Before the United States Environmental Protection Agency
Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule; Supplemental Proposal
85 Fed. Reg. 12,479 (Mar. 3, 2020)
Docket EPA-HQ-OPPT-2013-0225

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's" and "the Agency's") supplemental proposal for a significant new use rule ("SNUR") for long-chain perfluoroalkyl carboxylate ("LCPFAC") chemical substances (the "Supplemental Proposal"). The Supplemental Proposal was issued pursuant to Section 5(a)(2) of the Toxic Substances Control Act ("TSCA") as amended in 2016; and is intended to satisfy certain requirements imposed by the amendments.

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, chemical substances and manufactured products (articles).[1] CUC encourages regulators, such as EPA, to develop a robust body of information concerning chemical substances and articles under consideration for regulatory action, including a thorough understanding of the conditions of use for such substances and articles. When such information is sought, acquired, and considered carefully by regulators, regulators can more effectively develop and implement potential requirements when necessary to effectively and efficiently protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with sustainable economic development in the United States.

I. Users and Importers of Products With Surface Coatings Have Important Concerns

CUC's members include US enterprises that operate on a global scale, and their manufacturing operations in the US may rely on affiliated companies and independent suppliers located in both the US and abroad. Consequently, CUC members acquire a wide range of formulations and articles from suppliers, often importing complex pieces of equipment that may contain a multitude of components, each of which are finished articles themselves. Accordingly, CUC has closely monitored and provided constructive public comment in those instances in which EPA has considered using its authority under TSCA to regulate manufactured articles on the basis of the chemical content of an article.

CUC members recently provided timely information to EPA concerning the difficulty importers of manufactured products, and their many components, would face if required to "self-identify" as "manufacturers" under the TSCA Fees Rule. CUC provided information to the Agency making it clear how CUC's members (and similar enterprises) are very *unlikely* to have the critical

[1] The members of CUC are Airbus S.A.S., The Boeing Company, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, and Raytheon Technologies.

information they would need from their various suppliers concerning the chemical composition of each component in an imported piece of equipment to be able to determine whether the goods might contain a surface coating that could be subject to an amended SNUR. CUC's efforts helped inform the Agency's decision to grant enforcement discretion for such entities and to commit to proposing exemptions from the requirements of the Fees Rule on a going-forward basis.

CUC members continue to think it is important that any TSCA regulatory proposals that would limit or restrict the manufacture, import, distribution and use of articles on the basis of their chemical content should be risk-based, and founded on reliable information that supports the conclusion that a substance of concern that might be present in an article will create significant opportunities for human exposures to, or environmental releases of, the substance. CUC supported the 2016 amendments to TSCA because of the standards added to Sections 5 and 6 of the Act which were specifically responsive to CUC's perspectives in this regard.

It is with these important considerations in mind, that CUC offers these comments on the LCPFAC Supplemental Proposal, the sole purpose of which appears to be to limit and require notification to EPA of the importation of articles that might contain a surface coating which might include one or more of the listed LCPFAC substances (including a vast number of unnamed substances that fit within a chemical formula-based definition in the SNUR).

II. EPA Must Provide a More Robust Demonstration that the "Reasonable Potential for Exposure" Justifies Requiring a Significant New Use Notification

The 2016 amendments to TSCA ensure that a specific statutory finding can be made before EPA may promulgate or amend a SNUR such as is reflected in the 2015 Proposal and the 2020 Supplemental Proposal to amend the LCPFAC SNUR. 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."[2]

In this instance, the Agency apparently has found that there is information to suggest that a "surface coating" on a manufactured article might be released over time (e.g., through photo degradation and ordinary wear and tear). However, the Agency has not made such a finding on a chemical- or article-specific basis, nor has it considered whether there are differences in potential releases depending on the type and nature of the myriad "surface coatings"[3] that might be covered by the rule.[4] In light of: (i) the large number of substances specifically listed in the Tables in the Supplemental Proposal; (ii) the overly-inclusive definition of the many possible

[2] 15 U.S.C. § 2604(a)(5).

[3] For example, potential releases from a stain repellant on a fabric might be vastly different than potential releases from the painted surface of an airplane part. To treat the two as the same does not satisfy the legislative mandate to make an affirmative finding as to either.

[4] Indeed, the Agency has not provided a definition of what constitutes a "surface coating" leaving uncertainty as to what parts of a manufactured article are to be considered a coated surface. The surface of a complex article can be the result of a complicated series of applications, treatments, and finishing steps. Distinguishing what constitutes the relevant surface that presents the risk of exposure necessitating this rule is essential to informing the regulated community of their potential obligations.

unnamed substances that fit within the broad contours of the terms of 40 CFR 721.10536(b)(1)[5]; (iii) the potential difference in nature and extent of any release from the myriad of "surface coatings" used; and (iv) the countless articles that could bear surface coatings containing such a substance, CUC considers the terms of the amended TSCA (and good public policy) to require EPA to more clearly demonstrate that there is a reasonable basis to conclude a more-than-theoretical level of exposure will occur from surface coated articles that might contain any one of the many varying substances that will become subject to the final rule. Moreover, to support the required statutory finding, consideration should be given by EPA to the nature of the article, its uses, and the contents of the coating. For example, are there data in the record that are inclusive of all of the listed substances? Are such releases of surface coating chemicals attributable to coatings applied to articles comprised of specific categories of substrates (e.g., metallic surfaces versus plastic or wooden materials)? If an article is not used in a manner that involves repeated contact with another article or human contact, are releases less likely to occur?

A well-considered approach might include in the Supplemental Proposal *only* those substances on the list which: (a) have a history of use, or the likelihood that they can be used, in surface coatings; (b) for which EPA has specific information which demonstrates it is reasonable to expect releases of the substance from the article; and (c) for which human or environmental exposures are likely to occur at scientifically meaningful levels.

III. Any Final SNUR Should Include a *De Minimis* Threshold

CUC members, as original equipment manufacturers (OEMs) and downstream users of innumerable different materials, rely on numerous suppliers to provide component parts and finished products that often undergo further assembly within member companies' facilities in the US and abroad. In addition, supply chain complexities include sub-suppliers (sub-tiers) that often are not disclosed to the OEM or finished product manufacturer. Thus, countless "articles" might be imported by CUC's members. Our members are unlikely to be advised by their suppliers whether a component part or a finished product has a "surface coating" containing one or more of the listed substances. For these reasons, it might provide some level of regulatory certainty if EPA could establish a quantifiable level of the listed substances that might be present in a surface coating on or in an article that would not require submission of a Significant New Use Notification. Moreover, CUC members would recommend a data-driven approach to setting such a level (based on the composition of known surface coating materials and the concentration

[5] The current SNUR that would be amended to remove the "articles" exemption includes countless substances, potentially both "existing" and "new", that are unidentified -- other than by a generic chemical formula. *See* 721.10536(b)(1) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified in this paragraph, where $5 < n < 21$ or $6 < m < 21$, are subject to reporting under this section for the significant new uses described in paragraph (b)(4)(i) and (b)(4)(iv) of this section. (i) CF3(CF2)n-COO M where M, = H+ or any other group where a formal dissociation can be made. (ii) CF3(CF2)n-CH=CH2. (iii) CF3(CF2)n-C(=O)-X, where X is any chemical moiety. (iv) CF3(CF2)m-CH2-X, where X is any chemical moiety. (v) CF3(CF2)m-Y-X, where Y = non-S, non-N heteroatom and where X is any chemical moiety. The Agency's January 2015 proposal to amend this SNUR, which is supplemented by the Agency's 2020 Federal Register notice, apparently brings this broad definition into the potential scope of the regulatory actions that could become part of a final Agency action that will be taken during June of this year. If that is not EPA's interpretation, it should be so stated in any final amendments to the underlying SNUR.

by weight of a listed LCPFAC substance that is likely to remain present on a dried coated surface).[6]

Further, CUC members recommend EPA consider harmonizing SNUR notification requirements with level(s) established in other markets, including those established in other major markets.[7] However, if established, such a *de minimis* level should apply solely to the presence of a listed substance *within the coated surface*, as CUC recommends that EPA should not use the Supplemental Proposal as a means to restrict the chemical content of coating *formulations* that are imported or blended and distributed in the US for uses to treat surfaces of products and articles.[8]

IV. Any Final SNUR Should Provide for a Safe Harbor that Allows Importers to Continue to Demonstrate Ongoing Use Prior to the Final SNUR's Effective Date

Businesses such as CUC members manufacture complex products that contain tens of thousands of components coming from large, global, multi-tiered supply chains. Obtaining even preliminary data about the presence of the regulated LCPFACs in the surface coatings of each component of imported articles before the comment period for the Supplemental Proposal ends would be impossible.[9]

For this and other reasons, CUC strongly encourages EPA to establish a "safe harbor" provision for importers of articles (inclusive of the many who will likely remain unaware of EPA's March

[6] It would be further beneficial if the Agency would identify an analytical standard and methodology for determining the concentration of LCPFACs in the relevant surface coating of a complex article. Many coating products undergo drying and curing operations that may eliminate minor constituents and/or chemically modify the composition of the coating.

[7] By way of example only, pursuant to Article 7(2) and Article 33 of REACH, notification to ECHA is required only when a substance of very high concern in present in an article above a quantifiable limit. However, Article 7(2) requires such notification to ECHA when substances of very high concern are present in articles being placed onto the market provided both of the following conditions are met: (i) the substance is present in the relevant articles above a concentration of 0.1% weight by weight, and (ii) the substance is present in these relevant articles when present in quantities totalling over one tonne per year. Moreover, exemption from the notification requirement is permitted when: (a) the producer or importer of an article can exclude the exposure of humans and the environment to the substance during normal or reasonably foreseeable conditions of use of the article, including its disposal.

[8] It is possible that there are existing, on-going uses of formulations intended to be applied as a surface coating being blended in or imported to the US, which might contain a listed substance at a greater percentage than it might be present in a final formulation or that might remain present on a surface coating on article.

[9] It appears that the Agency has likewise been challenged in its ability to understand the presence and potential uses of LCPFACs in imported articles. EPA states that its understanding of the use of LCPFACs in imported articles is based on progress reports submitted during the 2010/2015 PFOA Stewardship Program, the 2016 CDR submissions, market research, and review of safety data sheets. Other than potentially its market research, none of these sources addresses directly the use of LCPFACs in imported articles—SDS sheets are not required for articles, the CDR does not cover articles, and the progress reports are from manufacturers of the substances and not the overseas manufacturers of the imported articles containing those substances. It is likely therefore that the Agency is simply unaware of a substantial number of ongoing uses of LCPFACs in imported articles, including surface coatings, which seems to be confirmed by numerous comments in the administrative record indicating potential for widespread and continuing uses in a number of sectors. Given the lack of any solid basis for the Agency's understanding, it would behoove the Agency to confirm its understanding by further engaging with article importers and foreign manufacturers, distributors, and users of LCPFACs to confirm which LCPFACs are no longer in use in articles that are imported into the United States.

3, 2020 Supplemental Proposal) who seek to make EPA aware that their use of a listed substance in a surface coating was "ongoing" prior to the applicable effective date of the Supplemental Proposal.

CUC members and similarly situated enterprises that import manufactured components and finished articles (e.g., electronic parts and products, computers, printers, automobiles, aircraft components) are unlikely to have reasonably available the information they would need from their suppliers concerning the chemical composition of the "surface coatings" of each component.[10] Obtaining the information requires investigations through multiple tiers of the supply chain consisting of hundreds of suppliers, and in many cases chemical content may be shielded as confidential business information pursuant to existing agreements. Navigating these challenges to determine whether each imported article has a surface coating containing a listed substance is a time-intensive process, and CUC encourages EPA to allow a reasonable interval for importers to demonstrate that their use of an article containing a listed substance in a surface coating is ongoing.[11] Such a process should permit an importer to request that its supplier be permitted to provide information to an importer, or a confidential mechanism for the supplier to contact EPA directly to supply the information required to establish the content of a surface coating and that its use in coated articles was ongoing prior to the effective date for the modified SNUR. CUC believes the safe harbor process must be transparent, provide sufficient time for suppliers and customers to coordinate any necessary submissions, and permit the demonstration of ongoing uses to be easily substantiated using ordinary business records.

CUC also encourages EPA to provide that the "effective date" for determining whether a use was ongoing be *no earlier than* the March 3, 2020 date of publication of the Supplemental Proposal. This is the earliest date on which importers could reasonably be expected to be aware of an obligation to investigate the presence of particular chemicals in the "surface coatings" of imported articles.

V. EPA should define ongoing uses in a manner that is not company-specific.

To accommodate the very many uses that involve LCPFAC-containing surface coatings that are present on articles, and coating methods that were ongoing before the January 2015 proposed amendments, and continuing through the period of the March 2020 Supplemental Proposal, CUC believes that it would be necessary and appropriate for final determinations of ongoing uses to be categorical in nature, and be use- or technology-specific (e.g., surface coated "electronic products"; or "articles coated with a polymeric material"). CUC members also think it is important that the final rule include exemptions for ongoing uses of certain surface coatings that are based on their chemical content, rather than being determined and limited to a particular

[10] In the absence of a regulatory definition for the term "surface coating", making such a request of a supplier is especially challenging. See further discussion on the need for a clear definition in Section VI of these comments.
[11] The process established must clearly reflect the understanding that no entity (suppliers and their customers in the US) will be considered to be in violation of the SNUR during the period of inquiry and follow-up exchanges to be made with EPA throughout the process created.

company. As noted above, the need to rely on suppliers for chemical ingredient information means that chemical information available to importers is highly constrained. Some use information may be highly confidential, preventing companies from readily sharing such information and limiting entities at differing tiers in the supply chain from readily determining whether an imported product might have a surface coating that would qualify as an ongoing use.

VI. Any Final SNUR Should Include a Definition of "Surface Coating"

The proposed amendments do not include a definition of "surface coating". Section III of the preamble to the Supplemental Proposal includes only this passage as potential guidance concerning how the term might be interpreted in the context of any final amendments to the SNUR: "A coating is a material applied in a thin layer to a surface as a protective, decorative, or functional film. This term often refers to paints such as lacquers or enamels, but also refers to films applied to other materials including, but are not limited to, paints, varnishes, sealants, adhesives, inks, maskants, and temporary protective coatings."[12] The absence of a proposed regulatory definition of the term surface coating leaves considerable room for interpretation. For example, if an interior surface (e.g. a circuit board) of an electronic product is coated, but its exterior (chassis) surface is not, is this an article with a "surface coating"? If the circuit board in the example above is shipped to the US from an international supplier, is it subject to the rule only during the time before it is housed inside the finished chassis? Although the discussion of the term "coating" is in the Supplemental Proposal's preamble, the final rule must define "surface coating" specifically, or compliance within various affected industries, and the Agency's expectations with respect to reporting under a final SNUR, might differ considerably.

VII. The Economic Analysis May Understate the Costs of Investigating Products

EPA has significantly underestimated the economic impacts and costs of compliance with any final amendments to the SNUR if based on the Supplemental Proposal as drafted. CUC members consider the likely expenses they will incur simply to inquire of their numerous suppliers about the LCPFAC content of surface coatings on imported articles will significantly outstrip by orders of magnitude the estimates in the Agency's economic analysis. Moreover, the costs that regulated entities will incur to assemble and submit a SNUN if required, including the TSCA User Fees, and to interact with EPA personnel during the course of the Agency's review, also would substantially exceed the Agency's modest estimates. CUC recommends EPA more critically and realistically examine and update its economic analyses. CUC recommends EPA economists consider making direct contact with individuals within the regulated community who are familiar with supply chain operations and the difficulties that will arise when attempting to comply with a final SNUR. CUC members also encourage EPA economists to solicit input from individuals in the regulated community who are personally familiar with the time required by manufacturers and importers to complete and submit new substances and new use notifications and the time and effort required to respond to EPA requests for additional information in those contexts.

[12] Supplemental Proposal at 12,484.

Conclusion

CUC members appreciate the opportunity to contribute these comments and suggestions to the record on the Supplemental Proposal and would be pleased to meet with EPA personnel to discuss these comments.