meet the required criteria under EPCRA section 313(d)(2). EPA should carefully consider all comments made on this topic.

II. EPA Should Limit the Scope of Toxicity Value Sources that Are Relied Upon for Automatic Listing

Consistent with NDAA section 7321(c), additional PFAS are automatically added to the TRI list when certain criteria are met. These criteria include adding PFAS which have a "Final Toxicity Value."[16] In this proposed rulemaking, EPA provides a list of EPA events which it interprets as "finalizing a toxicity value."[17] EPA seeks to include its Provisional Peer-Reviewed Toxicity Values (PPRTVs) and EPA Transcriptomic Assessment Products (ETAP) on this list. We do not support using PPRTV and ETAP values to support TRI listings.

PPRTVs are used to support EPA's Superfund program. They are not considered to be tier one toxicity values and have uncertainty factors applied to reflect the limitations of the data. In addition, some PPRTVs are often considered to be screening values. PPRTVs are typically developed from a small evidence base. Because of the shortcomings in the data, these assessments are not sufficiently scientifically robust to support a finding of "known" or "reasonably anticipated" effects, as is required by EPCRA. EPA must rely upon more robust assessments to support the automatic listing of PFAS onto the TRI.

Similarly, ETAP values are developed for chemicals that lack traditional toxicity testing data. They are developed using a transcriptomics approach that measures gene activity, not adverse effects, and they are intended to be applied to data-poor chemicals that lack repeat dose studies in animals or suitable human evidence.[18] As described by EPA, "[t]he coordinated transcriptional changes used to identify the POD do not necessarily discriminate between specific hazards, adverse or adaptive effects, nor are they used to infer a mechanism or mode of action."[19] Because the values developed cannot identify adverse effects, these values are not sufficient to ensure that a PFAS chemical would meet the EPCRA listing criteria, which require an understanding of "known" or "reasonably anticipated" effects that are "serious or irreversible." Accordingly, ETAP values are not of sufficient rigor or specificity and should not be used to inform automatic listings of chemistries to the TRI.

III. Contrary to EPA's Assertion, Section 7321(d) of the NDAA Does Not Provide a Statutory Basis for Listing All of the Proposed PFAS Chemicals and Categories

In addition to failing to provide an adequate scientific record to support listing of certain PFAS and categories in the Proposed Rule, EPA's proposal also lacks a stable legal foundation. EPA

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[16] P. Law 116-92 § 7321(c)(1)(A)(i).
[17] 89 Fed. Reg. at 81799.
[18] *See* U.S. EPA, *Standard Methods for Development of EPA Transcriptomic Assessment Products (ETAPs)* (Mar. 6, 2024), available at: https://cfpub.epa.gov/si/si_public_record_Report.cfm?dirEntryId=360671&Lab=CCTE.
[19] EPA, Scientific Support for Transcriptomic Points of Departure, Mar. 2024, at page 16, available at: https://cfpub.epa.gov/si/si_public_record_Report.cfm?dirEntryId=360670&Lab=CCTE.

cites section 7321(d) of the NDAA as part of its authority to list the proposed PFAS to the TRI.[20] Despite already exceeding the two-year time frame directed by Congress to take action under section 7321(d), EPA broadens the scope of PFAS described by this section of the NDAA and infers an instruction from Congress to evaluate a broad scope of PFAS, when in reality the statute directs a narrow evaluation of certain PFAS for potential TRI listing. Section 7321(d) of the NDAA sets forth a specific list of PFAS for EPA to evaluate and determine whether TRI listing is appropriate. Through the NDAA, Congress directs EPA to "determine whether the substances and classes of substances described in paragraph (2) meet any one of the criteria described in section 313(d)(2) of [EPCRA]."[21] Paragraph (2) states, "the substances and classes of substances referred to in paragraph (1) are perfluoroalkyl and polyfluoroalkyl substances and classes of perfluoroalkyl and polyfluoroalkyl substances not described in subsection (b)(1), including – " and goes on to list 15 types of PFAS and categories of PFAS that should be considered for inclusion in the TRI.[22]

EPA goes beyond those 15 enumerated categories and proposes to list other PFAS outside of that list. While Congress did not explicitly limit its direction to EPA to consider only the listed categories, in context the best statutory reading does limit EPA from significantly expanding the range of substances beyond what is listed in Section 7321(d), due to time limitations and practicality considerations. This section of the NDAA directs EPA to carry out its determination within two years after the date of enactment of the Act.[23] Given this two-year time frame, which has already lapsed, EPA's expansion of its search to the entire universe of potential PFAS substances to be listed on the TRI is a wholly unreasonable undertaking. EPA attempted to cabin the scope of potential PFAS to consider for listing by analyzing at minimum those PFAS categorized as reportable pursuant to the TSCA PFAS Data Reporting Rule, in addition to other chemicals not on the TSCA inventory. Even if EPA's undertaking is focused only on substances that meet the definition of "PFAS" under the TSCA PFAS Reporting Rule (which comprised only a subset of the chemicals EPA considered in this Proposed Rule), it would be assessing 1,462 PFAS substances.[24] It would be unworkable for Congress to expect that any and all of these nearly 1,500 substances at minimum could or should be evaluated in only a two-year period after the date of enactment of the NDAA. The best reading of section 7321(d)(2) is that EPA was directed to evaluate the substances enumerated in the statute for TRI listing within the period of time allotted by the statute, rather than the arbitrarily broad reading of the statute EPA employed in the Proposed Rule to search far and wide for substances not on that list. Further, since EPA will not be able to finalize this rule until well after the two-year deadline, it should not reach beyond the 15 PFAS that Congress mandated.

While NDAA does not provide a statutory basis for EPA to list on the TRI PFAS substances which are not enumerated in section 7321(d)(2), EPCRA section 313(d) does provide the

[20] 89 Fed. Reg. at 81777.
[21] P. Law 116-92, § 7321(d)(1).
[22] P. Law 116-92, § 7321(d)(2).
[23] P. Law 116-92, § 7321(d)(1).
[24] U.S. EPA, *Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances*, 88 Fed. Reg. 70516, 70519 (Oct. 11, 2023).

authority for EPA to add and remove substances. But as described in section I above in detail, EPA has not provided sufficient scientific information to support listing many of those PFAS under the relevant section 313 criteria.

IV. EPA's Designation of These PFAS Listed Under Section 7321(d) as "Chemicals of Special Concern" Warranting a 100-Pound Reporting Threshold Is Arbitrary and Capricious

EPA has not asserted a lawful basis or developed an administrative record to support its consideration of all the PFAS chemicals proposed to be listed under this action as "chemicals of special concern" under 40 C.F.R. § 372.28. Through the NDAA, around 200 PFAS chemicals have been listed on the TRI, either by being added by name under section 7321(b) or after triggering one of NDAA's criteria for listing under section 7321(c). Each of these chemicals was listed with an initial congressionally determined reporting threshold of 100 pounds,[25] subject to EPA's revision if it determines a different threshold amount is warranted for a particular chemical.[26] As support for its proposal to add PFAS identified under section 7321(d) of the NDAA to the list at 40 C.F.R. § 372.28, EPA cites its finalization of a 2023 rule to categorize PFAS added to the TRI by NDAA sections 7321(b) and (c) as chemicals of special concern, highlighting NDAA's prescribed initial 100-pound reporting threshold for those chemicals.[27] EPA now proposes to add all of the PFAS described in this Proposed Rule to the list at 40 C.F.R. § 372.28, despite lacking the same underpinning rationale from the NDAA. Whereas sections 7321(b) and (c) do contain an initial 100-pound reporting threshold subject to revision by the Administrator, NDAA section 7321(d) – under which many of these chemicals are being listed – does not contain the same provision. It is silent on a lower reporting threshold. Had Congress wanted EPA to consider the 100-pound threshold as its starting point for all PFAS, or just for all PFAS added under section 7321(d), it could have included the 100-pound threshold language, as it did in sections 7321(b) and (c). Thus, EPA cannot rely on the same justification it provided for its 2023 rule to add this suite of PFAS to the list of chemicals of special concern.

Absent a statutory provision directing EPA to apply an initial reporting threshold of 100 pounds for each of the substances listed under section 7321(d) of the NDAA, EPA must rely on its authority under EPCRA section 313(f)(2), which authorizes the Administrator to "establish a threshold amount for a toxic chemical different from the amount established in paragraph (1)" (i.e., the default amounts of 10,000 and 25,000 pounds per year).[28] However, EPA does not even cite this provision in its Proposed Rule as a statutory basis for this action reducing the reporting threshold for this group of PFAS. EPA instead improperly cites the NDAA, which does not in

[25] P. Law 116-92, § 7321(b)(2)(A); § 7321(c)(2)(A) ("the threshold for reporting under section 313 the substances and classes of substances included in the toxics release inventory under paragraph (1) is 100 pounds.").
[26] P. Law 116-92, § 7321(b)(2)(B)(i); § 7321(c)(2)(B)(i) ("Not later than 5 years after the date of enactment of this Act, the Administrator shall . . . determine whether a revision to the threshold . . . is warranted.").
[27] 89 Fed. Reg. at 81798 (citing Environmental Protection Agency, *Changes to Reporting Requirements for Per- and Polyfluoroalkyl Substances and to Supplier Notifications for Chemicals of Special Concern; Community Right-to-Know Toxic Chemical Release Reporting; Proposed Rule*, 87 Fed. Reg. 74,379–74,387 (Dec. 5, 2022)).
[28] 42 U.S.C. § 11023(f).

fact set forth a baseline reporting threshold for EPA to consider when listing the substances set forth in section 7321(d).

Even if it had relied on the correct statutory provision authorizing this action, EPA still provides no technical or scientific justification for the 100-pound threshold, rendering it arbitrary and capricious. It cites the Agency's reason for first creating the list of chemicals of special concern in 1999 — to "increase the utility of TRI data by ensuring that the data collected and shared through TRI are topical and relevant."[29] In 1999, EPA added a list of chemicals identified as persistent, bioaccumulative, and toxic (PBT). In that rule, EPA added 18 chemicals and chemical categories to the list of chemicals of special concern on the basis that they meet the criteria for toxicity and persistence in the environment.[30] Here, however, EPA has not undertaken a substance-by-substance analysis to demonstrate that each one meets the only criteria EPA has used to add chemicals to this list in the past (i.e., the "persistence in the environment" and "tendency to bioaccumulate in the environment" in EPCRA section 313(d)(2)(C)) or any other criteria warranting heightened treatment.

Instead, EPA takes an arbitrarily broad approach of listing all PFAS that have been individually listed to the TRI as chemicals of special concern, as opposed to just those listed under sections 7321(b) and (c), as was done in the 2023 rulemaking at Congress' direction in the NDAA. Not all PFAS carry the same hazards, and EPA should acknowledge that each substance or category of substances has differing properties and risk profiles. Taking a "one size fits all" approach to such a large aggregation of substances, without requiring an individual assessment demonstrating that each one meets heightened criteria, is arbitrary and paves the way for EPA to automatically include all TRI-listed PFAS as chemicals of special concern in the future without an individualized scientific record justifying the heightened treatment. By proposing to treat such a disparate range of PFAS chemistries identically, EPA risks undermining the purported intent behind the list of chemicals of special concern, directing significant resources, focus, and enforcement efforts to chemicals that have not been shown to give rise to significant risks and potentially diluting the value of information transmitted to the public through the TRI program.

EPA attempts to justify its approach, stating that "EPA finds that it is appropriate to maintain consistency for all chemicals added to the TRI pursuant to the NDAA (i.e. those PFAS previously added by NDAA section 7321(b) and (c)). Therefore, EPA is proposing to establish a 100-pound . . . reporting threshold for the PFAS proposed for addition in this action."[31] Here, under the guise of maintaining "consistency," the Agency proposes an approach which would warrant treating potentially thousands of distinct and unrelated PFAS substances in the same

[29] 89 Fed. Reg. at 81798 (citing Environmental Protection Agency, *Persistent Bioaccumulative Toxic (PBT) Chemicals; Lowering of Reporting Thresholds for Certain PBT Chemicals; Addition of Certain PBT Chemicals; Community Right-to-Know Toxic Chemical Reporting*, 64 Fed. Reg. 58,666 (Oct. 29, 1999)).
[30] 64 Fed. Reg. at 58671 ("EPA has made the final determination that 18 of the chemicals and chemical categories proposed meet the EPCRA section 313 criteria for persistence and bioaccumulation. Thus, EPA is lowering the reporting threshold for all of these toxic chemicals.").
[31] 89 Fed. Reg. at 81797-81798.

manner in the future, without providing the administrative record to back up the approach for each individual substance.

EPA does not purport to propose to add this group of PFAS as chemicals of special concern due to their categorical persistent and bioaccumulative properties (as was done in 1999), and, even if it did purport to do that, its scientific record for each proposed PFAS to be listed would not support that finding. Absent a showing that these substances in fact individually meet some criteria for being considered chemicals of special concern deserving of a heightened reporting threshold, EPA's proposal to do so is arbitrary and capricious. EPA should instead use a quantitative, science-based regulatory approach that is based on sound, peer-reviewed science and a transparent and well-informed record.

In addition to taking an unlawfully broad approach to listing these PFAS as chemicals of special concern warranting a lower reporting threshold, EPA's Proposed Rule will be unworkable and impractical for industry to implement. Prior to EPA's 2023 rulemaking, the list of chemicals of special concern contained fewer than 20 substances and substance groups. This formerly narrow category carries a significantly lower reporting threshold than the standard threshold under EPCRA, and an exemption from the *de minimis* supplier notification, resulting in a much higher level of monitoring, tracking, and reporting required for these substances. The list is rapidly growing to now include a broad range of hundreds of PFAS substances, for which identifying low concentrations is often impractical, and may not even be scientifically possible. In addition, the listing of these PFAS as chemicals of special concern will have a substantial financial impact and administrative burden on companies throughout the value chain, especially small entities.

V. EPA Should Not List PFAS Categories on the TRI

EPA should not list categories of PFAS as proposed. As described above, EPA misinterprets NDAA section 7321(d), which directs EPA to evaluate "*classes* of [PFAS] not described in subsection (b)(1) . . ,"[32] rather than chemical *categories* of PFAS. Section 7321(d) lists the relevant individual substances and classes of PFAS in sections 7321(d)(2)(N) and 7321(d)(2)(O). These two classes, identified in sections 7321(d)(2)(N) and 7321(d)(2)(O), correspond to (1) substances for which a method to measure levels in drinking water has been validated by the Administrator and (2) substances that are used to manufacture fluorinated polymers, respectively. EPA's interpretation of the NDAA's use of "classes" of PFAS to indicate that the Agency should list *categories* for other individual PFAS is not supported by the statutory language. "Classes" and "categories" are well-accepted as being different, both in EPA's own treatment of the terms and under OECD guidance.[33] EPA's proposed categories, which include the associated salts, associated acyl/sulfonyl halides, and anhydrides of PFAS, are different from the "classes" that are discussed in the NDAA. Thus, the language of the NDAA does not support listing "categories" of PFAS as EPA has proposed.

[32] P. Law 116-92, § 7321(d)(2) (emphasis added).
[33] OECD, *Guidance on Grouping of Chemicals, Second Edition*, OECD Series on Testing and Assessment, No. 194 (2017), available at: https://doi.org/10.1787/9789264274679-en.

While the NDAA does not support the listing of categories, at a bare minimum EPA should include only PFAS that are identifiable by a CAS number, or list each individual PFAS separately, assuming that the individual PFAS meets the TRI listing criteria. EPA specifically seeks comment on this issue, asking if the categories should include PFAS beyond the examples provided for the individual categories.[34] The clear answer to this is no. If EPA cannot identify the chemical by CAS number, it should not be included in the category, and TRI reporting should not be required.

Allowing EPA to list categories that include PFAS that EPA has not yet identified will cause significant uncertainty for the regulated community and is arbitrary and capricious. EPA's Economic Assessment for the Proposed Rule provides a discussion of the benefits of improving consumer and public knowledge regarding PFAS.[35] However, when EPA lists chemicals on TRI as categories, these benefits will not occur. Researchers and communities will not learn from TRI reporting the composition of releases and the relative toxicity, likely fate, and transport, or the potential exposure of the individual PFAS in the category, since chemicals within the category have different physical and toxicological properties. Similarly, researchers and regulators would not be able to compare different facilities, since two facilities could report the same mass amount corresponding to a category but have very different amounts of individual chemicals within that mass. Similarly, researchers cannot compare the same facility over time due to the same uncertainty. Since chemicals within the same category may be substitutes for each other, reporting by category diminishes the incentive to switch to lower toxicity compounds, because this action will not reduce the reporting burden and associated costs. Finally, because reporting by categories does not provide useful information, the proposed data collection lacks practical utility under the Paperwork Reduction Act.

EPA's positions are inconsistent. If EPA believes that many PFAS generally meet the criteria for chemicals of special concern, and thus that the release and the use of small amounts of individual PFAS generally have policy relevance, it defeats the purpose to group many PFAS together in a category and gather information primarily on the larger total mass. EPA should refrain from listing categories and after considering risk and cost considerations, EPA should list only individual PFAS chemistries that meet the EPCRA listing criteria.

EPA's analysis should include balancing economic impacts with the benefits of improved public health and environmental protection. Yet, EPA has not provided this analysis.

VI. EPA's Cost Analysis Is Incomplete and Insufficient

The cost analysis provided by EPA in the Proposed Rule is insufficient and very likely underestimates costs. While previous economic analyses of TRI regulations have included capital costs for electronic data gathering, data storage, and reporting, the analysis in the

[34] 89 Fed. Reg. at 81804.
[35] EPA, Economic Analysis for the Addition of Certain Per- and Polyfluoroalkyl Substances; Community Right-to-Know Toxic Chemical Release Reporting Rulemaking: Proposed Rule (RIN 2070-AL03), Dec. 14, 2023, available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0538-0476.

Proposed Rule considers only the cost to fill out Form R.[36] EPA has not included any of the capital and equipment costs that may be associated with measuring PFAS levels. This leads to an underestimate of actual costs. In addition, tracking and reporting mixtures containing PFAS at concentrations less than the current *de minimis* thresholds would take significant time and effort across multiple industry sectors and would be burdensome for the TRI reporting facilities, further increasing the costs of its proposed rule. Before finalizing a proposal, which would remove the *de minimis* exemption, list additional substances as chemicals of special concern, and alter the supplier notification requirements, EPA must amend its economic analysis to correctly reflect the quantifiable costs of its proposal. As noted above, EPA has not accounted for the added costs of ensuring that potentially reportable releases are evaluated for even trace amounts of PFAS. And EPA must appropriately consider these costs.

In addition to including capital costs for electronic data gathering and data storage, EPA must also consider the added cost of tracking *de minimis* levels of the proposed PFAS in releases that must be reported. While EPA's TSCA section 8(a)(7) rulemaking's economic analyses also underestimated the costs,[37] EPA should at least include costs in this regulatory action comparable to those described in the section 8(a)(7) analyses.

EPA has provided no justification for why its "proxy approach" as described in the Proposed Rule economic analysis is sufficient. EPA uses proxy chemicals to estimate the incremental increase in Form R reports. As EPA notes, EPA's review of PFAS chemicals reported in the 2020 Chemical Data Reporting (CDR) rule is not informative because the reporting threshold was 25,000 pounds for the PFAS. Therefore, EPA relied on data from two other chemistries as proxies.[38] These two chemistries, pentachlorobenzene and hexachlorobenzene, are not appropriate proxies despite their 10-pound reporting threshold. EPA provides no discussion for why it expects changes that occurred when these two chemicals were listed to be a valid proxy for the PFAS chemistries that EPA proposes to list. In addition, EPA relies upon a method that assumes there will be a 15 percent increase in supplier notifications[39] and provides no justification for why this value is appropriate and is not an underestimate. EPA should provide a reasoned basis for using this value. And surprisingly, EPA provides no discussion of the uncertainties in this analysis.

EPA's cost analysis has also not considered the impacts on small businesses of removing the *de minimis* exemption, thus making the analysis conducted under the Regulatory Flexibility Act insufficient. Given that EPA estimates that upwards of 120,000 facilities subject to federal environmental programs have operated or currently operate in industry sectors with processes that may involve handling and/or release of PFAS,[40] EPA has likely underestimated the number

[36] 89 Fed. Reg. at 81809.
[37] See comments from the US Chamber of Commerce et al., Sept. 27, 2021, available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0549-0066.
[38] EPA, Economic Analysis for the Addition of Certain Per- and Polyfluoroalkyl Substances; Community Right-to-Know Toxic Chemical Release Reporting Rulemaking: Proposed Rule (RIN 2070-AL03), Dec. 14, 2023, available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0538-0476.
[39] *Id*.
[40] *See* EPA, PFAS Analytic Tools, available at https://echo.epa.gov/trends/pfas-tools.

of impacted small entities, as not all NAICS codes cited in the Proposed Rule preamble are included in the small-entity analysis, and EPA's high-end estimate of impacted small entities only includes 865 businesses. EPA should revise its analysis to include the impacts of removing this exemption, and the analysis must include the costs of requiring small businesses to measure all waste streams for low levels of PFAS.

Finally, EPA's economic analysis has not considered the costs of reporting that may be required by states and tribes. Some states, like Florida, require fees for using Form R, which are greater than using other TRI reporting forms.[41] Nor has EPA considered that reporting will need to include industries, state emergency responders, tribes, and airports that store AFFF. These arbitrary exclusions lead to an underestimation of the costs of this Proposed Rule.

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We appreciate the opportunity to comment on EPA's Proposed Rule. We support science and risk-based regulation of substances, including particular PFAS, that may pose risks to the public. EPA has not provided the necessary science or legal justifications for this Proposed Rule, and we request that EPA reconsider the proposed listings and the proposed changes EPA intends to make for all PFAS listings. Please contact Chuck Chaitovitz, Vice President of Environmental Affairs and Sustainability, at cchaitovitz@uschamber.com with any questions regarding these comments.

Sincerely,

Alliance for Chemical Distribution
American Apparel and Footwear Association
American Chemistry Council
American Coatings Association
American Fuel & Petrochemical Manufacturers
American Petroleum Institute
Council of Industrial Boiler Owners
National Association of Manufacturers
National Association for Surface Finishing
National Asphalt Pavement Association
National Council of Textile Organizations
National Oilseed Processors Association
National Mining Association
Plastics Industry Association
PRINTING United Alliance
SEMI
TRSA – The Linen, Uniform and Facility Services Association
U.S. Chamber of Commerce

[41] *See* https://www.epa.gov/toxics-release-inventory-tri-program/tri-state-contacts#:~:text=Facilities%20reporting%20electronically%20do%20not,Form%20A%20through%20E%2DPlan%20.