

February 3, 2023

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: Proposed Rule, 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, 87 Fed. Reg. 74,379–74,387 (December 5, 2022)

Dear Dr. Freedhoff:

The U.S. Chamber of Commerce (“Chamber”) and our coalition of companies and trade associations appreciate the opportunity to comment on the 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”).<sup>1</sup> The coalition represented in this letter (“Coalition”) includes businesses in many areas of the broad economy that are potentially impacted by this Proposed Rule, including aerospace, agriculture, automotive, construction, electronics, energy, mining, health care, telecommunications, and textiles, and other community stakeholders (e.g., first responder services, water and wastewater utilities, and waste management facilities). The Coalition’s members include members with facilities subject to the Emergency Planning and Community Right-to-Know Act (“EPCRA”) reporting requirements under the Toxics Release Inventory (“TRI”) Program.

The Coalition supports the goals of EPCRA and the TRI program to provide the public with meaningful information about the risk of exposure to certain toxic chemicals. The members of the Coalition are also dedicated to promoting the safety of our companies’ employees and the communities where we live and operate. With these commitments in mind, we are eager to work with U.S. Environmental Protection Agency (“EPA”) and all stakeholders to protect human health and the environment through the risk-based approach enshrined in long-standing U.S. environmental law and policy. In doing so, it is important for EPA to fully evaluate and take into consideration the human health,

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<sup>1</sup> 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. 74,379 (proposed Dec. 5, 2022) (to be codified at 40 C.F.R. Part 372).

environmental, economic, safety, and other practical impacts of any potential regulatory requirements and to utilize appropriate processes and criteria to ensure that evaluation of regulatory actions is based on risk and the best science-based data and information to demonstrate the national impact on public health and the environment.

The Coalition recognizes that Congress specifically added many of the per- and polyfluoroalkyl substances (“PFAS”) at issue in this rulemaking directly to the TRI reporting list through the National Defense Authorization Act of 2020 (“NDAA”). In doing so, however, Congress did not authorize or express an intention for EPA to take further steps to place more onerous reporting requirements on these substances. Nor did Congress preclude or truncate the application of ordinary administrative law requirements to the agency action proposed here. If anything, the fact that this large group of substances did not go through an initial scientific review by EPA or any public notice and comment process before the listing suggests that EPA should take a more individualized and methodical assessment of each substance before taking further actions to ensure that there is a scientific justification for the treatment.

As it stands, the Coalition is concerned that EPA’s unscientific proposal would place unnecessary compliance burdens and enforcement risks on the business community, especially small entities, without resulting in commensurate emergency response or public information benefits. Instead, the proposed disclosures may mislead the public by requiring reporting of *de minimis* amounts of substances for which there are insufficient health risk data and may make it more difficult for the public to distinguish between the level of risk posed by exposure to these various substances. Furthermore, by designating all PFAS as Chemicals of Special Concern, including additional unspecified PFAS that will be automatically listed by virtue of the NDAA in the future, EPA risks causing confusion to members of the public. As a result, the Proposed Rule would undermine rather than further EPCRA’s disclosure purpose. In addition, EPA must consider and analyze intermediate regulatory options, such as the option of removing the *de minimis* exemption or of adding a Chemicals of Special Concern designation for only those PFAS with a known risk profile that justify such treatment, or the option of differentiating between the PFAS chemistries already on the TRI and those that were specifically added through the NDAA.

As further detailed below, EPA’s current approach must be revised because it is arbitrary and capricious, an abuse of discretion, unsupported by record evidence, and contrary to law in violation of the Administrative Procedure Act (“APA”). In particular, the Proposed Rule:

- Is invalid because EPA, in relying solely on Congress’s determination (made for a different purpose) concerning a 100-pound reporting threshold, has not developed a record indicating that all PFAS listed pursuant to the NDAA should be treated as Chemicals of Special Concern and lose the *de minimis* exemption.
- Underestimates and does not justify the burdens and cost of compliance that the Proposed Rule would place on the regulated community.

- Fails to accurately account for the costs that the Proposed Rule would impose on small businesses, in violation of the Regulatory Flexibility Act.
- Does not comply with the Paperwork Reduction Act (“PRA”).
- Raises serious enforcement and due process concerns that have not been adequately considered by EPA.<sup>2</sup>

In order to avoid these legal deficiencies, the Coalition requests that EPA take the following actions:

- Withdraw the current proposal and instead separately propose the removal of the *de minimis* exemption for individual or a limited number of PFAS chemistries (if any) for which EPA has sufficient scientific support for doing so in stand-alone individualized rulemakings.
- Withdraw or separately propose adding individual or a limited number of PFAS (if any) to the list of Chemicals of Special Concern for those PFAS (if any) where EPA has sufficient scientific support for doing so in stand-alone individualized rulemakings.
- Withdraw or separately propose the removal of the *de minimis* exemption for the supplier notification requirement for Chemicals of Special Concern in a stand-alone rulemaking.
- Sequence finalizing any new rules regarding the treatment of PFAS chemicals under the TRI program after EPA’s Toxic Substances Control Act (“TSCA”) Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances rule<sup>3</sup> (“TSCA PFAS Proposed Rule”) has been finalized to prevent duplicative, unnecessary, or conflicting reporting obligations.
- Revise the economic analysis for this or any future TRI rulemakings to accurately reflect the costs of these requirements and ensure that they do not outweigh the benefits.
- Convene a Small Business Regulatory Enforcement Fairness Act (“SBREFA”) panel to provide advice and recommendations on regulatory alternatives to minimize the burden on small companies.

While the Coalition does not support the inclusion of the proposed removal of the *de minimis* exemption for the supplier notification requirement, if EPA retains this provision in any final rule, the Coalition alternatively requests that any supplier notification requirements that are included in any final rule be simplified to reduce the burdens imposed by this requirement. In order to reduce the problems presented by EPA’s current approach, EPA should at the very least pare down supplier notification requirements so that they only include the particular name or CAS number of the PFAS and a range of the concentration

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<sup>2</sup> See 5 U.S.C. § 557.

<sup>3</sup> TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 86 Fed. Reg. 33,926 (June 28, 2021).

and/or amount would be adequate to provide purchasers with transparent, adequate information for their own reporting and notification requirements.

We respectfully note that we requested an extension to the comment period for the Proposed Rule, which was denied. The period provided has not been sufficient for stakeholders to consider and comment on all of the implications of the Proposed Rule and the significant shift in policy that it represents, particularly in light of the holiday season and numerous other proposals released by EPA for public comment during the same time period. In consideration of the issues raised below, we ask that EPA reopen the comment period after issuing a revised proposal or proposals.

**I. EPA has not developed an administrative record indicating that all PFAS chemicals should uniformly lose the use of the *de minimis* exemption or be considered as Chemicals of Special Concern.**

As the agency is aware, PFAS is a broad term that is used to refer to several thousand chemicals that share certain common structural features. Through the NDAA, almost 200 of these chemicals have been listed automatically on the TRI, either by having been expressly added to the list or after triggering one of the NDAA's criteria for listing, each with a congressionally determined initial reporting threshold of 100 pounds. On the sole basis of this threshold, EPA now is undertaking this Proposed Rulemaking, which would automatically designate all PFAS listed under these NDAA triggers as "Chemicals of Special Concern," a heightened category within the broader TRI that is reserved for chemicals which have been shown to be persistent, bioaccumulative, and toxic ("PBT"). Historically, when singling out a chemical or group of chemicals as Chemicals of Special Concern, the EPA has performed assessments or reviewed data both on the chemicals' hazards and separately on the PBT criteria. However, in this Proposed Rulemaking, EPA is taking this new regulatory step without such assessments for many of the nearly 200 PFAS listed so far by the NDAA provisions. EPA is doing so based on its misplaced interpretation of Congress's establishing an initial 100-pound threshold for the PFAS listed via the NDAA. This is an overbroad reading of the relevant NDAA provisions and goes beyond the scope of what Congress directed EPA to do.

Not all PFAS carry the same hazards, and only a few have been shown to be associated with, and may cause, health impacts.<sup>4</sup> EPA knows, and should acknowledge, that this rulemaking addresses nearly 200 separate and distinct chemicals, each of which has different properties and risk profiles. Taking a "one-size-fits-all" regulatory approach to such a large group of substances is concerning in its own right, and made more so by the fact that any future PFAS chemical added through the NDAA will also be added as a Chemical of Special Concern without an individualized assessment. Applying this heightened level

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<sup>4</sup> See, e.g., Minnesota Department of Health, Per- and polyfluoroalkyl substances (PFAS) and Health (Sept. 6, 2022), <https://www.health.state.mn.us/communities/environment/hazardous/docs/pfashealth.pdf>.

of regulation to any PFAS chemical that triggers TRI listing via the NDAA is not an approach that is anchored in science. This approach is problematic here and should not be precedent-setting for other substances where EPA has not performed the assessments necessary to determine whether the heightened regulatory approach is justified or evidence that it effectively advances the purposes of the TRI.

EPA admits it has not studied [in detail] the vast majority of PFAS subject to the proposed rule.<sup>5</sup> EPA acknowledges that “exposure to high levels of *certain* PFAS *may* lead to adverse health outcomes,” but has not shown that these potential hazards can be generalized to all 189 substances.<sup>6</sup> EPA also contends that “some PFAS have the ability to bioaccumulate,”<sup>7</sup> but likewise has not shown that this can be generalized, nor that the potential for bioaccumulation, on its own, warrants designation as Chemicals of Special Concern. This is particularly concerning, as EPA is simultaneously proposing to designate the new PFAS chemicals as Chemicals of Special Concern without performing individual assessments while *further* proposing to remove *de minimis* exemptions for supplier notifications. Although EPCRA allows thresholds to be established by “classes of chemicals or categories of facilities,”<sup>8</sup> EPCRA also contemplates that chemicals on the TRI already have undergone an individual assessment, adding “a chemical” one at a time in order to be listed on the TRI in the first place.<sup>9</sup> EPA has not established, however, that it has reached a similar conclusion for PFAS as a class; on the contrary, the PFAS listed via the NDAA are being added as separate chemicals, not regulated as a group of similar compounds. Indeed, in the past, EPA has acknowledged that “just because two chemicals have similar structures does not always mean they will have similar toxic endpoints at similar doses.”<sup>10</sup> Designating all PFAS listed under the NDAA provisions as Chemicals of Special Concern would represent a significant expansion of the universe of substances considered Chemicals of Special Concern: there are currently fewer than 20 substances and substance groups in this category, and EPA is proposing to add nearly 200 new substances

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<sup>5</sup> See, e.g., EPA, “Our Current Understanding of the Human Health and Environmental Risks of PFAS,” <https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas> (last updated Mar. 16, 2022) (“There are thousands of PFAS with potentially varying effects and toxicity levels, yet most studies focus on a limited number of better known PFAS compounds.”); EPA, “PFAS Strategic Roadmap: EPA’s Commitments to Action 2021–2024,” p. 7 (2021), [https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap\\_final-508.pdf](https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf) (noting that “significant gaps remain related to the impacts of other PFAS on human health and in the environment”); Agency for Toxic Substances and Disease Registry and the Environmental Protection Agency (EPA), *Toxicological Profile for Perfluoroalkyls* (May 2021) (indicating that a comprehensive sampling of literature related to PFAS only includes 12 PFAS, and that most studies were on PFOA and PFOS).

<sup>6</sup> EPA, “Our Current Understanding of the Human Health and Environmental Risks of PFAS” (emphasis added).

<sup>7</sup> E.g., Proposed PFAS Rule, 74381

<sup>8</sup> 42 U.S.C. §§ 11002(a)(3)(B), 11021(b).

<sup>9</sup> 42 U.S.C. § 11023(d)(2).

<sup>10</sup> Addition of Certain Chemicals; Community Right-to-Know Toxic Chemical Release Reporting, 87 Fed. Reg. 73,475, 73,482 (Nov. 30, 2022) (to be codified at 40 C.F.R. pt. 372).

without any individualized assessment, and without establishing that their effects are similar enough to be treated as a group.

In order to avoid finalizing a rule that is arbitrary and capricious, is an abuse of discretion, and is not in accordance with law, EPA should instead use a quantitative, risk-based regulatory approach that is based on sound, peer-reviewed science and a transparent and well-informed record. PFAS chemistries should each be evaluated independently, or in appropriate sub-categories. Alleged hazards associated with one member of the PFAS class should not be attributed to other members of the broader PFAS class without clear scientific justification. Any grouping of PFAS for risk assessment should also be justified scientifically within the administrative record. We have [linked](#) the recommendations that we previously provided to the Science Advisory Board on questions to be considered when developing subcategories and request that EPA take these considerations into account as it reviews and revises this proposal.

- A. EPA is misinterpreting Congress' direction in the NDAA, which only uses the flexibility provided under EPCRA to set an initial reporting threshold for the listed PFAS chemicals and does not direct EPA to further regulate them as Chemicals of Special Concern.

EPA misinterprets Congress' direction in proposing to automatically treat the PFAS listed via the NDAA as Chemicals of Special Concern and to remove the *de minimis* exemption. Even though Congress has determined that certain new PFAS chemicals should be subject to TRI reporting, that does not mean that they all pose the same risks when released in small quantities, or that Congress intended EPA's proposed result. EPA asserts that, because Congress "set a 100-pound reporting threshold for PFAS," Congress "indicates a concern for small quantities of such PFAS" which justifies the downward threshold revision.<sup>11</sup> However, in the NDAA, Congress specifically required that EPA undertake a review to determine if a revision is warranted for the threshold amount.<sup>12</sup> This indicates that Congress did not intend for this smaller threshold quantity to be set in stone, but instead expected the agency to independently review the thresholds set in the NDAA and expected EPA to do so based on the statutory criteria for determining a threshold amount under EPCRA, which requires an individualized assessment grounded in the best available science and the transparency and public participation in this process that are required by the APA. Congress reasonably expected EPA to update these thresholds once additional information about their risk profiles was developed, and for EPA to use that updated data as the basis for its individualized regulatory determinations.

Had Congress wanted to permanently set the thresholds for all listed PFAS at 100 pounds, it could have done so; it also could have explicitly directed EPA to designate these PFAS as Chemicals of Special Concern, and it did not. Indeed, legislation to lower the reporting threshold for PFAS has been introduced

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<sup>11</sup> 87 Fed. Reg. at 74,382.

<sup>12</sup> National Defense Authorization Act for Fiscal Year 2020, Pub. L. No. 116-92 § 7321(b)(2)(B).

several times and failed, indicating that there is not congressional will to take the step that EPA would make with this rulemaking. Similarly, Congress also could have specified that the *de minimis* reporting exemption was not available for these substances as they become listed via the NDAA. It did not. As a result, Congress did not exempt EPA from its obligation to continue to follow the requirements of both EPCRA and the APA in considering establishing any further requirements for these substances, including a science-based individualized assessment of how to treat each newly added substance under the TRI program. EPA cannot use its interpretation of the NDAA to abdicate reasoned decision-making under EPCRA or the APA.

Likewise, the NDAA does not provide congressional direction that these substances should be treated uniformly as Chemicals of Special Concern. This is particularly true for PFAS that may be added to the TRI in the future. In the NDAA, Congress specified that PFAS other than those specifically identified in the NDAA will be added to the TRI following the determination of a final toxicity value, a significant new use rule (“SNUR”), or the addition of a PFAS to an existing SNUR, or the addition of a PFAS as an “active chemical substance” via a covered determination under TSCA. These represent first-line analyses, the results of which may not always show that a chemical should be treated as a Chemical of Special Concern. For example, promulgation of a final toxicity value alone represents EPA’s conservative estimate of a level of exposure that is likely to be without an appreciable risk of deleterious effects during a lifetime, and should function as the beginning of a wider assessment, not prompt special treatment on its own.<sup>13</sup> The U.S. Army Public Health Center, when describing the uses of toxicity values, cautions that factors such as whether animal or human data are used “may render a chemical to appear more potent than another, when similar scientific uncertainty may actually be present.”<sup>14</sup> Similarly, a SNUR may be issued for a variety of reasons, and does not necessarily imply that the affected substance presents an unreasonable risk.<sup>15</sup> Whether a chemical for which a SNUR has been issued should be treated as a Chemical of Special Concern should be evaluated on an individual basis.

Here, the toxicological profile included in the administrative record for this Proposed Rule is limited to 10 perfluoroalkyl categories, chemicals, and associated salts—PFBA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnA, PFDoDA, PFBS, PFHxS, PFOS, and FOSA. EPA has not presented any basis in the administrative record sufficient to show that all 189 PFAS currently listed by the NDAA, or to be listed in the future, reasonably can be listed as Chemicals of Special Concern based on their similar hazards. Indeed, it would be impossible for EPA to reach this conclusion, as EPA does not know which PFAS will trigger TRI listing via the NDAA provisions in the future. By contrast, for previous Chemicals of Special Concern, EPA has conducted multiple separate analyses, both on the individual chemicals’

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<sup>13</sup> See U.S. Army Pub. Health Ctr., Tech. Guide No. 373: Environmental Human Health Risk Assessment Toxicity Values (Dec. 2020).

<sup>14</sup> *Id.* at 3.

<sup>15</sup> TSCA § 5(A)(2)(A)–(D); 40 C.F.R. § 721.170(a).

hazards and to determine whether they are PBT, before determining that such chemicals rise to the level of “special concern.”<sup>16</sup> Even while listing multiple separate chemicals in a single rulemaking, EPA addressed and presented evidence on the individual health and environmental hazards of each, and failed to do so in this Proposed Rule. In order to comply with its legal obligations and create final rules supported by an adequate administrative and scientific record, EPA must likewise ensure that there is sufficient science-based and peer-reviewed support in the record to list each PFAS as a Chemical of Special Concern. At the very least, in order to comply with the APA, EPA must provide a sufficient explanation for why it has deviated from its past listing practice.

It is true that precedent exists for listing substances as Chemicals of Special Concern that originally were placed onto the TRI by an act of Congress (*e.g.*, Aldrin). However, those substances were added onto the list 13 years after they were placed on the TRI and had received much more scientific research, as shown by how EPA explained in detail why each individual chemical was being listed as a Chemical of Special Concern.<sup>17</sup>

- B. Automatically treating PFAS listed under the NDAA as Chemicals of Special Concern dilutes the value of the category and risks confusing and misleading TRI data users.

It is inappropriate for EPA to automatically consider all PFAS that undergo these first-line analyses specified in the NDAA as Chemicals of Special Concern. Currently, the list of Chemicals of Special Concern is a targeted list of fewer than 20 substances and substance groups, and EPA has not created an administrative record here indicating that the recently added PFAS chemistries warrant this designation, much less the ones that will be automatically added in the future under the NDAA or other legislation.

EPA specifically notes “improved understanding, awareness, and decision-making related to the provision and distribution of information on releases and waste management” as “benefits” of the Proposed Rule.<sup>18</sup> But by proposing to treat all listed PFAS chemistries identically, EPA risks undermining these purported benefits and the purpose of the TRI program and the narrower Chemicals of Special

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<sup>16</sup> “EPA conducted a hazard assessment on each chemical being proposed for addition to the EPCRA section 313 list of toxic chemicals. This assessment was separate and independent from the review conducted to determine each chemical’s persistence and bioaccumulation potential, although EPA considered some of the same data in certain of its hazard assessments. EPA found that each chemical being proposed for addition meets the criteria for chronic human toxicity and/or environmental toxicity, as set forth at EPCRA section 313(d)(2)(B)–(C).” 64 Fed. Reg. 688, 689 (Jan. 5, 1999).

<sup>17</sup> 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) (to be codified at 40 CFR pt. 372).

<sup>18</sup> EPA, *Economic Analysis for the Proposed Changes to Reporting Requirements for Per- and Polyfluoroalkyl Substances and to Supplier Notifications Requirements for Chemicals of Special Concern Community Right-to-Know Toxic Chemical Release Reporting*, EPA-HQ-TRI-2022-0270-0039 at ES-7 (Nov. 4, 2022) [hereinafter “Economic Assessment”].



Concern list by focusing the business community, local responders, and enforcement efforts on chemicals that have not been shown to give rise to significant risks, or by misleading stakeholders into thinking that all listed PFAS pose the same risks. This concern is magnified by the fact that TRI data is used by the general public, and members of the public may not have the scientific or regulatory sophistication to distinguish among the risks that may be posed by these various substances—particularly when little or no additional risk information is currently available. By designating all PFAS which have triggered the NDAA provisions as Chemicals of Special Concern, EPA’s proposal risks misleading the public into believing that all included PFAS chemistries pose risks when released in small quantities, which is likely to result in unjustified concerns and misallocated resources.<sup>19</sup> By inundating the public with information on such a broad group of chemicals, EPA risks diluting the value of the information and misleading the public as to whether and to what extent there is any risk. This approach would distract limited resources from chemicals that pose the most meaningful risks and thus undermine the purpose of EPCRA.<sup>20</sup> This diminishing value is particularly true for the included PFAS where EPA does not have risk assessment information to share with the public.

This concern is all the more pronounced here as these PFAS chemistries were added by Congress without EPA’s performing a science-based, risk assessment regarding the characteristics and the risks these chemicals would pose in the event of a release, much less a release in *de minimis* amounts. EPA therefore should engage in a peer-reviewed, transparent, chemical-specific review to determine the appropriate treatment of individual PFAS or similarly categorized groups of PFAS under the TRI reporting rules. As part of this process, the public should be afforded the opportunity to review EPA’s scientific assessment and evidentiary record for any asserted health or environmental hazards from exposure to particular PFAS in low concentrations, thus fulfilling the APA’s public participation goals and requirements and helping to ensure better resulting regulations.

EPA’s proposed approach to remove the exemption for all PFAS and to list them all as Chemicals of Special Concern without any individualized findings would therefore violate the APA and EPCRA because it would be arbitrary and capricious, abuse of discretion, not in accordance with law, and not supported by the record.

**II. EPA should reconsider its proposed removal of the *de minimis* supplier notification exemption for all Chemicals of Special Concern, or at the very least address any proposed removal of this breadth in a separate rulemaking.**

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<sup>19</sup> EPA has not established in the administrative record that any of the listed PFAS chemistries pose health risks at *de minimis* thresholds.

<sup>20</sup> LEPCs are already stretched thin and underfunded. See EPA, 2008 Nationwide Survey of Local Emergency Planning Committees (LEPCs) (2008), [https://www.epa.gov/sites/default/files/2013-08/documents/2008\\_lepcsurv.pdf](https://www.epa.gov/sites/default/files/2013-08/documents/2008_lepcsurv.pdf).

EPA has not created an administrative record supporting its proposed changes to the supplier notification requirements for Chemicals of Special Concern, and the new requirement is even more unsupportable if nearly 200 PFAS are added to the list of Chemicals of Special Concern. Once again, EPA must undertake an individualized or sub-category-based assessment using the best available science to demonstrate why the supplier notification is warranted for each Chemical of Special Concern, even when used in very low concentrations, in order to avoid violating the APA.

In the proposal, EPA notes that “[t]he *de minimis* exemption to the Supplier Notification Requirements allows suppliers to not provide notifications for mixtures or trade name products containing the listed toxic chemicals if the chemicals are present at concentrations below 1% of the mixture (0.1% for carcinogens). The *de minimis* exemption is not a small quantity exemption, it is a small concentration exemption.” EPA does not indicate how or why mixtures with low concentrations of each Chemical of Special Concern, or any listed PFAS, pose risks that justify these additional regulatory requirements. Absent record evidence that specific chemicals pose risks in diluted concentrations, EPA should not require additional regulatory burdens for such chemicals, much less regulate a group of chemicals more strictly without attention to their individual characteristics. Because this proposed provision does not include any individualized, science-based justification, it would violate the APA if it were made final.

To justify the proposed requirement, the Proposed Rule states that “EPA’s understanding is that downstream purchasers of products may lack information on the presence of PFAS in such products.”<sup>21</sup> However, EPA does not consider the extent to which the suppliers subject to this requirement will have this information when PFAS chemistries are diluted to *de minimis* concentrations, nor the extent that suppliers of other Chemicals of Special Concern will have this information. In fact, EPA states that it has no data on the increased burdens presented by this aspect of the Proposed Rule, and therefore assumes that increase to be so small it did not need to be accounted for in EPA’s economic analysis, instead relying on an existing value established in 2011.<sup>22</sup> EPA cannot assume that the increase is negligible or that this value has remained static over the past 12 years and should not finalize this proposed change until it has actually received the information it seeks on the increased burden of additional supplier notifications. Indeed the costs will likely be complicated to accurately capture (particularly under EPA’s overly-simplistic approach) given the wide variety of chemicals and end products that will be implicated by this proposal. While EPA’s prior work in this area is out of date, at a minimum EPA should revisit comments provided during the 1988 TRI rulemaking process making as part of the review in this rulemaking to ensure the correct categories of burden and costs associated with Supplier Notifications associated with nearly 200 chemicals now proposed to lose the *de-minimis* exemption are accurately evaluated.<sup>23</sup>

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<sup>21</sup> *Id.*

<sup>22</sup> Economic Analysis, p. 3-6.

<sup>23</sup> See 53 Fed. Reg. 4,525 (Feb. 16, 1988).

Removing this requirement for all Chemicals of Special Concern, and not just PFAS, is particularly problematic due to its broader scope and its potential to affect particularly small businesses that are otherwise not required to report under TRI. It is notable that the supplier notification requirements apply to a broader class of businesses than those required to report under TRI, and would lack the TRI's exclusion of businesses with ten or fewer employees. This aspect of the proposal should therefore be handled through a separate rulemaking to ensure that affected suppliers have sufficient notice and an opportunity to comment on the implications of this proposal in order to meet the Agency's obligations under the APA.

While any removal of the *de minimis* exemption for the supplier notification remains impractical to implement—and legally problematic given the present administrative record—if EPA finalizes any *de minimis* supplier notification exemption, then at the very least it create a safe harbor and should not require that supplier notifications be sent for products “potentially” containing Chemicals of Special Concern at levels at or near zero because determining such concentration impractical, and may not always be scientifically possible. To the extent that any supplier notification requirements are in the final rule, the Coalition requests that they be simple in nature to limit the practical and legal issues posed by this proposed requirement. A pared down supplier notification that only states the type of PFAS and a range of the concentration and/or amount would be adequate to provide purchasers with the information needed for their own reporting and notification requirements. This would accomplish EPA's goal of transparency and information sharing while minimizing the burden placed upon businesses. At the very least, EPA should also ensure that any finalized notification requirements are aligned with requirements from other federal agencies and do not create duplicative or inconsistent requirements.

In any event, any potential alternatives should at the very least be decided in a separate rulemaking to allow both the regulated community and EPA the necessary time and information to evaluate the impacts the loss of this exemption would have. As noted above, Coalition members anticipate that the economic impacts will be difficult to quantify due to the vast variety of chemicals and end products affected, and require time to make use of existing resources to more accurately identify the potential impacts and consider different approaches.

**III. EPA underestimates the burdens this Proposed Rule will place on the regulated business community and underestimated the costs of compliance and fails to consider the burdens associated with determining whether a business is subject to the Proposed Rule in the first place.**

It will be difficult, if not impossible to track PFAS in the *de minimis* quantities that EPA would require. While certain industry sectors have the ability to track certain uses of PFAS more readily (for example, the occurrence of certain PFAS in drinking water with approved methods), tracking and reporting of 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, given methods may not exist. The burdens of this proposal are compounded by the fact that EPA is simultaneously proposing to remove several regulatory provisions meant to lessen burdens for the regulated community.

Before finalizing any rule that would remove the *de minimis* exemption, list additional substances as Chemicals of Special Concern, or alter the supplier notification requirements, EPA must amend its economic analysis to correctly reflect the quantifiable costs of its proposal. Failure to do so, or finalizing a rule where the costs greatly outweigh the benefits and the disparity is not explained, would violate the APA.<sup>24</sup>

**A. EPA incorrectly performed the economic analysis on the effects of the Proposed Rule and thus underestimated the burdens.**

EPA has failed to estimate the costs of supplier notifications, just as it failed to do in the TSCA 8(a)(7) PFAS Proposed Rule. Instead, EPA incorrectly assumed that the “incremental change in supplier notification burden due to this rule is not large enough to undermine [Ratio-Based Burden Methodology] estimates of non-form burden.”<sup>25</sup> But as EPA found in the TSCA 8(a)(7) PFAS rulemaking, the costs of supplier notifications are significant, and it is alarming that EPA makes this claim here a few weeks after it updated its costs for the TSCA proposal from approximately \$10.8 million to \$875 million in social costs. Further, as with the TSCA 8(a)(7) rulemaking, the quantified costs in this proposal are not linked to any quantified benefits. EPA only estimates the TRI compliance costs; however, for the benefits, EPA states that the proposed requirements “can lead to voluntary initiatives by industry to review production processes, set goals for reductions in emissions, and institute ‘good neighbor’ policies.”<sup>26</sup> EPA also states that the “provision of information can lead to follow-on activities that create additional costs and

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<sup>24</sup> See *Michigan v. EPA*, 576 U.S. 743 (2015).

<sup>25</sup> Economic Analysis at 1-10.

<sup>26</sup> *Id.* at 5-1 – 5-2.

benefits.”<sup>27</sup> Either these costs should be included, or the indirect or follow-on benefits should be eliminated from the Economic Analysis.

EPA has also drastically underestimated the time and cost that would be involved in rule familiarization and compliance determination if this proposal were made final. Because the Proposed Rule covers hundreds of substances found in a wide variety of mixtures and products, it would take substantially more time for businesses to determine whether they are subject to the new requirements. As EPA correctly notes, these determinations would require someone with an engineering, scientific, or technical background. They would also require the input of someone knowledgeable in regulatory and legal requirements, which for many businesses would require either internal coordination between several highly skilled individuals or even departments within the company or the hiring of external consultants. Small entities are particularly likely to be forced to hire consultants to assist in the relevant analysis.

In addition, the widespread use of PFAS means that many entities that would not be subject to the new reporting requirements would nonetheless need to familiarize themselves with the Proposed Rule and perform a compliance analysis before they are able to confirm that they are not required to report. EPA failed to fully consider the impact on businesses who make a non-reporter compliance determination. It would cost the average entity far more to merely familiarize themselves with the Proposed Rule, and the costs of making these determinations would be more widespread, than EPA estimates. EPA’s Economic Analysis should be updated to reflect this reality. As of now, EPA has “assumed that non-reporter compliance determination burden is already included in the existing compliance determination burden estimates” because “it is assumed that the added PFAS to the list of Chemicals of Special Concern constitute a modest change when compared with the total number of chemicals subject to the program.”<sup>28</sup> But these non-reporter compliance costs would be meaningful. As described above, many entities, and in particular small businesses with limited staff, would be forced to spend significant time determining non-reporter status because individuals from legal, operations, and management would all have to read the regulations, review the company records, and reach a determination on a rulemaking that covers hundreds of substances, even when in *de minimis* amounts, when diluted, and when in mixtures. The new requirements proposed to be added by this rulemaking will be particularly time-consuming to review and assess because EPA is simultaneously proposing to alter several inter-related parts within the TRI program, and to expand the substances to which those requirements apply. Businesses would thus be forced to spend time not only reviewing for PFAS above the 100-pound threshold, but also for PFAS in small concentration levels.

[EPA’s methodology to estimate the anticipated number of reports is flawed. EPA tries to find proxy chemicals based on other TRI reporting; however, the real burden is the lack of a *de minimis* exemption.

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<sup>27</sup> *Id.*

<sup>28</sup> Economic Analysis, p. 3-2.

Rather, EPA should assume that all facilities in certain sectors (*e.g.*, waste management) would be required to report a significant number of the PFAS.]

B. This Proposed Rule likely would have a substantial impact on a significant number of small entities.

This Proposed Rule, if made final, likely would have a substantial impact on a significant number of small entities, particularly small entities in the waste management and recycling businesses, and EPA must therefore consult thoroughly with the SBA before moving forward to finalize any rule. EPA estimates that this Proposed Rule would apply to 467 to 1,313 small entities. The Coalition believes that EPA has underestimated the number of small entities that would be subject to this proposal and does not account for the number of small entities that would not be subject to the Proposed Rule but would nonetheless incur costs associated with rule familiarization and making a compliance determination. Indeed it is reasonable to assume that EPA has underestimated the number of impacted small entities, 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.<sup>29</sup> But even assuming EPA's figures are correct, the proposal's likely impact on small entities is sufficiently impactful that EPA should consult with the SBA before finalizing any rule. Particular consideration should be given to these impacts, given that the proposed changes to the supplier notification requirements would have broader impacts than the changes proposed to the TRI, with the potential to impact businesses not otherwise subject to TRI reporting due to their small size.

The removal of *de minimis* exemptions would likely have a disproportionate effect on small businesses who are unfamiliar with the reporting scheme. Furthermore, this proposed change comes at a time when EPA just acknowledged that its proposed TSCA rulemaking would result in upwardly revised, estimated cost of \$863,483,965 for small businesses for a "one-time reporting"—an upward revision of approximately \$862 million.<sup>30</sup> EPA also inappropriately collapses the analysis of the impact of the proposed *de minimis* change with the impact of the proposed PFAS change, creating an improper burden assessment.

The proposal also lacks transparency on how its estimated cost burden on small entities provided in the Proposed Rule<sup>31</sup> were made, providing no explanation for how those numbers were reached. This

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<sup>29</sup> See EPA, PFAS Analytic Tools, *available at* <https://echo.epa.gov/trends/pfas-tools>.

<sup>30</sup> TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Notice of Data Availability and Request for Comment, 87 Fed. Reg. 72,439, 72,440 (Nov. 25, 2022).

<sup>31</sup> EPA claims that the "average cost per small firm is \$2,714 (at a 3% discount rate) or \$2,765 (at a 7% discount rate). The total cost for small entities is \$1,267,363–\$3,563,272 (at a 3% discount rate) or \$1,291,213–\$3,630,327 (at a 7% discount rate)." Proposed Rule, p. 74,386.

violates the *Portland Cement* doctrine, which requires agencies to provide data during the rulemaking process.<sup>32</sup> EPA also incorrectly assumes that “no small governments or small organizations are expected to be affected by this action.”<sup>33</sup> Many local governments and other public authorities own landfills. For example, 20 of the 27 municipal solid waste landfills in the State of New York are owned by local governments.<sup>34</sup> Besides receiving PFAS-contaminated items, these waste facilities may use or spread trace amounts of PFAS in their processing and treatment of waste (including the incineration of waste which has the possibility to spread PFAS amounts).<sup>35</sup> Under this proposed rule, government entities would be expected to comply with TRI reporting requirements, placing more of a strain on budgets that are already stretched thin.

As EPA did with the TSCA rulemaking, the agency must reconsider its economic analysis, and solicit feedback on how to minimize burdens on the small business community. EPA should also provide more details on its modeled cost for small business entities. We also request that EPA convene a SBREFA panel to provide advice and recommendations on regulatory alternatives to minimize the burden on small entities.

- C. EPA has not explained why this rulemaking and its associated costs are justified in light of the other PFAS-regulatory actions that EPA has or intends to undertake.

EPA is already taking, or has taken, action to address PFAS under a number of different statutory authorities and programs.<sup>36</sup> With so much activity happening across multiple programs with overlapping implications for the regulated community, it is imperative that EPA and other federal agencies implement a consistent approach for assessing and regulating specific PFAS. Before finalizing any rules under EPCRA, EPA should use the appropriate interagency processes to coordinate regulatory actions among all interested agencies so that government regulations, actions, and communications are consistent and

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<sup>32</sup> *Portland Cement Association v. Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973). In one case in which it held that the Federal Motor Carrier Safety Administration had not shared critical materials that were used in reaching a decision, the Court of Appeals for the D.C. Circuit held that “[a]s we have explained, ‘integral’ to these requirements ‘is the agency’s duty ‘to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules.... An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.’” *Owner-Operator Indep. Drivers Ass’n, Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 199 (D.C. Cir. 2007) (internal citations omitted).

<sup>33</sup> Proposed PFAS Rule, p. 74,386.

<sup>34</sup> Thomas P. DiNapoli, *Local Governments and Municipal Solid Waste Landfill Business*, Office of the New York State Comptroller, p. 1 (Dec. 2018), <https://www.osc.state.ny.us/files/local-government/publications/pdf/landfills-2018.pdf>.

<sup>35</sup> Cheryl Hogue, *3 PFAS Disposal Technologies Are Most Promising, US EPA Says*, c&en: Chemical & Engineering News (Dec. 21, 2020), <https://cen.acs.org/environment/pollution/3-PFAS-disposal-technologies-promising/98/web/2020/12>.

<sup>36</sup> See generally <https://www.epa.gov/pfas/previous-actions-address-pfas>. In addition, for example, EPA is pursuing this goal in its TSCA section 8(a)(7) rulemaking. See 86 Fed. Reg. 33,926 (June 28, 2021).

coordinated for maximum effectiveness. As part of this process, EPA needs to ensure that it has timed the review of these rules in such a way as to allow both the agency and the regulated public a chance to understand and appreciate the implications of each rulemaking for the others. Otherwise, EPA risks creating confusing, conflicting, unnecessary, and overly burdensome regulatory requirements that violate both the APA and basic tenets of good government. At the very least, EPA should explain what other regulations are in the rulemaking process and how those rules would impact the burdens of this rulemaking. Without this information, the public cannot fully appreciate or comment on the agency's proposal or its costs.

For example, EPA is simultaneously undertaking the TSCA PFAS Proposed Rule, which would also require the disclosure of information related to a number of PFAS from many of the same entities that would be subject to this Proposed Rule. In the TSCA PFAS Proposed Rule, EPA is proposing to require each person who has manufactured a PFAS in any year since January 1, 2011, to report and maintain records for each year.<sup>37</sup> The TSCA PFAS Proposed Rule would require all manufacturers of a chemical substance or a mixture containing PFAS (including article manufacturers and importers in any year since 2011) to report information to EPA related to chemical identity, categories of use, volumes manufactured and processed, byproducts, environmental and health effects, worker exposure, and disposal.<sup>38</sup> EPA has not indicated in this Proposed Rule how the information it would collect by removing the *de minimis* exemption would meaningfully benefit the public when taking into account the data that it already intends to collect under other statutory schemes. Likewise, EPA should coordinate with its sister agencies to ensure consistent approaches that do not result in duplicative or conflicting reporting requirements and focus on the specific, science-based concerns regarding some or all of these chemicals.

Given the amount of activity in the PFAS regulatory space at this time, EPA should at the very least wait until it has finalized any requirements stemming from the TSCA PFAS Proposed Reporting and Recordkeeping Rule before reaching a determination about whether to finalize any requirements related to this Proposed Rule. Once the agency has determined what, if any, requirements to make final under TSCA Section 8(a)(7), it can better assess what new requirements, if any, are actually necessary under the TRI program for some, any, or all PFAS chemistries. Uncoordinated, overlapping rulemakings will almost certainly lead to unnecessary and overly burdensome regulatory requirements.

#### **IV. The Proposed Rule Violates the Paperwork Reduction Act**

The Paperwork Reduction Act ("PRA") was intended to minimize the time, effort, and financial resources expended by individuals and small businesses in complying with federal agency reporting

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<sup>37</sup> See EPA, TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 86 Fed. Reg. 33,926 (June 28, 2021). See generally <https://www.epa.gov/pfas/epa-actions-address-pfas>.

<sup>38</sup> 86 Fed. Reg. 33,926.



requirements and information gathering activities. The purpose of the *de minimis* exemption for reporting and for supplier notifications that EPA is proposing to remove were likewise designed to reduce the paperwork burden on businesses using PFAS and Chemicals of Special Concern below certain thresholds. Accordingly, removing the *de minimis* exemptions goes against the purpose of the PRA and should be carefully reviewed by both the EPA and the Office of Management and Budget.

By making this large group of chemicals subject to additional reporting requirements without conducting individual risk assessments on the substances, EPA will create additional paperwork for certain chemicals that do not pose risks that justify such treatment and will make it more difficult for the regulated community, the public, and EPA to determine which facilities and chemicals require the most attention. This will divert resources without providing practical utility, let alone commensurate benefits.

- A. EPA must demonstrate that its collection has practical utility and is the least burdensome approach to comply with the PRA.

EPA has recognized that practical utility means that the data must be valid and be able to be used by the Agency in a timely manner. Based on EPA's current approach, facilities' estimates will differ substantially and will lack practical utility because EPA will be unable to properly analyze and compare the reported data. EPA should focus on first collecting the data that are most useful and most likely to be accurate, focusing on removing the *de minimis* exemption only for the specific PFAS and Chemicals of Special Concern, if any, for which EPA has independently peer-reviewed toxicity data indicating that the value of additional reporting would justify the associated burdens. If, for example, EPA collects data concerning specific PFAS for which human health effects data may not be known for several years, data collected today will be out of date by then and lack practical utility.<sup>39</sup> Similarly, if EPA requires companies to estimate their use of a specific PFAS that currently lacks a valid quantification method, EPA's collected data will have varying quality, accuracy, and precision, and cannot be independently verified—in other words, the data will not be scientific and will be devoid of practical utility. As previously suggested, EPA could maximize the practical utility of the regulation by waiting for the TSCA PFAS Proposed Rule to be finalized and data collected so that EPA knows which data needs to be prioritized. Furthermore, prioritizing specific PFAS and Chemicals of Special Concern would be the least burdensome approach and would “minimize the cost to the Federal Government.”<sup>40</sup>

EPA should, at the very least, consider a phased and tiered reporting system to collect the data that are most useful, most likely to be accurate, first. Examples of this category of information are

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<sup>39</sup> See 44 USC § 3508 (“Before approving a proposed collection of information, the Director shall determine whether the collection of information by the agency is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility.”).

<sup>40</sup> 44 U.S.C. § 3501(5).

independently peer-reviewed toxicity data concerning specific PFAS or subcategories of PFAS for which EPA and respondents can use EPA-approved test methods, based on sound science, to validate the reported data. Furthermore, to the extent that EPA is arguing that it already has created a tiered system with exemptions to minimize the regulatory burden by using both Form A and Form R, the Coalition points out that removing the *de minimis* exemption would eliminate the ability to use Form A, which is one of the most useful methods for appropriately minimizing the reporting burden.

The Coalition therefore recommends that EPA further tailor the proposed data collection to comply with the PRA's requirement to collect data with practical utility in the least burdensome manner, especially for small businesses, by leaving the *de minimis* exemption in place for PFAS where EPA has not yet undertaken sufficient risk analysis to know whether they pose a risk that justifies these additional burdens.

## **V. EPA's Proposed Rule raises serious enforcement and due process concerns.**

As noted above, this Proposed Rule (if made final) is likely to impact far more entities than EPA has identified because the regulated PFAS are so ubiquitous. For the same reason, the Proposed Rule, if made final, would raise due process and enforcement risks for entities that are unlikely to know that they have PFAS-containing materials subject to the proposed requirements or to have otherwise triggered TRI reporting requirements. Ordinarily, EPA could expect that a business handling quantities of heavily-regulated materials would be on notice that its operations were subject to environmental and emergency response requirements. But the fact that PFAS are found in such a broad array of products not ordinarily subject to such rules means that EPA's Proposed Rule would subject many businesses to reporting requirements that they have no reason to know about.

EPA's proposal would unfairly subject businesses to additional requirements under EPCRA's liability regime without providing them with reasonable notice that they are subject to these concerns.<sup>41</sup> This proposal would subject these businesses to potential civil and administrative penalties under a strict liability regime for failing to report.<sup>42</sup> Besides businesses who are unfamiliar with EPCRA, this Proposed Rule would be particularly troublesome for companies that import materials from overseas countries that do not have the same material reporting requirements as the United States.

These enforcement and due process concerns are even greater in this rulemaking, as EPA is proposing to remove this requirement from many distinct chemicals at the same time; under EPA's

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<sup>41</sup> Cf. *Sessions v. Dimaya*, 138 S. Ct. 1204, 1212 (2018) ("The prohibition of vagueness in criminal statutes' . . . is an 'essential' of due process, required by both 'ordinary notions of fair play and the settled rules of law.' The void-for-vagueness doctrine, as we have called it, guarantees that ordinary people have 'fair notice' of the conduct a statute proscribes.... And the doctrine guards against arbitrary or discriminatory law enforcement.").

<sup>42</sup> See 42 U.S.C. 11045(a)–(c).

approach, new PFAS would be automatically added in the future. EPA's own statements indicate that facilities that might be subject to these proposed requirements are unlikely to be aware of them, as it notes that "[i]n the first year of reporting for the initial 172 listed PFAS, EPA only received 89 reports from 38 facilities covering 43 different PFAS." Likewise, EPA is proposing to remove the supplier notification *de minimis* exemption because "EPA's understanding is that downstream purchasers of products may lack information on the presence of PFAS in such products."<sup>43</sup> As EPA's statements show, unless an entity is using PFAS chemistries in *more than de minimis quantities*---particularly in non-foam mixtures or forms---the entity is unlikely to know that it has a TRI reporting or supplier notification obligation. This is particularly true for smaller entities.

EPA's proposal to remove the *de minimis* exemption from the supplier notification for all Chemicals of Special Concern presents the same due process and enforcement concerns. If anything, these concerns are heightened for suppliers, which consist of a broader group than those who are required to report under the TRI, including businesses that have fewer than 10 full-time employees.<sup>44</sup> The chemicals that would be impacted by this aspect of the rule are also broader than just the recently added PFAS, and any removal of the *de minimis* exemption on this scale should be addressed separately.

Companies familiar with EPCRA may be caught off guard, and perhaps unaware of, the change to supplier notification requirements for Chemicals of Special Concern because that change was proposed together with the *de minimis* exemption provisions for PFAS. Coalition members have reported instances where the proposed removal of supplier notifications for Chemicals of Special Concern were nearly missed in internal review due to the difference in reporting obligations within the entity and the Proposed Rule's overarching emphasis on PFAS.

In order to remedy these due process and notice concerns, EPA at the very least should (1) separately propose the supplier notification requirements for existing Chemicals of Special Concern for public notice and comment and (2) separately propose supplier notification requirements for individual PFAS substances. As previously noted in this letter, EPA has not yet created a record demonstrating that a one-size-fits-all regulatory approach is justified for PFAS or the existing Chemicals of Special Concern. Rather than adding unjustified regulatory burdens and enforcement risks associated with these new provisions, EPA should individually assess the need for such requirements and provide the regulated public with sufficient time to review and become aware of these proposed requirements.

## **VI. For purposes of TRI reporting, EPA is correct not to define PFAS at this time.**

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<sup>43</sup> Proposed PFAS Rule, 87 Fed. Reg. 74,384.

<sup>44</sup> EPA GuideME, Supplier Notification Requirements, available at [https://ordspub.epa.gov/ords/guideme\\_ext/f?p=guideme:gd:::gd:supplier\\_notification](https://ordspub.epa.gov/ords/guideme_ext/f?p=guideme:gd:::gd:supplier_notification).

EPA is requesting comment on its decision not to define PFAS in this rulemaking. The Coalition agrees with EPA's decision not to define PFAS in this rulemaking for two reasons. First, if EPA decides to create a regulatory definition of "PFAS," it should do so through a stand-alone rulemaking to ensure sufficient notice and public comment, as required by the APA.<sup>45</sup> The business community supports a consensus approach starting with a recent Delaware definition<sup>46</sup> and would be pleased to partner with EPA and Congress to fully evaluate the most effective definition for PFAS. Regulatory definitions cannot be adopted in the abstract.

Second, rather than attempting to define "PFAS" as part of this proposed rule, EPA should instead focus on making individualized findings about the individual chemicals that Congress required EPA to add under the NDAA and consider on a chemical-by-chemical basis what the appropriate treatment is for that substance under the EPCRA/TRI framework. This more measured approach would yield greater consensus about how to regulate PFAS chemistries and would lead to more narrowly tailored solutions, efficiently maximizing the resources of both EPA and the Coalition. Such studies could also reveal more effective ways of classifying PFAS into appropriate subgroupings, particularly where endpoints, such as toxicity or mode of action of the PFAS are similar, and add much-needed clarity to the current dearth of information regarding the effects of different types of PFAS. If anything, the difficulties in accurately defining PFAS as a broader group speak to why EPA should not attempt to select a one-size-fits-all regulatory approach for nearly 200 substances that fall within this umbrella term, particularly for a statutory scheme designed to be based on risk.

## **VII. Conclusion**

The Coalition appreciates the opportunity to comment on EPA's proposal. The Coalition supports science-based regulation of substances, including particular PFAS, that may pose risks to the public. The Coalition nonetheless respectfully submits that EPA's proposed rule, if made final, would be deemed arbitrary and capricious under the APA and otherwise in violation of law, for the reasons suggested above.

The business community understands and appreciates the value of collecting data, preparing for emergency responses, and accelerating cleanup in impacted communities. However, EPA must focus on the data that will optimize the human health benefits of policies and will limit the burdens on impacted

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<sup>45</sup> The Coalition notes that regulatory definitions always purposefully encompass some elements and exclude others. These decisions should be highly intentional and should be made with a clear view of how the definition will be used in a particular regulation. Policy choices about which elements should or should not be included then can be debated and made reasonably in light of the specific intended regulatory use. A regulatory definition developed for one purpose may be underinclusive or overinclusive if used for another. No PFAS definition even can be debated without first identifying how the definition would be used in regulation and the categories EPA may seek to include or exclude in light of its purpose.

<sup>46</sup> See Del. Code tit. 29, § 8092(4) (2021).

sectors. We therefore urge EPA to implement a more measured, phased approach in determining whether specific PFAS should be designated as Chemicals of Special Concern and in considering whether to remove the *de minimis* exemption for particular PFAS chemistries and other Chemicals of Special Concern that appropriately accounts for the actual risk data for particular substances and the burdens that would be imposed on regulated entities with regard to reasonably reporting the required information.

Sincerely,

Aerospace Industries Association  
Alliance for Automotive Innovation  
American Chemistry Council  
American Forest & Paper Association  
American Fuel and Petrochemical Manufacturers  
American Petroleum Institute  
Flexible Packaging Association  
Fluid Sealing Association  
National Association of Chemical Distributors  
National Association of Manufacturers  
National Association of Printing Ink Manufacturers  
National Association for Surface Finishing  
National Council of Textile Organizations  
National Mining Association  
National Oilseed Processors Association  
PRINTING United Alliance  
TRSA –The Linen, Uniform and Facility Services Association  
U.S. Chamber of Commerce