Before the United States
Environmental Protection Agency
Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA)
88 Fed. Reg. 34100 (May 26, 2023); Docket EPA-HQ-OPPT-2022-0902

Comments of the Chemical Users Coalition

The Chemical Users Coalition (CUC)[1] 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).

Introduction

CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances. Our Members depend on the continuing availability of innovative new chemistries to enable advancements in the Members' product lines and their ability to remain competitive internationally. Consequently, our Members encourage EPA to develop regulatory approaches that permit both innovation and the use of new chemicals and manufacturing techniques that further environmental sustainability. Thus, CUC supports amendments to the new chemicals regulations that will: align the rules with the 2016 amendments to TSCA; implement needed improvements in electronic interfaces used by Notification submitters; and recognize the contribution that new chemicals can make to environmental sustainability and continued economic development in the United States. This is critical in the area of TSCA Section 5 policies, which necessarily address emerging developments in the chemicals sector and in product manufacturing.

CUC is submitting these comments to address several areas of concern in the proposed amendments because, if implemented without changes, the proposed amendments will certainly have an impact on CUC Members. CUC has a lengthy history of providing comments to EPA on policies and requirements pertaining to the new chemicals review program as it has an effect on products and materials that are critical to the CUC Members, including those engaged in industries as diverse as the commercial, industrial, and consumer use electronics sector, the aerospace and defense industries, and semiconductor manufacturing and related applications. CUC Members are also contributors of technologies relied on, for example, in the automotive and transportation sectors, and in energy production and storage.

While CUC Members generally are not submitters of premanufacture notices (PMNs), low volume exemptions (LVEs), or significant new use notices (SNUNs), as businesses that rely on suppliers of specialized chemical formulations and products produced using them, CUC Members are concerned about certain features of the proposed amendments. In particular, CUC is concerned

[1] The Members of CUC are Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, National Electrical Manufacturers Association, RTX, Sony Electronics Inc., and TDK U.S.A. Corporation.

that: (a) EPA is considering sweeping measures that might revoke authorizations previously granted to the submitters of LVEs; (b) broad new policies are being implemented based on assumptions and generalizations about groups of chemicals in the absence of data supporting such assumptions; and (c) such actions will potentially interrupt CUC Members' current supply chains as well as their abilities to innovate. When the new chemicals review process is unpredictable, US competitiveness in the global economy is harmed, and significant sectors of the US economy can be adversely affected.

Making Improvements to Notification Forms and CDX Interface

CUC supports EPA's efforts to update the CDX platform for submitting new chemical and new use notifications. EPA's efforts to communicate with PMN submitters regarding the information deficiencies the Agency has seen over the years have been beneficial. Consequently, CUC also supports measures that ensure the Notification forms are thoroughly completed and all pertinent information in a PMN or LVE submitter's possession or control is included at the time of submission. Improvements to CDX data entry templates should enhance the database and make it as user-friendly as possible while ensuring Notifications are fully completed. CUC agrees that the Notification Form and CDX interface should provide EPA personnel access to the information at the time the Notification is initially submitted. CUC supports such improvements with the expectation the improvements will speed the Notification review process and result in fewer requests for additional information from the submitter.

CUC recommends against implementing CDX redesign features which would be punitive in nature, such as systems enabling EPA reviewers to summarily declare a Notification to be incomplete late in the review process if information submitted later appears (in EPA's sole judgment) to have been reasonably available when the Notification was first provided to EPA. Furthermore, such changes are unnecessary since the current regulations at 40 CFR 720.65(c) already provide such authority. EPA notes in the preamble that it rarely exercises its current authority in this regard. This is not a sufficient basis for making changes to the scope and terms of the existing provisions.

LVE Eligibility Criteria

CUC Members are 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 LVEs and low release and exposure exemptions (LoREXs) from the full PMN review process. None of these measures are necessitated by the 2016 amendments to TSCA, nor did the amendments empower the Agency to make them.

LVEs and LoREXs were designed to make the review process more efficient for scenarios in which a substance is shown (by meeting the terms of the exemption) to have reduced or no human exposure opportunities or material environmental releases. The regulations were specifically written to require the Exemption Holder to be "bound" to follow all of the terms in the submitted application which pertain to the controls and measures which have any bearing on exposures, releases, and risks. *See* 40 CFR 723.50(j). The regulations for these exemptions make clear that deviations from the application's express terms (without EPA's consent) would constitute a violation of the LVE/LoREX regulations. This feature of the PMN Exemptions rules appears to

have been lost on EPA and to have been ignored in its preamble justifying these proposed amendments. This is disappointing to CUC Members as it suggests EPA considers the current regulations to permit Exemption Holders to do otherwise. EPA's proposed approach inappropriately concedes the mistaken assumption that Exemption Holders who manufacture substances pursuant to the terms of the exemptions do so without any EPA oversight or regulatory restrictions. That is not only a mistaken assumption, it is simply not consistent with how the regulations are interpreted by the Program Office staff and EPA personnel who enforce the rule provisions. Exemption Holders take the new chemicals regulations very seriously, including their obligations under the Exemptions they have been granted.

This proposed policy change is concerning to CUC Members because it would exclude an entire category of substances from eligibility for the exemptions, will actually serve to create more work for EPA, and will not streamline the new chemicals program at all. In fact, the proposed categorical approach for determining chemicals to be ineligible for LVEs and LoREXs will require the entities proposing to manufacture such substances to submit PMNs which, in turn, will likely require EPA to conduct a detailed risk assessment, and to consider (and presumably evaluate) any reasonably foreseeable uses of the same substance, and then to issue a Section 5(e) Order. The categorical exclusion will unnecessarily burden the Agency's already strapped resources and make the situation worse in an already "underperforming" new chemicals program. EPA should refocus its attention on the many resource-saving benefits of the LVE and LoREX process which should continue to be a way for EPA to oversee and limit the total quantities and methods by which chemical substances of potential concern may be produced and to legally bind the Exemption Holders to those terms indefinitely. As required by Section 723.50(j), the current regulations specifically require the Exemption Holder to advise EPA and seek the Agency's consent *before* modifying any risk-related facets of its conditions of manufacture and use of the so-called "exempt" substance.

Categorical Exclusions Are Not Appropriate

CUC considers such "categorial" exclusions from eligibility to be improper when the statute requires EPA to make risk-based determinations with regard to all new chemical Notifications (and Exemptions) on the basis of the risks presented *under the conditions of use described in the Notification* submitted to EPA. *See* Section 5(a)(3) of the amended Act. LVEs and LoREXs do not present issues with regard to "reasonably foreseen other uses" and thus permit EPA to make exposure-driven determinations of risk where warranted. EPA's proposal does the opposite as it prejudges what a potential exemption submitter's conditions of use might be, and without consideration of the information EPA might acquire in an LVE or LoREX application. The 2016 amendments to TSCA require EPA to evaluate chemical substances on the basis of the information available and using the best available science and a "weight of the evidence" approach. *See* Sections 26(h) through (j). Global and categorical determinations to exclude potentially thousands of PFAS within the proposed structural definition (and substances that might fit EPA's PBT criteria) from consideration for an exemption ignore the statutory considerations (such as "exposures") that must be taken into account and reduces the "risk" equation (which includes, by definition, assessing both hazard and exposure) to a conclusion in the absence of information or assessment of the science.

CUC Considers Use of a Structural PFAS Definition for a Categorical Exclusion to Be in Error

EPA has proposed a three-part structural definition for PFAS that would include any chemical substance that contains at least one of these three structures:

(i) R–(CF2)–CF(R′)R″, where both the CF2 and CF moieties are saturated carbons;

(ii) R–CF2OCF2–R′, where R and R′ can either be F, O, or saturated carbons; or

(iii) CF3C(CF3)R′R″, where R′ and R″ can either be F or saturated carbons.

This PFAS definition is overly broad, including substances, such as fluoropolymers, which are critically important in countless applications in commerce, and which can be produced and used in a manner that does not present unreasonable risks. A categorical determination is completely contrary to the "science-based" approach required to be used for Agency decision-making as specified in Section 26 of the amended Act.

CUC Is Concerned About PBTs Being Ineligible for LVEs and LoREXs

CUC recognizes and supports EPA's careful scrutiny in the new chemicals program of substances that are persistent, bioaccumulative, and toxic. However, certain PBTs can be used responsibly and in applications which prevent human exposures and eliminate opportunities for environmental releases. The LVE and LoREX applications and review processes are intended to evaluate such controls and methods and their adequacy before granting the exemption. Nevertheless, EPA is proposing to define a PBT chemical substance using the criteria in a nearly-25-year-old policy statement[2] without any substantive update or evaluation of the Policy (and to expand the scope of the Policy to "any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance, or any reasonably anticipated impurities in the substance").

CUC is concerned because the PBT portion of the proposal is confusing. It is unclear when and how the PBT "exclusion" applies, and how the PBT determination would be made. It initially appears EPA intends to categorically exclude any PBT substance even before an application would be submitted by "codifying" the PBT Policy in the proposed regulatory text. Elsewhere in the preamble, EPA appears willing to accept LVE applications for potential PBTs and then to make the determinations itself, and to then deny the applications for any substances that would receive—on a scale of 1 to 3 for the potential for persistence, bioaccumulation, and toxicity—a score of "2 or above" for all three characteristics. It also is unclear how transparent EPA's determination would be, as the Agency describes its determination would be reached using physical-chemical properties, as well as "structural activity alerts, analogue data, and test data." To complicate matters further, it also appears the Agency intends for the new PBT exclusion to apply not only to the substance described in the LVE or LoREX application, but also to "extend to [consideration] of any reasonably anticipated metabolites, environmental transformation products, or byproducts of the chemical substance, as well as any reasonably anticipated impurities in the substance." *See* 88 Fed. Reg. at 34114. Finally, it is suggested that the PBT exclusion will also consider the exposure facet of the risk equation, and that EPA will consider whether the potential PBT, under the use conditions proposed, will result in any anticipated environmental releases and potentially

[2] PBTs 1999 policy statement (64 FR 60194; Nov. 4, 1999).

unreasonable exposures to humans or environmental organisms, and that such circumstances would make the substance ineligible for the LVE or LoREX. *See* 88 Fed. Reg. at 34115.

CUC recommends EPA simply withdraw its proposed exclusion for PBTs and focus instead on advising LVE and LoREX submitters regarding what items of physical-chemical property data EPA wants to see supplied with the application if the Agency considers such information to be a necessary condition for evaluating a LVE or LoREX application for a potential PBT. In fact, the proposed amendments to Section 720.45 and the PMN on-line Form are intended to do just that. Rather than attempting to find a way to categorically exclude categories of chemical substance from LVE and LoREX eligibility, CUC recommends EPA should make clear to submitters that the Agency will be focusing its review on the issues of persistence and bioaccumulation in addition to the hazard profile and the potential for human exposures and environmental releases likely to occur under the proposed conditions of use. Retaining a straightforward LVE and LoREX review process will avoid the unnecessary complications and process changes being proposed for potential PBTs. If such a straight forward approach is challenging for EPA to accomplish in a 30-day review period, EPA should consider proposing a 45-day review period, not excluding entire categories of chemicals from consideration.

Potential Revocation of Previously Granted PFAS LVEs

CUC is strongly opposed to EPA's consideration of a massive revocation of all previously granted LVEs for any substances that fall within EPA's proposed PFAS structural definition. For the reasons stated above, this is an inappropriate measure that is problematic to chemical users in general, especially those who rely on suppliers of specialty, small-volume chemical substances. The reasons for CUC's objections include:

- The PFAS definition is overly broad, and may include PFAS which are of lesser concern.
- Categorical decisions 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 when making determinations using the best available science. A categorical determination does neither and is contrary to Section 26 of the amended Act.[3]
- Such summary actions would also have profound and unintended consequences on businesses that rely on highly specialized chemistries—including CUC Members engaged in semiconductor manufacturing, the electronics industry generally, consumer products production and distribution, and the aeronautics, space and national defense sectors—as well as on our economy more generally.
- Blanket revocations of exemptions for PFAS will be disruptive to critical supply chains for commercially active substances, and would create a complete lack of confidence (here and

[3] Section 26 of the amended law requires the Agency to consider "best available science" when making decisions under Section 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 a science-based determination.

abroad) in the reliability of EPA's prior regulatory decisions. Such actions will further encourage businesses to move their R&D and manufacturing efforts off-shore.

Other Areas of Concern to CUC

- CUC 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. Given the improvements being made to expand the CDX interface and to enhance the on-line Notification form to ensure all forms are properly completed before submission, CUC recommends EPA should modify the proposal to establish a 14-day period within which EPA will make its administrative "completeness" determinations for new chemical Notifications.

- CUC opposes EPA's proposal that the Agency may retroactively determine (in its sole discretion) that a Notification that was submitted is "incomplete" on the basis of new information submitted to EPA that suggests the original submission did not include all information that was reasonably ascertainable. Such determinations would "reset" the 90-day review period to begin again and would present an opportunity for abuses of EPA's discretion. This also will make Notification submitters reluctant to generate and submit any new information or data they might obtain during the course of the Notification review period, something which would inhibit, not enhance, a thorough review of a proposed condition of use. EPA's existing authority under the regulation does not require amendments.

- CUC has always advocated for EPA to consider information supplied in the PMN concerning the Notification submitter's "pollution prevention" efforts. The Agency should find an orderly and understandable process whereby it will evaluate and incorporate into its new chemicals decision-making the many benefits a new substance might provide in comparison to existing chemicals for which the new substance might act as a replacement. New substances often enable new manufacturing and use conditions which might reduce human exposures or environmental releases of chemical substances, including through achieving process efficiencies and even waste handling practices. The overall "benefits" picture for a new chemical substance must be a factor in assessing a PMN, LVE, or LoREX application. The notice form has provided space for this information for many years; the new chemicals review process should be clarified so that submitters of Notifications are assured their information has been considered, and so that explanations are provided when information is not considered.

- CUC also supports EPA's proposal that it may inform an LVE or LoREX holder whenever a chemical substance that is the subject of an exemption becomes subject to either a *proposed* or final significant new use rule that describes the chemical substance by a generic chemical name. CUC suggests this practice begin immediately. Exemption holders and applicants alike should be advised of this so they can consider the implications of such information. The information is critical to persons who may import, process, or use a chemical that may become subject to a SNUR as this has compliance implications in particular for chemical users as well as for persons who are subject to CDR reporting requirements.

- CUC finds EPA's economic and burden estimates for the proposed rule to be startling, unusual, and apparently intended to persuade the regulated community the measures will alleviate the burdens on Notification submitters. This is incongruous with the changes and categorical decisions on policy to be imposed which will hinder, not streamline, the general exemption and application processes. The "burden estimates" EPA has provided reflect a conclusion that the changes in the proposed rule will actually decrease the total annual burden to the industry "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 spend more time on completing the Notification prior to submission. This is especially curious given that the improvements being planned for the CDX interface are purported to require the submitters to spend more, rather than less, time completing all elements of the Notification form and addressing all details of importance. In addition, the proposed categorial exclusions from eligibility for all PFAS and all PBTs will mean that a greater number of PMNs would 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. More, rather than fewer, businesses will be required to file PMNs rather than LVEs or LoREX applications, and they will need to wait a greater number of days before they learn of EPA's determination on their pending new chemical submissions. This is not likely to lessen regulatory burdens at all, and certainly not to the extent implied by EPA's economic assessment.

Conclusion

CUC appreciates the opportunity to provide input to OPPT on its proposed amendments to the TSCA new chemicals regulations. CUC Members would be pleased to meet and confer with key personnel who are responsible for oversight of the new chemicals program and the consideration of the proposed amendments to the regulations.