Before the United States
Environmental Protection Agency
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

Comments of the Chemicals 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 Rule ("SNUR") for Per- and Poly-Fluoroalkyl Chemical Substances Designated as Inactive on the Toxic Substances Control Act (TSCA) Inventory.

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. 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.

CUC's comments regarding the Inactive PFAS SNUR proposal focus primarily on CUC's concerns that:

- the proposed SNUR undercuts the process established under the 2016 amendments to TSCA to move a chemical substances from the "inactive" Inventory to the "active" Inventory;
- SNURs should be restricted to capturing truly "new" uses, and not uses that were once ongoing or have already been the subject of a Premanufacture Notice (PMN);
- the scope of the proposed SNUR is unnecessarily large—encompassing 330 substances as well as a substance that fit within a "structural definition", which imposes a significant compliance burden; the exemptions for articles, impurities, and byproducts must be maintained;
- a list of affected substances inclusive of their CAS Registry Number (or specific ACCESSION number (or other assigned unique identifier number) should be provided, and therefore EPA must review chemical identity confidential business information ("CBI") claims to determine if CAS Registry Numbers can be provided; and,
- the cutoff date establishing what uses will be considered to be a "new uses" should be at least 6 months after the date the SNUR is issued in final form.

TSCA Inventory and Reactivating Dormant Substances and Uses

Section 8(b) of TSCA requires EPA to compile, keep current, and publish a list of each chemical substance that is manufactured or processed, including imported, in the United States for uses

under TSCA. This list, which was initially published in 1979, is called the "TSCA Inventory." If a chemical is on the Inventory, the substance is considered an "existing" chemical substance in U.S. commerce and may be used. Any chemical substance that is not on the Inventory is considered a "new chemical substance" and generally may not be used prior to a review by EPA.

The 2016 amendments to TSCA required EPA to designate chemical substances on the TSCA Inventory as either "active" or "inactive" in U.S. commerce. Chemical substances manufactured, imported, or processed in the U.S. during a 10-year period ending on June 21, 2016, and whose "current use" was reported to the EPA as part of the designation process, were considered to be "active." Those chemical substances that were not reported as being "used" in that period were designated as "inactive." This activity was formalized in the TSCA Inventory Notification (Active-Inactive) Requirements Rule (''Active-Inactive rule'').[1]

Before reintroducing inactive substances into U.S. commerce, manufacturers and processors are required to notify EPA, via a "Notice of Activity Form B," found in EPA's Central Data Exchange (CDX).[2] Upon receiving such notification, EPA will change the commercial activity designation of inactive substances to active. Consistent with Congress's intention, the final "active/inactive" regulations provide that no new substantive review by EPA of the chemical substances is needed for such substances to be moved from the "inactive" to "active" Inventory.

EPA is now proposing that 330 PFAS that are currently designated as inactive be subject to a SNUR that would deem *any* future manufacture, import, or process of any of these chemicals a significant "new" use. Consequently, prior to any such future use, a Significant New Use Notification, and therefore an EPA review, is required.

This proposal appears to undercut the simple notification procedure that Congress included when TSCA was amended. As mentioned, all that is required under TSCA to change the status of a substance from inactive to active is a notification. Congress did not include a provision that requires any form of substantive review of the substance prior to change of status. Congress understood that an inactive substance is one that had not been used for a period of time. Yet, Congress chose not to mandate any review prior to allowing the substance to be used once again. EPA is looking to change this paradigm—at least for these 330 PFAS. This could create a troubling precedent that effectively negates a key provision of the 2016 amendments to TSCA.

Furthermore, 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.

In the case of the proposed Inactive PFAS SNUR, EPA appears not to have undertaken a chemical-by-chemical review during which each of these criteria is evaluated for the three hundred

[1] *See*, 88 Fed. Reg. 37540 (Aug. 11, 2017).
[2] 40 CFR 710.25(c), 710.39

substances, and findings on a chemical-specific basis have not been provided. Instead, EPA concluded that simply because these substances were PFAS, and because *some* PFAS are associated with potential risks to human health and the environment, review of all of these substances, triggered by submission of a Significant New Use Notification ("SNUN"), should be required for any use being undertaken – including uses that may have been carefully evaluated by EPA at the time the substances first reported pursuant to the premanufacture notification process. TSCA provides the specific predicates to issuance of a SNUR, and it appears that they have not been met. Mere changing of status from inactive to active cannot suffice to meet the SNUR criteria; otherwise, Congress would not have permitted a change in status to be accomplished simply by notification. EPA must articulate, with specificity, the reasons for subjecting the 330 PFAS to a SNUR. The fact they are currently "inactive" is neither legally nor technically sufficient.

EPA's preamble to the rule disingenuously asserts that, "Before TSCA was amended in 2016, EPA completed formal reviews on only about 20% of new chemicals and had no authority to address new chemicals about which the Agency lacked sufficient information, which is part of the reason why many chemicals, including PFAS, were allowed into commerce without a complete review." This assertion implies that all but 20% of previously-reviewed PMNs were randomly ignored and blindly authorized for import or manufacture without reasonable consideration by EPA personnel. This is simply not the case and it is inaccurate to rely on such an erroneous assertion as the principle basis for an Agency finding to support this proposed rule. The fact that EPA reviewers were able to conduct efficient and time-sensitive reviews prior to the 2016 amendments that permitted certain "low-risk" substances and "low-risk" uses to timely enter commerce does not mean the Agency turned a blind eye to the potential health or environmental effects of 80% of the new chemicals reviewed prior to 2016. Furthermore, and contrary to the language in the proposal's preamble, the pre-2016 statute did grant EPA authority pursuant to 5(e) to issue Orders to restrict substances "pending the development" of data sufficient to perform a more complete evaluation. Truly hundreds of Section 5(e) Orders were issued before 2016 and hundreds of Significant New Use Rules were issued prior to 2016 for the substances that were subject to such Orders. In fact, the Agency established as many as 50-different "categories" of new chemicals of concern that routinely resulted in EPA undertaking a "detailed review" for such substances (among others) and prompted Section 5(e) Orders and SNURs to be issued on such bases. Furthermore, substances intended for production in large quantities also were routinely subject to "exposure-based" 5(e) Orders which compelled the PMN submitter to generate additional data to be provided to EPA at established intervals. The Agency does a disservice to itself and its employees by implying that prior to 2016, the New Chemicals Program did not meaningfully evaluate each chemical substance that was reported in a PMN.

Active Uses

TSCA grants EPA the authority to regulate the manufacturing or processing of "any chemical substance for a use which the Administrator has determined . . . is a significant new use." Both prior to 2016, and under the amended law, the relevant provision of TSCA is unambiguous: SNURs are intended to address "new" uses; i.e., uses that were not previously existing. The dormant status of an Inventory-listed substance for a period of time does not mean that a previous use should be considered "new" under the law once that use resumes.

Some of the substances listed by EPA as being subject to this SNUR were already reviewed by EPA via the PMN process. EPA, therefore, already has information concerning the previously ongoing uses. By proposing to subject these existing uses of a substance to review pursuant to a SNUR, EPA is plainly attempting to get a second opportunity to review these substances. This is not what Congress intended when amending TSCA in 2016; if it was, Congress could have revised the pertinent provisions of the Act (which it did not), an activity that TSCA provides for via SNUR. Congress established other authorities in TSCA for EPA mechanisms, to obtain information about existing chemicals and their potential hazards and past or current uses, such as Section 4 test rules and test orders, and Section 8(a) and (d) regulations.

CUC notes that there have been circumstances when EPA has promulgated a SNUR to address uses that had been deliberately discontinued. However, these cases were situations where the manufacturers (and importers) of those substances at the time voluntarily agreed to phase out their uses of a substance, and EPA used the SNUR mechanism to "level the playing field" and to ensure that the substances would not once again enter the marketplace without the Agency's awareness. In these situations, the manufacturers consented to EPA taking such action and were fully aware of the circumstances and the new restriction on the substance's use that the SNUR imposed (and were supportive of EPA's use of SNURs in that manner). That situation simply does not exist in this case. EPA is unilaterally taking action to restrict uses of a chemical that are not necessarily "new." That action is not supported by the SNUR provisions in TSCA. Accordingly, the SNUR, if finalized, should cover only actual "new" uses of the inactive PFAS substances, and exclude uses that were identified in previously submitted and reviewed PMNs.

Furthermore, the scope of the proposed "any use" SNUR trigger is significant, encompassing over 300 substances. To reduce what is a significant compliance burden, CUC believes that EPA must only focus on truly new uses of these substances, and not those uses that have already been undertaken in the past.

Exemptions

Assuming EPA intends to finalize some form of the proposed SNUR, the standard SNUR exemptions for impurities, byproducts, and imported and processed articles must be maintained. As EPA has acknowledged, the reporting of commercial activity under the Active-Inactive Rule 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 byproducts not used for commercial purposes. Accordingly, it is possible that there is ongoing use of the substances that are the subject of the proposed SNUR as impurities, byproducts, and articles, and TSCA Inventory "inactive" or "active" categorization is not indicative of their use in these manners.

The general SNUR exemptions that appear at 40 CFR 721 address articles and impurities. The general SNUR exemptions limit the application of the exemption for byproducts. However, as noted, the manufacture or processing of a byproduct was exempt from reporting under the Active-Inactive Rule, and therefore requiring reporting on the manufacture of any byproducts that were exempt under the features of the "active"/"inactive" rule should not be required for in the "inactive PFAS" rule. To do so would not be appropriate. Aside from the aforementioned reason to maintain the exemptions, CUC Members are concerned because removing standard TSCA PMN and SNUR

exemptions, especially those with respect to substances imported or processed in manufactured articles, creates 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 multiple facilities outside the U.S. CUC therefore supports retaining these exemptions for the final version of this proposed SNUR.

CUC also believes that additional exemptions should be included. The Active-Inactive Rule included many exemptions from the notification requirements. These exemptions include substances manufactured and processed solely for export, those manufactured or processed solely for test marketing, non-isolated intermediates, and all of the other exemptions from PMN requirements listed at 40 CFR 720.30(h). Accordingly, because the "inactive"/"active" rule did not require such uses to be reported, the resulting TSCA Inventory designation as "inactive" or "active" is not indicative of potentially on-going uses in these manners, and these uses should be exempt from the "Inactive PFAS" SNUR as well.

Additionally, the use of the "Structural Definition" approach implies that substances within the scope of the definition that are not specifically listed in the Inventory, would become subject to the proposed SNUR. Thus, EPA should affirmatively state that substances produced under a Low Volume Exemption (or Test Market Exemption) are not subject to this SNUR, given that they are not listed in the Inventory (and whether or not they fit the "structural definition"). EPA should also affirmatively state that the obligations under the SNUR apply only to manufacturers (including importers) and processors, and that users who are not processors are exempt from any of the SNUR requirements.

Articles

EPA has requested comments concerning whether the articles exemption should be made inapplicable at some point in the future. CUC reminds EPA that 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 SSNUN 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." CUC considers 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 substance subject to a SNUR in a manufactured article. EPA would need to make 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. There are likely to be countless PFAS that are not reasonably expected to be released from an article in a manner that creates an unreasonable risk.

Definition of PFAS and CBI

EPA states in the preamble that the proposed SNUR is applicable to 330 substances. However, rather than listing those substances explicitly in the SNUR, EPA instead provides a structural definition of PFAS and proposes that substances that meet that definition and are designated as inactive in the Inventory would be subject to the SNUR. The use of a structural definition for PFAS is problematic. Providing a structural definition for the scope of substances subject to the SNUR creates ambiguity and the opportunity for inadvertent non-compliance with EPA regulations. As EPA has already identified the relevant substances, the regulated community should not have to guess at which substances EPA intends to be subject to the proposed SNUR. The proposed approach creates regulatory uncertainty and exposes to potential EPA enforcement actions companies that might be less sophisticated or lack the resources or technological capacities to understand—or even be aware of—the proposed SNUR. Thus, in the text of the final SNUR itself, EPA must clearly delineate the specific PFAS that are within scope by publishing the specific substances identified by CAS Registry Number.

Accordingly, EPA must identify in some fashion all substances for which chemical identity has been claimed as CBI, regardless as to whether "fluor" or "fluorine" appears in the name. Otherwise a situation arises whereby potential users may simply not know if a particular substance is subject to this SNUR. CUC requests that EPA provide a notification 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 available. Being that the substances subject to this SNUR 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, EPA must provide some form of unique identifier that will enable manufacturers, importers, and processors to recognize that a specific substance is subject to the SNUR. If there are no universally known unique identifiers, EPA should consider exempting such substances from the scope of the SNUR, as compliance with the SNUR would be extremely difficult, if not impossible, for such substances.

Lastly, as stated, CUC believes that a structural definition for PFAS should not be used in the SNUR. Should EPA move ahead with a definition, CUC believes that EPA should be consistent with the definition of PFAS the Agency uses. In comparison with EPA's definition of PFAS under the Drinking Water Contaminant Candidate List,[3] the proposed SNUR's definition expands the scope by also allowing the R groups to be hydrogen.

Effective Date

EPA's usual practice when promulgating SNURs is to designate a use as a significant new use as of the date of the publication of the proposed rule, as opposed to using the effective date of the rule. Therefore, for purposes of the proposed SNUR, uses occurring after January 26, 2023, would be new uses. Persons who wish to begin commercial manufacturing (including importing) or processing of the chemical substances for a significant new use identified as of January 26, 2023, would have to first comply with all applicable SNUR notification requirements. The CUC believes that because the proposed SNUR contains novel elements, such as deeming potentially on-going,

[3] 87 FR 68060

as well as "previously-reviewed" (i.e., PMN-identified) uses as "new" simply due to their "inactive" Inventory status, that the date for designation as a new (versus "on-going") use should be at least six months following the final rule's effective date. This gives all affected entities time to understand the terms of the final SNUR and ensure that the current uses of the affected substances are known to all manufacturers and processors. Further, EPA should permit affected entities that are "downstream" processors and users of chemical substances a period of "amnesty" to submit notifications of "on-going" uses during this six-month period and to continue such uses without risk of an EPA enforcement action. This will be critical because the unusual nature of this proposal creates the likelihood that entities who may in good faith have acquired existing stocks of substances and mixtures previously provided by suppliers who may have discontinued production, to exhaust such stocks (and find alternatives) without risk of punishment.

Conclusion

CUC appreciates the opportunity to comment on the Proposed SNUR 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.