Before the United States
Environmental Protection Agency
Significant New Use Rules on Certain Chemical Substances (22-1.5e; PFAS SNURs)
87 Fed. Reg. 74,072 (December 2, 2022); Docket EPA-HQ-OPPT-2021-0847

Comments of the Chemical Users Coalition

The Chemical Users Coalition ("CUC") appreciates the opportunity to provide these comments regarding the U.S. Environmental Protection Agency's ("EPA") proposed Significant New Use Rules ("SNURs") for 35 chemical substances which the Agency identifies as "PFAS".[2] The Proposed SNURs all belatedly follow-up on predicate Section 5(e) Consent Orders which were issued prior to the 2016 amendments to the Toxic Substances Control Act (TSCA) and imposed risk-based limitations on the conditions of manufacture of the substances in the US.

CUC is an association of companies from diverse industries interested in chemical regulatory policy from the perspective of entities that typically acquire and use, rather than manufacture or import, chemical substances.[3] CUC encourages regulators seeking to develop and implement requirements to protect health and the environment to do so in a manner that enables the regulated communities to pursue technological innovation simultaneously with sustainable economic development in the United States. This is particularly important in the area of chemical regulatory policy, which necessarily addresses how core technologies and products can be adapted to address emerging information about health and environmental risk.

In sum, CUC's comments regarding the SNURs focus primarily on: the lack of clarity in the hazard communications requirements and related reporting triggers, especially as these could related to processors of the affected chemical substances; the difficulties presented by the use of "generic chemical identities" in certain SNURs to identify the substances subject to the proposed rules; the use of a reporting trigger for certain substances of 2,500 lbs./year; and the Agency's proposal to eliminate the exemption at 40 CFR §721.45(i) from the reporting obligations for entities that are operating pursuant to Section 5(e) Consent Orders. CUC encourages EPA to clarify the obligations of manufacturers and processors of these substances under the SNURs, and the timeline for those obligations. CUC also encourages EPA to consider whether the SNURs could be revised to mitigate uncertainty for downstream users, like CUCs members.

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[2] PFAS is not a defined term in the proposed rule or its preamble. CUC presumes PFAS is intended to mean certain "per- and polyfluoroalkyl substances". However, CUC recommends this terms be clarified in the preamble of any final SNURs issued pursuant to the December 2022 proposals. Moreover, CUC Members consider it to be important for EPA to provide a clear and well-reasoned basis for issuing SNURs simply on the basis that the substances are "PFAS" without further explanation. Without articulating such a basis in the Proposed Rule's preamble, EPA risks undermining the credibility of the SNUR program more generally.

[3] The members of CUC include Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, National Electrical Manufacturers Association, Raytheon Technologies Corporation, Sony Electronics, Inc., and TDK U.S.A. Corporation.

I. Clarification is Needed for the Hazard Communications Related Reporting Triggers

CUC requests that EPA clarify the hazard communications requirements in the Proposed SNURs. The Preamble to the Proposed SNURs advises that each of the affected substances were the subject of previously issued TSCA Section 5(e) Consent Orders. Apparently, among the requirements imposed by the predicate Section 5(e) Consent Orders were "certain hazard communication requirements". However, the specific hazard communications requirements for the various Proposed SNURs are not described in further detail in the Preamble or the Proposed Rule language where ordinarily the Agency would more clearly specify elements that should be included in the hazard communication program (e.g., working training, use of labeling, Safety Data Sheets, etc.) as well as the toxicity end points of concern, the routes of exposure to avoid, and the personal protection equipment or other mechanisms by which such concerns can be mitigated in the workplace. *See*, e.g., the SNURs codified at 40 CFR §721.550. Nevertheless, the only reporting triggers related to hazard communications that are being proposed in the current rulemaking are described very generally in the Preamble to include engaging in the activity of manufacturing, importing or processing of the substances in "the absence of this [i.e., hazard communications] protective measure" -- without further elaboration. However, the reporting trigger articulated in the hazard communications provision in the corresponding proposed rule language in the individual SNURs only states (in pertinent part), "[a] significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS…".

The lack of clarity in the Preamble seems unnecessary as EPA should be able to state with specificity its expectations for how the potential hazards of the affected substances should be described in any workplace hazard communication program without violating any concerns for revealing TSCA confidential business information. This would enable any potentially regulated entity to ensure its existing hazard communications program conforms with Agency expectations and to more readily recognize what EPA would consider to be any "significant new" information the entity might acquire with respect to the substance's potential hazards.

The proposed requirements imply that any entity that might be manufacturing, importing, or processing one of the affected substances already has in place a hazard communication program, and that it should be updated when the manufacturer, importer, or processor becomes aware of any significant new information concerning the substances potential hazards. If this is EPA's intention, the proposed requirements would be redundant with the Occupational Health and Safety Administration (OSHA) Hazard Communication Standard (HCS) and be unnecessary. *See* HCS at 29 CFR 1910.1200(f0 and (g). If this is the Agency's objective, EPA may not have a sufficient basis to support its presumption that the SNURs being proposed are necessary because entities that employ workers in the US already are subject to the HCS, and it is therefore unlikely the Proposed SNURs will

ever prompt SNU notification being submitted to EPA reporting that an employer manufacturing or processing the identified substances does not intend to update its existing hazard communications program when significant new information concerning a chemical substance hazard is received.

For these reasons, CUC Members request the Proposed SNURs be revised to either omit the hazard communications requirement and reporting triggers if the hazard communications provisions are, in fact, redundant with the OSHA Hazard Communication Standards or to modify the Preamble and Proposed Rule language to provide additional clarity to enable potential manufacturers, importers, and processors of these chemical substances to understand and interpret EPA's objectives.

II. Generic Identities in SNURs Present Difficulties for Processors of Substances

CUC Members respect the importance of protecting TSCA confidential business information. Our Members also acknowledge EPA's statutory authority and its regulatory objective to receive notice of significant new uses of chemical substances and to be provided the opportunity to review such uses and take action to restrict them if certain standards under Section 5(e) are met. However, prior to finalizing the language for these SNURs, CUC requests that EPA consider the impact of the use of generic chemical identities in the Proposed Rules and the impact of doing so on downstream users and processors of chemical substances. For these reasons, we encourage the Agency, whenever possible, to provide the CAS Registry Number in final SNURs. This might be accomplished if EPA were to contact the original PMN submitters of the substances for which only generic names have been provide in the Proposed SNUR and to request they voluntarily relinquish their CBI claims. In light of the fact that many of the PMNs for the substances were submitted more than 20 years ago, the importance of maintaining those CBI claims may have diminished greatly.

CUC recommends that the obligations for submitting a notification to EPA be limited in each of the proposed SNURs to only manufacturers and importers of the chemical substances, and *not* to processors of the SNUR substances (or mixtures containing the substances).

From a business perspective, it is difficult for downstream processors and users of chemical substances which are acquired as formulations to determine the specific chemical content of the products they acquire. This is because often the suppliers to do not provide a detailed break-down of each of the chemical components that may be present in such formations and mixtures. This may be due in part to trade secret and confidentiality considerations; it also may be due to a lack of transparency about the chemical components of such materials throughout multiple tiers of the supply chain. Considering that the focus of the 35 SNURs being proposed on identifying significant new uses of certain PFAS which are already regulated under Section 5(e) Consent Orders and are subject to a lower threshold for CDR Reporting (some of which may not even be identified as "active" substances in commerce), it follows that the Agency can reasonably limit the entities responsible for reporting to just manufacturers and importers as these are the entities who will be the first to become aware of plans that might involve new uses of the substances.

Given the vintage of many of the Consent Orders which were issued for the 35 substances (many are 20 years old), it would be inherently unfair to impose such SNUR reporting requirements at this late date on a processor or user of a formulation that it may have been acquiring for many years in good faith reliance on the representation of its supplier that the processor's intended uses were not restricted in any way. Moreover, given the lack of transparency with regard to the full chemical contents of formulations that may be acquired by downstream processors and users of chemical formulations, there is an enhanced possibility that such processor or user of one or more of the 35 substances may already be using such a substance in a manner that could subject the entity to a SNUR reporting requirement. In such cases, those uses would be "on going" and would not be considered "new" under EPA's long-standing interpretation of Section 5(a)(2) that an ***on-going*** use cannot be defined to be a significant "new" use.[4]

For the foregoing reasons, CUC recommends: (a) the Agency undertake efforts to obtain the necessary clearances to identify the SNUR substances by CAS Number to the extent permitted by Section 14 and (b) the final rules clarify the reporting triggers in the Proposed SNURs are limited to activities that are intended to be undertaken by manufacturers and importers, and not by processors of the affected substances.

III. EPA Has Not Provided Sufficient Bases for the Reporting Trigger of 2,500 lbs./year.

For several of the affected substances that are subject to Section 5(e) Consent Orders, EPA has proposed a reporting trigger for production exceeding 2,500 pounds per year in two instances. In the first instance, EPA has proposed this trigger (in addition to an "any use other than the use in the PMN" trigger) when a notice of commencement had not been received for the chemical and it is thus not on the TSCA Inventory. In the second instance, the same production-based trigger has been proposed for those substances that *are* listed on the TSCA Inventory and for which there was no CDR reporting submitted for the substance for the 2020 reporting cycle.

CUC Members find no legal bases or need for the 2,500 lb./year reporting trigger. First, the 2,500 lb./year reporting trigger is completely unnecessary for those substances which are not on the TSCA Inventory. For substances which do not appear on the Inventory, as a practical and legal matter, any entity *other* than the original PMN submitter (who would have signed the Section 5(e) Consent Order) that intends to manufacture or import the substance must provide a PMN to EPA (or submit a *bona fide* intent to manufacture inquiry). In such instances, EPA would be receiving a Section 5 notification and be in a position to fully assess the conditions of manufacture or import that would be proposed through such notification. The entire proposed SNUR in such instances is completely unnecessary.[5] In the second instance where the substance is on the Inventory and EPA did not receive a CDR report for the substance in 2020, the 2,500 lb./year SNUR trigger also is not needed because the "any use other than the use authorized in the Section 5(e)

[4] 83 Fed. Reg. at 40,995 ("To establish a significant new use, EPA must determine that the use is not ongoing.").

[5] EPA would have already limited the activities in which the original PMN submitter may engage through the existing Section 5(e) Consent Order.

Order" trigger, and the existing CDR requirements, ensure EPA will learn (through CDR reporting) the identity of any entity that produces the substance in quantities greater than 2,500 lbs. per year and, through the "any use other than the Section 5(e) Order" EPA will learn through the SNUR reports when any new uses are proposed.

For these reasons CUC Members recommend EPA drop the 2,500 lb./year notification requirement in any final SNURs.

IV. EPA Should Not Eliminate the Exemption at 40 CFR §721.45(i).

EPA is proposing to eliminate for purposes of these Proposed SNURs the exemption from reporting for persons who are the original PMN submitter and are producing a SNUR-ed substance in a manner that is fully consistent with the terms of a Section 5(e) Consent Order. The terms of the current exemption appear at 40 CFR §721.45(i). Apparently, the Agency wants to remove the exemption because it wishes to impose notification requirements on the original PMN submitters for uses that were not otherwise limited or restricted by requirements in the Section 5(e) Consent Orders to which the original PMN submitters previously agreed. Removing the exemption will have the effect of enabling the Agency to have a second (and perhaps more) opportunity to impose restrictions on the signatories to Consent Orders without needing to promulgate a Section 6 rule to do so. CUC Members consider such an approach to be unwarranted and unfair. CUC Members must presume the proposal to remove the exemption is necessary because EPA considers the original Section 5(e) Consent Orders it issued not to limit the PMN submitter to only those uses described in the PMN.

Removing the exemption for entities that have been lawfully abiding by the terms of the Consent Orders they negotiated in good faith with EPA in some cases more than 20 years ago would be patently unfair. Moreover, this could impose a requirement on a chemical manufacturer to reach out to all of its long-standing customers to determine whether any of their uses of a chemical substance (of which the manufacturer may be completely unaware) would be considered to be potentially significant new uses for which notification could be required. The resource burden this proposal would impose on the manufactures of these substances has not properly been contemplated by EPA, and its potential costs should be carefully considered in contrast to any benefit the regulatory requirement would provide.

V. Other General Comments

CUC Members note that it does not appear from the rulemaking record that the Agency has performed a substantial regulatory impact analysis for other efforts to assess the costs of compliance with the SNURs. The proposal states that EPA has concluded the final SNURs will not have a significant adverse economic impact because it appears no one is currently engaged in the "new uses" that would trigger reporting under the rules. However, this conclusion overlooks the fact that entities that acquire formulations and finished manufactured products that contain chemical substances must nevertheless be diligent about the contents of such materials anytime a new SNUR is proposed or promulgated. Such "due diligence" costs are substantially exacerbated when the

identities of the substances are unknown, and when a business may have thousands of different suppliers (both foreign and domestic) of formulations and finished products. CUC believes a more objective economic evaluation of the proposed PFAS SNURs would reveal such "hidden" costs -- such as the Agency learned when it recently revised its estimates of the economic impacts of its proposed TSCA § 8(a)(7) reporting rule for PFAS.[6]

CUC Members reiterate our strong recommendation that the Agency should retain not only the exemptions noted in our comments above, but all of the standard SNUR exemptions codified at 40 CFR §721.45 as they would otherwise pertain to this rulemaking. In certain recent SNURs, EPA has removed the standard SNUR reporting exemption codified at 40 CFR §721.45(f) pertaining to importation and processing of articles that contain certain PFAS materials. *See*, e.g., the so-called " LCPFAC coatings SNUR" codified at 40 CFR §721.10536 (85 Fed. Reg. 45124, July 27, 2020). Such actions to remove standard reporting exemptions, especially those with respect to substances imported or processed in manufactured articles, create significant confusions 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 several facilities abroad.

CUC Members are taking this opportunity to remind EPA that the 2016 amendments to TSCA ensure 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 Significant New Use Notification (SNUN) for import of a chemical substance as part of an article only "if 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."[7] CUC Members have consistently been concerned about the Agency's approach to using SNURs as a vehicle to restrict or require reporting on the presence of certain substances in articles. Our Members consider the terms of the 2016 amendment to TSCA (and good public policy more generally) to require EPA to very clearly address the technical underpinnings for concluding there is a more-than-theoretical basis to expect that exposures will occur from the presence of a SNUR-ed substance in a manufactured article. The same principle should apply whenever EPA is proposing to remove one or more of the standard exemptions; the Agency should be able to link the activity that will no longer be exempt from reporting to potential human exposures or environmental releases that would be more likely to occur during the previously exempt activity (e.g., R&D activities, imported or processed substances in articles, manufacture or processing a substance as an impurity, etc.).

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[6] *See* EPA's Notice of Data Availability and Request for Comment for its Initial Regulatory Flexibility Analysis at 87 Fed. Reg. 72,439 (Nov. 25, 2022) Docket EPA-HQ-OPPT-2020-0549. CUC's comments on the IRFA can be found here:
http://www.chemicaluserscoalition.org/ckfinder/userfiles/files/Comments%20of%20CUC%20on%20IFRA%20and%20Updated%20Economic%20Analysis%20for%20TSCA%208(a)(7)%20Rule.pdf

[7] 15 U.S.C. § 2604(a)(5).

Conclusion

CUC appreciates the opportunity to comment on the 35 Proposed SNURs and would be pleased to meet with EPA personnel to discuss these comments and related issues if doing so would assist the Agency in finalizing these rules.