Semiconductor Industry Association (SIA)
Comments on the
Proposed TSCA §8(a)(7) Reporting Rule for PFAS

86 Fed. Reg. 33,926 (June 28, 2021)
Docket EPA-HQ-OPPT-2020-0549

September 25, 2021

The Semiconductor Industry Association (SIA) appreciates the opportunity to submit the following comments on the proposed Toxic Substances Control Act (TSCA) Section 8(a)(7) rule collecting data and information on per- and polyfluoroalkyl substances (PFAS). SIA is prepared to meet with appropriate Agency personnel to discuss these comments and related issues.

SIA is the trade association representing leading U.S. companies engaged in the research, design, and manufacture of semiconductors. Semiconductors are the fundamental enabling technology of modern electronics that has transformed virtually all aspects of our economy, ranging from information technology, telecommunications, health care, transportation, energy, and national defense. The US is the global leader in the semiconductor industry, and continued US leadership in semiconductor technology is essential to America's continued global economic leadership. More information about SIA and the semiconductor industry is available at www.semiconductors.org.

1. Introduction and Summary of Comments

EPA should modify the proposed TSCA reporting rule significantly to reduce the impact the rule will have on SIA members and other similarly situated sectors of the US economy and make compliance with the rule more feasible. SIA's recommendations include:

- Reporting on articles containing PFAS should not be included in the final rule. SIA members do not have access to, and cannot reliably report on, the chemical content of complex articles they may import. Also, EPA is not required by law to include articles containing PFAS within the scope of the Section 8(a)(7) final rule.
- EPA should significantly reduce the number of PFAS subject to the reporting rule and eliminate the use of a "structural definition" for PFAS in any final version of the rule.
- EPA should consider excluding entities that do not manufacture or import PFAS and mixtures that contain PFAS, if the entities solely acquire (including import) for processing and use at their US facilities formulated products or articles in which PFAS could be present (including as impurities or byproducts).
- EPA should not require reporting for PFAS and mixtures (and articles) containing PFAS that are used solely in research and development activities.
- EPA should establish levels which represent thresholds for the presence of PFAS and exclude from reporting information concerning PFAS when present below a *de minimis* threshold (e.g., $\leq$ 0.1% by weight in articles - if reporting on imported articles is ultimately required).
- EPA must provide more definitive guidance on the level of due diligence that would be acceptable to meet the "known to or reasonably ascertainable by" standard.
- The reporting timelines should be reconsidered for the final rule.
- EPA has not accurately assessed the viability of, and costs required for, compliance when estimating the economic impacts of the proposed rule and must do so and make such a revised assessment available for public scrutiny and interagency review before the rule can be issued in final form.

A requirement to report on PFAS in categories of uses SIA seeks to exempt will not generate the submission of material new data and information to EPA regarding human exposures and environmental releases of PFAS which are not already reported in the public literature. Requiring such reporting therefore does not serve the statutory intent behind TSCA's Section 8 reporting authorities. This is among the many reasons EPA has exempted such categories of information from numerous other TSCA reporting rules and should do so here to remain consistent with its prior practices.

2. SIA concerns and comments about reporting on PFAS

A. PFAS in Articles Should be Excluded from the Rule

Semiconductor manufacturing facilities ("fabs") are massive facilities, typically containing hundreds to thousands of individual manufacturing equipment assemblies ("'tools"), many of which are interconnected by tens of miles of piping. Individual tools contain thousands of individual components, each one consisting of hundreds of precise parts designed for specific functionality. To acquire and maintain fab equipment, SIA members often act as importers (i.e., "manufacturers" for TSCA purposes) of products and articles. In many cases, the imported items can include finished equipment or their many components (and replacement parts). However, SIA members generally are not made aware of the chemical content of such articles and components. Due to their functions, such articles and their components are manufactured in such a way that they cannot intentionally release their chemical components; if they did, the components could malfunction and potentially damage semiconductors and other materials produced in member facilities.

Semiconductor process tools are highly complex articles. As noted above, U.S. fabs may import process tools used to manufacture semiconductor devices. These tools consist of hundreds of components and tens of thousands of parts obtained through a complex international supply chain. For example, as the *New York Times* reported earlier this year, the extreme ultraviolet tool required to pattern leading edge semiconductor devices "requires 40 shipping containers, 20 trucks and three Boeing 747s.… 'It's definitely the most complicated machine humans have built,' said Darío Gil, a senior vice president at IBM."[1] Due to the sheer number of components and parts and the complex supply chains associated with them, it is not logistically feasible for semiconductor companies to identify articles that contain PFAS.

Suppliers of articles do not provide information on chemical content. SIA members who import articles face obstacles that make it difficult, if not impossible, to identify imported articles that contain PFAS. The complex nature of the technical equipment used in semiconductor manufacturing and the thousands of component parts such equipment may contain make it impossible, even with an unlimited amount of time and resources, to discern the presence (if any) of PFAS in such articles. This is because of the international nature of SIA members' supply chains, and the confidentiality concerns that arise in a competitive industry in which suppliers closely guard their sensitive trade secrets (including the composition of equipment and component parts). These challenges are exacerbated by the numerous layers in such supply chains, the varying national and international regulatory regimes, and even basic language barriers.

Historical information EPA seeks on articles is not available. The need to obtain information about the presence of PFAS in articles going back more than 10 years would present even

[1] Don Clark, *The Tech Cold War's 'Most Complicated Machine' that's Out of China's Reach*, N.Y. TIMES (July 19, 2021), https://www.nytimes.com/2021/07/04/technology/tech-cold-war-chips.html.

more significant challenges. Component manufacturers and replacement part manufacturers are not always in direct contact with SIA members. Furthermore, because of the complexity of parts, the multi-layered and international nature of supply chains, and absence of information regarding PFAS content in articles, gathering historical information is in many cases infeasible.

EPA is not required by law to include articles containing PFAS within the scope of the Section 8(a)(7) final rule. The pertinent section of the National Defense Authorization Act for Fiscal Year 2020 (NDAA), which added Section 8(a)(7) to TSCA, does not require inclusion of articles. The NDAA only obligates EPA to issue a final rule by 2023 that requires "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). No mention of the presence of PFAS in articles is made. Further, the pertinent language is similar to the language of the core provision 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." Heretofore, the Agency has not interpreted the language previously to require reporting on the presence of specific chemical substances in manufactured articles for Section 8(a)(1) rules, such as the Chemical Data Reporting regulations (CDR), and has not promulgated a Section 8(a) rule which did so.

If article importers are required to report, then EPA should limit the requirements to specific available information that is reasonably and practically available. If EPA elects not to exclude importers of articles that might contain PFAS, it should considerably minimize the reporting obligations to require only the submission of unpublished health and safety studies that are known to or reasonably ascertainable by these entities. Although EPA does offer the option for a reporter to claim that the presence of PFAS was not known or reasonably ascertainable at the time of import, thereby alleviating the burden of reporting under the Rule, that standard does not eliminate the requirement and significant burden related to researching each article (finished article or part) imported from each supplier in the past ten years. Furthermore, if the final rule includes articles containing PFAS within its scope, a *de minimis* threshold should apply. For example, reporting should not be required unless an importer knows or can reasonably ascertain that PFAS content is greater than 0.1% by weight of the finished product or article.[2]

B. PFAS Must be Better Defined; Scope of Substances Included Narrowed

The proposed rule includes not only a list of substances by name and CAS Registry numbers, but also requires manufacturers and importers to report on any PFAS that meets the rule's "structural definition." The use of a structural definition approach to define the substances for which reporting must be submitted creates unnecessary ambiguity due to the "non-exhaustive" nature of the substances within its scope. This creates an impossible challenge for entities (such as importers of manufactured materials) that are not the actual manufacturers of the numerous products and component parts in which PFAS might be present. This approach also creates opportunities for countless potential violations of TSCA. Given the dearth of information that is provided by suppliers about the potential presence of PFAS in manufactured articles,

[2] SIA does not concede that PFAS should be categorically considered to be "substances of very high concern," nevertheless, the 0.1% standard would align with the EU restrictions on chemicals designated pursuant to REACH as substances of very high concern and the notifications required within the supply chain when such substances are present in articles. See e.g., ECHA Guidance on requirements for substances in articles, "Article 7(2) of the REACH Regulation must be interpreted as meaning that, for the purposes of application of that provision, it is for the producer to determine whether a Candidate List substance of very high concern, is present in a concentration above 0.1% weight by weight of any article it produces and, for the importer of a product made up of more than one article, to determine for each article whether such a substance is present in a concentration above 0.1% weight by weight of that article." https://echa.europa.eu/documents/10162/23036412/articles_en.pdf.

much less the specific "structure" of the chemical components therein, it will not be feasible for entities such as SIA members that are not manufacturers of such articles to ensure their compliance with the reporting requirements. The proposed rule, in its present form, requires entities that merely acquire and use formulations and articles, especially the importers of such products and articles, to undertake significant, and affirmative efforts by making inquiries with their suppliers simply to determine their compliance obligations under the proposed regulation. Thus, importers of products or article must take steps in an effort to a "prove a negative" with respect to the chemical content of the materials they acquire (but do not themselves manufacture). This means that potentially *every* enterprise in the US that imports *any product* which might contain PFAS will need to commence immediately making inquiries throughout their supply chains with regards to the potential presence of any PFAS that fits within the Agency's structural formula. This is made staggeringly more difficult by the non-exclusiveness of the structural definition approach.

SIA requests that EPA narrow the scope of the rule to target it more reasonably to gathering data on PFAS that are active in US commerce and that can be identified in a finite list to be included in the final rule identifying those PFAS for which reporting will be required by a specific CAS number – or that can be otherwise determined to be on the TSCA Inventory (and in US commerce) by use of an EPA accession number, low volume exemption (LVE) number, or other unique identifier.

Furthermore, SIA recommends EPA specifically exclude from the reporting requirements a subset of substances that are not generally considered to be bioaccumulative and toxic substances that, in the absence of the use of EPA's "structural" approach, would not traditionally be considered PFAS. Specifically, SIA recommends the rule be modified to exclude from reporting certain fluorinated gases and heat transfer fluids for which EPA already is gathering data pertinent to use and environmental release pursuant to the Greenhouse Gas Reporting Program (GHGRP).[3] As proposed, the TSCA Section 8(a) reporting regulation would exclude certain gases that are hydrofluorocarbons (HFCs) from the structural definition.[4] It is reasonable for EPA to also exclude perfluorocarbon (PFCs) gases and fluorinated heat transfer fluids (F-HTFs) when excluding HFCs because PFCs and F-HTFs are among those substances for which reporting is required annually under the (GHGRP). Such an exclusion can reasonably be made and would fulfill the Agency's obligations under Section 8(a)(5) of the statute to avoid imposing reporting requirements that are unnecessary or duplicative while minimizing reporting costs and burdens.

In addition, SIA recommends that fluoropolymers with high molecular weights, low water solubility, low levels of extractables, and low residual monomer and oligomer content be excluded from reporting. Such substances present minimal risk to human health and the environment, and their inclusion on the list of reportable substances leaves SIA members and similar entities with an impracticable reporting obligation, due to the ubiquity of some fluoropolymers such as polytetrafluoroethylene (PTFE) in numerous articles and components that are part of the complex manufacturing processes and equipment that SIA members use to produce semiconductors and products that contain them.

[3] The GHGRP regulations are codified at 40 CFR Part 98.

[4] The structural definition currently includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R′)R″ where both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R′ or R″) can be hydrogen.

C. Processors and Users should be Exempt

Entities that only acquire and use PFAS-containing formulations and articles should be explicitly exempt from reporting. The Agency should exclude from the reporting obligations entities that are not "chemical manufacturers" in the traditional sense (i.e., entities that are not engaged in producing and marketing chemical substances that are derived using reactive chemistries). While the rule implies this is the Agency's general intent, EPA should specifically exclude entities that do not manufacture or import PFAS and mixtures that contain PFAS, if the entities solely acquire (including import) for processing and use at their U.S. facilities formulated products or articles in which PFAS could be present (including as impurities or byproducts). Specifically, the rule and preamble should be clarified in this regard and affirmatively state that the rule requires reporting only from entities that strictly manufacture or act as the importer of record of PFAS shipments, and to exclude entities that solely process or use formulations, products, and articles that contain PFAS. This is a reasonable approach because manufacturers of PFAS are the entities most likely to have unpublished health or environmental effects data for PFAS, and to have the capacity to obtain and report on the other information items enumerated in TSCA Section 8(a)(2)(A)–(G). Moreover, manufacturers are the only entities mentioned in the NDAA. If EPA does not clarify that processors and entities that only acquire and use PFAS are exempt from reporting, there will be unnecessary confusion and duplicative reporting will occur. Duplicative reporting imposes resource burdens on both the regulated industries and EPA personnel who will need to sort through the reported information, simply to determine if the information has already been received by the Agency.

D. Exempt PFAS when Used only in Research and Development

EPA also should exempt from reporting information concerning PFAS when such substances are present in chemical substances and mixtures that are used solely in research and development activities. R&D chemical substances are unlikely to have any associated test data that EPA could use for these purposes. Under Section 8(a)(5) of TSCA, EPA is required "to the extent feasible" to "not require reporting which is unnecessary or duplicative". Since R&D chemical substances are not active in US commerce, that is, they are not contributing to any potential ongoing hazards nor exposures to consumers or the general population, it is unclear how EPA considers information on R&D chemical substances necessary in carrying out its TSCA Section 8(a) obligations. Requiring reporting on R&D substances is unnecessary and discourages US innovation and otherwise pushes additional innovation offshore at a time when the US government is attempting to enhance the US economy and the country's competitiveness in several key sectors, including semiconductor manufacturing.

E. Reporting on PFAS when Present at Low Levels should not be Required

The proposed rule appears to require reporting on PFAS when present at any level (no matter how small) in a formulation, product, or article. This requirement puts SIA members at risk of non-compliance if a member might import a formulated product or finished article that might be determined to contain some small detectable level of PFAS based on testing conducted by EPA enforcement personnel. EPA does not require notification of impurities under TSCA Section 5, nor does it require reporting under the CDR rule (*See* 40 C.F.R. § 711.10(c), incorporating 40 C.F.R. § 720.30((h)(1) by reference). This is not to say that the hazard potential of impurities is low; rather, the presence of impurities is generally below levels that may present an appreciable opportunity for exposure and ultimately risk. EPA has within its discretion to exclude from reporting instances where the presence of PFAS is unintentional (e.g., as an impurity or inadvertent byproduct) or at *de minimis* levels. Moreover, there is little benefit to EPA from obtaining information from importers of products or articles on the presence of small quantities

of PFAS byproducts or impurities. Given limited Agency resources, and the likelihood that entities that acquire, but do not manufacture, chemicals might be unaware of, and unable to detect, the presence of PFAS at low concentrations, SIA recommends EPA establish a *de minimis* standard for the amount of PFAS that mUSt be present in an article, or other chemical product, before reporting would be required. Specifically, SIA recommends that -- if EPA continues to include imported articles in the regulation -- the presence of PFAS present in an article need not be reported if present at ≤ 0.1% by weight.[5]

As a matter of practicality, and in keeping with other TSCA rules, EPA also should consider more broadly exempting all substances that otherwise would be excluded from reporting under the requirements for new chemicals and new uses (such as those uses enumerated in 40 CFR 720.30(g) and (h)).

F. More Definitive Guidance is Needed to Clarify the "known to or reasonably ascertainable" Standard

Particularly if the Section 8(a)(7) rule includes a requirement to report on PFAS when present at any level in a formulation, product, or mixture, and even when present in an imported article, EPA mUSt provide more definitive guidance on the level of due diligence that would be acceptable to meet the "known to or reasonably ascertainable by" standard. SIA requests that EPA make clear that a processor, user, or importer of a product or article is not required to sample an acquired product or article or to conduct analytical testing to search for PFAS content. Moreover, EPA should also clarify that if an entity has acquired a product or article and has made (and maintained records of) inquiries to suppliers about the presence of PFAS in a product or article, the entity may reasonably rely on its suppliers' responses -- and will not be subject to an EPA enforcement action with respect to this regulation when promulgated if the suppliers' representations are relied on in good faith. Further, the final rule should provide that if an importer has a record that it has made such reasonable inquiries of a supplier, and the supplier has refused to reveal its product's chemical contents to an importer/customer, or advised that such information is not known to the supplier, the customer may lawfully assume in good faith the imported article does not trigger reporting under the rule.

If EPA does not clarify *and narrow* the scope of inquiry required to satisfy the regulation, it will make compliance with the standard impracticable and produce duplicative information. EPA is seeking information from certain entities (such as article importers) that can only be obtained through inquiries to their upstream suppliers. While the assembler of an article might (through such inquiries) gain an understanding that PFAS might be present in the components in the articles they assemble, the article importer will still lack the level of knowledge sufficient to respond to the regulation as proposed. Nevertheless, all importers of any article, even those who import articles that may not even contain PFAS, will need to check with their own employees, and with each of their upstream suppliers, to determine whether they have any knowledge that can be "reasonably ascertained" of the presence of PFAS in each article they might import. As currently written, it is not only foreseeable, but likely, that a broad range of entities will be seeking, and reporting, simultaneously the same detailed information from multiple contacts within upstream suppliers and downstream users supply chains.

[5] Without conceding that PFAS can be considered to be substances of very high concern *per se*, the <0.1% standard would align with the EU restrictions on the presence in articles of chemicals designated pursuant to REACH as SVHCs. EPA also should consider implementing a *de minimis* standard of >1.0% by weight for the presence of PFAS in formulations and other products that do not qualify as articles. This would be generally consistent with EPA's standard in its TRI reporting rules for chemicals among the listings for PFAS. *See* rules codified at 40 CFR Part 372 and https://www.epa.gov/toxics-release-inventory-tri-program/addition-certain-pfas-tri-national-defense-authorization-act.

G. Timelines should be Reconsidered

EPA should reconsider the timelines for reporting under the Section 8(a)(7) rule. For example, SIA recommends that the submission period should not open until one full year after the rule is issued in final form to allow importers and other entities who are not "chemical manufacturers" *per se* sufficient time to work with their supply chains and gather needed information. The duration of the submission period should be at least 12 months thereafter to allow submitters ample opportunity to address information gathering and technical issues with reporting (e.g., opening new CDX accounts, getting authorizations for reporting by others in the supply chain).

H. EPA's Economic Analysis Should be Amended

The economic analysis for the proposed rule significantly underestimates the rule's costs for compliance because it does not include estimates of the costs that would be imposed on article importers and because EPA has dramatically understated the time it will take for affected entities to gather information on the presence of PFAS in various products and articles. Furthermore, compliance with the rule as proposed is not feasible even with unlimited time and resources. EPA has not met its obligations under the pertinent Executive Orders and the requirements of the Office of Management and Budget to reliably estimate the impacts of an agency's proposed regulation for purposes of assessing impacts on the national economy.[6] EPA must revise upward its estimates of time burden and costs. The time required for rule familiarization and form completion, and the associated costs, will be significantly greater for companies that are importers of articles, because they previously have not been subject to TSCA reporting requirements, such as CDR. EPA must revise the economic analysis to include all potential entities that will be expected to comply with the regulation, including those that must assess whether any of the products they import might contain PFAS, even if they never have to submit a report. The supply chain for SIA members is such that this could include thousands of upstream suppliers that are separate enterprises in numerous countries. Moreover, if the scope of reportable PFAS is not significantly limited, and the requirements for importers of articles remain as proposed, EPA must further assume companies will need to hire additional personnel or retain experts/consultants to assist in identifying the chemicals and products within scope and to make and interpret inquiries throughout the international supply chain. Even with these additional resources, compliance with the rule as proposed is not feasible.

3. Summary and Conclusion

SIA members are very concerned about the scope, breadth, and feasibility of the proposed reporting rule and recommend the Agency confer immediately with stakeholders to ensure the requirements in the proposal more closely align with the letter of the directives in the NDAA and the congressional intent of Section 8(a) of TSCA. After doing so, SIA encourages the Agency to reasonably conclude that it should modify the proposal to reduce the scope of reporting by better defining or completely eliminating the structural definition included in the proposed rule and instead relying on a more discrete and finite list of substances (identified by CAS number, accession number, LVE, or other unique identifier number) for which reporting would be required. SIA highly recommends that EPA consider excluding entities that do not manufacture or import PFAS and mixtures that contain PFAS, if the entities solely acquire (including import) formulated products or articles in which PFAS could be present (including as impurities or byproducts) for processing and USe at their US facilities. Furthermore, EPA must more accurately assess the burdens and economic impacts of the proposed rule and must make such a revised assessment available for public scrutiny and interagency review before the rule can be issued in final form. In addition, EPA should not require reporting on the presence of PFAS in

[6] *See*, e.g., E.O. 12866 and 13563.

articles. If reporting on articles is required (which is fundamentally ill-advised) reporting should be exempted for the presence of PFAS in an article below a *de minimis* threshold (e.g., ≤ 0.1% by weight). The final rule also should exclude from reporting substances used only for R&D, substances excluded from other reporting such as substances in the exclusion categories identified at 40 CFR 720.30(g) and (h), and substances already subject to the reporting requirements of the GHGRP.

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SIA thanks the Agency for considering these comments and reiterates our interest in meeting with EPA staff to discuss our comments and concerns.