

Comments of the
Semiconductor Industry Association (SIA)
On the
Proposed Amendments to TSCA Section 5 (New Chemicals/Significant New Uses) Procedures

88 Fed. Reg. 34100 (May 26, 2023)

Docket # EPA-HQ-OPPT-2022-0902

Submitted July 28, 2023

The Semiconductor Industry Association (SIA) submits these comments to the Office of Pollution Prevention and Toxics (OPPT) in response to the proposed Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA).

SIA is the trade association representing leading U.S. companies engaged in the design and manufacture of semiconductors. The U.S. is the global leader in the semiconductor industry, and continued U.S. leadership in semiconductor technology is essential to America's economic growth, technology leadership, and national security. More information about SIA and the semiconductor industry is available at www.semiconductors.org.

The semiconductor industry relies on the availability of innovative chemistries needed to implement new production methods and related technologies necessary for keeping up with the ever-increasing demand for semiconductors. SIA supports amendments to the regulations that will enable EPA to acquire the information needed to timely and efficiently review premanufacture notifications (PMNs), Low Volume Exemption (LVE) applications, and Significant New Use Notices (SNUNs). Having a reliable pipeline for new chemical formulations that can be deployed in the semiconductor fabrication process, as well as in the components of manufacturing process tools and facilities infrastructure is a critical feature of SIA Members' success. This is especially true as the industry is striving to expand its facilities and production capabilities in the U.S. as both Congress and the Administration have encouraged with enactment of the CHIPS and Science Act (P.L. 117-167).

SIA strongly supports the revisions and procedural changes to the Agency's New Chemicals Regulations that will improve the review process and the timing of authorizations. However, SIA is particularly concerned that EPA is considering: (a) categorical exclusions of chemicals from LVE and LoREX eligibility, and (b) based on the exclusions, the Agency is considering revocations of LVE's that have been granted previously. SIA Member companies generally are not submitters of PMNs, LVEs, or SNUNs, but rely on various suppliers of highly specialized chemical formulations which often are the subject to PMNs and LVEs. Bringing a new formulation through the development phases and eventually into use in semiconductor manufacturing facilities is a multi-year process. The introduction and use of a new formulation in semiconductor manufacturing processes may require more than a ten-year period to move from the R&D phase, into pilot efforts, and eventually into commercial use in manufacturing facilities ("fabs"). When the new chemicals review processes are unpredictable and are unnecessarily delayed or impeded, supply chains and significant sectors of the U.S. economy can be adversely affected. Thus, the new chemicals review program is a subject of great importance, having an effect on products and materials that are critical to the aerospace, automotive, defense, and energy sectors, as well as on consumer products.

SIA Opposes EPA Categorical Exclusions from LVE Eligibility Generally

SIA is particularly concerned by EPA's announcement that it intends to amend the LVE regulations to make per- and polyfluoroalkyl substances ("PFAS") and certain persistent, bioaccumulative, toxic ("PBT") chemical substances ineligible for low volume exemptions (LVEs) and low exposure/low release exemptions (LoREXs) from the full PMN review process. SIA considers it to be more appropriate for EPA to simply decide to grant or deny an application for a LVE or LoREX exemption on a case-specific basis considering the actual conditions of use being proposed in an application. Making a blanket determination to exclude an entire category of chemicals from consideration, which (by EPA's estimates of the scope of its PFAS definition) could exclude thousands of potential new chemicals from eligibility without EPA ever entertaining an application from the manufacturer or importer of the substance. This approach is short-sighted and will undermine EPA's ability to process its current backlog of PMN reviews because the proposed exclusions will lead to additional notifications coming through the process as PMNs (for which EPA will inevitably need to issue Section 5(e) Consent Orders).

Category-Based *Revocations* of Previously-Granted LVEs Would Be Devastating

SIA's primary concern with the proposed rule amendment is EPA's consideration of a revocation of all previously-granted LVEs for any substances that fall within EPA's proposed PFAS structural definition. There are multiple reasons why undertaking a categorical revocation of existing (previously-granted) LVEs would reflect bad public policy and a breach of good faith with LVE Exemption holders. Among the reasons are these:

- As discussed further below, the PFAS definition is overly broad, and includes substances (such as fluoropolymers) for which it is highly unlikely their existing uses under a LVE would be considered upon reevaluation to present "unreasonable" risks – yet that should be the legal and policy basis for considering any revocation of a previously-granted LVE application;
- Categorical decisions (in the absence of evaluating specific conditions of use) are contrary to the terms of the Act, which requires that the actual conditions of use of the substance in question be evaluated based on all information reasonably available, and to apply a weight of the evidence approach using the best available science. A categorical determination does neither and is in opposition to Section 26 of the Act.¹
- Such summary actions would also have profound and unintended consequences on the semiconductor manufacturing sector and the numerous sectors of the U.S. economy and our national defense systems that rely on semiconductors.

A recent survey undertaken by members of the Semiconductor PFAS Consortium has found that suppliers of formulations used in the semiconductor industry currently rely on more than 200 commercially-active LVEs for substances that likely fall within EPA's proposed PFAS definition. These substances are active in current uses in US commerce, and revoking these LVEs would result in the semiconductor industry being unable to manufacture devices in the U.S. The economic consequences of such a summary action by EPA are immeasurable. If these LVEs were revoked and 200 new PMNs were to be submitted (and EPA determined to issue Consent

¹ Section 26 of the amended law requires the Agency to consider "best available science" when making decisions under Sections 5 of the Act. EPA is to apply a "weight of the evidence" approach and to consider all "reasonably available information." A categorical determination to revoke LVEs for all PFAS is neither a risk-based nor science-based determination.

Orders for each one) the New Chemicals Program would be overwhelmed and semiconductor production in the U.S. could come to a halt.

EPA's Categorical Approach Will Make More Work for EPA Without Reducing Risks to Health or the Environment

EPA's proposal reflects a lack of appreciation of the many benefits of the LVE and LoREX regulations. Rather than "exempting" chemicals for which LVE or LoREX exemptions are granted, the regulations explicitly require the Notification submitter (i.e., the Exemption Holder) to produce and use the substance exactly, and only, under the conditions of the use proposed in the exemption application submitted. Deviations from the application's express terms (without EPA's consent) would constitute a violation of the LVE/LoREX regulations and the statute itself.

Moreover, LVE and LoREX substances which enter commerce in the U.S. may only be produced by the Exemption Holder – and are never included on the TSCA Inventory of Chemical Substances. Substances which do not appear on the Inventory may only be produced by a valid Exemption Holder, or by another entity that submits a PMN which is subsequently reviewed and approved by EPA. Thus, as a practical matter, the LVE and LoREX exemption process performs the same regulatory functions as Section 5(e) Consent Order and "follow-on" SNUR do for PMN submitters and any other market entrants. By keeping LVE and LoREX chemicals off the Inventory, the exemptions process eliminates the need to draft a 5(e) Order and propose and finalize a SNUR (saving EPA considerable time and human resources). However, by excluding an entire category of substances from LVE or LoREX exemption eligibility, even those for which EPA has concerns, the Agency will actually be creating more work for itself, and doing so will have the opposite effect of streamlining the new chemicals program. In fact, categorical ineligibility for the LVE and LoREX criteria will require the entities proposing to manufacture such substances to submit PMNs which, in turn, will require EPA to conduct a lengthy risk assessment, to consider (and presumably evaluate) any reasonably foreseeable (alternative) uses of the same substance, and then to issue a Section 5(e) Order and eventual SNUR. It is unclear that there is a credible risk-benefit basis for this proposed amendment; and there is a compelling argument that it will further constrain the efficient functioning of the New Chemicals Program generally.

The categorical exclusions (and revocations) will unnecessarily burden the Agency's already strapped resources in the New Chemicals Program. If EPA believes the current 30-day timeline for reviewing LVEs is unobtainable, then EPA should have proposed a 45- or 60-day review period for LVEs and LoREX applications. The benefits of the LVE and LoREX exemptions process has, and could continue to be, a way for EPA to:

- limit the quantities and methods and manner in which PFAS and PBTs that will be used only in very limited quantities;
- restrict releases (if any) to the lowest practically achievable levels;
- legally bind the Exemption Holder to those terms indefinitely; and
- require the Exemption Holder to specifically advise EPA and to seek the Agency's consent *before* making any changes in its production practices that would modify any risk-related facets of its conditions of use of the exempt substance.

A Categorical Exclusion is Not Warranted

SIA considers “categorical” exclusions from LVE and LoREX eligibility to be unwarranted and improper under the statute and current regulations, which SIA interprets to require EPA to make determinations with regard to all new chemical Notifications (and Exemption applications) on the basis of the risks presented under the conditions of use described in the Notification submitted to EPA. However, EPA’s proposal does not do this because it prejudices what a potential exemption notice submitter’s conditions of use might be, and without giving any consideration of the information EPA might acquire in an exemption application. The 2016 amendments to TSCA require EPA to evaluate chemical substances and to make risk-management determinations based on the information available and using the best available science. Making a determination for potentially thousands of PFAS that fit within the proposed structural definition (and for all substances that might meet EPA’s PBT criteria) ignores the statutory considerations that must be taken into account and reduces the “risk” equation (which is supposed to include an assessment of both hazard and exposure) to one based on conjecture alone.

SIA is Concerned with the Use of a Structural PFAS Definition for a Categorical Exclusion

The proposed three-part structural definition for PFAS which includes fluoropolymers.

- (i) $R-(CF_2)-CF(R')R''$, where both the CF_2 and CF moieties are saturated carbons;
- (ii) $R-CF_2OCF_2-R'$, where R and R' can either be F , O , or saturated carbons; or
- (iii) $CF_3C(CF_3)R'R''$, where R' and R'' can either be F or saturated carbons.

Although Section 26(c) may permit EPA to take actions with respect to a category of chemical substances, it should do so when there is a data-drive basis to conclude all members of the category which “are similar in molecular structure” also present similar risk profiles. Here, the proposed structural definition is overly broad, and it includes substances, including fluoropolymers, that could readily meet the LVE criteria, as well as other PFAS that are being developed for important to low-volume, low release applications that are essential to the semiconductor manufacturing industry and in making semiconductors and related materials of critical importance to US economy and national defense.

Such an approach is contrary to the terms of Section 5(a)(3) of the amended statute, which requires that the actual conditions of use of the substance under consideration in a Notification or Exemption application and to make a determination based on all information available, using a weight of the evidence approach, and the best available science. A categorical determination is completely contrary to the approach specified in Section 26 of the Act which calls for a weight of the evidence approach using the best available science, not blanket, categorical determinations which are not evidence-based.

Having multiple definitions within the Agency as well as other regulatory bodies is confusing and inefficient. Furthermore, a structural definition approach cannot be deployed on a large scale and in a practical manner across the chemical manufacturing and importer community and where multiple entities in a variety of countries need to understand and apply the approach. A structural definition approach requires a highly skilled and knowledgeable chemist to review every chemical individually. Having multiple definitions within the Agency as well as other regulatory bodies creates additional confusion and creates inefficiencies.

SIA Also is Concerned About Making PBTs Categorically Ineligible for LVEs and LoREX Exemptions

For the reasons discussed below, SIA recommends the Agency abandon its proposal to “codify” EPA’s “long-standing” practice that, when a chemical substance under LVE or LoREX review (or “any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance, or any reasonably anticipated impurities in the substance”) as PBT “with anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms”, would be ineligible for the LVE or LoREX exemptions. EPA’s proposal states the proposed “codified” approach would make such substances ineligible, but the Agency advises applicants would not be prohibited from submitting an LVE or a LoREX exemption application for such a substance. This approach is apparently being taken because “the finding that a substance is PBT would be made by EPA during the review of the notice.”

The proposal is confusing at best and runs completely contrary to the way the exemptions process (under the existing regulations) has worked successfully for many years. The exemptions process is intended to provide EPA with the information it requires to make an unreasonable risk determination based on a chemical substance’s physical-chemical characteristics, as well as the other factors affecting risk, specifically both hazard and exposure. Submitting a LVE or LoREX application simply to get a determination from EPA of whether it would determine a substance to be a PBT is a waste of resources (both EPA’s and the submitter’s), and a waste of time, and it is an even greater exercise in futility if EPA is not also going to assess the hazards and potential exposures and releases of the substance being reviewed under the entirety of the conditions of use being proposed in the application.

Curiously, although EPA states that it will make the PBT determination itself, EPA proposes to define a PBT chemical substance as described in the Agency’s 1999 PBTs policy document (64 FR 60194; Nov. 4, 1999). The proposal to categorically exclude PBTs is made further confusing because the proposal appears to only make a categorical ineligibility determination apply to PBTs (to be determined based on EPA’s affirmative review) for which there will be “anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms.” The proposal seems intent to turn the entire exemption process on its head by making a categorical ineligibility determination which is defined based on a review that EPA intends to conduct of the substance under consideration, and implicitly on the potential exposures and releases that will result during its intended use. A more direct approach, and one having greater simplicity and credibility, would be for EPA to simply announce that, among the criteria EPA intends to consider when evaluating LVE and LoREX applications are: the physical-chemical characteristics of a substance, the potential toxicity of the substance, the substance’s potential to persist in the environment, its potential to bioaccumulate, and the likelihood that under its proposed conditions of use that there will be human exposures and environmental releases that present an unreasonable risk to health or the environment.

SIA Supports Improving EPA’s Notification Forms Electronic Submission Tools.

SIA encourages EPA to update and improve the CDX platform for submitting new chemical and new use Notifications. SIA understands the importance of ensuring the Notification forms are thoroughly completed and that all pertinent information and data in the submitter’s possession or control are included at the time of submission. SIA supports improving CDX formatting and data entry templates which will enhance the database and ensure Notifications are fully completed and robust, and that will ensure EPA personnel have ready access to the information at the time the Notification is initially submitted. SIA favors such improvements based on our understanding that

this will enable the Notification review process to occur more swiftly and with fewer requests being made for additional information from the submitter.

SIA does not support implementing enhancements to EPA's current authorities, or new data-driven systems, which permit EPA to summarily declare a Notification to be incomplete because new information has been provided during the course of the PMN review period that EPA staff believe should have been provided at the time the PMN was originally submitted. However, the current regulations already enable EPA to declare a Notice to be incomplete within the first 30 days after receipt of the initial Notification, or within 30 days of receipt of new information received which is indicative that the Notification was incomplete. See §721.65(c). The proposed changes would allow EPA to deem a Notification to be incomplete when the Notice submitter provides new information but has not demonstrated "to EPA's satisfaction" that the information was not previously "known to or reasonably ascertainable by the submitter." This change appears intended simply to grant EPA reviewers additional discretion in this regard. The regulations already require submitters to prepare Notifications completely, to provide all studies and data in its possession or control, and to identify any other studies which are known to or reasonably ascertainable by the submitter. Further, Notification submitters must advise EPA of studies that are incomplete at the time the Notification is submitted and to promptly provide such data when they become available. See 40 CFR §§720.40 and 720.50. The amendments imply the Agency believes Notification submitters may be intentionally withholding data from their PMNs and LVE submissions. This is a mistaken assumption, for which EPA has not provided any basis in the rulemaking record. Instead, Notification submitters often are prompted to generate new or additional information during the review period to rebut unforeseen (or mistaken) assumptions EPA staff have made about human exposures or environmental releases of a substance under a particular proposed condition of use. SIA considers such amendments to be inappropriate because the amendments will further discourage Notification submitters from providing additional data that may be helpful to EPA's review of a Notification.

Other Areas of Concern to SIA Members

- SIA supports EPA's proposal to change the procedures for Agency review of Notices that would permit EPA to determine within the first days of the Notice Review Period that a Notification is incomplete, and the review period has not started. However, SIA does not agree with the 30-day period proposed for making such determinations. If EPA is expanding, as proposed, the CDX interface to ensure all PMNs are properly completed online before submission, then the "completeness" determinations could be made within 14 days of submission, and in a manner that permits the Notification submitter to correct the deficiencies and resubmit as soon as possible, perhaps at a reduced administrative fee.
- SIA strongly supports any efforts to ensure EPA considers and addresses information supplied in the PMN concerning the Notification submitter's "pollution prevention" efforts. The Agency should, at long last, begin to account for and incorporate into its new chemicals decision making the many benefits a new substance might provide in comparison to existing chemicals, and the manufacturing and use conditions surrounding substances for which the new substance might act as a replacement or alternative. The overall "benefits" of a new chemical substance might include the use of the new substance as a substitute for existing substances, or to enable alternative manufacturing or processing techniques to be used, including those that might reduce energy consumption, reduce the use of water or raw materials or processing materials of greater concern, or to permit modifications in a production process to produce fewer emissions or generate less waste. The Notice form has provided

space for this for more than two decades, but the review process does not seem to take this information into account when making determinations.

- SIA also supports EPA’s proposal that it may inform an LVE or LoREX exemption holder whenever a chemical substance that is the subject of their exemption is subject to either a proposed or final SNUR that describes the chemical substance by a generic chemical name. SIA recommends that this practice begin immediately, and be retroactive in nature, so an exemption holder may carefully consider such information.
- SIA requests that EPA reexamine its economic and burden estimates for the proposed rule. The economic assessment appears to completely ignore the potential resource burdens to be imposed by EPA’s proposal to categorically declare PFAS to be ineligible for LVE and LoREX exemptions. The considerable burden the delays in the PMN program already impose are nearly incalculable. Yet, the “burden estimates” EPA has provided reflect a conclusion that the changes in the proposed rule will actually decrease the total annual burden to businesses that generate new chemical “by approximately 4,518 hours, while total annual costs to industry submitters are expected to have a net increase of \$45,120.” Furthermore, EPA estimates the Agency will “experience an annual cost savings of approximately \$923,280.” These figures appear to ignore that a substantial part of the proposal is devoted to ensuring Notification submitters thoroughly complete their Notification prior to submission. The improvements being made to the CDX interface appear designed to require the submitters to spend more, rather than less, time in front of a computer screen. Furthermore, the categorial exclusion from eligibility for all PFAS and all PBTs will mean that a greater number of PMNs will still be submitted in the future. This will, as discussed above, serve to increase, rather than lessen, time spent by EPA personnel reviewing and responding to Notifications. Because more submitters will be required to file PMNs rather than LVEs or LoREX applications, they will need to wait a greater number of days before they learn of EPA’s determination on their pending new chemical submissions. EPA also must reasonably assess the economic consequences of the disruption such an action would cause in the US semiconductor sector, and the various economic sectors that rely on semiconductors. The action also would have a devastating effect on US competitiveness in the international semiconductor markets. Furthermore, If EPA were to revoke existing LVEs granted for PFAS substances, the economic burdens imposed by such an action would go well beyond the times spent by a PMN submitter to fill out and submit an application form to EPA to “replace” a previously-granted LVE. The economic impacts that would be felt by revoking such existing PFAS authorizations would include U.S. based semiconductor manufacturing facilities to shut down while seeking alternative chemicals.

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SIA appreciates the opportunity to provide input to OCSP on its proposed amendments to the TSCA new chemicals regulations.