Comments on
Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical
Substances; Significant New Use Rule; Supplemental Proposal

Submitted April 17, 2020

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments on the Environmental Protection Agency’s (EPA) supplemental notice of proposed rulemaking on long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances “to make inapplicable the exemption for persons who import a subset of LCPFAC chemical substances as part of surface coatings on articles.” This supplemental notice would amend EPA’s original 2015 proposed SNUR on LCPFAS and perfluoroalkyl sulfonate (PFAS) chemicals.

Introduction and Summary

In finalizing the SNUR, EPA must:

1) reject the premise of a safe harbor provision, which is unprecedented and would only serve to defeat the purpose of the SNUR;

2) not adopt the scientifically flawed, overly rigid, and unnecessary approach of setting an a priori threshold or de minimis level for determining the “reasonable potential for exposure” for articles;

3) not narrow the category of articles to which the revocation of the article exemption applies to those containing LCPFAC chemicals as “part of a surface coating,” and instead retain its applicability to all imported articles containing the specified chemicals;

4) not eliminate regulatory language regarding applicability of general SNUR regulations or explain why such language is not necessary; and

5) revoke the exemption from notification for processors of LCPFAC chemicals as a part of an article.


EDF generally supported EPA’s 2015 Proposal to require companies to notify EPA before manufacturing (including importing) or processing LCPFAC and PFAS chemical substances or importing articles containing them, thereby affording EPA the ability to evaluate the potential risks associated with such proposed uses before allowing them to commence.

As we described further in our previous comments, LCPFACs and PFAS have been demonstrated to be associated with a number of adverse health effects, including adverse birth outcomes, developmental and reproductive effects, and immune system suppression. Further, these chemical substances are also persistent and bioaccumulative – requiring an extremely long time to degrade in the environment or be excreted from the body.

In recognition of the risks that these chemicals present, EPA worked with companies starting in the early 2000s to phase out the domestic production of PFOS as well as PFOA and related chemicals. Through promulgation of a SNUR, EPA would prevent the potential restarting of domestic production as well as import of bulk chemicals, formulations or articles containing the subject chemicals, without prior notification to and review by EPA. EDF generally supported, with suggested amendments, EPA’s approach. We incorporate our previous comments by reference.

However, the 2015 Proposal languished for many years, with interest in it only revived as part of the agency’s PFAS Action Plan in February 2019. In December 2019, Congress mandated through the National Defense Authorization Act that EPA finalize the SNUR by June 22, 2020.

In addition to the issues we raised in 2015, EPA’s 2020 Supplemental Proposal raises five major concerns, which we expand on below. We urge EPA to take these comments and our previous comments into consideration in finalizing the SNUR.

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Response to Request for Comment

1. EPA should reject the premise of a “safe harbor” provision, which would be unprecedented and would defeat the purpose of the SNUR by enabling significant new uses to be deemed ongoing up until the effective date of the final SNUR.

EPA bases its consideration of a “safe harbor” provision on concerns for importers who may be unfamiliar with the SNUR process and not be aware that they have an ongoing use. EPA suggests that TSCA section 5(a)(5) grants EPA discretion that could provide a legal basis to create a safe harbor for importers, but EPA does not explain how the provision does so or how EPA might create one, instead requesting help from commenters:

Finally, EPA notes that diverse importers of articles could be affected by this rule, and that some may be unfamiliar with the SNUR process and may not identify at the time of this rulemaking that they have an ongoing use of a LCPFAC. EPA requests comment on whether or not the Agency should include a safe harbor provision for importers of articles that can demonstrate their use was ongoing prior to the effective date of this rule. EPA requests that commenters discuss the text of section 5(a)(5) and how the discretion granted therein could be exercised to allow for a safe harbor provision. EPA also requests specific language that could be used in structuring such a safe harbor provision.7

In previous article SNURs, whether issued before or after the Lautenberg Act, EPA has never attempted to create any “safe harbor” for importers.8 In the 2019 asbestos SNUR, for example, EPA explained its long-standing approach to setting the date used for determining whether a proposed new use would be deemed ongoing. For decades, that practice has been to set the date of proposal of a SNUR in the Federal Register as the date previous to which a use must have been occurring to be deemed ongoing and not be eligible to be designated a significant new use. In fact, in the asbestos SNUR EPA expressly used the date of web posting of the proposed rule, which pre-dated publication of the proposed rule in the Federal Register. EPA explained:

[T]he objective of EPA’s approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final

7 85 Fed. Reg. at 12482.
rule. In developing this rule, EPA has recognized that, given EPA’s general practice of posting proposed and final SNURs on its website a week or more in advance of Federal Register publication, this objective could be thwarted even before that publication.9

EPA’s call for comments on a safe harbor provision raises numerous concerns. First, the suggestion that a use be allowed to commence and proceed indefinitely after the publication of a proposed SNUR without the submission of a SNUN would be a radical change at odds with the common-sense interpretation of section 5(a) that EPA has followed consistently for decades regarding the date used to determine whether an ongoing use exists. This interpretation has extended to SNURs in which a prior exemption from notification for articles was revoked, such as the 2019 asbestos SNUR. EPA continues to follow this interpretation, even in the March 2020 supplemental proposal itself. Here EPA specifically points to the January 21, 2015 proposal date as the key date, stating that “[u]ses arising after the publication from the proposed rule are distinguished from uses that exist as of the date of publication of the proposed rule. The former would be new uses, the latter ongoing uses ....”10 EPA notes that this interpretation dates back 30 years, set forth in a Federal Register notice dated April 24, 1990.11

Yet EPA’s position on the safe harbor elsewhere in the 2020 Supplemental Proposal’s preamble would allow a significant new use to commence through the import of an article containing LCPFAC chemical substances without requiring that EPA be notified and have a chance to review a SNUN for that use. The 2020 Supplemental Proposal thus appears to be internally inconsistent. This may be why EPA is seeking refuge in section 5(a)(5), but it has offered no rationale based on that provision.

Second, nothing in the language of section 5(a)(5) supports a reading that it allows uses of the chemical substances at issue in articles to be treated differently than other uses. That provision is about when EPA may require notification for “articles subject to” a SNUR, not about rewriting basic SNUR concepts for articles. For example, nothing in that provision justifies creating two different dates for determining when a new use comes into existence, one for imported articles and a different one for other new uses. But that it precisely what EPA’s safe harbor concept seeks to do.

Third, EPA’s proposed safe harbor concept does not address the agency’s alleged concern that some importers might be unfamiliar with the SNUR process and not have identified ongoing uses at the time of issuance of the proposed rule. For entities that are not aware of the SNUR process, it would not seem likely – and EPA has provided no basis for concluding – that allowing until

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9 84 Fed. Reg. at 17354.
the effective date of the final rule instead of during the comment period to identify ongoing uses would make any difference.

EPA has not treated importers any differently than other manufacturers in past SNURs that lifted the article exemption, whether the erionite fibers SNUR promulgated decades ago or the asbestos SNUR promulgated just last year. EPA has provided no factual basis for doing so now and points to no new development or specific reason that would warrant such a radical departure from its longstanding approach. There is no reason to believe, for example, that importers of LCPFAC-containing articles are any less sophisticated than importers of other chemical substances subject to SNURs for whom EPA provided no such benefit, or that importers today are less knowledgeable about TSCA requirements than importers, say, in the 1980’s.

EPA itself pointed out in the final benzidine SNUR that the legislative history of the original TSCA shows that Congress wanted importers to be treated like domestic manufacturers. As EPA stated in its 2014 final rule, “[O]ne of the intended goals of TSCA [was] to hold importers to ‘the same responsibilities and obligations as domestic manufacturers.’”12 Yet the safe harbor for importers of LCPFAC articles would put importers in a more favorable position than domestic manufacturers of articles.

Finally, it is not the role of EPA to absolve importers of responsibility for not tracking relevant EPA regulations and thus failing to identify an ongoing use. If EPA is concerned that the regulated community is insufficiently aware of its proposed rulemaking and its implications, it should conduct outreach during the rulemaking process to reach the intended audience.

2. EPA should not adopt the scientifically flawed, overly rigid and unnecessary approach of setting an a priori threshold or de minimis level for determining the “reasonable potential for exposure” for article.

EPA has requested comment on “whether or not the Agency should affirmatively establish an explicit threshold at which, or explicit criteria for determining whether, a significant new use exhibits a reasonable potential for exposure that justifies notification.”13 EPA should not do so.

The concept that EPA could or should a priori set a level of some sort that could confidently be presumed to universally lead to exposures that would present no or extremely low risk presumes EPA would already have access to information sufficient to make such a sweeping risk-based determination across a broad range of intended and reasonably foreseeable conditions of use, even in the absence of information specific to any such use.

Setting such a threshold level based, say, by specifying the content of LCPFAC chemicals in an article would fail to address the breadth of factors specific to a particular article and across the lifecycle of that article, that would affect the actual release of the chemicals that would or could occur over time, and the duration, intensity, frequency, and number of resulting environmental and human exposures, including to potentially exposed or susceptible subpopulations. Such factors are myriad and, to name just a few, would include the specific nature of the article, how the chemicals are incorporated into the article, and how the article is made, processed, used and disposed of. Exposure would also depend on the volume of the article produced and used, how it is distributed, who uses it or is otherwise exposed to it, and so on. These are the very types of information that a SNUR is intended to require be submitted to EPA in the form of a SNUN and reviewed by the agency.

As EPA has itself noted, LCPFAC chemicals are persistent and can bioaccumulate, which greatly complicates accurately predicting exposure to them even with access to detailed information on a specific use. Attempting to account for these properties a priori and in a generic fashion would be rife with deficiencies.

A threshold approach would also subvert the very purpose of TSCA’s significant new use provision in section 5(a)(2), which is expressly not risk-based and instead is designed to engender a subsequent process under which EPA obtains and must review case-specific information that is sufficient to make a risk-based decision on that case. In the 2020 Supplemental Proposal, EPA notes:

Consistent with EPA’s past practice for issuing SNURs under TSCA section 5(a)(2), EPA’s decision to propose a SNUR for a particular chemical is not based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the existence of a SNUR requires a notice, upon receipt of which EPA would conduct an assessment.14

Adopting a threshold approach would effectively negate and circumvent this sensible approach already established under TSCA by imposing a risk-based “bar” that would have to be cleared before EPA could do what section 5(a)(2) already authorizes it to do.

EPA cites certain case law, Alabama Power Co. v. Costle, that EPA asserts provides it with authority to adopt a threshold approach.15 The de minimis doctrine discussed in the Alabama Power case is simply irrelevant to the issues presented by section 5(a)(5) of TSCA. The de minimis doctrine allows agencies to exempt trivial matters from otherwise clear statutory commands, e.g., crafting a de minimis exemption from a statutory requirement to regulate all

14 85 Fed. Reg. at 12484. See also Id. at 12486.
15 Id. at 12482, citing Alabama Power Co. v. Costle, 636 F.2d 323, 360-61 (D.C. Cir. 1980).
emissions sources. In Alabama Power, the court explained that “[u]nless Congress has been extraordinarily rigid, there is likely a basis for an implication of de minimis authority to provide exemption when the burdens of regulation yield a gain of trivial or no value” and where compliance with a statutory requirement would “mandate pointless expenditures of effort.” That is not the situation presented by the language of section 5(a)(5) at issue here. That language authorizes EPA to require notifications regarding the import or processing of chemical substances as part of an article if the Administrator determines that “the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.” There is no statutory requirement from which EPA could apply de minimis authority to carve out an exemption; there is simply a statutory phrase including the term “reasonable potential for exposure” for EPA to interpret and apply in determining whether to exercise its authority to require notification. EPA’s invocation of de minimis authority is plainly misplaced.

Even if it could somehow be invoked properly, the test for applying de minimis authority is not met. Here ensuring that EPA conducts a careful review of the use of a potentially dangerous LCPFAC chemical in an article prior to allowing import of the article clearly provides significant value in terms of public health and environmental protection. The modest effort required of importers to provide advance notification to EPA of their intent in order to facilitate such a review of potential risk hardly qualifies as a “pointless expenditure of effort.”

3. **EPA should not narrow the category of articles to which the revocation of the article exemption applies to those containing LCPFAC chemicals as “part of a surface coating,” and instead retain its applicability to all imported articles containing the specified chemicals.**

The 2020 Supplemental Proposal would limit the revocation of the notification exemption to imported articles that contain LCPFAC chemicals as part of a surface coating rather than extending to all imported articles containing LCPFAC chemicals (as had been proposed in 2015). EPA asserts that Section 5(a)(5) of TSCA, which was added in 2016 by the Lautenberg Act, gives it the authority for the new limitation. Section 5(a)(5) specifically addresses articles and states:

> **ARTICLE CONSIDERATION.**—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.
While section 5(a)(5) leaves room for EPA discretion with respect to the determination of whether to require notification, Congress did not provide the agency with unreviewable discretion. To be a lawful exercise of discretion, the agency’s use of the discretion afforded by the Lautenberg Act must still be able to withstand judicial review under the applicable standard, whether the arbitrary and capricious standard or substantial evidence standard.

Furthermore, the agency’s actions in this rulemaking are still subject to notice and comment requirements under the Administrative Procedure Act and must comport with logical outgrowth requirements. The impact of these rulemaking legal principles is affected by the context of the rulemaking at issue, particularly the fact that the 2015 Proposal was broader than the 2020 Supplemental Proposal in terms of the universe of imported articles for which the exemption from notification requirements was proposed to be revoked.

A. Background and analysis of the article exemption, the 2015 Proposal, and the 2020 Supplemental Proposal

In this subsection, we review the origins and application of the article exemption; the strong basis for the 2015 Proposal; and the legal deficiencies in EPA’s proposed narrowing of the scope of the SNUR in its 2020 Supplemental Proposal.

i. An Abbreviated History of the Article Exemption

EPA promulgated the exemption from notification for articles in 1984 as part of the general SNUR provisions of 40 CFR Part 721 Subpart A. As originally promulgated, the exemption was contained in 40 CFR § 721.19(f) and provided an exemption for persons otherwise subject to the notification requirements if the “person imports or processes the substance as part of an article.” EPA explained the exemption as being justified because of the agency’s belief “that people and the environment will generally not be exposed to substances in articles.” The agency went on to say that it could eliminate the exemption if warranted for particular substances. EPA stated that “for specific significant new uses of specific chemical substances, EPA may decide to eliminate [the exemption] if EPA decides that review under a SNUR is warranted for specific substances … in articles.” These stated rationales for the original article exemption do not differ significantly from those now codified in TSCA through the addition of section 5(a)(5) in 2016. EPA already indicated its ability to lift the exemption where there was potential for exposure in a particular case warranting notification. Codification into TSCA does not translate into a significant expansion of the authority and discretion EPA already had in making decisions to revoke the article exemption.

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17 Id. at 35021.
18 Id. at 35014.
19 Id.
Over time, EPA has revoked the exemption from notification for articles in a number of instances, including for asbestos during the Trump Administration.\textsuperscript{20} In cases that preceded passage of the Lautenberg Act, the Agency relied on concerns about potential exposures from articles and did not differentiate among categories or types of articles based on how the chemical substances were contained in the articles.\textsuperscript{21}

Perhaps the most significant of the pre-Lautenberg Act actions was the 2014 benzidine SNUR, gauging by the extensive response to comments regarding article-related issues contained in the final rule notice. For example, in responding to comments questioning its legal authority to eliminate the article exemption, EPA not only laid out the history of the exemption and EPA’s retention of the authority to revoke it, but further stated that:

To the extent that potential exposure to a chemical substance as part of an article contributes to the EPA’s determination pursuant to the factors in section 5(a)(2) of TSCA that the new use is significant (\textit{i.e.}, EPA has reason to anticipate that use as part of an article would raise important questions, related to potential exposure, that EPA should have an opportunity to review before such use could resume or occur), it is appropriate to make the exemption inapplicable.\textsuperscript{22}

Interestingly, in the benzidine final rule, EPA rejected commenters’ suggestion that it develop some new policy framework regarding article SNURs after going through further notice and

\textsuperscript{20} See, e.g., Erionite Fiber; Significant New Use of a Chemical Substance, 56 Fed. Reg. 56470 (Nov. 5, 1991); Mercury Switches in Motor Vehicles; Significant New Use Rule, 72 Fed. Reg. 56903 (Oct. 5, 2007); Benzidine-Based Chemical Substances; Di-n-pentyl Phthalate (DnPP); and Alkanes, C12-13, Chloro; Significant New Use Rule, 79 Fed. Reg. 22891(Dec. 29, 2014); Restrictions on Discontinued Uses of Asbestos; Significant New Use Rule, 84 Fed. Reg. 17345 (Apr. 25, 2019). There may well be other instances, but these are the ones reviewed for this memorandum.

\textsuperscript{21} See Erionite Fiber, 56 Fed. Reg. at 56472 (40 CFR §721.1054(2) provides: “Exemptions. Section 721.45 applies to this section except for §721.45(f). A person who intends to import or process the substance identified in paragraph (a)(1) of this section as \textit{part of an article} is subject to the notification provisions of §721.25.”); Mercury Switches, 72 Fed. Reg. at 56911(40 CFR §721.10068(c)(1) states: “Suspension or revocation of certain notification exemptions. The provisions of § 721.45(f) do not apply to this section. A person who imports or processes elemental mercury as \textit{part of an article} is not exempt from submitting a significant new use notice’’); Benzidine, 79 Fed. Reg. at 77911 (40 CFR §721.1660(b)(1) states: “Revocation of certain notification exemptions. The provisions of § 721.45(f) do not apply to this section. A person who imports or processes a chemical substance identified in paragraph (a)(1) of this section as \textit{part of an article} for a significant new use described in paragraph (a)(2) of this section is not exempt from submitting a significant new use notice.”) (emphasis added in all examples).

\textsuperscript{22} 79 Fed. Reg. at 77897.
comment. After noting that knowledge about chemical exposures from articles had evolved since the 1984 establishment of the exemption, EPA stated that no detailed, complicated framework was necessary in light of the “minimal rationale” EPA had provided for establishing the exemption in the first place—i.e., EPA’s belief in 1984 that people and the environment would not generally be exposed to substances contained in articles. EPA also explained at length the ways people could be exposed to the substances at issue, particularly in semi-closed settings, and the evidence of the presence in biota of the substances at issue. In addition, EPA rejected contentions by commenters that it needed to engage in a detailed analysis of the variety of articles containing benzidine-based substances before proceeding to revoke the article exemption. EPA stated that it was more efficient to review specific article issues in the context of individual notices regarding intended new uses submitted to the agency later.

Also of importance is that EPA put the revocation of the article exemption into a context broader than just the benzidine SNUR. EPA rejected the argument that it needed to engage in some far-reaching and detailed analyses of individual articles or article categories in order to eliminate the article exemption and clearly explained the reasons that it would be preferable to engage in such analyses in the context of evaluating notices regarding individual new uses.

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23 Id. at 77898.
24 Id.
25 Id. (“Given the variety of substances and uses addressed under SNUR regulations, EPA believes it is more efficient to address article-specific issues as they actually arise within each regulatory action than to develop, as suggested by the commenter, an anticipatory ‘policy framework’ document. The importers and processors of chemical substances present in articles are generally in the best position to know which chemical substances are used in which types of articles. When EPA identifies a particular chemical substance in a SNUR, such stakeholders have an opportunity to identify, in their public comments, any article-specific issues that concern them. Furthermore, these issues are likely to be more accurately identified and more appropriately addressed in connection with the development of a SNUR for particular chemical substances than they would be if they were reviewed generically. In this case, commenters did not raise any issues specific to certain articles.”).
26 Id. (“Furthermore, the particular analytical standards the commenter suggests are not commensurate with the establishment of a one-time notice requirement intended to give EPA an opportunity to later evaluate the need for testing or other regulatory action under TSCA. Requiring upfront answers to the very questions EPA would evaluate after receiving a significant new use notice, as a pre-condition of requiring the notices, would undermine the statutory authorization to issue SNURs in the first place. EPA’s decision to propose a SNUR for a particular chemical use and to make the exemption at 40 CFR 721.45(f) inapplicable to that SNUR need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency is acting because it has reason to anticipate that such
The legislative history of section 5(a)(5) adds some useful context. The legislative history indicates that Senate Democrats who were key negotiators of the 2016 TSCA amendments did not consider the new provision to raise some substantial new hurdle to EPA’s authority to deal with articles in SNURs and that EPA’s ability to deal with imports of articles containing chemical substances subject to SNURs was important. The statement by the Democratic Members indicates that section 5(a)(5) was intended to clarify that potential exposure was a relevant consideration in applying SNURs to articles and was not intended to require EPA to conduct an exposure assessment or develop evidence that exposure through articles will definitely occur. The Senate Democrats also emphasized specifically that it was critical that EPA continue to be able to use its SNUR authority to scrutinize imported articles.27

In the asbestos SNUR, which was promulgated by the current Administration well after Congress added section 5(a)(5) to TSCA, EPA did not engage in any complicated attempt to interpret the new provision; rather, EPA applied its language quite straightforwardly in the context of the uses of asbestos at issue in the SNUR. Consistent with pre-Lautenberg Act revocations of the article use would raise important new questions related to the substance’s potential to threaten health or the environment, and that EPA should have an opportunity to consider those questions before such use could occur. Since the use designated as a significant new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the significant new use, in articles or otherwise, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.”).

27 Cong. Rec. S3519 (June 7, 2016). In full the paragraph states: “Section 5(a)(5) addresses the application of significant new use rules (SNURs) to articles or categories of articles containing substances of concern. It provides that in promulgating such SNURs, EPA must make ‘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.’ This language clarifies that potential exposure is a relevant factor in applying SNURs to articles. Exposure is a relevant factor in identifying other significant new uses of a chemical substance as well. It is not intended to require EPA to conduct an exposure assessment or provide evidence that exposure to the substance through the article or category of articles will in fact occur. Rather, since the goal of SNURs is to bring to EPA’s attention and enable it to evaluate uses of chemicals that could present unreasonable risks, a reasonable expectation of possible exposure based on the nature of the substance or the potential uses of the article or category of articles will be sufficient to ‘warrant notification.’” EPA has successfully used the SNUR authority in the existing law to provide for scrutiny of imported articles (many of which are widely used consumer products) that contain unsafe chemicals that have been restricted or discontinued in the U.S. and it’s critical that SNURs continue to perform this important public health function under the amended law.”
exemption, EPA first noted that the exemption “is based on an assumption that people and the environment will generally not be exposed to chemical substances in articles.” EPA then noted its understanding that asbestos can become friable over time, and based on that understanding, stated its intent “to evaluate potential risk of exposure to human health and the environment for any intended significant new use of asbestos (including as part of an article).” EPA then stated that its understanding “warrants making the article exemption … inapplicable” and proceeded to make a finding under section 5(a)(5):

Considering the potential friability of asbestos, even when incorporated in articles, and the health risks associated with exposure to asbestos, EPA affirmatively finds under TSCA section 5(a)(5) that notification is justified by the reasonable potential for exposure to asbestos through the articles subject to this SNUR. EPA intends to evaluate such potential uses whether in the form of an article, or not, for any associated risks or hazards that might exist before those uses would begin. EPA has reason to anticipate that importing or processing asbestos as part of an article would create the potential for exposure to asbestos, and that EPA should have an opportunity to review the intended use before such use could occur.

The regulatory text eliminated the article exemption for all articles containing the identified chemical substances for the significant new uses identified in the SNUR.  

**ii. The 2015 Proposal**

In 2015, prior to the existence of Section 5(a)(5), EPA proposed to revoke the notification exemption for “importers of the chemical substances [subject to the SNUR] as part of an article for the corresponding significant new uses.” EPA requested comment on the potential for exposure from those articles and whether there were ongoing uses of the chemical substances as part of an article.

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28 84 Fed. Reg. at 17354.
29 *Id.*
30 *Id.*
31 *Id.*
32 54 Fed. Reg. at 17359 (40 CFR §721.11095(b)(1) states: “40 CFR 721.45(f) does not apply to this section. A person who intends to manufacture (including import) or process the substance identified in paragraph (a)(1) of this section for the significant new use identified in paragraph (a)(2) of this section as part of an article is subject to the notification provisions of § 721.25.”).
33 80 Fed. Reg. at 2891.
34 *Id.* at 2891-92.
The 2015 Proposal laid out concerns regarding the health and environmental effects of LCPFAC and PFAS chemical substances that applied to both the chemical substances in a bulk form and when they were incorporated in articles. EPA stated:

LCPFAC and PFAS chemical substances are found world-wide in the environment, wildlife, and humans. They are bioaccumulative in wildlife and humans, and are persistent in the environment. They are toxic to laboratory animals, producing reproductive, developmental, and systemic effects in laboratory tests. The exact sources and pathways by which these chemicals move into and through the environment and allow humans and wildlife to become exposed are not fully understood, but are likely to include releases from manufacturing of the chemicals, processing of these chemicals into products, and aging, wear, and disposal of products containing them.\(^{35}\)

The agency also pointed out that PFAS substances degrade into perfluoroalkylsulfonic acid (PFASA), a highly persistent and bioaccumulative chemical substance. EPA further stated that “PFASA can continue to be formed by any PFAS containing chemical substances introduced into the environment."\(^{36}\) Specifically with respect to articles treated with these chemicals, EPA stated that the “widespread presence of PFAS chemical substances in human blood samples nationwide suggests other pathways of exposure, possibly including the release of PFAS from treated articles.”\(^{37}\)

In its explanation in the 2015 Proposal of the basis for its significant new use determination, EPA explicitly addressed articles containing LCPFAC chemical substances. Noting that EPA’s Office of Research and Development had “conducted research demonstrating that the perfluorinated chemicals contained in articles can be released from those articles,”\(^{38}\) EPA stated that it:

*believes any new use of LCPFAC chemical substances as part of articles would increase the duration and magnitude of human and environmental exposure to the substances.* Based on these considerations, EPA has preliminarily determined that importing LCPFAC chemical substances listed in Table 1 of Unit I. and PFOA or its salts as part of articles both constitutes a significant new use and warrants making the exemption at 40 CFR 721.45(f) inapplicable to importers of articles.\(^{39}\)

\(^{35}\) *Id.* at 2890 (emphasis added). See also *id.* at 2889.

\(^{36}\) *Id.* at 2889-90.

\(^{37}\) *Id.* at 2890.

\(^{38}\) *Id.* at 2891.

\(^{39}\) *Id.* (emphasis added).
As this preliminary determination by EPA was phrased in terms of “any new use of LCPFAC chemical substances as part of articles,” it was not limited to the use of LCPFAC as part of surface coatings on articles. A determination regarding all articles is reasonable in light of EPA’s concerns about “the aging, wear, and disposal of products containing them,” processes which would act on articles containing LCPFAC chemical substances in ways other than just in coatings on their surface.

With respect to the issue of the revocation of the notification exemption for articles, EPA stated that it “believes that the assumption underpinning this exemption, that people and the environment will generally not be exposed to chemical substances as part of articles, does not hold true.” EPA specifically requested comment on the “potential for exposure to these chemical substances via those articles and for comments on the ongoing uses of these chemical substances as part of these articles.”

Consistent with the preamble of the 2015 Proposal, the regulatory text in the proposal clearly included all imported articles containing LCPFAC chemical substances in the revocation language. It contained provisions regarding certain chemical substances that are part of carpets and others that are part of any article and handled them in the same way, i.e., part of a carpet or part of an article. Section 721.10536(c) stated that:

With respect to imports of carpets, the provisions of §721.45(f) do not apply to this section. With respect to imports of articles, the provisions of §721.45(f) also do not apply to a chemical substance identified in paragraphs (b)(2) or (b)(3) of this section. A person who imports a chemical substance identified in paragraphs(b)(1) of this section as part of a carpet or a chemical substance identified in paragraphs (b)(2) or (b)(3) of this section as part of an article is not exempt from submitting a significant new use notice.

iii. The 2020 Supplemental Proposal

a. Proposal to narrow the scope of the articles to which the SNUR would apply

The 2020 Supplemental Proposal seeks to narrow the initial proposed revocation of the notification exemption for articles to apply only to importers of LCPFAC chemical substances that are a part of a surface coating of an article. Because EPA does not propose to change the original proposed language insofar as it applies to carpets, it thereby eliminates the similar

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40 Id. at 2890.
41 Id.
42 Id. at 2892.
43 Id. at 2897.
treatment of carpets and articles more generally that was originally proposed. The regulatory text in the supplemental proposal states:

With respect to imports of carpets, the provisions of §721.45(f) do not apply to this section. With respect to imports of articles, the provisions of §721.45(f) also do not apply to a chemical substance identified in paragraphs (b)(2) or (b)(3) of this section when they are part of a surface coating of an article. A person who imports a chemical substance identified in paragraphs (b)(1) of this section as part of a carpet or a chemical substance identified in paragraphs (b)(2) or (b)(3) of this section as part of a surface coating on an article is not exempt from submitting a significant new use notice.  

EPA offers two justifications for this change from the 2015 Proposal to the 2020 Supplemental Proposal. First, EPA asserts that the 2020 Supplemental Proposal “better defines the articles subject to the rule by defining the subject articles as ‘imported articles where certain LCPFAC chemical substances are part of surface coating on the articles’ rather than what was originally proposed, ‘imports of articles.’” Notably, EPA fails to propose any definition for its new term “surface coating.” Second, EPA contends that it issued the 2020 Supplemental Proposal “to be responsive to the article consideration provision” added by the Lautenberg Act in 2016. Neither justification supports the narrowing of the notification exemption revocation, however.

EPA’s first proffered explanation, that the 2020 Supplemental Proposal “better defines the articles subject to the rule,” is plainly a makeweight. The 2020 Supplemental Proposal narrows the scope of the articles subject to the rule but does not “better define” them. There is no lack of clarity in subjecting all articles containing the chemical substances at issue to notification requirements. Indeed, in past SNURs in which EPA revoked the exemption from notification requirements for articles, EPA revoked the exemption for all articles containing the chemical substances at issue. Clearly, there is nothing unclear about lifting the notification exemption for all articles containing the chemical substances subject to the SNUR. (On the contrary, narrowing the scope to imported articles where chemical substances are “part of a surface coating on an article” – without even providing a definition for this term – provides less clarity.)

EPA’s second justification, that it is responding to the new language of section 5(a)(5) added to TSCA by the Lautenberg Act, is no better: Nothing about that language means that EPA could not proceed with its original proposal to apply the SNUN notification requirement to importers of all articles containing LCPFAC chemical substances. This is readily apparent when one takes

45 Id. at 12480.
46 Id.
47 See, e.g., Benzidine-Based Chemical Substances; Di-n-pentyl Phthalate (DnPP); and Alkanes, C12-13, Chloro; Significant New Use Rule, 79 Fed. Reg. 22891 (Dec. 29, 2014).
into account the rationale contained in the 2015 Proposal regarding its treatment of articles, which was discussed above.

As described earlier, section 5(a)(5) authorizes EPA to require notification regarding articles “if the Administrator makes an affirmative finding in a [SNUR] that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.” While it is true that this statutory language provides EPA with discretion to require notification, EPA ignores what it previously determined at the beginning of this rulemaking and set forth in the 2015 Proposal regarding all articles containing LCPFAC chemical substances, and EPA ignores the fact that it fails to point to anything in the record or comments submitted to EPA on the 2015 Proposal that justifies the narrower scope of the notification revocation.48

In the 2015 Proposal, EPA stated that it “believes any new use of LCPFAC chemical substances as part of articles would increase the duration and magnitude of human and environmental exposure to the substances.”49 Furthermore, EPA stated that it “believes that the assumption underpinning [the exemption from notification requirements for articles], that people and the environment will generally not be exposed to chemical substances as part of articles, does not hold true.”50 EPA specifically requested comment on the “potential for exposure to these chemical substances via those articles and for comments on the ongoing uses of these chemical substances as part of these articles.”51

In the 2020 Supplemental Proposal, EPA states that “[a]fter considering the reasonable potential for exposure from articles under TSCA section 5(a)(5), EPA is now issuing a supplemental proposal to make inapplicable the exemption for persons who import certain LCPFAC chemical substances when those LCPFAC chemical substances are part of a surface coating on articles.”52 EPA goes on to define the category of articles subject to the rule as articles where “LCPFAC chemical substances are part of the surface coating on articles” and find that the “category of articles is expected to exhibit reasonable potential for exposure to LCPFAC chemical substances.”53 EPA’s analysis of the underpinnings of its findings regarding the reasonable potential for exposure from articles with surface coatings containing LCPFAC chemical substances

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48 A review of the comments submitted on the 2015 Proposal failed to uncover any comments raising this issue, though there were comments regarding alleged continuing uses of LCPFAC substances in articles that should be carved out from the SNUR since they were continuing uses as of the 2015 Proposal.
50 Id. As discussed above, EPA justified the establishment of the article exemption in its regulations on the basis of this rationale in 1984. See 49 Fed. Reg. at 35014.
52 85 Fed. Reg. at 12481.
53 Id. at 12484.
substances is devoid of any discussion of a lack of potential for exposure from articles containing LCPFAC chemical substances other than in their surface coatings. Indeed, EPA explicitly states that it “is not making a finding on the reasonable potential for exposure from articles that do not contain LCPFAC chemical substances as a surface coating.”

EPA’s failure to address the potential for exposure from articles containing LCPFAC substances other than as part of a surface coating is highly problematic in the context of the ongoing rulemaking. EPA originally proposed treating all articles containing LCPFAC substances in the same way and made preliminary findings regarding exposure from them without differentiating between kinds or categories of articles. In the 2020 Supplemental Proposal, the agency has offered no justification for any distinction between surface-coated articles and other articles containing LCPFAC chemical substances. Consequently, the 2020 Supplemental Proposal contains no rationale for defining surface-coated articles as the only category of articles subject to the SNUR.

This is a significant deficiency in EPA’s approach in the 2020 Supplemental Proposal. EPA appears to have decided to re-define the category of articles and then determined that that re-defined category of articles has a reasonable potential for exposure, but there is nothing in EPA’s supplemental notice that justifies or explains how or why it re-defined that category. This failure is particularly glaring in light of the 2015 Proposal, which treated all articles containing LCPFAC substances in the same way, premising that treatment on EPA’s concerns about potential exposure from all such articles. Without a reasoned explanation, EPA’s determination now that only surface-coated articles are the appropriate category is both arbitrary and capricious and lacks a substantial evidence basis.

Notably, EPA did not point to anything in the record of the rulemaking, including the comments submitted on the 2015 Proposal, that would explain or justify its determination that LCPFAC-coated articles was the appropriate category. This is not surprising since our review of the comments submitted on the 2015 Proposal failed to reveal any comments suggesting differential treatment for articles based on whether they were surface-coated or contained LCPFACs in some other way; nor does it appear, based on our review, that any of the new studies added into the record since the 2015 Proposal support such a distinction. In the absence of any comments or other information in the record suggesting this approach, it is not apparent how EPA determined that surface-coated articles were the appropriate category of articles.

The 2020 Supplemental Proposal itself contains language that suggests environmental releases of LCPFAC chemical substances from articles are plausible, even if the substances are not in the surface coating on the article. According to EPA:

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54 Id.
As an unbound, unincorporated component of a surface coating (Refs. 15 and 16), LCPFAC chemical substances can thereby be released from the coating as a result of this degradation of the coating layer. Additionally, because LCPFAC chemical substances used in this category of articles are coating the surface, if the underlying substrate of the article is degraded and released, the LCPFAC surface coating could be released at the same time.55

The first sentence of this quotation, albeit discussing LCPFAC chemical substances as unbound, unincorporated components of a coatings, refers to the degradation of the coating layer. Thus, EPA itself recognized that the coating layer may degrade, which could expose the underlying substrate, which could then release LCPFAC chemical substances if they were contained underneath the coating. Such a possibility would seem quite possible and is wholly consistent with EPA’s concerns asserted in 2015 about the “aging, wear, and disposal of products” containing LCPFAC chemical substances. The second sentence points to the degradation and release of the substrate of an article as a possible cause of releases of LCPFAC substances from the surface coating. This statement recognizes that the substrate of an article could degrade and be released, and it supports a concern that even if there were no LCPFAC surface coating, there is reasonable potential for LCPFAC substances in the substrate as it degrades to be released to the environment. See additional relevant discussion of these issues in section 3.B. of these comments.

Moreover, in the 2020 Supplemental Proposal, EPA expressly stated it is not making a finding regarding the “reasonable potential for exposure” from articles other than ones coated with LCPFAC-containing substances. However, in the 2015 Proposal, EPA preliminarily found that any use of LCPFAC in articles would increase human and environmental exposure and stated that the assumption behind the article exemption that there would generally not be exposure to LCPFAC substances from articles did not hold. EPA has not explained in the supplemental notice the difference it sees between the section 5(a)(5) standard of “reasonable potential for exposure” and what EPA contended in 2015 for all articles, which was a sufficient chance of human or environmental exposure from any article containing LCPFACs. Is EPA’s position now that the latter was less than a “reasonable potential for exposure”?56

Inasmuch as EPA will be taking final action on both the 2015 Proposal and the 2020 Supplemental Proposal when it takes final action on this rulemaking,56 EPA should have to explain its decision not to finalize and address its initial proposal to require notification for all articles. It is insufficient for EPA merely to say it is not making a finding one way or the other about the reasonable potential for exposure from articles that it had in 2015 apparently believed presented enough of an exposure risk to conclude that the assumption underpinning the notification exemption did not hold. Given what EPA said in the 2015 Proposal, it should have

55 Id.
56 Id. at 12480.
explained in the 2020 Supplemental Proposal why either (1) it now sees no potential for exposure to LCPFACs from non-surface-coated articles or (2) it does not view the chances of exposure it saw from such articles as presenting a “reasonable potential for exposure.”

b. Call for comments on the use of a de minimis or threshold approach to determine “reasonable potential for exposure”

The concerns just discussed are particularly germane in light of EPA’s request for comment on the use of a de minimis or other threshold for determining the “reasonable potential for exposure.” As part of that discussion EPA indicates its view that the “reasonable potential for exposure” specified in section 5(a)(5) would extend down to just above cases where “the risk of exposure is very low.” Inasmuch as EPA has an outstanding proposal in which it stated its belief that articles containing LCPFAC substances other than in surface coatings presented some risk of exposure, it should have to explain why that level of risk does not satisfy the section 5(a)(5) criterion of “reasonable potential,” which EPA seems itself to define as all but a “very low” risk of exposure, indeed one that might be characterized as approaching or even below de minimis levels (whatever they might be in this context).

EPA’s request for comments about how and at what levels it could establish thresholds, including whether it could adopt a de minimis threshold, is deficient as a basis for proceeding to a final rule. It provides no criteria or metrics for what a threshold would be other than establishing it would need to be set a level below which there would be a “very low” risk of exposure, perhaps based on some level of LCPFAC substance content in the article. As discussed in section 2 of these comments, it would seem very difficult to establish such a level, however, as the risk of exposure to people and the environment would depend not just on the LCPFAC substance content of an article but on the volume of the articles produced, the manner in which a LCPFAC substance was used in the production of the article, the manner in which an article was used and disposed of, and other factors – factors that would only be elucidated through receipt and review of a SNUN.

Basically, EPA’s question is far more in the vein of an ANPRM issue than a proposal, as it essentially opens the issue for comment without providing any effective thoughts from the agency as to what an appropriate threshold would look like or measure. Moreover, EPA’s reference to authority to establish a de minimis level is anomalous since de minimis authority is a judicially-based authority used by agencies when Congress specifies a requirement with no

57 See further discussion of EDF’s concerns with the de minimis approach in section 2 of these comments.
58 Id. at 12482.
59 Id. EPA stated that one of the rationales for a threshold would be that “[b]elow the selected threshold level, there is no ‘reasonable potential for exposure’ within the meaning of section 5(a)(5) (i.e., the risk of exposure is very low).”
exceptions, such as a requirement applicable to any or all sources. Here, Congress has specified a standard in general terms—reasonable potential for exposure—that the agency has the ability to interpret and apply (as it did in the asbestos SNUR last year). It simply makes no sense to suggest the use of *de minimis* authority in this context. It is nevertheless notable that EPA is suggesting that *de minimis* levels of risk of exposure would satisfy the reasonable potential for exposure standard of section 5(a)(5), as they would represent a very low level of exposure risk.

**B. Uses of LCPFACs in articles are not limited to surface coatings, and such uses also have a “reasonable potential of exposure.”**

As noted above, EPA states that it is not making a finding regarding “reasonable potential of exposure” for uses of LCPFACs in articles that are not applications involving surface coating. However, there are other ways in which LCPFACs chemicals can be used in articles and a sufficient basis to expect they present a “reasonable potential for exposure.”

Below we highlight several ways in which LCPFAC chemicals can be used other than in surface coatings.

- In response to the 2015 Proposal, Brooks Automation, Inc. submitted a comment to the docket highlighting several non-surface coating uses (e.g., gaskets, hoses, motors, electrical wiring, and robots):

  We believe that LCPFAC and PFAS chemical substances are likely present in articles that we purchase from others for final assembly in our products that we manufacture and sell to others. These articles include coatings, seals, gaskets, hoses, motors, electrical wiring, corrosion resistance coatings, robots and other components. We are not able to confirm this with confidence, as our equipment is assembled from many thousands of parts and we have very complex supply chains. Conducting the due diligence necessary for a robust confirmation would likely take years.60

- In 2013, the United Nationals Environmental Programme (UNEP) and Organisation for Economic Co-operation and Development (OECD) released a synthesis paper on per- and polyfluorinated chemicals (PFCs), including a summary of historical and current uses.61

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Potential uses of PFCs in articles not involving surface coatings include uses in insulators, firefighting protective clothing, and other textiles, leather and apparel.

- A 2015 Swedish Chemicals Agency (KEMI) report highlights textile and apparel uses: “[v]arious highly fluorinated substances are used extensively by the textile industry in a range of textile-related articles such as outer garments, umbrellas, bags, sails, tents, parasols, car seat covers, leather articles, shoes, carpets, etc.”62 The report describes that protective clothing can either be surface-treated “or produced from fluoropolymers such as woven porous PTFE [polytetrafluoroethylene] or similar materials.”63 It further describes that such chemicals may be laminated onto textile material to impart mechanical strength to develop a porous membrane, which may then be covered by a nylon or polyester outer layer, and hence they are not on the surface of the finished article.

As discussed in section 3.A.iii.a of these comments, there is sufficient evidence to conclude that there is also a “reasonable potential of exposure” from these non-surface coating uses. First, as EPA explains, “In most cases, LCPFAC chemical substances are not incorporated into the article and bound to the article matrix but are rather added or applied as a coating…” (p. 12484, emphasis added). Because LCPFAC chemical substances are not typically bound to the matrix of the article, they can more easily be released – whether they are added as unbound chemical to the article or applied as a surface coating.

Second, EPA refers to numerous natural processes that can lead to or accelerate releases of LCPFAC from surface coatings: volatilization, abiotic reaction with water, hydrolysis, photolysis, biodegradation, microbial of abiotic processes.64 Most, if not all, of these processes are equally relevant to LCPFAC present in articles other than as surface coatings.

Third, EPA fails to recognize that articles have a lifecycle, including production, distribution, use, recycling and/or disposal. Even if one were to accept the premise that an article has limited LCPFAC exposure potential during the use stage of its lifecycle because the chemicals are not on the surface, those same articles could very well release the chemicals at other points, for example, during the recycling or disposal stage. Release potential is further supported by EPA’s statement, cited above, that the underlying substrate of the article can degrade and its contents released.65

63 Id. at p. 34.
64 85 Fed. Reg. at 12485.
C. EPA has failed to define “surface coating” and any definition must be broad.

The 2020 Supplemental Proposal fails to define the term “part of a surface coating on [or of] an article.” Any reliance by EPA on this or a similar term must be defined in a manner that encompass all settings in which LCPFAC chemicals may be exposed via, or accessible from, the surface of the article to processes that could result in their release.

Any such definition would need to encompass any article containing a component to which LCPFAC chemicals are applied to, or where the chemicals are present on or accessible from, the surface of that component. Those components may well be managed separately from the finished article during various lifecycle stages, including manufacture, distribution, or disposal of the components, leading to direct exposure potential.

The example of carpets (albeit proposed to be treated differently here) makes clear that there are articles where LCPFAC substances are applied to or infused throughout a component (e.g., yarn), which is then used to make the finished article – leaving the LCPFAC chemicals exposed and subject to processes than could lead to their release. As described by the Plastic Industry Associations, “Guide to the Safe Handling of Fluoropolymer Resins”:

> coating with fluoropolymer dispersions may involve the following processing steps: mixing of dispersions with other ingredients, applying the formulated dispersion onto surfaces, fabrics or yarns, by spraying or passing them through a dispersion bath, followed by drying, baking or sintering of the coated product.\(^{66}\)

In other cases, an LCPFAC chemical is added to or mixed with another material such as a plastic resin, with some of the chemical present at the material’s surface even though the chemical is not applied to the material as a surface coating.

While we oppose EPA’s narrowing of the article exemption, any invoking of the term “part of a surface coating on an article” or a related term demands a definition that encompasses all such scenarios, and is not limited to cases where a coating is applied to the surface of the final product or its components.

4. EPA must retain regulatory language regarding applicability of general SNUR regulations or explain that the general provisions still apply.

An additional concerning change made by the 2020 Supplemental Proposal is EPA’s deletion of a sentence in section 721.10536(c) of the proposed regulatory text. The sentence in the 2015 Proposal’s regulatory text at the beginning of subsection (c) stated that “[t]he provisions of subpart A of this part apply to this section except as modified by this paragraph (c).” This

sentence has been included in SNURs for decades and EPA has not explained why it is now proposing to remove it.

The 2019 asbestos SNUR also did not contain this language in its regulatory text. However, the preamble to the asbestos SNUR explained that the general provisions still applied.68

5. EPA should now revoke the exemption from notification for processors of LCPFAC chemicals as a part of an article, as its prior justification for not doing so no longer applies and its new justification is insufficient.

In its 2015 proposal EPA stated: “EPA is proposing that the exemption at 40 CFR 721.45(f) remain in effect for persons who process chemical substances as part of articles because existing stocks of articles may still contain LCPFAC or PFAS chemical substances.”69

In the comments EDF filed on the 2015 Proposal, we noted that it was our understanding that EPA decided to retain the article exemption for domestic processors of articles in order to allow for recycling of these then-existing stocks of products, recycling being deemed a form of processing by EPA.70

In the 2020 Supplemental Proposal, however, EPA states:

As to processors, it is EPA’s understanding that there is no ongoing manufacturing or processing of LCPFAC chemical substances in the U.S. Based on that understanding, EPA does not expect that there would be any future such processing, and EPA therefore is not proposing that this Supplemental Proposed Rule apply to processors.”71

The first sentence of this statement indicates that the previous rationale – that there were existing stocks of articles that may still have contained LCPFAC chemical substances – is no longer the case. Yet EPA still proposes not to lift the exemption, its only justification for not doing so being that “EPA does not expect that there would be any future such processing.” EPA provides no support for its “expectation.” Moreover, the purpose and benefit of applying the SNUR to such processing would be to ensure that it could not resume absent prior notification to and

67 See, e.g., Erionite Fiber, 56 Fed. Reg. at 56472 (Section 7212.1054(b)).
68 84 Fed. Reg. at 17354.
69 80 Fed. Reg at 2891.
71 85 Fed. Reg at 12480.
review by EPA. EPA should revoke the notification exemption for processing as well as import of LCPFAC chemicals as part of articles.

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EDF appreciates the opportunity to provide comments and EPA’s consideration of them.