

**Comments of the
Semiconductor Industry Association (SIA)
To the
Environmental Protection Agency (EPA)
In the
Per- and Poly-Fluoroalkyl Chemical Substances
Designated as Inactive on the TSCA Inventory;
Significant New Use Rule
88 Fed. Reg. 4,937 (January 26, 2023)
Docket EPA-HQ-OPPT-2022-0867
Submitted March 27, 2023**

The Semiconductor Industry Association (SIA)¹ submits these comments in response to the U.S. Environmental Protection Agency's (EPA's or the Agency's) Per- and Poly-Fluoroalkyl Chemical Substances Designated as Inactive on the TSCA Inventory; Significant New Use Rule ("proposed SNUR").

Introduction and Summary of Comments

EPA is taking a novel approach with the Proposed SNUR by seeking to categorize past uses of chemical substances that are not in active commerce as "new uses." If this proposal is issued in final form, EPA should retain certain critical elements of the Proposed Rule and modify others to ease concerns related to compliance with the terms of the proposed rule and to lessen the impact it may have on SIA members and other sectors (including "downstream users") that are similarly situated in the U.S. economy.

SIA's recommendations include:

- Restricting the SNUR "triggers" to require reporting on only truly "new" uses of the affected chemical substances, and excluding uses that were previously considered to be "ongoing" or were the subject of a Premanufacture Notice (PMN). As the proposed SNUR encompasses more than 300 substances, the scope is very broad and therefore the compliance burden will be significant; focus only on truly "new" uses will ease the burden.
- EPA should retain the standard exemptions in the proposed SNUR for articles, impurities, and byproducts. Furthermore, EPA should include exemptions for all use categories for which TSCA Inventory reporting was not required under the TSCA Inventory Notification (Active-Inactive) Requirements Rule ("Active-Inactive rule") and the CDR Rules.
- EPA must provide a list of chemical substances, using CAS Registry Numbers, which are subject to the SNUR in the body of the rule itself. The structural definition should be eliminated, as it is unclear and may lead to confusion and inadvertent noncompliance.

¹ The Semiconductor Industry Association (SIA) is the voice of the semiconductor industry, one of America's top export industries and a key driver of America's economic strength, national security, and global competitiveness. Semiconductors – the tiny chips that enable modern technologies – power incredible products and services that have transformed our lives and our economy. The semiconductor industry directly employs over a quarter of a million workers in the United States, and U.S. semiconductor company sales totaled \$275 billion in 2022. SIA represents 99 percent of the U.S. semiconductor industry by revenue and nearly two-thirds of non-U.S. chip firms. Through this coalition, SIA seeks to strengthen leadership of semiconductor manufacturing, design, and research by working with Congress, the Administration, and key industry stakeholders around the world to encourage policies that fuel innovation, propel business, and drive international competition. Additional information is available at www.semiconductors.org.

A. The SNUR Must Apply Only to Truly New Uses

Prior to EPA promulgating a SNUR, TSCA Section 5(a) requires EPA to consider: the projected volume of manufacturing and processing of a chemical substance; the extent to which a use changes the type or form of exposure of humans or the environment to a chemical substance; the extent to which a use increases the magnitude and duration of exposure of humans or the environment to a chemical substance; and the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

The proposed SNUR does not reflect that any assessment was performed by EPA on a chemical-by-chemical basis for the criteria to be evaluated for each of the affected substances. EPA appears to have concluded that because these substances are considered to be PFAS, and because certain PFAS are associated with potential risks to human health and the environment, then any use should trigger submission of a Significant New Use Notification (“SNUN”). EPA also appears to have concluded that such reporting should be required prior to resuming uses that previously may have been carefully evaluated by EPA at the time the substances were first reported through premanufacture notices (“PMNs”). TSCA provides EPA should under undertake a more well-reasoned assessment before issuing a SNUR, and it appears this has not been done here. The change of Inventory status from inactive to active cannot provide a sufficient basis to meet the statutory SNUR criteria; otherwise, Congress, in the 2016 amendments to TSCA, would not have permitted a change in Inventory status from inactive to active to be accomplished simply by notification.

SNURs are intended to address “new” uses; i.e., uses that were not previously existing. The fact that a substance may not have been in an active status during a recent period should not be sufficient for considering any use of the substance to be considered “new” under the law once that use resumes. Furthermore, it is likely that at a minimum, some of the 330 affected substances were already reviewed by EPA via the PMN process. EPA, therefore, may already have information concerning the previously ongoing uses.

Furthermore, the scope of the proposed SNUR is significant, affecting any use of over 300 substances. To reduce what is a considerable compliance burden, and to ensure that the SNUR comports with the provisions of TSCA, EPA should only focus on truly new uses of these substances, and not those uses that have already been undertaken.

B. Proposed Exemptions Must Be Maintained; Additional Exemptions Are Warranted

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.

SIA members who import articles face obstacles that make it difficult, if not impossible, to identify imported articles that may 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.

Assuming EPA intends to finalize some form of the proposed SNUR, the standard SNUR exemptions for impurities, byproducts, and most importantly, imported and processed articles, must be maintained. As EPA has acknowledged, under the Active-Inactive Rule, reporting was not required for the manufacture or processing of chemical substances that were part of an article, for small quantities used in research and development, and for byproducts not used for commercial purposes. It is therefore possible that there are ongoing uses of the substances that are the subject of the proposed SNUR as impurities, byproducts, and in articles. TSCA Inventory "inactive" or "active" categorization is not indicative of their use in these manners, and omitting these exemptions should not be considered as a regulatory option.

The general SNUR exemptions that appear at 40 CFR 721 address articles and impurities. The general SNUR exemptions, as EPA notes, limit the application of the exemption for byproducts. However, the manufacture or processing of a byproduct was exempt from reporting under the Active-Inactive Rule. Therefore, manufacture of byproducts that were exempt under the Active-Inactive Rule should be exempt from the proposed SNUR as well. Removing standard TSCA PMN and SNUR exemptions, especially those with respect to substances imported or processed in manufactured articles, creates significant confusion in the regulated community and can lead to substantial disruptions in the supply chain for complex articles that often are manufactured in multi-stage, sequential processes at numerous facilities, including those outside the U.S. Consequently, these exemptions should be retained in the final version of this proposed SNUR.

The Active-Inactive Rule included many additional exemptions from the notification requirements, not only the ones specifically mentioned by the Agency in the Proposal and discussed in the passages above. There are exemptions from the Active/Inactive notification rule that also are present in the CDR rule and the PMN rules – specifically those codified in 40 CFR 720.30(h). These include, by way of example, substances manufactured and processed solely for export, those manufactured or processed for test marketing, non-isolated intermediates, and a series of highly fact-specific exemptions enumerated in the subparagraphs of §720.30(h). These uses should also be exempt from the final version of this proposed SNUR.

SIA also requests the Agency should clarify, for a rule as potentially complex as one which relies on a "structural definition" to describe the chemical substances affected, that the obligations under the SNUR apply only to manufacturers (including importers) and processors, and that users of these "inactive" PFAS who are not processors are exempt from any of the SNUR requirements.

C. The Exemption for Articles Must Be Maintained

SIA is responding to the Agency's request for comments concerning the articles exemption and whether it should be made inapplicable to PFAS at some point in the future. SIA requests that the "articles" exemption be retained indefinitely. The 2016 amendments to TSCA require that a specific statutory finding must be made before EPA may promulgate or amend a SNUR to require significant new use reporting based on the presence of a specific chemical substance in a manufactured article. Accordingly, EPA may require a SNUN for import of a chemical substance as part of an article only where "the Administrator makes an affirmative finding ... that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification." The 2016 amendments to TSCA made clear that EPA must address the scientific bases for concluding there is a more-than-theoretical reason to anticipate that exposures will occur from the presence of a substance subject to a SNUR in a manufactured article. SIA expects that the Agency would need to make such a finding on a chemical- or article-specific basis, considering whether there are differences in potential releases depending on the type and nature of the myriad substances and applications that might be covered by any SNUR addressing articles, especially one which covers greater than 300 substances based only on a broad categorization. There are likely to be many PFAS that are not reasonably expected to be released from an article in a manner that creates an unreasonable risk, and therefore such substances should not be subject to this proposed or any SNUR without the necessary foundation.

D. The SNUR Must List the Specific PFAS subject to the SNUR; The Structural Definition Should Be Eliminated.

EPA states in the preamble that the proposed SNUR is applicable to 330 substances. EPA provides a structural definition of PFAS and proposes that substances that meet that structural definition and are designated as inactive in the Inventory would be subject to the SNUR. EPA could simply have listed those substances explicitly in the SNUR, which would eliminate ambiguity and confusion. By providing only a structural definition to define the scope of substances subject to the SNUR, EPA has created unnecessary ambiguity and the opportunity for inadvertent non-compliance with the final regulation if it is not revised substantially. EPA has already identified the relevant substances it considers to be within the scope of the structural definition. Consequently, there is no need for the regulated community to need to evaluate the substances acquired for use or to "guess" as to which substances EPA intends to be subject to the proposed SNUR. Therefore, EPA should clearly delineate in the actual text of the SNUR the specific PFAS that are within scope, by publishing the specific substances identified by CAS Registry Number or, in the case of confidential chemical identities, by EPA accession number or other unique identifier assigned by EPA and known to the manufacturers and importers of the substances.

Furthermore, EPA must determine a finite way to identify all substances for which a chemical identity has been claimed as CBI, regardless as to whether the letters "fluor" or "fluorine" appears in the generic chemical name assigned (and by the use of Accession number and/or other unique identifier). Otherwise, users – current and potential – may simply not know if a particular substance is subject to this SNUR. EPA should provide notice to the original PMN submitters that the Agency intends to disclose these identities where the claim is not substantiated by the PMN submitter. When the claim is not substantiated in accordance with the provisions of Section 14 of TSCA, the chemical identity could then be made publicly available. For substances subject to this SNUR that apparently are not in active commerce, there is a high likelihood that CBI protection is no longer warranted or needed. In the circumstance where CBI

claims are substantiated by the last known manufacturer (or other entity asserting the CBI claim initially), EPA must work with that entity to provide some form of unique identifier that will enable manufacturers, importers, and processors to recognize that a specific substance is subject to the SNUR.

Conclusion

The revisions to the proposed SNUR, and the exemptions which SIA suggests in these comments, will substantially improve the SNUR and reduce the economic burdens and compliance difficulties of the rule as proposed. By making these changes, EPA is not relinquishing its ability to address potential human exposures and environmental releases of these PFAS if truly “new” uses are proposed.

SIA thanks the Agency for the opportunity to comment and reiterates our willingness to meet with EPA staff to discuss our comments and concerns.