

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families, Breast Cancer Prevention Partners, Defend Our Health, Earthjustice, and Environmental Working Group on the Environmental Protection Agency’s Draft Compliance Guide for Imported Articles Containing Surface Coatings Subject to the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule

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On December 16, 2020, the Environmental Protection Agency (“EPA”) released for public comment a draft Compliance Guide (“draft guidance”) for imported articles containing surface coatings that are subject to EPA’s Significant New Use Rule (“SNUR”) for long-chain perfluoroalkyl carboxylate and perfluoroalkyl sulfonate chemical substances.¹ The SNUR, finalized on July 27, 2020 under section 5(a)(2) of the Toxic Substances Control Act (“TSCA”),² places important restrictions on new uses of a subset of perfluoroalkyl and polyfluoroalkyl substances (“PFAS”). This class of chemicals is of significant concern because of its persistence, widespread accumulation in people and wildlife and toxic health effects. The SNUR, first proposed in 2015 and finalized at the direction of Congress, applies to several long-chain perfluoroalkyl (“LCPFAC”) chemical substances, including perfluorooctanoic acid (“PFOA”), that were phased out at EPA’s request because of their serious risks to health and the environment.

These comments on the draft guidance are being filed by Safer Chemicals Healthy Families, Breast Cancer Prevention Partners, Defend Our Health, Earthjustice, and Environmental Working Group. Our organizations are committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day. We took a leadership role during the TSCA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today. Along with many other groups, we have strongly supported restrictions on PFAS to protect health and the environment and advocated for the aggressive use of SNURs prevent the reintroduction of PFAS uses that are no longer in commerce. We submitted detailed comments on EPA’s supplemental SNUR proposal for LCPFAC substances in March of 2020, calling on the Agency to strengthen its requirements.

As we discuss below, our groups are concerned that changes to the draft guidance made during the White House interagency review process are not consistent with the final SNUR as promulgated and would undermine its intent and effectiveness. These changes should be removed from the guidance and the EPA text that was deleted during interagency review should be restored.

¹ 85 Fed. Reg 81466

² 85 Fed. Reg. 45113

While we believe the remainder of the draft guidance correctly describes the SNUR and related EPA regulations, some portions are incomplete and may create confusion. We recommend that EPA add clarifying language to prevent misunderstanding of the SNUR's requirements.

I. White House Changes in the Guidance are Contrary to the Letter and Intent of the SNUR and Must be Removed

The draft guidance contains a significant and unwarranted limitation on the surface coatings subject to the SNUR. On page 8, the draft provides that a surface coating containing an LCPFAC is only covered by the SNUR (1) if the article on which it is used is in "direct contact with humans or the environment during the article's normal use or reuse" or (2) where the surface coating is on an "internal component of an article facing the interior of the article", "that component is in contact with humans or the environment during the article's normal use or reuse."

These limitations on the application of the SNUR were not included in the original version of the draft guidance developed by EPA. Instead, they were inserted during the interagency review process coordinated by Office of Management and Budget (OMB), presumably at the direction of the White House. The draft guidance as revised during interagency review under Executive Order 13891 shows the White House inserts and the original EPA text that was deleted:³

What constitutes a surface coating subject to the SNUR?

In the context of the LCPFAC SNUR, EPA considers any LCPFAC (from the list in Table 1 or PFOA and its salts) ~~containing that meets one of the following two criteria to be a surface coating covered by the SNUR:~~

- ~~1.~~ coating on any surface of ~~any article~~ an article that is in direct contact with humans or the environment during the article's normal use or reuse, whether the coating is ~~applied to oriented towards~~ the interior ~~facing surface~~ or the exterior ~~surface of an article, to be covered by the SNUR.~~ The general nature of a coating is that it is applied to a surface (e.g., the Cambridge dictionary (online) defines coating as "a layer of a particular substance that covers a surface"). Additionally, EPA considers all coating layers and their chemical components, even when they are not the outermost layer of an article, to be included as part of a "surface coating." For example, imported articles may be comprised of multiple components and a surface ~~the article;~~
- ~~2.~~ coating on any ~~of those components~~ internal component, even if ~~on~~ facing the interior of the article, ~~would subject the article to~~ if that component is in contact with humans or the SNUR environment during the article's normal use or reuse.

The deleted language would have applied the SNUR to "any LCPFAC . . . containing coating on any surface of any article, whether the coating is applied to the interior facing surface or the exterior surface of an article" (emphasis added.) According to the deleted language, "imported articles may be comprised of multiple components and a surface coating on any of those components, even if on the interior of the article, would subject the article to the SNUR."

The White House revisions significantly narrow EPA's original approach by adding a new requirement – "direct contact with humans or the environment during the article's normal use or reuse" – that is not part of the SNUR as promulgated. 40 CFR § 721.10536(c)(1) revokes the SNUR article exemption in §

³ <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2020-0621-0003>.

721.45(f) for listed LCPFACs “when they are part of a surface coating of an article” and states that any person who imports such substances “as part of a surface coating on an article is not exempt from submitting a significant new use notice.” This obligation is unconditional; there is no qualification that the article and its components must be “in direct contact with humans or the environment.” To add this limitation is thus not authorized by the SNUR itself and is unlawful.

The White House-inserted qualifiers are also contrary to the rationale for the SNUR consistently articulated by EPA and reiterated in the preamble to the final rule. As the preamble explains, LCPFACs, like other PFAS, are persistent and known to accumulate in people and wildlife and cause numerous adverse health effects: ⁴

“LCPFAC and perfluoroalkyl sulfonate chemical substances have been found in the blood of the general human population, as well as in wildlife, indicating that exposure to these chemical substances is widespread (Refs. 5, 6, and 7). PFOA and its salts, which are considered LCPFAC chemical substances, have been a primary focus of studies related to the LCPFAC class of chemical substances. PFOA is persistent, widely present in humans and the environment, has a half-life in humans of 2.3–3.8 years, and can cause adverse effects in laboratory animals, including cancer and developmental and systemic toxicity (Refs. 5, 8, 9, 10, and 11). Human epidemiology data report associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney) (Ref. 12). PFOA precursors, chemicals which degrade or may degrade to PFOA, are also present worldwide in humans and the environment and, in some cases, might be more toxic and be present at higher concentrations than PFOA (Refs. 13, 14, 15, 16, and 17). Multiple pathways of exposure, including through drinking water, food, house dust, and releases from treated articles, are possible.”

Given these serious concerns, the Agency concluded that the *possibility* that listed LCPFACs may be released from surface coatings on articles and result in human exposure or environmental release warranted Agency review before “new” uses of these articles are introduced into commerce:⁵

“EPA has provided support that there is a reasonable potential for exposure through the citation of peer-reviewed literature, which documents that LCPFAC chemical substances either have the reasonable potential to migrate from articles or that LCPFAC chemical substances do migrate from articles. In order to require notification for the import or processing of an article under TSCA section 5, it is not necessary to definitively show or illustrate the mechanisms by which exposure to a chemical substance through an article may occur. Since the use designated as a significant new use does not currently exist, EPA defers a detailed consideration of potential exposures related to that use until there is a specific condition of use and data to review.”

Thus, “EPA has reason to anticipate that importing articles that have certain LCPFAC chemical substances as part of a surface coating would create a reasonable potential for exposure to these

⁴ 85 Fed. Reg. 45113.

⁵ 85 Fed. Reg. 45114.

LCPFAC chemical substances, and that EPA should have an opportunity to review the use before such use could occur.”

In the preamble to the final rule, EPA rejected “establishing a de minimis threshold for determining ‘reasonable potential for exposure.’” EPA explained that, under TSCA section 5(a)(5), “[i]f there is evidence that a chemical substance is or may be released from an article such that there is a reasonable potential of exposure to the chemical substance, EPA thinks the Agency can reasonably find the statutory criterion to be met in most or all cases. For this final rule, EPA believes that the reasonable potential for exposure was adequately demonstrated by the studies cited in both the 2015 proposed rule (Ref. 1) and the 2020 supplement to the proposed rule (Ref. 2).”⁶ For example, the preamble explicitly states that the SNUR applies to “[a]rticles that have surface coatings that contain certain LCPFAC chemical substances that have been cured or undergone chemical reaction after being applied to an article.”⁷ This is because “[e]ven when LCPFAC are bound within the matrix of the coating, they can still be released from the coating over time and present a reasonable potential for exposure.”⁸

In short, the SNUR is based on evidence that the listed LCPFACs are known to migrate from surface coatings on articles, not that migration occurs in every case, and that, because the presence of LCPFAC chemical substances in surface coatings for articles *would create a reasonable potential for exposure*,” the Agency “should have an opportunity to review the use before such use could occur.”

This emphasis on “potential for exposure” would be undermined if importers could unilaterally bypass SNUR restrictions by determining that, in their judgment, an article or article component has no “direct contact with humans or the environment.” This would rewrite the SNUR by triggering notification requirements based on *actual exposure* rather than *potential for exposure*. As written, the SNUR gives EPA the role of examining the health and environmental impacts of new uses of articles containing harmful LCPFACs to determine the extent of exposure and release and potential for harm. The draft guidance would prevent EPA from performing this role by giving importers broad latitude to withhold new uses from EPA review based on the claimed absence of exposure and release. This would prevent EPA from examining whether release might occur under different use conditions or at a later stage in the article’s life cycle, such as disposal.

II. Because the White House’s rewording of the draft guidance violates the letter and intent of the final SNUR, it is ultra vires.

An agency interpretation is substantively invalid when “it conflict[s] with the text of the regulation the agency purported to interpret.” *Perez v. Mortgage Bankers Ass’n*, 575 U.S. 92, 104-05 (2015). Courts have “refused to give deference to an agency’s interpretation of an unambiguous regulation, observing that to defer in such a case would allow the agency ‘to create *de facto* a new regulation.’ ” *Id.* at 104 (quoting *Christensen v. Harris Cty.*, 529 U.S. 576, 588 (2000)). To comply with these principles, the inserted language should be removed and replaced by EPA’s original text. To retain the inserted language in the final guidance would be unlawful.

⁶ 85 Fed Reg. 45120

⁷ The draft guidance reiterates (at 9) that “[a]rticles that have surface coatings that contain certain LCPFAC chemical substances that have been cured or undergone chemical reaction after being applied to an article are subject to the SNUR.”

⁸ 85 Fed. Reg. 45114

III. EPA Should Add Clarifying Language to the Guidance to Avoid Confusion

Definition of Article

The draft guidance explains (at 7) that:

“An imported article must have an end-use function dependent in whole or in part upon a shape or design that was present at the point of import. If the shape and design of an item at the point of import does not serve any function with respect to the item’s end use, then the item being imported is not an article.”

As an example, the draft guidance cites “plastic or metallic blocks or sheets imported and then processed in such a way that they entirely lose the shape they had at the point of import (e.g., by being melted down, molded, extruded, cut up extensively or into small pieces, or further reacted).”

While the imported blocks or sheets in this example may not be “articles,” this does not mean that they are exempt from the SNUR if they contain LCPFACs, as an uninformed reader might infer. The blocks and sheets would qualify as “mixtures,” which are defined by EPA as “any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction.” 40 CFR § 720.3(u). As a result, the presence of listed LCPFACs in imported blocks or sheets would trigger application of the SNUR, which prohibits importations of these chemicals, either as part of a surface coating or simply as a mixture component.

We recommend that, to avoid confusion, EPA explain in the final guidance that imported products containing LCPFACs will be deemed to be TSCA “mixtures” even if they do not satisfy the definition of “articles” and, as such, would be subject to the SNUR.

Application of the SNUR to Processors

Consistent with the SNUR, the draft guidance advises (at 10) that “[p]rocessors of articles are not subject to the SNUR [because] EPA is retaining the exemption at 40 CFR 721.45(f) for persons who process chemical substances as part of articles.” While correct, this statement fails to note that processors of listed LCPFACs as chemical substances or components of mixtures are outside the general SNUR article exemption at 40 CFR 721.45(f) and thus subject to the SNUR. It would be helpful for the guidance to point this out to avoid confusion.

Import Certification

The draft guidance notes (at 11) that the “final LCPFAC SNUR does not require TSCA section 13 import certification for the subject chemical substances when part of articles (i.e., not as part of a surface coating on articles).” Again, to avoid confusion, EPA should point out that articles generally are not subject to import certification requirements but these requirements do apply to all importers of chemical substances (including LCPFACs) individually or as components of mixtures.

Compliance Date

Finally, in a discussion of the compliance date for the SNUR, the draft guidance (at 12) indicates that the “final LCPFAC SNUR, which lifts the articles exemption for a subset of LCPFAC chemical substances as part of a surface coating on articles, is effective September 25, 2020.” This statement is accurate but incomplete. To prevent misunderstanding, EPA should add that, as of the SNUR’s effective date, articles

containing LCPFACs as part of surface coatings that were first imported after the SNUR's date of proposal on January 21, 2015 can no longer be imported lawfully unless a Significant New Use Notice is submitted and EPA has completed the 90-day review process without taking action. EPA makes this point elsewhere in the draft guidance, but it should be reinforced here so the regulated community is fully on notice of the consequences of the SNUR's effective date.

Conclusion

EPA must remove from the guidance language inserted by the White House that is contrary to the letter and intent of the SNUR and restore correct text that was deleted. It must also add clarifying language to the guidance to prevent confusion about SNUR requirements.

If you have any questions about these comments, please contact Bob Sussman, Safer Chemicals Healthy Families counsel, at bobsussman1@comcast.net.

Thank you for this opportunity to comment.

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