Before the United States Environmental Protection Agency
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 (Nov. 25, 2022)
Docket EPA-HQ-OPPT-2020-0549

Comments of the Chemical Users Coalition

Introduction

Chemical Users Coalition (CUC) appreciates the opportunity to provide these comments regarding the US Environmental Protection Agency's (EPA's or the Agency's) Initial Regulatory Flexibility Analysis (IRFA) and Updated Economic Analysis for the proposed rule for reporting and recordkeeping requirements for perfluoroalkyl and polyfluoroalkyl substances (PFAS) under Section 8(a)(7) of the Toxic Substances Control Act (TSCA) (the Proposed Rule).[1] CUC supports EPA's efforts to more critically assess the economic consequences of the proposed TSCA 8(a)(7) rulemaking and to consider such consequences in light of the net benefit of such rulemakings. CUC considers such an undertaking to be a fundamental obligation of EPA in accordance with its obligations under Executive Orders 12866 and 13563. In furtherance of these requirements, CUC continues to strongly support substantial changes being made to the terms of the proposed regulation to more appropriately balance these considerations and to specifically reduce the burdens that will otherwise be imposed if CUC's prior recommendations are not implemented.

CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances.[2] CUC members operate on a global scale, with manufacturing operations in the US that may rely on affiliated companies and independent suppliers and sub-suppliers located both in the US and abroad. Consequently, CUC members acquire a wide range of formulations and articles from suppliers, often importing complex pieces of equipment that may contain a multitude of components, each of which is itself a finished article. CUC members are committed to encouraging responsible chemical regulatory policies that protect human health and the environment while enabling the regulated community's ability to develop and timely pursue technological innovation. CUC members consider such goals to be completely compatible with environmentally sustainable economic development in the US. In addition, CUC members support greater transparency in their supply chains about the chemical content of the products and components they acquire.

CUC understands the Agency's intention with regard to the TSCA Section 8(a)(7) rule has been to implement congressionally mandated requirements and to develop a robust body of information concerning chemical substances and articles when such materials are under consideration for regulatory action. However, CUC believes EPA should use its regulatory authority to develop this body of information judiciously, and in ways that focus on gathering

[1] 86 Fed. Reg. 33926 (June 28, 2021).
[2] CUC's members are Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, the National Electrical Manufacturers Association, Raytheon Technologies Corporation, Sony Electronics, Inc., and TDK U.S.A. Corporation.

information that will be most germane to making determinations with respect to potential health or environmental risks while taking into account which regulated entities are in the best position to have or to obtain the information in a timely and reliable fashion. CUC's previously submitted comments on the proposed TSCA 8(a)(7) rule (attached as an Appendix for ease of reference) provided exhaustive recommendations for amending the proposed regulation with this in mind, and we reiterate them and incorporate those comments by reference here.

Overview of CUC's Comments on the Initial Regulatory Flexibility Analysis and Updated Economic Analysis

Although EPA's Updated Economic Analysis presents a more accurate picture of the effort certain companies will have to expend to comply with the Proposed Rule, the analysis still vastly understates the amount of work entailed in complying with the Proposed Rule's requirements. It is essential that EPA's analysis of the cost burden reflect the actual costs all companies, not just smaller businesses, will incur and for EPA to take into account the diminishing returns of costly compliance requirements. EPA should instead adopt less burdensome alternatives that would still achieve TSCA Section 8(a)(7)'s mandate. As discussed in CUC's comments on the Proposed Rule, alternatives that use a finite list of PFAS and incorporate common TSCA exemptions are consistent with the statute and will provide EPA with the information needed to better understand the universe of PFAS in the US marketplace.

The Updated Economic Analysis Still Understates the Costs of Compliance

The Updated Analysis Underestimates the Time Associated with Compliance Activities

The Updated Economic Analysis presents a more realistic picture of the Proposed Rule's cost burden than the draft economic analysis due to the updated analysis's inclusion of article importers and of estimates for article importers' costs of determining whether any articles they import contain PFAS. However, the updated analysis's estimates of the time and cost associated with rule familiarization, article importer compliance determination, and form completion are still too low. The estimates do not reflect the considerable effort that will be required for article importers (such as many of the CUC Members) to perform these tasks, given the ubiquitous nature of PFAS use, the difficulty in assessing PFAS content in articles within multi-tiered supply chains, and the lengthy lookback period dating to 2011. The updated analysis therefore still fails to fully disclose the significant burden the rule will place on companies.

For example, with respect to rule familiarization burden and cost (Table 1), the time estimates do not appear to take into account the large number of employees who would be involved in assessing the content of articles and would thus need to be familiar with the rule. With respect to the tasks required for the article importer compliance determination, CUC believes that the estimates in the Updated Economic Analysis of the time each company will spend on identifying types of imported articles that potentially use PFAS (13 hours), identifying the suppliers involved (24 hours), and collecting data from suppliers (20.2 hours) are much too low. Factors that weigh in favor of significantly higher estimates include the number of parts that a given product model includes, the multiple tiers of suppliers, and difficulty of applying a PFAS definition of uncertain scope. As mentioned in CUC's comments on the Proposed Rule, which are attached as an Appendix, one CUC member estimated that for a given product model, the number of Tier 1

production suppliers would be 4,000 and that there are approximately 185,000 unique part numbers. This example could suggest that the CUC Member would need to assess the chemical composition of as many as 185,000 components in that product alone. It is clear that the internal information gathering as well as any required external data collection efforts for this given product model would take substantially more time than the estimates in the table on page 9. Similarly, estimates in Table 5 for the time that will be spent by article importers on form completion are too low, due in large part to the underestimate of the number of reports each importer will need to file, as discussed in the following section.

The Updated Economic Analysis Underestimates the Number of PFAS Each Article Importer Will Report

In the IRFA, EPA assumed that article importers would submit reports for five PFAS (see page 36), but CUC Members believe that the actual number will be five to six times that number of PFAS, and potentially even more as additional information accumulates regarding the use of PFAS in the supply chain. Reporting for this higher number of PFAS would significantly increase the number of hours expended for reporting tasks. Even assuming some companies would report on less than five PFAS, CUC recommends that EPA use a significantly higher number of PFAS per firm in its analysis so as to more accurately disclose the total burden on industry.

It Is Not Reasonable to Use the Same Per-Company Costs of Compliance for Small and Large Companies

It is reasonable to estimate that many larger companies may import and/or produce and distribute an even greater number of products than smaller enterprises and that larger companies therefore could incur even higher costs than smaller companies in order to determine compliance obligations for their entire product lines and to submit a higher number of reports than smaller firms will submit. Although the IRFA acknowledges in places that large companies are likely to import a higher number of PFAS (see, e.g., page 36), the calculations in the Updated Economic Analysis use the same per-firm costs for most tasks, regardless of whether the firm is small or large. (The exception is structural definition familiarization, for which the analysis assumes small firms' costs will be *higher*.)

To provide a clearer picture of the burden on industry, the economic analysis should more accurately disclose the anticipated costs burdens for those companies (including larger enterprises) with more expansive product lines that will require much more extensive diligence and reporting than the assumptions in the economic analysis reflect. This should be corrected when the final record is prepared to address the underestimate it currently reflects.

EPA Should Implement Regulatory Alternatives to Target Reporting Requirements to Maximize Benefits

As discussed above, the cost burden of compliance will be even higher than the Updated Economic Analysis estimates. However, even the updated analysis's estimate is staggeringly high, and it is imperative that EPA tailor the final rule to reduce the compliance burden of the rule while still gathering information needed to facilitate an understanding of the presence of PFAS in US commerce and the assessment of risk. CUC recommends that the final rule ultimately incorporate

regulatory alternatives considered in the IRFA, including limiting the scope of PFAS to a finite list, rather than using a structural definition; including a reporting threshold; and including common TSCA exemptions. In particular, CUC recommends that the final rule include an exemption for substances used solely for research and development purposes and that it provide for an exemption for substances that are present in substances, mixtures, and articles as byproducts and impurities. CUC also continues to recommend that EPA exclude PFAS present in articles in the final rule. In the alternative, CUC recommends that the final rule adopt simplified reporting requirements specifically for article importers, including permitting them to reasonably rely on their suppliers' representations with regard to PFAS content (or the absence thereof) and enabling range reporting. If PFAS in articles is included within the final rule's scope, the rule also should provide safe harbors from enforcement for article importers who learn about the presence of PFAS in a product after the reporting deadline.

CUC's comments on the Proposed Rule, which are attached as an Appendix and incorporated here by reference, set forth in detail many reasons why it would be appropriate and consistent with the statute for EPA to incorporate these alternatives into the final rule. The following discussion provides an overview and additional information about the need to tailor the scope of the final rule.

The Final Rule Should Limit the Scope to a Finite List of PFAS

CUC recommends the use of a finite list of PFAS to define the scope of substances subject to the TSCA Section 8(a)(7) reporting requirements. The PFAS subject to the final rule should be identified by their CASRNs, as the CASRN is a universally recognized chemical substance identifier. As discussed in CUC's comments on the Proposed Rule, given that the structural definition of PFAS could encompass thousands of fluorinated compounds, the regulated community should not have to "guess" at which of those compounds EPA intends to be subject to the substantial reporting burdens on this rule.

CUC recommends that EPA consider using the Toxics Release Inventory (TRI) list of 180 discrete PFAS with CASRN at 40 C.F.R. § 372.65(d) and/or (e), which would harmonize the reporting under TSCA Section 8(a)(7) with the scope of reporting under TRI. CUC believes any steps to align different regulatory programs are beneficial both to regulated entities and to administration of regulatory programs. Any PFAS added to the TRI list pursuant to the National Defense Authorization Act for Fiscal Year 2022 prior to publication of the final rule could be included within the scope. Alternatively, the list of identified PFAS in the Proposed Rule could be a suitable finite list inclusive only of those substances known to have been in commerce (i.e., listed on the TSCA Inventory or actively imported or manufactured during that period pursuant to a TSCA Low Volume or Low Release and Exposure Exemption) during the lookback period. CUC does <u>not</u> think that use of the CompTox list, which lists over 10,000 PFAS, would serve the purposes of simplifying compliance.

The Final Rule Should Incorporate a Reporting Threshold

CUC recommends that the final rule include a 25,000- or 2,500-pound threshold for reporting of total PFAS. Use of these thresholds would align the PFAS reporting program with thresholds under the Chemical Data Reporting requirements. Harmonization of the PFAS

reporting requirement with existing requirements would ease the reporting burden for regulated entities and the administrative burden for the Agency.[3]

The Final Rule Should Include Common TSCA Exemptions, Including an Exemption for Articles

The final rule should incorporate the most common TSCA exemptions for substances used exclusively for research and development purposes and for byproducts and impurities. As discussed in CUC's comments on the Proposed Rule, the limited additional data that would be obtained from requiring reporting on PFAS used in R&D activities would provide a negligible amount of information to support EPA's mission to identify and better understand PFAS and would thus add unnecessary complexity to the reporting obligation.

In addition, CUC continues to urge EPA to exclude articles from the reporting requirement. CUC's comments on the Proposed Rule, attached as an Appendix, explain that the inclusion of articles is not supported by the National Defense Authorization Act for Fiscal Year 2021, which added TSCA Section 8(a)(7), and that inclusion of articles will not yield many of the types of information that EPA hopes to obtain since article importers are unlikely to have information on environmental and health effects, environmental releases and disposal data, and occupational exposure.

The final rule also should clarify that it does not apply to processors and other downstream users since Section 8(a)(7) unambiguously applies only to manufacturers.

If Article Importers Are Not Exempt, CUC Urges EPA to Adopt Simplified Reporting Requirements and to Provide for the Exercise of Enforcement Discretion

Although CUC strongly encourages EPA to exempt imported articles from the final rule, if EPA decides to include articles within the final rule's scope, the Agency should apply simplified reporting requirements to article importers, including by developing a simplified reporting form for article importers along the lines of the alternative described on page 71 of the IRFA. This form should maximize the ease with which article importers can provide information. One alternative to consider might be specifying ranges for the aggregate amount of PFAS in the total number of articles imported by the entity during a period of time (such as the two calendar years preceding the effective date) if such information is readily available to and already known by the entity. CUC agrees that providing additional information and documentation if information is known or reasonably ascertainable should be optional, not a requirement. Moreover, the reporting requirements should make very clear that an article importer may reasonably rely on representations provided by suppliers with respect to PFAS content. In addition, consideration should be given to only requiring information on articles that were imported during a limited and more contemporaneous period (e.g., as suggested above, during the two calendar years that immediately precede the rule's effective date).

[3] The impact that a reporting threshold would have on reducing the cost burden would depend on the requirements that the "known to or reasonably ascertainable standard" imposes since companies would still have obligations to conduct rule familiarization and data collection activities. If EPA clarifies the standard along the lines that are set forth in various places in the IRFA (see discussion below), a reporting threshold could have substantial benefits for industry. However, if companies are required to conduct extensive surveys of the supply chain to determine whether the thresholds are met, this task still would require significant time and resources.

In addition, EPA should establish an "amnesty" or "safe harbor" to encourage the submission of information by importers of articles who learn of the presence of PFAS in an article after the submission period ends. As discussed in CUC's comments on the Proposed Rule, the availability of a safe harbor will create incentives for importers of articles to submit corrections. Providing opportunities to correct filings without threat of adverse consequences for doing so will enhance EPA's ability to develop the body of knowledge it seeks.

The Final Rule Should Clarify the "Known to or Reasonably Ascertainable by" Standard

The Proposed Rule requires that companies report information "to the extent known to or reasonably ascertainable by them." It is essential that the final rule clarify the obligations that the "known to or reasonably ascertainable by" standard imposes. In general, CUC supports EPA's proposition in the IRFA that submitters "need not conduct extensive supply chain surveys" (i.e., new across-the-board surveys of suppliers) (IRFA, page 7) and requests that this kind of detail be provided either in the rule itself or in another prominent place. CUC appreciates that other information presented in the General Scenarios on pages 6-8 of the IRFA reflects acknowledgment and understanding of the complexities involved in gathering PFAS-related information for articles, including that the "known to" standard "does not necessarily require that the submitter conduct an exhaustive survey of all employers." The final rule should make clear that testing for the presence of PFAS is beyond the "known to or reasonably ascertainable by" standard, as is stated multiple times in the IRFA (see, e.g., pages 8, 33, 36, 39). Moreover, EPA should state affirmatively that an importer of a product, and especially an article, may reasonably rely on the representations of its suppliers and that the failure of a supplier to respond to timely and direct inquiries from a customer seeking such information also is compliant if documented. The contours of the diligence standard must be clearly drawn in order for the regulated community to benefit and for reporting to be consistent.

Conclusion

CUC appreciates that EPA has made efforts to more accurately characterize the burdens the Proposed Rule would impose and hopes these comments will help the Agency to understand the ways in which its economic analysis continues to understate the costs the regulated community, and article importers in particular, will incur if the Proposed Rule's broadly applicable requirements are carried over into the final rule. The costs of broadly construing the statute are not in proportion to the limited benefits that accrue by extending Section 8(a)(7) far beyond the ordinary scope of other TSCA reporting rules. To avoid diminishing informational returns from the reporting, EPA should target the final rule to more effectively gather the information it needs. In particular, EPA should exclude articles containing PFAS from the scope of reportable chemical substances; establish a finite list of reportable PFAS; include a reporting threshold; include an exemption for PFAS used solely for R&D purposes; and include an exemption for PFAS generated or present as a byproduct or impurity. If articles are not excluded from the final rule's scope, EPA must simplify the reporting requirements for article importers and establish a safe harbor for importers of PFAS-containing articles who belatedly learn of the presence of PFAS. In addition, EPA must provide greater clarity regarding the "known to or reasonably ascertainable by" standard to ensure that it does not impose due diligence obligations that are not balanced by an informational benefit.

In closing, CUC members appreciate the opportunity to provide comments on the IRFA and Updated Economic Analysis. CUC members would be pleased to meet with EPA personnel to discuss these comments and related issues as the Agency continues its efforts to implement Section 8(a)(7).

Appendix

Before the United States Environmental Protection Agency
TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Proposed Rule, 86 Fed. Reg. 33,926 (June 28, 2021),
Docket EPA-HQ-OPPT-2020-0549

Comments of the Chemical Users Coalition

Introduction

Chemical Users Coalition (CUC) appreciates the opportunity to provide these comments regarding the US Environmental Protection Agency's (EPA's and the Agency's) proposed rule for reporting and recordkeeping requirements for perfluoroalkyl and polyfluoroalkyl substances (PFAS) under Section 8(a)(7) of the Toxic Substances Control Act (TSCA) (the Proposed Rule).[1]

CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances.[2] CUC members operate on a global scale, with manufacturing operations in the US that may rely on affiliated companies and independent suppliers and sub-suppliers located both in the US and abroad. Consequently, CUC members acquire a wide range of formulations and articles from suppliers, often importing complex pieces of equipment that may contain a multitude of components, each of which is itself a finished article. CUC members are committed to encouraging responsible chemical regulatory policies that protect human health and the environment while enabling the regulated community's ability to develop and timely pursue technological innovation. CUC members consider such goals to be completely compatible with environmentally sustainable economic development in the US. In addition, CUC members support greater transparency in their supply chains about the chemical content of the products and components they acquire.

In the past, CUC has encouraged EPA to develop a robust body of information concerning chemical substances and articles when such materials are under consideration for regulatory action, including a thorough investigation of the published literature to develop a basic and contemporary understanding of the conditions of use for such substances and articles. CUC believes EPA should use its regulatory authority to develop this body of information in ways that take into account which regulated entities are in the best position to have or to obtain the information. Moreover, EPA regulatory efforts with longer lead times will serve to encourage further communication within and across supply chains globally and further enable the Agency's objectives to promote responsible environmental practices with regard to manufactured articles that generally have moved with very few restrictions in international commerce.

[1] 86 Fed. Reg. 33926 (June 28, 2021).
[2] CUC's members include Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, Raytheon Technologies Corporation, Sony Electronics, Inc., and TDK U.S.A. Corporation.

Overview of CUC's Comments on the Proposed Rule

In CUC's view, the sweeping scope of the Proposed Rule is not called for by the statute, including the defense funding legislation which prompted the rulemaking. EPA has taken the position that it lacks authority to include exemptions in the Proposed Rule due to the language of Section 8(a)(7), which the defense funding legislation added. This is not a correct interpretation of either that provision or of Section 8 as a whole. In particular, Section 8(a)(5), which EPA concedes applies to this rulemaking, provides ample authority for EPA to adopt exemptions. The Proposed Rule would impose significant and impracticable demands on importers of articles, small businesses, and entities that use PFAS in research and development exercises, as well as on other entities whose importation or domestic uses of PFAS-containing products and formulations have historically been exempt from TSCA reporting requirements. The Proposed Rule would impose these burdens without the reasonable likelihood the Agency will receive useful new data or materially different exposure- and use-related information from such entities. The Proposed Rule therefore runs afoul of Section 8(a)(5)'s directives that EPA not require reporting that is unnecessary or duplicative, minimize the costs of compliance for small businesses, and apply reporting obligations "to those persons likely to have information relevant to the effective implementation" of TSCA.

The terms of the Proposed Rule are overly inclusive and ambiguous as the Agency appears to seek to collect data on substances that may not be among those in US commerce, including through defining the rule to include any and all substances which fit within a "structural definition"—regardless of whether a substance has been or is presently available in commerce—if the substances have been manufactured or imported (even if present only as an impurity or unintentionally present chemical constituent in a formulation, product, or article) in any of the years since January 2011.

The Agency has not sufficiently assessed, nor has it made the necessary effort required to attempt to quantify, the economic burdens that will be imposed by the Proposed Rule. The preamble to the Proposed Rule—and the draft economic analysis supporting the rule—acknowledge, but do not fully disclose or specifically quantify, the new and unusual compliance burdens the rule would place on importers of articles and other entities that are unlikely to have an awareness of the presence of PFAS in products and articles they import to the US. Due to complex global supply chains, the number of businesses that fall within the Proposed Rule's reach is far greater than EPA's estimates of affected firms, particularly to the extent the Proposed Rule covers manufactured articles. Although CUC is not in a position to accurately estimate the number of companies that would be subject to the Proposed Rule, it is likely that the rule, as proposed, would impose extensive reporting and recordkeeping obligations on thousands of entities that import and use articles and research materials that might contain PFAS if assayed. Such entities are not "chemical manufacturers" or even "formulators" of traditional commercial use chemical-based products, and they are unlikely to have health or safety studies germane to the prioritization or risk evaluation of PFAS.[3] Many makers of components and other complex articles do not have direct

[3] For example, polytetrafluoroethylene (PTFE) is found in hundreds of formulated products, and it can be anticipated that an even greater number of articles and other fabricated parts contain PTFE, but that information has not been disclosed in the ordinary course of transactions between manufacturers and their suppliers, and there are not reliable sources of such information. Yet importers of formulation or articles containing PTFE would be subject to the

channels of communication or relationships with the component producers that would facilitate reliable inquiries. Nevertheless, EPA's interpretation of the "known to or reasonably ascertainable" standard implicitly imposes on such entitles affirmative information-gathering obligations beyond merely submitting to EPA information in company files or readily known to company employees. Manufacturers and assemblers of components and finished articles confront significant obstacles in their investigations up and down the supply chain, including confidential business information (CBI) and language issues. Nor is it practicable for chemical users and importers of articles to conduct analyses of imported articles or finished products to determine product content. These challenges would be exacerbated by the sheer number of reportable PFAS as well as ambiguity in the definition of what constitutes reportable PFAS.

Lastly, many entities that are manufacturers and assemblers of simple and complex articles, and the suppliers and importers of the components of such articles, do not have Central Data Exchange (CDX) accounts, and the Agency has overlooked the time, effort, and expense required to identify and train company personnel in complexities of CDX reporting. EPA should more critically and carefully examine these costs and burdens; especially in light of the minimal likelihood that EPA will gather information or test data it does not already have or can reasonably expect to obtain from the manufacturers of PFAS that also must report under the Proposed Rule.

In light of these concerns, and others noted in these comments, CUC requests that EPA amend the Proposed Rule before issuing it in final form to direct EPA's information-gathering efforts to those entities and for those substances for which there is the greatest likelihood that existing studies and information requested can be economically obtained and would be specifically worthwhile to EPA's regulatory efforts under TSCA. Making such changes would more closely align the rule with the intention of TSCA and the defense funding legislation that prompted the rulemaking.

Specifically, the final rule should exclude from the rule's scope those entities that do not manufacture PFAS but only act as importers of articles containing PFAS. EPA should take additional steps to reduce the compliance burden of the rule while still gathering information needed to facilitate an understanding of the presence of PFAS in US commerce and the assessment of risk. The other changes to the rule should include:

- More clearly delineating the PFAS that are within the rule's scope by limiting the number of PFAS substances subject to the rule and by removing the structural definition approach and instead providing a specific list of substances identified by CAS Registry Number or by (in the case of confidential chemicals) EPA accession number or other globally recognized unique identifier assigned by EPA and known to the manufactures and importers of the substances.
- Providing more clarity regarding the "known to or reasonably ascertainable" standard to ensure that the obligations imposed by such a standard do not impose onerous information-gathering burdens without a concomitant information benefit.

reporting and recordkeeping rule and would be obliged (based on EPA's interpretation of the "known to or reasonably ascertainable" standard) to make inquiries of their suppliers. The preamble to the proposed rule implies that failing to comply with this level of inquiry with potentially every single supplier of a formulated product or an article could subject an importer to excruciatingly high TSCA penalties.

- Including a *de minimis* threshold for reporting.
- Extending the timeframe for reporting.
- Clarifying that the rule does not apply to processors and other downstream users.
- Exempting importers of articles that contain PFAS; if this is not accomplished, the EPA should establish an "amnesty" or "safe harbor" to encourage the submission of information by importers of articles who learn of the presence of PFAS in an article after the submission period ends.
- Including a research and development exemption.
- Excluding PFAS generated or present only as a byproduct or impurity from the reporting requirement.
- Exempting small businesses.

Depending on how EPA revises the Proposed Rule, the draft economic analysis should be substantially revised to include more accurate estimates for the time burden and costs that affected entities will incur, and also significantly increase the estimated number of entities that will be affected.

The Final Rule Should Not Include Articles Containing PFAS Within Its Scope

Inclusion of Articles Is Not Supported by the NDAA

Articles containing PFAS should not be included within the scope of the Section 8(a)(7) final rule. Section 7351 (Subtitle E) of the National Defense Authorization Act for Fiscal Year 2020 (NDAA)—which added Section 8(a)(7), the "PFAS data call"—to TSCA, does not require inclusion of articles. Indeed, the NDAA specifically targets manufacturers of the PFAS substances themselves, not "articles" containing those substances. The NDAA directed EPA to require "each person who has manufactured a chemical substance that *is* a [PFAS]" to submit a report including the information specified in Section 8(a)(2)(A)–(G).[4] This language cannot reasonably be read to include articles that are not themselves PFAS substances but merely contain such substances. Had Congress intended the legislation to include articles that *contain* another substance, it certainly could have said so.[5] Here, Congress chose to target manufacturers of the PFAS substances themselves, as indicated by the specific phrase "chemical substance" (instead of a term such as "article" or "product" or "appliance") and by the word "is" (instead of a more inclusive term such as "contains"). Where Congress omits expansive modifiers, they should not be inferred.[6]

There appears to be little legislative history for the NDAA, but the PFAS data call provision also was included in the PFAS Action Act of 2019 legislation in the House of Representatives.[7] It

[4] 15 U.S.C. § 2607(a)(7) (emphasis added).
[5] *See, e.g.*, 42 U.S.C. § 7671j(c) (regulating "product[s] containing a class II substance"); *cf.* 42 U.S.C. § 7412(b)(1) (explicitly defining certain specified chemical compounds and glycol ethers to include "any unique chemical substance that *contains* the named chemical (i.e., antimony, arsenic, etc.) as part of that chemical's infrastructure" (emphasis added)).
[6] *See, e.g.*, Am. Fuel & Petrochemical Mfrs. v. EPA, 3 F.4th 373, 382 (D.C. Cir. 2021) ("Had Congress intended to exempt a range of ethanol fuels from the 9-psi limit, it could have referred to fuel containing 'at least' or 'not more than' 10% ethanol, much as appeared in the House version of the 1-psi waiver. The reference to E10 without modifiers suggests that Congress intended Subsection 7545(h)(4) to apply to E10." (citation omitted)).
[7] H.R. 535, 116th Cong. (2019).

is notable that the Committee on Energy and Commerce's report on this bill described the data call as applying to "manufacturers of PFAS chemicals." This plain language summary conveys Congress's intent that information be collected only from manufacturers and importers of the PFAS chemicals themselves.[8]

The key language from the NDAA is similar to the language of Section 8(a)(1), which directs EPA to issue regulations to require recordkeeping and reporting by "each person … who manufactures or processes or proposes to manufacture or process a chemical substance." To our knowledge, EPA has not interpreted the language in Section 8(a)(1) to specifically require reporting on articles, and has not previously required Section 8(a) reporting for specific chemical substances when present in manufactured articles. Nor does Section 8(a)(2)(A)–(G) specify reporting and recordkeeping on articles; indeed, the nature of the information elements in Section 8(a)(2)(A)–(G) demonstrates that they were not developed with the intention that they be applied to articles at all. Thus, Section 8(a)(7) should not be interpreted to apply to articles. At the very least, it is within EPA's discretion not to require reporting for articles under Section 8(a)(7).

Moreover, EPA's regulatory definition of "article" in 40 C.F.R. § 704.3 is not consistent with the Proposed Rule's inclusion of articles within the scope of chemical substances that must be reported. Section 704.3 defines "article" to mean

> a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.

This definition is incompatible with considering articles to themselves be chemical substances. In view of this definition and the Agency's historical treatment of articles, it is not appropriate to include articles within the final rule's scope.[9]

Including Articles Will Yield Little Information Useful to EPA and Thus Is Contrary to EPA Obligations Under Section 8(a)

First, EPA's proposal would require article importers to report information on PFAS usage that they will need to seek from article producers located outside the United States. As such, EPA

[8] H.R. REP. NO. 116-364, at 20 (2019).

[9] At the very least, EPA must affirmatively state in the regulation that reporting on PFAS content of articles is explicitly required, which it has not done in the language of the proposed regulatory text, and EPA must provide a sound legal basis for doing so. The failure to make such an explicit statement and to provide the predicate legal basis for such an interpretation, creates regulatory ambiguity and uncertainty generally. This lack of specificity in the rule language is exactly the situation that resulted from the complete miscommunication that occurred when the Agency informally interpreted (in webinars and other public statements—but not in the rulemaking text) its final TSCA "fees rule" for risk evaluations to apply to importers of articles containing a chemical substance.

will obtain no data on articles produced in the United States (other than limited data potentially supplied in information reported by manufacturers of PFAS compounds), and EPA will not obtain information regarding volumes, exposures, or categories of use associated with articles production or distribution within the United States. Rather, the proposal will require article importers to undertake substantial efforts to query their foreign supply chains to discern what information foreign article producers may have regarding their production of articles and the content of the products they supply to customers in the United States. For the reasons below, that information will be unreliable and incomplete, and the level of effort required is disproportionate to EPA's information needs.

Second, article importers simply do not have the information that EPA is seeking, and the required data reporting elements are not tailored to understanding PFAS volumes, exposures, or categories of use in articles imported into the United States. EPA proposes that article importers report the information described in subparagraphs (A) through (G) of TSCA Section 8(a)(2). However, those data elements[10] are clearly likely to be known to the manufacturers of the individual PFAS compounds themselves, and are certainly highly unlikely to be known to, much less reasonably ascertainable by, the makers or importers of articles that contain PFAS. Nevertheless, as described below, each article importer would likely have to undertake a massive effort to query its supply chain for information that is not directly relevant to the potential presence of PFAS in articles.

The Agency's request for such information from importers of articles being made in the context of a Section 8(a) rule directly contradicts its obligations under Sections 8(a)(2)(E) and 8(a)(5) to not require the development of new data, to not require unnecessary reporting, to minimize the costs of compliance for small businesses, and to apply reporting obligations to parties likely to have information relevant to effective TSCA implementation.[11]

Including Articles Will Require a Massive Undertaking to Query the Supply Chain and Collate Information that May or May Not Be Reportable

EPA should take into account the substantial constraints on the ability of entities such as CUC members who import articles that may contain PFAS to collect the information required by the Proposed Rule. Such entities are limited both in their ability to identify articles that contain PFAS and in their capacity to collect the information the Proposed Rule would require to be reported.[12]

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[10] For example, the Section 8(a)(2)(A)–(G) information items include the trade name of the PFAS, the intended use of the substance, the amount of the chemical produced for each intended use, the byproducts resulting from the manufacture of the substance, data on the environmental and health effects of the chemical.

[11] *See, e.g.*, 15 U.S.C. § 2607(a)(2)(E), (a)(5).

[12] Despite these limits on their capacities to identify products and collect information, the "known to or reasonably ascertainable" standard as presently described by EPA may require such entities to go to considerable lengths to collect information that will be of dubious value to the Agency. For example, some companies may know that PFAS is in existing material and design specifications and may therefore be able to infer that suppliers using those or similar specifications are supplying articles that contain PFAS. Under the "known to or reasonably ascertainable" standard, based on that inference, would such an entity have to undertake extensive inquiry to further ascertain the supplier's information, and even where precise data is unavailable, would the EPA proposal require reporting of "reasonable estimates" if supplier responses are incomplete?

As mentioned above, CUC members assemble, manufacture, and distribute exceptionally complex products; some can be minute, while others are of immense scale and have incredible levels of intricacy. These products are used in the aerospace and defense industries, commercial equipment, transportation products, IT equipment, and consumer appliances and electronics. The products require and contain thousands of components and parts acquired and assembled by potentially thousands of global suppliers, each of whom may never have a direct business relationship or contact with the manufacturer of the finished product. Given the broad universe of PFAS set forth the Proposed Rule and the thousands of suppliers involved in the production of components in any single article or end-use product, efforts to determine which components may contain PFAS are still in nascent stages. As discussed in more detail below, see page 17, one year is insufficient to complete the required investigations and reporting. The investigations themselves would take at least one year, and very likely longer, to complete, and the information companies are able to gather will necessarily be incomplete. The recent experience of CUC members in the context of the PIP (3:1) rule confirms that such investigations will require at least one year; that effort is addressing only a single, identifiable chemical substance with a non-confidential CAS number.

The complexity of CUC members' international supply chains makes locating the presence of PFAS in components challenging. A PFAS-containing part supplier may not be a direct supplier to a CUC member of a component or semi-assembled part. Each supply chain tier will need to identify the applicable components, and the importer of any given article would be consolidating that information. Other factors—including supplier concerns about CBI—present additional complexities that make it difficult for importers of articles and component parts to gain a full understanding of the chemical composition of such products. CBI issues can particularly pose hurdles to timely acquisition of information about chemical composition when a company is dealing with suppliers who in turn are working with sub-suppliers in a highly competitive field with technologically sophisticated products.

Moreover, many PFAS have not been regulated by EPA or by other regulatory bodies. Nor has the presence of most PFAS otherwise been monitored or regulated in commercial markets. In the absence of an economic or regulatory necessity to identify or make known the presence of PFAS in products and components, their presence in many chemical formulations, products, and articles has heretofore been largely unknown to the numerous users and manufacturers who acquire these formulations, products, and articles. Assessing throughout an international and multi-faceted supply chain whether a complex manufactured article might contain any number of chemicals identified as PFAS using the "structural definition" being proposed by EPA will very likely require an exponentially greater amount of resources and time than will be required to address PIP (3:1).

In addition, chemical testing or analysis of articles is not a viable option, particularly within the timeframes that the Proposed Rule would require. The process of chemically analyzing the composition of finished articles presents technical challenges that would make it impossible for CUC members to reasonably and responsibly ascertain whether articles they import contain PFAS.

Section 8(a)(7)'s requirement that information be provided for each year since January 1, 2011, not only increases the compliance challenges posed by complex products and international

supply chains but also reinforces the argument that articles containing PFAS should not be included within the rule's scope. If articles are included, there necessarily would be significant data gaps in information provided about imported articles because companies' records are likely to be—at best—incomplete over this timeframe. In some cases, the historical information may be unavailable because corporate recordkeeping policies were based on then-applicable statutory and regulatory requirements and/or on internal company standards. As noted above, articles typically have not been covered by TSCA Section 8(a) reporting requirements. Moreover, other TSCA Section 8(a) regulations—which might be viewed as providing a guideline for what kinds of recordkeeping requirements are reasonable—impose much shorter recordkeeping timeframes. For example, Sections 704.11 and 704.102(g) require retention of records for three years, and Sections 704.25(f), 704.33(g), 704.95(f), and 704.104(f) impose five-year retention requirements.

More anecdotally, in CUC members' experience, company standards and policies were unlikely to require the collection and maintenance of the information the Proposed Rule requires to be reported, to the extent it relates to articles. (If the scope of PFAS is defined to include substances that are currently being monitored (based on other jurisdictions), information may be available to a limited extent, e.g., for products manufactured after a certain date.) Given the timeframe for reporting, conducting an investigation for goods imported 10 years ago is not realistic.

At the very least, EPA should consider crafting the final rule to reflect a more nuanced (or tiered) approach in the depth or breadth or kinds of information that must be reported and by which entities. EPA could consider imposing, first, a reporting regime that requires information to be submitted only by manufacturers and importers of PFAS as chemical substances or within formulations (mixtures). Perhaps this initial round would be similar to the information reported for CDR purposes, and include submission of any unpublished health and environmental studies (including physical-chemical properties information). After receiving and assessing more carefully the information received and then available to EPA, the Agency could decide whether to trigger a second reporting exercise. For example, if EPA were to determine on the basis of the initial round of reporting received from manufacturers of PFAS that there continues to be a need for information concerning the presence of PFAS in articles, then EPA could consider the use of TSCA 8(a) and/or 8(d) to call in any remaining unpublished studies and target the 8(d) requirement to certain industries (or entities within specific NAICS codes) that are considered most likely to have such unknown or new information for PFAS.[13]

Additional Comments on the Proposed Rule[14]

More Clarity Is Needed Regarding the "Known to or Reasonably Ascertainable" Standard

[13] As discussed below, CUC requests that PFAS used in small quantities and solely for research and development purposes and PFAS generated or present as a byproduct or impurity should be excluded from reporting. If EPA decided to implement a phased reporting scheme, reporting on these categories of PFAS should be included in the second phase of reporting.

[14] Without conceding that the final rule should require reporting by importers of articles, the following comments are particularly relevant if EPA includes importers of articles containing PFAS within the scope of entities subject to the final rule.

In particular, EPA should provide language in the final rule that specifies that "known to or reasonably ascertainable by" does not include obtaining records that have been destroyed or were not required to be maintained under federal or state laws, nor a company's ordinary record retention policies and practices. The Proposed Rule defines "known to or reasonably ascertainable by" to mean "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." As discussed above, it is unlikely that regulatory standards in place during the relevant time period (since 2011) imposed information collection, reporting, and recordkeeping requirements on importers of articles (and not at all with regard to the chemical content of such articles). Therefore, an importer of articles would not reasonably be expected to have policies and practices in place that required maintenance of records including the Proposed Rule's data elements going back to 2011.

Furthermore, as discussed above, companies' practices during the relevant period are unlikely to have involved collection of information from suppliers and sub-suppliers about the PFAS content of components, articles, and finished products, especially given the largely unregulated category of numerous substances EPA now proposes to include in the scope of PFAS. The definition of "known to or reasonably ascertainable by" should explicitly acknowledge or otherwise reflect that a reasonable article importer would not have possessed or controlled such information during the relevant period.

For these and other reasons discussed in these comments, CUC recommends EPA explicitly apply a different standard of inquiry to those entities that act as the importer of an article that might contain PFAS. Specifically, EPA should clarify that the Agency expects importers of articles to report only the information that is explicitly "known to" the company, or in its "possession or control."

To the extent that supply chain queries are nevertheless required by the "known or reasonably ascertainable by" standard, EPA must provide more definitive guidance on the level of due diligence that EPA would accept as meeting the standard. For example, the preamble and the language in the final rule should clarify that if a supplier refuses or neglects to reveal its product's chemical content to an entity that might have a reporting obligation (e.g., the supplier claims such information to be confidential and not subject to such disclosure), the requesting party will be determined to have met its obligations under the known to or reasonably ascertainable by standard, and will not be subject to an enforcement action if the requesting party reasonably relied only on the information it has in its possession or had obtained.

In addition, the final rule should provide clarity on the Proposed Rule's provision in Section 705.15 that "reasonable estimates may be submitted" when "actual data is not known to or reasonably ascertainable by a submitter." EPA should provide additional guidance about what "reasonable estimates" are and also clarify whether such estimates are an option that submitters "may" choose to submit in the event that actual data are not known or reasonably ascertainable (as the regulations state), or if "reasonable estimates" are required to be reported to the EPA in such circumstances (as the preamble suggests[15]). In particular, the final rule should provide more guidance on what types of information reasonable estimates may rely on in the context of articles, components, and finished products. The requirements for "reasonable estimates" in the context of

[15] *See* 86 Fed. Reg. at 33929.

articles, components, and finished products—where importers may lack objective methods for such estimates—could result in creation and submission of information of questionable value. The final rule should not require such estimates in the context of PFAS content of articles, components, and finished products.

The Final Rule Should More Clearly Delineate the PFAS that Are Within Its Scope

EPA should focus its attention and rulemaking efforts to gathering data on substances that are in commerce and identifiable based on their inclusion on the TSCA Inventory (by specific non-confidential chemical identity and CAS Registry number, or by an accession number or other form of unique identifier). Providing a structural definition to define the scope of substances for which reporting will be required creates ambiguity and the opportunity for inadvertent non-compliance with EPA regulations. Given that EPA's structural definition of PFAS could encompass thousands of fluorinated compounds, the regulated community should not have to "guess" at which of those compounds EPA intends to be subject to the substantial reporting burdens on this rule. The failure to issue an explicit regulation that more specifically identifies the substances for which reporting is required creates regulatory uncertainty, and the approach exposes to potential EPA enforcement actions countless companies that might be less sophisticated, or lack the resources or technological capacities to understand—or even be aware of—the reporting obligations being proposed by this rulemaking.[16] Thus, in the final rule EPA must clearly delineate the specific PFAS that are within the rule's scope by limiting the number of PFAS subject to the rule and by publishing specific lists of the substances identified by CAS Registry Number or by (in the case of confidential chemicals) EPA accession number or other unique identifier assigned by EPA and which is known to the manufacturers and importers of the substances.

CUC members recognize there may be challenges in defining what substances constitute reportable PFAS under Section 8(a)(7). However, the Proposed Rule's "structural formula" approach and the inclusion of a lengthy yet "non-exhaustive" list of reportable PFAS create ambiguity, as well as opportunities for inadvertent non-compliance, especially for entities that are not the actual manufacturers of a chemical substance, formulation, or article.[17] CUC does not believe it is reasonable to place importers of articles, including components and finished products that incorporate such articles, in the position of making inquiries throughout their supply chains based on such an open-ended definition of PFAS.

EPA should make every effort to include a more discrete list of covered PFAS for which data would be required in the final rule. It appears that the current non-exhaustive list of 1,364 PFAS includes even "legacy" short- and long-chain PFAS that are no longer manufactured, as well as certain butyl compounds. The ambiguity created by the regulation can be eliminated by eliminating the "structural definition" approach.

Fluoropolymers Should Be Excluded from the Rule's Scope

[16] The vagueness of the ambiguity created by the structural definition and vagueness of the scope of substances covered by the rule also could create "due process" concerns in the context of any future EPA enforcement action.

[17] An example of problems caused by the lack of a definitive list is that the non-exhaustive list of PFAS in the proposed list 225 PFAS that are not included in EPA's PFAS Structure Lists located on EPA's CompTox Chemicals Dashboard.

EPA should exclude fluoropolymers from the final rule's list of reportable PFAS. Including fluoropolymers on the list, or in the final structural definition, particularly if articles containing fluoropolymers are included within the rule's scope, would result in a vast scale of reporting that would produce negligible useful information to the Agency. For example, individual companies would have to investigate and report on every piece of imported equipment or mechanical assembly, and even seals and gaskets, that contain fluoropolymers, including polytetrafluoroethylene (PTFE). Inclusion of fluoropolymers on the list could also sweep many more entities into the rule's scope since they are widely used in articles and products and in components of articles large and small. Such a vast scale of reporting is unlikely to result in collection of information that will be useful to assessing risk. EPA has previously found that the probability of exposure to high molecular weight, water-insoluble polymers resulting in unreasonable risk to human health or the environment is "exceedingly low"[18] Notably, the Chemical Data Reporting rule includes an exemption for polymers,[19] and the new chemical program also includes an exemption for polymers.[20] EPA did not regulate fluoropolymers in its Significant New Use Rule for Long-Chain Perfluoroalkyl Carboxylate (LCPFAC) and Perfluoroalkyl Sulfonate Chemical Substances.[21] Given that EPA has previously excluded polymers, and fluoropolymers in particular, from reporting and regulation under other TSCA rules, the Agency should also limit reporting on fluoropolymers under this rule.[22]

Unless importers of articles have a definite list of PFAS that are subject to the reporting requirement, conducting internal and external investigations would be extremely burdensome. It is very likely, for example, that information on non-regulated PFAS is not available to article manufacturers and importers because first- and second-tier suppliers (e.g., of component parts of complex articles) are unlikely to have such information. This is further complicated in the fabricated products (articles) industry, where chemical composition is lesser known and more difficult to obtain. Unlike formulated products, articles lack safety data sheets, materials assays, and other basic chemical/compositional information. Data concerning the health and environmental effects, or even physical-chemical properties, of PFAS are far more likely to be in the possession and control of the entities that manufacture the basic chemistries, not the manufacturers and assemblers of components and end-product articles.

EPA Should Have Differing Reporting Requirements for Differing PFAS

A final reporting rule should distinguish the kinds of data required based on the commercial status of the PFAS. For example, EPA may have a reasonable basis to want to greatly expand its database on health and environmental effect of PFAS and therefore could require submission of any available health and environmental effects studies on PFAS that have been manufactured or imported in the 10-year-plus period covered by the Proposed Rule. However, EPA might limit its

[18] 60 Fed. Reg. 16316, 16322 (Mar. 29, 1995).
[19] 40 C.F.R. § 711.6(a)(1).
[20] 40 C.F.R. § 723.250.
[21] 85 Fed. Reg. 45109 (July 27, 2020) (final LCPFAC SNUR); 80 Fed. Reg. 2885 (Jan. 21, 2015) (proposed LCPFAC SNUR).
[22] If the Agency has identified specific fluoropolymers to be of particular concern, those substances should be included explicitly on the list and EPA should request information on those substances from the entities that are manufacturers of the listed substances.

effort to require exposure-related data (such as worker exposure, manufacturing site, numbers of workers exposed, etc.) to only those substances that are listed on the "Active Inventory" so that information is collected only for substances that are most likely to be currently in commerce. It is not reasonable, nor is it likely to be fruitful, to require an entity that may have phased out manufacture or import (or use) of a specific PFAS to have retained reliable exposure-related information beyond a limited period following completion of the phase-out.

EPA also should consider prioritizing specific PFAS substances and limiting the kinds of data required for certain substances that heretofore have not been the subject of national or international scrutiny (and for which there is less likely to be existing unpublished data). For example, EPA might consider more expansive reporting and recordkeeping requirements for PFAS chemicals that have been or are currently being considered for regulation in other national and international jurisdictions.[23] In contrast, less information might be required for PFAS that are not subject to any regulatory requirements in the US or abroad.

Finally, the Agency might consider a more carefully tailored final rule that requests differing kinds of information and levels of detail from differing kinds of entities. For example, if, notwithstanding the plain language of Section 8, EPA requires reporting by importers of articles that contain PFAS, the rule should include less extensive information requirements for such entities.[24] This would minimize reporting burdens but still meet the Agency's policy objective of learning as much as can be known about the potential health or environmental effects of PFAS.

EPA Has Authority to Include Exemptions from the Reporting Obligation

In public statements and in the preamble to the Proposed Rule, EPA has concluded that it lacks statutory authority to adopt any exemptions. This interpretation misconstrues the language of Section 8(a)(7) and the rest of Section 8.

First, EPA appears to take "each person" (as added by the NDAA) in Section 8(a)(7) literally.[25] Yet Section 8(a)(1) uses the same "each person" language, and EPA has routinely adopted exemptions for reporting rules adopted under that provision.[26] Similarly, Section 8(b)(10)(D)(i) requires "any person" who manufactures mercury or mercury-added products to

[23] Certain PFAS subgroups are regulated in various countries and markets and thus are more likely to have been the subject of study and monitoring the makers and importers of the substances. Examples include certain substances listed in EPA's LCPFAC SNUR; Perfluorohexanoic acid (PFHxA) and its salts as defined under EU REACH; Perfluorooctanoic acid (PFOA) and its salts, as defined under EU POPs treaty implementation programs; and Perfluorooctane sulfonates (PFOS) as defined under EU POPs implementation programs. Other previously identified PFAS include those identified on the Agency has included in the proposed fifth Unregulated Contaminant Monitoring Rule.

[24] If EPA adopts this approach, it should also tailor the reporting obligations for importers and manufacturers of substances that are used solely in small quantities for research and development efforts.

[25] Section 8(a)(7) provides that "each person who has manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance in any year since January 1, 2011" shall be required to submit information.

[26] Section 8(a)(1) begins: "The Administrator shall promulgate rules under which—(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require …."

submit reports. Notwithstanding that broad language, EPA included exemptions from the reporting rule implementing that provision.

Other examples of similar language include:

- Section 4(b)(3)(B), which requires "each person" who manufactures or processes a chemical substance for which testing is required by a test rule to conduct that testing. Test rules routinely include in Tier 2 (essentially an exemption category) a variety of persons who do manufacture a test rule substance when done so only for purposes which are normally exempted.
- Section 5(a)(1), which provides that "no person" may manufacture a new chemical substance or manufacture or process a chemical substance for a use which EPA has declared to be a significant new use. Both the PMN rules and the significant new use rule (SNUR) regulations include multiple exemptions, including those CUC requests be included in the PFAS reporting rule.

Thus, EPA is incorrect in concluding that the "each person" language of section 8(a)(7) precludes it from adopting exemptions.

EPA has also misconstrued Section 8(a)(5), which expressly authorizes adoption of exemptions. Section 8(a)(5) provides:

> In carrying out this section, the Administrator shall, to the extent feasible—
> (A) not require reporting which is unnecessary or duplicative;
> (B) minimize the cost of compliance with this section and the rules issued thereunder on small manufacturers and processors; and
> (C) apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

Section 8(a)(5) applies to "this section," meaning all of Section 8—and thus including Section 8(a)(7). Indeed, EPA concedes in the preamble of the Proposed Rule that this rulemaking is subject to Section 8(a)(5).[27]

In a variety of Section 8 rulemakings, EPA has cited Section 8(a)(5) to justify its decision to adopt exemptions, including the following:

- TSCA Inventory Notification (Active-Inactive) Requirements, 82 Fed. Reg. 37520, 37531 (Aug. 11, 2017) ("EPA does not agree with the commenter's assertion that subsection (a)(5)(A) is solely concerned with the manner of reporting, such that the scope of reporting would be unaffected. It is difficult to see how one could make a notification requirement less unnecessary or less duplicative except by tailoring the scope of persons who are required to submit the notification.")
- Nanoscale materials reporting rule, 82 Fed. Reg. 3641, 3642–43 (Jan. 12, 2017) ("However, persons that manufacture or process, or intend to manufacture or process these

[27] 86 Fed. Reg. 33926, 33929, 33930 (June 28, 2021).

chemical substances as part of articles, as impurities, or in small quantities solely for research and development will not be subject to this action …. EPA is issuing this rule under TSCA section 8(a), 15 U.S.C. 2607(a), in compliance with the requirements of section 8(a)(5).")

- Mercury reporting rule, 83 Fed. Reg. 30054, 30063 (June 27, 2018) ("These goals are guided by statutory mandates not only in TSCA section 8(b)(10), but also in TSCA section 8(a)(5).")

These numerous examples clearly illustrate how EPA has previously regarded Section 8(a)(5) to authorize exemptions from "each person" or "any person" language when it appears elsewhere in Section 8. Moreover, the Agency has stipulated that Section 8(a)(5) applies to this Section 8(a)(7) rulemaking. Accordingly, EPA should reasonably conclude in this instance that it does have statutory authority to adopt exemptions.

For these reasons, and more, EPA should also implement the Section 8(a)(5) mandates again unnecessary, burdensome, and duplicative reporting by adopting exemptions, as explained in greater detail below.[28]

The Final Rule Should Include a De Minimis Threshold for Reporting

If the final rule includes articles containing PFAS within its scope, a *de minimis* threshold should apply. For example, reporting should not be required if PFAS content is less than 1% of the concentration present in a formulated solution or dry solid (e.g., powder or granule or fiber) or 1% by weight of the finished product or article.

The Final Rule Should Focus on Large Volume Importers

Entities that manufacture or import substances only in small quantities (e.g., < 2,500 lbs. per year, such as the lower limit that applies for the CDR reporting of substances subject to SNURs and TSCA 5(e) Orders) should be excluded from some or all of the information reporting requirements (such as exposure and use information).

As discussed in more detail below, CUC sees no reason why EPA should require reporting from entities that manufacture or import PFAS solely for research and development purposes. Additionally, small businesses should be exempt from Section 8(a) reporting. Congress specifically directed the Agency in Section 8(a)(1)(B) of both the original and amended law to exempt such entities from Section 8(a) reporting requirements.

The Final Rule Should Include a Research and Development Exemption

Substances, mixtures, and articles that are used in small quantities and solely for research and development (R&D) purposes should not be subject to reporting under the final rule. Section 8(a)(1)(B) explicitly excludes such substances and mixtures. The manufacture, import, and use of

[28] As discussed earlier in CUC's comments, the inclusion of articles containing PFAS within the Proposed Rule's scope also is at odds with EPA's obligations under Section 8(a)(5).

substances solely for R&D activities do not result in large-scale human exposures or environmental releases of PFAS.

EPA can apply the same principles as it applies to the TSCA Premanufacture Notice (PMN) rules[29] to define what constitutes R&D and to provide that only substances that qualify for the R&D PMN exemption would be exempt from Section 8(a)(7) reporting. The PMN requirements include that R&D be carried out under the supervision of a "technically qualified" individual, creating an assurance of safe handling and low opportunities for releases. In addition to incorporating the PMN requirements by reference, the preamble to the final rule could also refer persons to the Agency's interpretive guidance on R&D issued in 1986 for the TSCA new chemicals R&D exemption for a better understanding of the kinds of activities that the Agency considers to be legitimate R&D.

Including an exemption for R&D would promote critically important R&D work in the United States without diminishing the robustness of information collected under the Section 8(a)(7) rule. Prototypical articles and parts imported for R&D uses in the US as well as substances and mixtures used in laboratories and in real-life comparative trials in R&D exercises are typically conducted in a controlled environment and in small quantities. The limited additional data that could be gleaned from including PFAS substances used in R&D activities in the Section 8(a)(7) reporting obligation therefore would provide a negligible amount of information to support EPA's mission to identify and better understand PFAS.

The Final Rule Should Not Require Reporting of PFAS Generated or Present as a Byproduct or Impurity

The final rule should exclude reporting on PFAS when they are generated or present in another formulation or article as a byproduct or impurity. The final rule should exempt such substances entirely or require that only domestic manufacturers of PFAS report on byproducts and impurities.

Measuring the presence of a PFAS as an unintentionally present chemical that occurs during a production, disposal, or use process, or that might remain present in an article, is a technical challenge. This reporting requirement presents significant compliance challenges because it creates enormous opportunities for determinations that a product or article imported in good faith might later be shown through sophisticated testing to contain some small detectable level of PFAS. There is scant benefit to EPA to obtain such information from importers of products or articles.

The Final Rule Should <u>Not</u> Be Extended to Apply to Processors and Other Downstream Users

Congress did not intend for the rule to cover processors, and EPA should not require PFAS reporting by processors or other downstream users under its more general Section 8(a) authorities. Requiring processors to submit information would be burdensome and potentially result in duplicative reporting.

[29] *See* 40 C.F.R. § 720.36.

The plain text of Section 7531 of the NDAA as codified in Section 8(a)(7) provides that the reporting rule shall apply to "each person who has manufactured a chemical substance" that is a PFAS. Since other subsections in Section 8 specifically include processors within their scope,[30] the omission of processors from Section 8(a)(7) makes clear that Congress did not intend to bring processors within the scope of the PFAS reporting rule.

EPA should clarify in the final rule that only the initial importer of a PFAS-containing substance or formulation —and not any downstream "users" or "processors" of such a substance or formulation—must report. Providing this clarification in the final rule will avoid the potential for double counting. If the final rule does not explicitly limit reporting to the initial importer, the total volumes reported will potentially overstate the amount of PFAS in commerce. Reporting may also distort or misrepresent other information elements. The potential for duplications and distortions would create additional work for EPA since additional analysis would be required to establish an accurate understanding of the presence of PFAS in US commerce.

Moreover, the substantial burdens that reporting would impose on processors would not be justified by the incremental amount of any additional information that might be obtained.

The Final Rule Should Extend the Timeframe for Reporting

In the final rule, EPA should expand both the time between the rule's effective date and the commencement of the submission period and also the duration of the submission period. The Proposed Rule concerns hundreds of chemical substances and potentially pertains to thousands of articles, components, and finished articles with complex supply chains. In addition, as previously discussed, the Proposed Rule, with its application to articles, imposes obligations on numerous parties not previously subject to TSCA requirements. These parties will need to spend a great deal of time familiarizing themselves with the rule and with the mechanics of submitting information to EPA via the CDX; EPA will need to implement training opportunities for such entitles in addition to engaging in significant outreach to the public to make every sector that imports manufactured articles (including retailers and distributors of finished consumer and commercial use products) aware of the rule and its many requirements.

In consideration of these factors, the start date of the submission period should be considerably more than six months after the final rule's effective date because businesses will need more than six months to understand the scope of the final rule and its requirements and to investigate their supply chains. EPA must engage in significant public outreach to industry sectors that do not have a "TSCA awareness" and provide ample time to educate them and familiarize them with the rule and its final requirements. CUC also requests that the duration of the submission period that would only commence thereafter be at least one full year in length to allow submitters ample opportunity to collect and consolidate information from supply chains and to address technical issues that arise, including potential issues that require further consultation with the supply chain.

Even if the reportable PFAS were limited to select subgroups that are already being monitored under a company's supply chain management system, it would take—at the very least—

[30] *See* 15 U.S.C. § 2607(a)(1), (b)(4), (c), (d), (e).

many months to gather the necessary information because this type of request would be new for most suppliers, particularly due to its use of structural formulas and its inclusion of PFAS chemicals that have not previously been regulated or monitored. Drawing upon recent experiences with respect to PIP 3:1,[31] it would be a safe assumption that conducting the supply chain investigation to identify articles and products that contain one non-regulated PFAS chemical and to collect the required information would take at least one year, but is likely to take 18 to 24 months in the view of some CUC members. Given the vast number of non-regulated PFAS covered by the Proposed Rule, EPA must anticipate that the difficulties the final PFAS reporting rule could create will expand exponentially beyond the scope of the issues that arose immediately following the promulgation of the single-chemical PIP rule. Thus, it is reasonable that EPA must expect that the overall time to fully comply with submissions for all reportable PFAS would likely extend significantly beyond the one-year estimate. CUC recommends that the final rule should provide at least one year, and preferably two years, for data gathering and at least an additional year for collating and submitting the data.

The Final Rule Should Include a Safe Harbor for Importers of Articles

While CUC members strongly recommend the final rule specifically exclude reporting on the presence of PFAS in imported articles, if the final rule includes articles containing PFAS within its scope, the rule should establish a reasonable "amnesty" provision or "safe harbor" for importers of articles who learn of the presence of PFAS in imported articles *after* the submission period ends. EPA should clarify it has no intention to impose TSCA penalties for entities that have made a good faith effort to comply with the regulation and nevertheless might acquire such information after the reporting period has concluded.

It is reasonably likely that situations may occur where an entity that imports and uses manufactured articles and component parts may discover after the submission period ends that it imported articles containing PFAS during the relevant time period that it did not report. Entities might also learn that articles about which they did report included additional PFAS that were not included in the report submitted by the entity. These situations are particularly likely to occur given the large number of non-regulated PFAS that the Proposed Rule potentially encompasses and the complexity of manufactured products and their supply chains.

In addition to advising companies the Agency has no intention to bring enforcement actions against entities that do acquire such information belatedly, if the Agency wishes to encourage late reporting of such information, it could keep open the database for reporting or corrections indefinitely and advise businesses they can supplement or correct their reports indefinitely without risk of any compliance/enforcement action being taken for doing so.

Such an approach will create incentives for importers of articles to submit corrections, even if late (or amended) reporting is made necessary by such discoveries. Providing such "amnesty" for an entity to correct its filings, and without threat of adverse consequences for doing so, will enhance EPA's ability to develop its body of knowledge about PFAS in US commerce.

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[31] *See* 86 Fed. Reg. 14,398 (Mar. 16, 2021); Comments of the Chemical Users Coalition on Persistent, Bioaccumulative, and Toxic Chemicals Under Section 6(h) of TSCA, 86 Fed. Reg. 14,398 (March 16, 2021) (not dated), *available at* https://bit.ly/3zaDskB.

Comments on the Draft Economic Analysis

The draft economic analysis for the Proposed Rule significantly underestimates the rule's costs, both because it does not include article importers as affected firms and because its estimates of costs understate the time it will take for affected firms to comply. US Census data suggest that thousands of additional importing companies beyond what EPA has estimated could be subject to this rule if articles are within scope, and they all would be required to investigate whether every imported article or component of an article they import could contain a reportable substance.[32]

With respect to the number of affected firms, EPA must ensure that the economic analysis is not confined only to entities that will eventually end up submitting reports. If importers of articles are included within the final rule's scope, the economic analysis also must include an estimate not only of the number of importers who will be required to report but also an estimate of the number of entities that will have to assess their product lines to determine whether they must submit reports. Considering the complexity of the global supply chain, this would also include thousands of upstream suppliers that are separate commercial entities in a variety of nations. If the scope of PFAS is not clearly defined or limited, the cost of subject matter experts/consultants (to assist reporting companies in identifying the chemicals in scope) should be taken into consideration as well.

EPA must also revise upward its estimates of time burden and costs. The time required for rule familiarization and form completion, and the associated costs, will be greater for importers of articles, who previously have not been subject to TSCA requirements. Article importers generally will not have the benefit of familiarity with TSCA terminology and procedures, or with EPA's CDX. Moreover, the elements required to be reported are tailored to reporting on chemical substances themselves, not articles, components, or finished products. For example, reporting production volumes for articles would require a knowledge of chemical composition that article importers are unlikely to possess and that would be impracticable for importers to obtain. Because many or most importers of articles are unlikely to have been subject to previous TSCA reporting obligations, EPA should also assume that all article importers will incur the costs associated with registering with CDX and providing an electronic signature.

The complexity of the products manufactured by CUC members and similar businesses means that identification of the types of imported articles that potentially use PFAS, as well as the identification of all involved suppliers and the collection of data from suppliers, will be extremely labor- and time-intensive tasks due to the involvement of hundreds and potentially thousands of suppliers and sub-suppliers. One CUC member estimates the number of Tier 1 production suppliers to be 4,000, and estimates that there are approximately 185,000 unique part numbers in active use for a given product model. The estimated costs in Table 3-9 (Page 3-14) therefore severely understate the cost of compliance efforts, given the number of people who would be involved both in internal information gathering as well as external data collection efforts. Although the analysis correctly notes that costs will vary depending on the complexity of supply

[32] *See* U.S. Census Bureau, Department of Commerce, "A Profile of U.S. Importing and Exporting Companies, 2018-2019," Release Number: CB21-52, Table 7c.

chains and the size of a company, the cost ranges are unrealistically low. For manufacturers of complex products, identifying the type of imported articles that potentially use PFAS will involve evaluation of thousands of components. The task is made more challenging because of the ambiguity of the structural definition and the presence of many non-regulated PFAS within the rule's scope. Identifying, and collecting data from, suppliers will also be much more time-consuming than the cost ranges in Table 3-9 reflect due to the multiple tiers of suppliers, language barriers, varying degrees of technical and regulatory sophistication, and CBI issues.

CUC is not in a position to estimate the total number of entities, including small businesses, that may import articles containing PFAS, but it is clear that EPA's estimate of 234 affected firms will have to be substantially increased if the estimate is to reflect the number of importers affected by the Proposed Rule. Again, that estimate should include not only entities who will be required to submit reports but also entities that must investigate their supply chains to determine whether they need to submit reports.

Conclusion

The sweeping scope of the Proposed Rule is not called for by the statute and is at odds with EPA's obligations under Section 8(a) of TSCA, particularly EPA's obligations to not require unnecessary reporting and to apply reporting obligations to the persons likely to have information relevant to EPA's implementation of TSCA. Compliance with the Proposed Rule would necessitate extensive and costly querying throughout the supply chains of CUC members, both to determine which imported articles, products, or components may have contained PFAS and to elicit information responsive to the Proposed Rule's elements. These efforts would be unlikely, however, to elicit more than a minimal amount of relevant information.

To rectify these issues, EPA should target its final rule to effectively gather the information it needs. In particular, EPA should exclude articles containing PFAS from the scope of reportable chemical substances; include a *de minimis* threshold for reporting; include an exemption for small business; include an exemption for small quantities used solely for R&D purposes; and include an exemption for PFAS generated or present as a byproduct or impurity. In addition, EPA should more clearly delineate the PFAS within the final rule's scope and exclude certain substances from the scope of reportable PFAS. Other changes should be made to make the final rule more workable, including extending the timeframe for reporting, establishing a safe harbor for importers of PFAS-containing articles who belatedly learn of the presence of PFAS, and providing greater clarity regarding the "known to or reasonably ascertainable" standard to ensure that it does not impose due diligence obligations that are not balanced by an informational benefit.

In closing, CUC members appreciate the opportunity to provide comments on the Proposed Rule. CUC members would be pleased to meet with EPA personnel to discuss these comments and related issues as the Agency continues its efforts to implement Section 8(a)(7).