

December 18, 2019

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COMMENTS ON THE SUPPLEMENTAL NOTICE OF PROPOSED RULEMAKING

COMMENT 1: Reviewers are aware of the complexities and burden on EPA to establish that a given use of a chemical is no longer in use for articles in US commerce. Given the complex nature of tracking chemicals in articles as part of an end product on the market, particularly for this SNUR, we strongly recommend and encourage EPA adding a safe harbor provision for importers of articles that can demonstrate the use was ongoing prior the effective date (date of the proposal) if those uses were missed (not identified) during the rulemaking process and not included in the final SNUR. EPA acknowledges difficulties in complying that are likely as a result of long and diverse supply chains and should consider providing an assurance for good-faith actors who might otherwise violate the law on technicalities beyond their reasonable control. We would like to note that a safe harbor provision is not new to US regulations or even statutes, so proposing a safe harbor provision would not be precedent setting, but rather, the exclusion of providing that could be considered precedent setting. Nothing in TSCA or its amendments prevents EPA from providing it in this case. In addition to adding a safe harbor provision, we would further recommend EPA solicit comment on this provision.

EPA Response: EPA makes every effort to notify manufacturers and processors of chemical substances that may be subject to a given rule, so that they may participate in the regulatory processes. EPA does not believe there should be a safe-harbor provision in the rule for uses not included in the SNUR. A safe-harbor provision provides incentives for importers to not submit comments to EPA during the public comment information on ongoing uses not recognized in a proposed rule. EPA also notes that the Agency's general SNUR regulations contain an exemption for a person who "manufactures, imports, or processes the substance only as an impurity." 40 CFR 721.45(d). An impurity is "a chemical substance which is unintentionally present with another chemical substance." 40 CFR 720.3(m) (which applies pursuant to 40 CFR 721.3). Additionally, EPA notes that the scenario described in the comment would not necessarily exclude the importer of articles from doing so permanently; rather, it would require the importer to submit a Significant New Use Notice (SNUN), undergo EPA review and determination of potential risks associated with the significant new use, and comply with any action associated with EPA's determination.

Follow-up Comment 1: Agreed that a safe-harbor provision should not be provided for uses not included in the SNUR. The safe-harbor provision is requested for those uses that would be considered ongoing because they were in fact ongoing at the time of the proposal but not necessarily known or identified as such during the comment period process. Not sure why an importer would knowingly not take advantage of an opportunity to note its ongoing use of a chemical so that it does not have to pay the SNUN fee. Can EPA elaborate as to why it believes that importers would be incentivized to not note their ongoing uses?

The impurity exception is useful and seems necessary but it is meant to apply to an unintentional presence of a chemical rather than an ongoing but unknown import of a chemical as part of an article.

Once again, the scenario described in the comment is not meant to exclude anyone from reporting, instead, it is meant to provide importers of articles with ongoing use (that were not identified during public comment) a chance to demonstrate that their use was ongoing prior to the effective date so that they do not have to incur the cost of a SNUN.

In addition, we strongly urge the agency to reconsider this provision. EPA has acknowledge and recognized that there are many instances, due to a lack of knowledge (through complete information from manufacture to final product) in the supply chain, of what chemicals are in final products, especially those that are complex items. It is therefore foreseeable that importers may not be aware of the chemicals that are in surface coatings of products subject to this rule.

EPA Follow-up Response: EPA appreciates the comment but maintains that a safe-harbor provision is not appropriate for this rule. While EPA acknowledges that imported articles may have a complex supply chain, the most effective method to ensure that the LCPFAC chemical substances in this SNUR are not present in imported articles is to encourage importers to know with specificity the contents of what they are importing and to work with their foreign manufacturers to ensure that an article does not contain certain LCPFAC chemical substances.

EPA provided notice to importers in the 2015 proposed rule and will again provide notice of the proposed requirements in this supplemental proposal. A safe harbor approach undermines clarity for what uses are allowed and thus raises fair notice issues in the context of compliance monitoring. EPA believes a safe-harbor provision would enable importers to remain ignorant of the contents of imported articles if an importer is able to claim that they were unaware that the article contained a substance subject to a rule.

COMMENT 2: The U.S. Department of Defense (DoD) does not have information available that indicates that mission critical uses of the Long-Chain Perfluoroalkyl Carboxylate (LCPFAC) chemical substances used as part of surface coatings on articles do not exist. Therefore, we require additional information to be able to assess the impact of the rule to the DoD.

In order to assess the impacts of this rulemaking, we suggest that EPA consider information in the TSCA inventory and other sources to identify ongoing domestic production of the subject chemicals by small businesses and provide insights on the potential for defense-related applications of any ongoing uses that have not already been identified. A similar effort to identify international sources of the subject chemicals and any associated ongoing uses is needed.

EPA Response: EPA understands DoDs concerns; however, EPA does not believe that any mission critical uses will be impacted by the rule. Prior to issuing the 2015 proposal for this SNUR, EPA reviewed the Chemical Data Reporting (CDR) information and consulted with the major manufacturers of the these LCPFAC chemical substances. With the issuance of the 2015 proposal of this SNUR, EPA requested comment on whether there were currently any ongoing uses, including use as part of articles, of any of the LCPFAC chemical substances that were not identified in the 2012 CDR (the most

recent reporting cycle for CDR that was available at the time the 2015 proposal was issued). With few exceptions, the LCPFAC chemical substances subject to the supplemental proposal have been phased out by the manufacturers of these chemical substances (i.e., the participants of the 2010/2015 PFOA Stewardship Program). Reports to the 2016 CDR (which cover 2012-2015) did not indicate any additional ongoing uses and do not provide more up-to-date information than what EPA received during the public comment period for the 2015 proposed SNUR. As part of the public comment period for the 2015 proposal, EPA was made aware of certain ongoing uses of these chemical substances (e.g., the use of LCPFAC chemical substances in an antireflective coating, photoresists, or surfactant for use in photomicro lithography and other process to produce semiconductors or similar components of electronic or other miniaturized devices). The public comments that notified EPA of ongoing uses came from large and small business. For the supplemental rule, there will be an additional opportunity for public comments and business may notify EPA of ongoing uses. EPA will exclude from the rule ongoing uses of LCPFAC chemical substances, such as use in the production of semiconductors, when EPA finalizes rule.

Follow-up comment 2: Regarding the highlighted text, in these products, are LCPAS in surface coatings or in the body of the product? From the SIA industry comments it appears there could be residuals in a semiconductor or similar components. Would the SIA need to know if the LCPFAC are in a coating to be covered?

Also, do importers of articles need to know exactly which LCPFAC are in their products for them to be an existing use, or would EPA acknowledge that LCPFAC broadly are in semiconductors and thus it is an existing use? And this rulemaking would not apply?

EPA Follow-up Response: To the best of EPA's understanding, for use in semiconductors, LCPFAC chemical substances are used as part of a surface coatings for these products. Additionally, EPA's understanding is that LCPFAC chemical substances in articles are only used as part of a surface coating. Any uses of LCPFAC chemical substances in an article other than as part of a surface coating, are not the subject of this SNUR.

Companies such as those represented by SIA would need to know if the specified LCPFAC chemicals are in a coating. EPA reiterates that the only known ongoing and discontinued uses of LCPFAC chemical substances in articles are as a part of a surface coating. The use of LCPFAC chemical substances in articles, particularly the chemicals that are outlined in Table 1 of the rule and that were phased out as part of the PFOA Stewardship Program, have largely ceased. These chemicals were domestically manufactured solely by the members of the PFOA Stewardship Program, who phased out the domestic manufacture and use of these chemicals by the end of 2015. EPA is proposing to lift the articles exemption only for the LCPFAC chemical substances that the PFOA Stewardship Program participants phased out.

As for importers of articles more broadly, those importers may need to know which LCPFAC are present in their product. This degree of specificity of the ongoing uses will be one of the considerations during development of the future final rule.

COMMENT 3: There does not appear to be a standard definition of “ongoing use.” Confusion regarding the term “ongoing use” is compounded by the ambiguity of the term “new use.” This reviewer recommends EPA provide a draft standard definition of “ongoing use” for interagency review which would provide clarity on the applicability of this rule to current activities in contrast to new activities and to support interagency internal assessments of ongoing uses versus potential new uses.

EPA Response: EPA appreciates the comment. EPA has previously described what is meant by “ongoing uses” and “new uses.” The original NPRM addressed this topic. For purposes of this SNUR, the NPRM explained: “As discussed in the Federal Register of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule.” 80 FR 2885 at page 2892. EPA also explained: “Uses arising after the publication of the proposed rule are distinguished from uses that exist at publication of the proposed rule. The former would be new uses, the latter ongoing uses, except that uses that are ongoing as of the publication of the proposed rule would not be considered ongoing uses if they have ceased by the date of issuance of a final rule...” 80 FR 2885 at page 2892. The NPRM was published on January 21, 2015 and further elaborates on this topic. To provide clarification, EPA will add the following at Line 151, after the sentence, “This supplemental proposal to the proposed SNUR would furthermore preclude the commencement of import of such articles until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.”:

As discussed in the Federal Register of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. This rule was proposed on January 21, 2015. Uses arising after the publication of the proposed rule are distinguished from uses that exist at publication of the proposed rule. The former would be new uses, the latter ongoing uses, except that uses that are ongoing as of the publication of the proposed rule would not be considered ongoing uses if they have ceased by the date of issuance of a final rule.

Follow-up Comment 3: Regarding the highlighted text, since EPA is significantly changing the scope of the rule, to cover surface coatings, for both the supplemental and proposed rule should the date of publication of this supplemental be used as the date for designating new uses? Not the 2015 date?

EPA Follow-up Response: EPA is not significantly changing the scope of the proposed rule; rather the change is only to narrow the category of articles subject to the rule. In the 2015 proposal, EPA proposed to broadly lift the articles exemption. Since the supplemental proposal narrows the scope, the public had sufficient notice of the articles that would be subject to the rule. EPA believes that the 2015 date of publication should remain as the date for designating new uses. The uses subject to the rule are uses that have been either discontinued or uses that did not previously exist in the United States. Ongoing uses are outside the scope of the SNUR and would not be subject to the rule.

COMMENT 4: Page 1, Summary. Please rewrite this summary to be much clearer about the differences between what is proposed here and what was proposed in the original NPRM. Please be specific. "Updates" is not informative. Does it expand the category of articles from the original proposal? Does it restrict from the original proposal? Are we talking about the same set of chemicals as the original proposal, or a different set?

"This supplemental proposal would require importers to notify EPA at least 90 days before commencing the import of these chemical substances in certain articles for the significant new use described in this document. The required significant new use notification would initiate EPA's evaluation of the conditions of use associated with the intended significant new use. Manufacturing (including import) or processing for the significant new use would be prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination. In a January 21, 2015, proposed LCPFAC SNUR (80 FR 2885), EPA proposed to make the article exemption inapplicable for persons who import a subset of LCPFAC chemical substances as part of all articles. This supplemental proposal ~~updates~~ narrows the category of articles to which the ~~January 21, 2015,~~ proposed LCPFAC SNUR would apply to those where the subset of LCPFAC chemicals are part of a surface coating. EPA is proposing this action to be responsive to the article consideration provision at section 5(a)(5), added with the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which states that articles can be subject to notification requirements as a significant new use provided that EPA makes an affirmative finding in a rule that the reasonable potential for exposure to a chemical from an article or category of articles justifies notification. ~~The required significant new use notification would initiate EPA's evaluation of the conditions of use associated with the intended significant new use. Manufacturing (including import) or processing for the significant new use would be prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.~~"

EPA Response: EPA will make the suggested edits with three modifications. Per the Office of the Federal Register, summaries cannot contain citations. As such, EPA will strike "(80 FR 2885)." Additionally, EPA prefers "better defines" as opposed to "narrows." Lastly, as a result of Comment 6, EPA will change "make the article exemption inapplicable for persons" to "require notification of significant new uses from persons".

The summary at lines 10-23 will now read:

"This supplemental proposal would require importers to notify EPA at least 90 days before commencing the import of these chemical substances in certain articles for the significant new use described in this document The required significant new use notification would initiate EPA's evaluation of the conditions of use associated with the intended significant new use. Manufacturing (including import) or processing for the significant new use would be prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required

in association with that determination. In a January 21, 2015, proposed LCPFAC SNUR (80 FR 2885), EPA proposed to make the article exemption inapplicable for persons require notification of significant new uses from persons who import a subset of LCPFAC chemical substances as part of all articles. This supplemental proposal ~~updates~~ ~~narrows~~ better defines the category of articles to which the ~~January 21, 2015,~~ proposed LCPFAC SNUR would apply to those where the subset of LCPFAC chemicals are part of a surface coating. EPA is proposing this action to be responsive to the article consideration provision at section 5(a)(5), added with the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which states that articles can be subject to notification requirements as a significant new use provided that EPA makes an affirmative finding in a rule that the reasonable potential for exposure to a chemical from an article or category of articles justifies notification. ~~The required significant new use notification would initiate EPA's evaluation of the conditions of use associated with the intended significant new use. Manufacturing (including import) or processing for the significant new use would be prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination."~~

Follow-up Comment 4: Why doesn't EPA want to use the word 'narrows'? It seems much clearer and is accurate, isn't it?

EPA Follow-up Response: EPA will accept the edit as originally proposed by the reviewer and use the word 'narrows.'

The summary at lines 10-23 will now read:

"This supplemental proposal would require importers to notify EPA at least 90 days before commencing the import of these chemical substances in certain articles for the significant new use described in this document. The required significant new use notification would initiate EPA's evaluation of the conditions of use associated with the intended significant new use. Manufacturing (including import) or processing for the significant new use would be prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination. ~~In a January 21, 2015, proposed LCPFAC SNUR (80 FR 2885), EPA proposed to make the article exemption inapplicable for persons require notification of significant new uses from persons who import a subset of LCPFAC chemical substances as part of all articles.~~ This supplemental proposal ~~updates~~ ~~narrows~~ the category of articles to which the ~~January 21, 2015,~~ proposed LCPFAC SNUR would apply to those where the subset of LCPFAC chemicals are part of a surface coating. EPA is proposing this action to be responsive to the article consideration provision at section 5(a)(5), added with the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which states that articles can be subject to notification requirements as a significant new use provided that EPA makes an affirmative finding in a rule that the reasonable potential for exposure to a chemical from an article or category of

~~articles justifies notification. The required significant new use notification would initiate EPA's evaluation of the conditions of use associated with the intended significant new use. Manufacturing (including import) or processing for the significant new use would be prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination."~~

COMMENT 8: Page 1. Does EPA mean as part of a surface coating on all articles or just some articles? There appear to be public comments suggesting that some articles (e.g., semiconductors) should be exempt. So would this exempt those articles, in which case this should be qualified throughout?

EPA Response: EPA is proposing to require notification for new uses (i.e., not ongoing uses) of imported articles containing LCPFAC chemical substances as part of a surface coating. Ongoing uses, such as those noted in the public comments received on the 2015 proposal, are outside the scope of the SNUR and would not be subject to the rule. On lines 131-143 of the draft supplemental proposal, EPA acknowledges the public comments pertaining to ongoing uses and states that EPA will recognize and exclude from the significant new use definition any ongoing uses of articles containing these chemicals. EPA will address uses not considered part of the SNUR, in response to the public comments on the proposal, as part of a final rule.

Follow-up Comment 8: Regarding the highlighted text, what is EPA's plan to handle comments that came in on the 2015 rule that can't identify a specific LCPFAC due to complexity of mixtures and residuals? Would these all be considered existing uses regardless of whether or not the specific LCPFAC changes in products?

This is important as it impacts many critical uses (semiconductors etc)

EPA Follow-up Response: EPA continues to consider the degree of specificity for ongoing uses that will be described in the future final rule. As with all comments received on an existing chemical SNUR, EPA will work to identify the specific LCPFAC chemical substance by engaging with the commenter as well as conducting its own analysis to further refine the use. When possible, EPA prefers to define ongoing uses with respect to the specific chemical and its use, rather than broad industry or categorical exclusions. EPA looks forward to working with the interagency group during the review of the future final rule to refine how EPA recognizes ongoing uses of these specific LCPFAC chemical substances.

COMMENT 20: Page 6. Regarding the following sentence, EPA has had these comments for 4 years. How much more work is left to understand these uses? Would it be possible for EPA to address the comments now?

"EPA continues to review these claims of ongoing use to understand whether these uses remain ongoing."

EPA Response: When EPA received the public comments in 2015, EPA began to reach out to commenters to gather additional information and clarify ongoing uses. Once the 2016 TSCA amendments came into effect, EPA paused outreach on these comments. EPA has since focused on developing this supplemental rule, which resulted from changes to TSCA under the Lautenberg Act. Given that four years has passed, EPA is continuing and revisiting prior outreach efforts with respect to comments that identified ongoing uses and will address the issue following comments received on the supplemental proposal as part of a final rule.

Follow-up Comment 20: Regarding the highlighted text, what is EPA's plan to handle comments that came in on the 2015 rule that can't identify a specific LCPFAC due to complexity of mixtures and residuals? Would these all be considered existing uses regardless of whether or not the specific LCPFAC changes in products?

This is important as it addresses a large industry where there are residuals that may or may not be in coatings.

EPA Follow-up Response: EPA continues to consider how it will define ongoing uses where commenters are unable to identify a specific LCPFAC due to the complexity of mixtures or possible residuals. That will be addressed in the future final rule, rather than this supplemental proposal. EPA looks forward to working with the interagency group during the review of the final rule to refine how EPA recognizes ongoing uses of these specific LCPFAC chemical substances.

COMMENT 23: Page 7. Recommended edit for clarity.

"This supplemental proposal to the proposed SNUR would require persons who intend to import these LCPFAC chemical substances only as part of a surface coating on certain articles"

EPA Response: EPA appreciates the edit and will make the change with some modification. EPA will not add "only" because EPA does not want to preclude potential future uses that may contain LCPFAC chemicals as a surface coating AND contain LCPFAC chemicals in another manner.

EPA will edit lines 144-145 to read:

"This supplemental proposal to the proposed SNUR would require persons who intend to import these LCPFAC chemical substances as part of a surface coating on certain articles"

Follow-up Comment 23: Why is EPA deleting "certain" in both these edits? What about carpets? Or is this going to apply to all articles, thus changing carpets?

EPA Follow-up Response: EPA did not make this change. The deletion of the word “certain” was introduced by an interagency reviewer that provided the edits in the first set of comments. EPA modified the edit to not include the word “only.”

Regarding carpets, the LCPFAC SNUR for carpets is a separate action that has already been finalized and, thus, is not the subject of this supplemental SNUR. This supplemental SNUR is on all articles that contain ‘certain’ LCPFAC chemicals as part of a surface coating.

COMMENT 38: Page 16. Regarding the following, what is the basis for picking a particular chemical for a SNUR? For background, it might be useful to cite factors in Section 5(a)(2) here.

“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”

EPA Response: EPA’s basis for selecting a chemical is described by the factors listed in Section 5(a)(2) in section Unit IV of the proposed rule.

In reviewing the supplemental proposal as part of the response to this comment, EPA discovered an error on page 4 where EPA refers to Unit IV of the supplemental proposal where the reference should have been to Unit IV of the proposed rule. As such, EPA will make the following change on line 86-87:

EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2) (see Unit IV. of the 2015 proposed rule (Ref. 1)).

Follow-up Comment 38: The addition of the correct reference is great, but it might be useful to provide a summary here.

EPA Follow-up Response: EPA appreciates the comment and will make the following edits, beginning at lines 86-87, to include the summary in the supplemental SNUR:

EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2) (~~see Unit IV. of the 2015 proposed rule (Ref. 1)).~~ Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) states that EPA’s determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

- The projected volume of manufacturing and processing of a chemical substance.
 - The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
 - The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
 - The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.
- In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

COMMENT 39: Page 16, Section A. Regarding the following sentence, please provide a citation for this. Is this always the case—are they always applied as a surface coating? Please clarify. When added as a coating, do we know if they are bound in a coating matrix? If so, when the matrix is released, how do we know LCPFAC are released? Are they never ‘bound’ in a coating matrix?

“LCPFAC chemical substances are not incorporated into the article and bound to the article matrix but are rather added or applied as a coating or as part of coating aid.”

EPA Response: LCPFAC are part of surface coatings used in a variety of articles to impart antiwetting and antisoiling properties to article surfaces. Surface coatings by their nature are unbound (not chemically bonded to the underlying substrate) and unincorporated (on the surface of the article rather than incorporated into the matrix of the article). These surface coatings have been unambiguously shown to be a source of LCPFAC in the environment, and hence, present the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule.

Citations:

- Washington et al. 2009. Degradability of an Acrylate-Linked, Fluorotelomer Polymer in Soil.
- Washington et al. 2015 Abiotic Hydrolysis of Fluorotelomer-Based Polymers as a Source of Perfluorocarboxylates at the Global Scale.
- Washington et al. 2015. Decades-Scale Degradation of Commercial, Side-Chain, Fluorotelomer-Based Polymers in Soils and Water.
- Washington et al. 2019. Determining global background soil PFAS loads and the fluorotelomer-based polymer degradation rates that can account for these loads.

Follow-up Comment 39: Regarding the highlighted text, is there never a case where a surface coating is bound to the underlying substrate?

What about if the LCPFAC is bound in the matrix of the surface coating such that if the surface coating is released from the substrate the bound/incorporated LCPFAC would not be released? Is this example not possible?

Providing the citations does not answer the question as the citations refer to specific products. I’m asking a broader question about the process of incorporating LCPFAC into the matrix of a surface coating or a case where a surface coating is not released from the substrate. Clearly there are cases where there is release, but EPA is assuming this is **always** the case. What is the evidence to support that this is **always** the case and that all surface coatings will release PFAS?

Does EPA believe that any release is a reasonable potential for exposure? How does EPA define ‘reasonable’? is this any exposure above zero?

EPA Follow-up Response: EPA is unaware of cases where a surface coating is bound to the underlying substrate. When LCPFAC are bound in the matrix of the coating, they can still be released from the coating over time and present a reasonable potential for exposure. Studies by EPA on degradation of fluorotelomers and fluoropolymers have

shown that these coatings degrade; however, half-lives and kinetics of the degradation are not yet well-defined (Washington et al. (Ref. 16)).

In adding section 5(a)(5), Congress did not define “reasonable potential for exposure” and did not intend 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, Congress left discretion for EPA to apply its expertise in applying the statute. In the context of this SNPRM and for SNURs more broadly, EPA has provided support for the reasonable potential of exposure through the citation of peer-review literature that documents that the chemical substance either has the potential to migrate from articles or clearly demonstrates the migration of the chemical substance from articles.

EPA would like to clarify that we do not always assume that a release will occur. Since the use designated as a significant new use does not currently exist, EPA is deferring a detailed consideration of potential exposures related to that use until there is a specific condition of use and data to review. If EPA receives a SNUN, EPA will evaluate the potential releases from the article as they relate to the uses identified in the notice and with information specific to that particular use and article. Rather than presuming that a release will always occur, EPA believes that there is reasonable potential for exposure and that notification is justified.

COMMENT 41: Page 16, Section A. Regarding the following text, are LCPFAC always unbound and unincorporated when they are part of surface coatings? Citation would be helpful to support this if it is the case.

“As an unbound, unincorporated component of a surface coating”

EPA Response: EPA appreciates the comment. EPA’s study of LCPFAC chemicals as a surface coating have been on applications where LCPFAC chemicals are unbound to the article and not incorporated into the article matrix. Surface coatings by their nature are unbound (not chemically bonded to the underlying substrate) and unincorporated (on the surface of the article rather than incorporated into the matrix of the article). The following two sources support this statement, and will be added at line 331:

- Bohnet, Matthias. Ullmann's encyclopedia of industrial chemistry. Wiley-Vch, 2003.
- Guide to the Safe Handling of Fluoropolymer Resins by Plastics Industry Association.

Follow-up Comment 41: Is this how LCFPAC chemicals are **always** used?

See previous comments on this. We worry EPA is assuming that LFPFAC in surface coatings are always releasable. Is this the case or does EPA not know?

Adding the citations while helpful does not answer the above questions.

Lines 308-309 make it sound as if LCPFAC are never incorporated and never bound in a surface coating. What is the citation for this statement? Or is this an EPA assumption based on EPA's study of LCPFAC chemicals.

EPA Follow-up Response: EPA is unaware of uses of LCPFAC chemical substances in articles other than as part of a surface coating. EPA welcomes any additional information on other uses of LCPFAC chemical substances in articles; however, for the purpose of this SNPRM, only the use of LCPFAC as part of surface coating on articles is relevant. Any other uses of LCPFAC chemical substances in articles are outside the scope of this SNUR.

The statements made related to LCPFAC chemicals being unbound and unincorporated are not EPA assumptions but rather rely on a general understanding of surface coatings, which are applied to the surface of a substrate and are unbound and unincorporated into the substance. When EPA says bound to the surface, EPA means chemically bound to the substrate on a molecular level. Coatings are, by their nature, unbound and unincorporated.

COMMENT 42: Page 16, Section A. Regarding the following text, do we know that the LCPFAC would be released from the surface coating matrix? To help inform this section it would be useful to describe the process/processes by which LCPFAC are put into surface coatings.

“LCPFAC surface coating could be released at the same time.”

EPA Response: EPA appreciates the comment. On lines 334-337 EPA states that:

LCPFAC chemical substances can be released continuously over years from treated jackets, furniture, and carpets into the air due to volatilization (Refs. 13, 14, and 15) and due to degradation of commercial LCPFAC coatings by simple abiotic reaction with water (Ref. 16).

These sources demonstrate that LCPFAC chemicals are released from the surface coating matrix. The text in question makes the point that LCPFAC chemicals would be released when the surface coating degrades or is released. When making this statement, EPA envisioned an article with a LCPFAC surface coating being scratched or abraded in a manner that would remove small parts of the surface coating. As the cited studies suggest, further release of LCPFAC chemicals would reasonably be expected to occur from the removed surface coating and lead to potential exposures to LCPFAC chemical substances.

EPA disagrees that it would be useful to describe the processes by which LCPFAC are put into surface coatings. Regardless of how they are incorporated into a surface coating or the manner of application, the degradation and release of the surface coating will result in release of the LCPFAC chemicals from the article.

Follow-up Comment 42: Regarding the highlighted text, this demonstrates release from these products only. Is that correct?

Has EPA examined the processes by which LCPFAC are put in surface coatings? A thorough examination and discussion of the processes would be helpful.

EPAs responses do not lead readers believe that EPA truly understands how all coatings are created and applied. Other than stating the cases where you know it's released, what other information can be provided to make us more confident that EPAs assumptions of 'always released' are correct?

What is the citation to support that this would happen in all cases with all processes?

EPA Follow-up Response: The reviewer is correct that these studies demonstrate releases from the articles that were the subject of the studies. The studies cited, which demonstrate the release of LCPFAC chemical substances from specific articles, serve as a suitable representation for other articles that could use these LCPFAC chemical substances as part of a surface coating. Regardless of how LCPFAC chemicals are applied as a part of surface coating, their potential for release is well supported by the scientific literature (See Refs. 12, 13, 14, 15, and 19 in the FRN).

As described in EPA Follow-up Response 39, EPA does not always assume that a release will occur. Since the use designated as a significant new use does not currently exist, EPA is deferring a detailed consideration of potential exposures related to that use until there is a specific condition of use and data to review. If EPA receives a SNUN, EPA would evaluate the potential releases from the article as they relate to the uses identified in the notice and with information specific to that particular use and article. Rather than presuming that a release will always occur, EPA believes that there is reasonable potential for exposure and that notification is justified.

COMMENT 44: Page 16. Regarding the following, the agency should provide a technical document with an analysis of the research cited to support the reasonable potential for exposure.

"based on the reasonable potential for exposure as shown through research on LCPFAC chemical substances. This category of articles is expected to exhibit reasonable potential for exposure to LCPFAC chemical substances, as elaborated herein."

EPA Response: EPA cites **these sources** to support the finding that reasonable potential of exposure from articles containing LCPFAC chemical substances exists and justifies notification to EPA of the significant new use, which meets the requirements of TSCA section 5(a)(5). EPA did not conduct an exposure analysis. **The Agency is seeking to be consistent with the approach taken in the recently-issued asbestos SNUR which also lifted the article exemption. Development of a separate technical document did not occur in that instance. EPA views development of such a technical document as potentially precedent-setting for future SNURs in which the article exemption could be lifted. EPA prefers to maintain consistency with the approach taken in the asbestos SNUR action,** but will certainly cite all sources used to meet the requirements of section 5(a)(5). All sources cited will be made publicly available: either be posted to the public docket or, for copywritten material, made available by request in the EPA public reading room. EPA can provide copies of all cited sources to the reviewers.

Follow-up Comment 44: Regarding the highlighted text, What sources? See comments above concerns still remain.

Regarding the second highlight, this is not a convincing argument as the asbestos situation was very very different. This is not a good reason for not providing the analysis requested.

EPA Follow-up Response: EPA appreciates the comment. "These sources" refers to the sources cited in the FRN. EPA disagrees regarding the asbestos SNUR. While the subject of that SNUR was a different chemical substance, both the asbestos SNUR and this SNPRM have the same standard to meet to lift the articles exemption by demonstrating reasonable potential for exposure to the chemical substance.

As stated in the response to Follow-up Comment 39, Congress did not intend for 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. A technical document with an analysis of the research cited is not required to conclude reasonable potential for exposure. For this SNPRM, EPA has provided support of reasonable potential of exposure through the citation of peer-review literature, which documents that LCPFAC chemical substances either have the potential to migrate from articles or that clearly demonstrates the migration of LCPFAC chemical substances from articles.

COMMENT 45: Page 17, references 13-19. EPA must provide a technical document (analysis of the research) to support these conclusions based on the referenced materials. Please provide a copy of these references for reviewers.

EPA Response: EPA can provide copies of all cited sources to the reviewers. EPA did not conduct an exposure analysis or analysis of the research cited, consistent with EPA's long-standing practice for SNURs. Please see also response to comment 44.

Follow-up Comment 45 (one of two): The request was not for an exposure analysis but rather for an accessible document that provides an assessment of the reference studies and their importance or relevance to EPA's determination. Since, EPA appears to be unwilling to provide this information in a separate document. Reviewer would like to request that the agency provide summary details of each reference cited and the relevance or reasoning to support the point it is used to make here. In responses to comments 49, 50, and 58. EPA provides some background information and justification for the use of some of those references. Something similar to that could be added for all the references.

EPA Follow-up Response: EPA reiterates our offer to provide the studies cited in the rule for interagency reviewers. The summary details of each of those studies is in the study abstract. EPA can add the background information provided in response to comments 49, 50, and 58 to the FRN, to provide additional information to the reader for Refs. 3, 13, 14, 15, 16, and 17. Please see edits below. EPA believes that the justification for inclusion of other references is clear from the context surrounding their citation.

In Unit III.A.i, at line 352, EPA will add:

EPA cites these studies (Refs. 13, 14, 15, 16, and 17) to support the Agency's conclusion that there is reasonable potential for exposure from the category of

articles that contain certain LCPFAC chemical substances as part of a surface coating.

Follow-up Comment 45 (two of two): Regarding the highlighted text, this response is not sufficient.

EPA Follow-up Response: EPA would like to emphasize that our long-standing practice for SNURs, including those published recently, does not include an exposure analysis or analysis of the research cited. EPA believes the information provided in the notice and the cited peer reviewed literature meets the statutory requirements: they support the reasonable potential of exposure to these LCPFAC chemical substances from articles. A technical document with an analysis of the research cited is not required to show reasonable potential for exposure.

COMMENT 46: Page 17. Regarding the following, if this is true in all cases, why does this SNPRM need to clarify that only articles with these chemicals *in surface coatings* are subject to the SNUR? Are there any cases, or could there be, in which these chemicals are added to articles *not* in surface coatings? If not, then this rule is effectively not changes the articles for which the exemption is lifted- just refining the definition.

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 or as part of coating aid.”

EPA Response: EPA’s understanding of past and current uses of LCPFAC chemicals substances in articles has been as a surface coating; this does not preclude the possibility of other uses in the future or unknown prior uses. EPA will accept the added to acknowledge this caveat. Lines 308-309 will be edited to read:

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 or as part of coating aid.

Follow-up Comment 46: Regarding the highlighted text, what if LCPFAC are bound in the matrix of the coating? Is there still ‘reasonable exposure’? Please explain.

EPA Follow-up Response: When LCPFAC are bound in the matrix of the coating, they can still be released from the coating over time and present a reasonable potential for exposure. Studies by EPA on degradation of fluorotelomers and fluoropolymers have shown that these coatings degrade; however, half-lives and kinetics of the degradation are not yet well-defined (Washington et al. (Ref. 16)).

COMMENT 49: Page 17, Section i. Regarding nonstick products we do not believe this is correct. The coatings used for nonstick cookware are polymers or copolymers of tetrafluoroethylene, hexafluoropropylene, and perfluoromethylvinylether. These are high MW polymers that are chemically-distinct from LCPFAC precursors and which are incapable of

degrading to LCPFAC compounds. Further, migration of PFAS substances from these coatings into food is almost negligible.

One caveat to this comment – LCPFAC has historically been used in the manufacture of coatings for cookware, but during processing the LCPFAC is driven off to negligible levels. It is not an example of “reasonable” exposure to LCPFAC from the use of the finished article, either oral or inhalation.

Also, the coating itself is not a LCPFAC. For that reason it would appear that it would not fall within the scope of the SNUR and if it is not included in the scope of the SNUR it should not be included as an example – doing so implies that it is covered by the SNUR, when it is not. Note that non-stick cookware is not included in the economic analysis which accompanies the SNUR.

EPA Response: EPA recognizes that non-stick cookware and other food contact uses are not a TSCA use and would not be subject the SNUR, which is why they are not included in the economic analysis. Nonstick coatings on cookware are an example of the release of LCPFAC chemical substances, which EPA uses as to demonstrate the reasonable potential of exposure from similarly-coated articles that may be imported in the future. While the polymerized coating may not be an LCPFAC chemical substance, studies have shown that “residual PFOA is not completely removed during the fabrication process of the nonstick coating for cookware” (Ref. 17). Research on these uses supports the potential exposure from articles that are within scope of the SNUR. EPA reiterates that it does not believe that these uses are ongoing and recognizes they are not subject to TSCA. In Comments 53 and 54 below, we have suggested the following edit at line 341:

Similarly, PFAS ~~can~~ could potentially be released from ~~other similar~~ packaging with PFAS coating that would be subject to TSCA.

Follow-up Comment 49: Regarding the highlight above, based on this, we recommend that all references, referrals and citations to non-TSCA uses be removed from the supplemental.

EPA should discuss what is relevant and known so instead of saying “similarly-coated articles” why doesn’t EPA just describe these articles without using an irrelevant reference to a non-TSCA use.

Discussing these non-TSCA uses is very confusing as most readers will think this action is relevant to them.

Does EPA believe that residual LCPFAC in articles is reasonable exposure? It sounds like the answer is yes. This is important for other articles beyond cookware.

Regarding the edits, these edits do not address the concern.

EPA Follow-up Response: EPA appreciates the comment and will remove the citations to non-TSCA uses. EPA will edit lines 337-342 as follows:

~~Research on non-stick coatings on cookware and food contact paper (e.g., popcorn bags) has shown LCPFACs to be released into the gas phase under normal cooking temperatures (Ref. 17). A 2017 study showed that per- and polyfluoroalkyl substances (PFAS) (including long-chain fluorotelomer alcohols) in grease-resistant food packaging can leach into food (Ref. 18).” Similarly, PFAS can be released from other packaging with PFAS coating.~~

COMMENT 50: Page 17, Section i., references 13, 14, and 15. These citations are studies that do not mimic the natural environment (eg 4 years kept in a bag). And in fact in one of the studies the levels released were considered by the authors to be negligible compared to dust levels.

The statute notes that the reasonable potential for exposure has to ‘justifies notification’. It would be helpful for EPA to describe how these non-natural studies, that show low level releases, justify the need for notification.

EPA Response: These studies are suitable for concluding there is reasonable potential for exposure from the category of articles that contain certain LCPFAC chemical substances as part of a surface coating. LCPFAC chemicals have been widely detected in a range of products and also in a wide range of media (drinking water, food, indoor air, dust, and soil). Given the past ubiquitous use of these chemicals, it is difficult to assess the particular source of these chemicals in homes or understand the particular mechanism of release. Studies such as those cited examine the release of LCPFAC chemical substances from products under controlled laboratory conditions as a proxy for potential real-world exposure. EPA believes that it is a reasonable assumption to conclude that if PFOA is released from controlled experiments, such as from a jacket stored in a sealed bag in the dark at room temperature, it will be also be released under normal use conditions.

Based on these studies and the other sources cited in the SNPRM, EPA is proposing that this potential for exposure is reasonable, and that it justifies notification. Section 5(a)(5) does not establish a threshold that an exposure must meet in order to be considered a “reasonable potential for exposure” and thus “justify notification.” See also the response to comment 51.

Follow-up Comment 50: Regarding the highlighted text, why does EPA believe that the releases under normal use would be more than negligible if in fact some of the studies cited only found negligible releases?

Regarding the highlighted text, while the statute does not establish a threshold, nothing precludes EPA for determining what in fact does justify notification. It seems EPA is setting the bar at any exposure. Is this correct?

EPA Follow-up Response: While negligible releases have been found by some studies, other studies have found more significant releases from articles containing certain LCPFAC chemical substances (Dinglasan (2006), Guo (2009), Lang (2016), Sinclair (2007), Schaidler (2017)). This supports EPA’s proposal to lift the articles exemption due to the reasonable potential for exposure to certain LCPFAC chemical

substances from articles that have these LCPFAC chemical substances as part of a surface coating.

Regarding the establishment of a threshold, EPA has applied section 5(a)(5) on a case-by-case basis. EPA is setting the bar for notification of a significant new use of these chemicals at the "reasonable potential for exposure;" since the use designated as a significant new use does not currently exist, EPA is deferring a detailed consideration of potential exposures related to that use until there is a specific condition of use and data to review.

- Dinglasan-Panlilio, Mary Joyce A., and Scott A. Mabury. "Significant residual fluorinated alcohols present in various fluorinated materials." *Environmental Science & Technology* 40.5 (2006): 1447-1453.
- Guo, Zhishi, et al. "Perfluorocarboxylic acid content in 116 articles of commerce." Research Triangle Park, NC: US Environmental Protection Agency (2009).
- Lang, Johnsie R., et al. "Release of per- and polyfluoroalkyl substances (PFASs) from carpet and clothing in model anaerobic landfill reactors." *Environmental Science & Technology* 50.10 (2016): 5024-5032.
- Sinclair, Ewan, et al. "Quantitation of gas-phase perfluoroalkyl surfactants and fluorotelomer alcohols released from nonstick cookware and microwave popcorn bags." *Environmental Science & Technology* 41.4 (2007): 1180-1185.
- Schaidler, Laurel A., et al. "Fluorinated Compounds in US Fast Food Packaging." *Environmental Science & Technology Letters* 4.3 (2017): 105-111.

COMMENT 51: Page 17, Section i., Ref 17. How high are the releases? Do they justify notification? Because this clause is in the statute, doesn't it imply that the drafters did not think that any release justified notification?

EPA Response: Section 5(a)(5) does not establish a threshold that an exposure must meet in order to be considered a "reasonable potential for exposure" and thus "justify notification."

TSCA Section 5(a)(5) states: "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." If a chemical substance is 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.

For this SNPRM, EPA has explained why the Agency thinks such a finding is appropriate in this case: "Given that the release of LCPFAC chemical substances from surface coatings on articles has been researched and confirmed and that these releases can reasonably be expected to result in exposure to the users of articles, EPA has reason to anticipate that importing or processing articles that have certain LCPFAC chemical substances as part of a surface coating would create the potential for exposure to these LCPFAC chemical substances, and that EPA should have an opportunity to review the intended use before such use could occur. Therefore, EPA affirmatively finds under

TSCA section 5(a)(5) that notification is justified by the reasonable potential for exposure to certain LCPFAC chemical substances when part of surface coatings for the articles identified in this SNUR." See lines 366-74.

Follow-up Comment 51: Regarding the highlighted text, what is keeping EPA from establishing one?

Regarding the highlighted text That the release justifies exposure?

Regarding the highlighted text, because there is release from some surface coatings, EPA believes this justifies notification for all articles with surface coatings? Is this correct?

EPA Follow-up Response: EPA appreciates the comment. As described in the response to Follow-up Comment 50, EPA believes that section 5(a)(5) should be applied on a case-by-case basis.

EPA believes that the reasonable potential for exposure is demonstrated by the cited studies that serve as a representation of exposures that could result from the new uses subject to the SNUR. The reviewer is correct that the release from some surface coatings supports EPA's proposal that notification should be required for new uses of certain LCPFAC chemical substances as part of a surface coating on articles, should these new uses arise. In showing that releases have been documented from articles using LCPFAC chemical substances as a surface coating, EPA proposes that the statutory standard has been met to show that there is reasonable potential for exposure from these new uses.

Furthermore, since the use designated as a significant new use does not currently exist, to establish a threshold would not be a reasonable use of resources. EPA is deferring a detailed consideration of potential exposures related to that use until or if there is a specific condition of use and data to review. If EPA receives a SNUN, EPA would evaluate the potential releases from the article as they relate to the uses identified in the notice and with information specific to that particular use and article. Rather than presuming that a release will always occur, EPA believes that there is reasonable potential for exposure and that notification is justified.

COMMENT 53: Page 17, Section i. Regarding the following sentence, again, LCPFACs are not used as nonstick coatings on cookware and are no longer authorized for use as greaseproofing coatings for food contact paper and paperboard.

This is a mis-representation of the data. The level of PFOA from non-stick cookware reported in Ref 17 is extremely low. This was verified in Begley et. al food additives and contaminants, October 2005, p. 1023-1031. Plus, since the publication of cited articles, manufacture of non-stick cookware has switched to more volatile emulsifiers than PFOA, so the potential for any residual is even less.

In addition, non-stick cookware and grease-resistant food packaging is not included in the economic analysis accompanying the SNUR, so it is unclear why they are listed here as examples.

Reference 18 never measured any migration into food. There is also a very big difference between trace detection and actual use of LCPFAC in food contact paper, which this reference never showed. Again, while it is true that PFAS compounds may migrate from coated articles, none of these would be LCPFAC chemicals.

“Research on non-stick coatings on cookware and food contact paper (e.g., popcorn bags) has shown LCPFACs to be released into the gas phase under normal cooking temperatures (Ref. 17). ~~A 2017 study showed that per- and polyfluoroalkyl substances (PFAS) (including long-chain fluorotelomer alcohols) in grease-resistant food packaging can leach into food (Ref. 18).~~”

EPA Response: EPA appreciates the comment. The source says that “PFASs in grease-resistant food packaging can leach into food and increase dietary exposure” and that the “prevalence of fluorinated chemicals in fast food packaging demonstrates their potentially significant contribution to dietary PFAS exposure and environmental contamination during production and disposal.” As noted in EPA’s response to Comment 49, food contact uses are outside the authorities of TSCA. EPA will make the following edit at Lines 339-342:

~~A 2017 study showed that per- and polyfluoroalkyl substances (PFAS) (including long-chain fluorotelomer alcohols) in grease-resistant food packaging can leach into food stated that per- and polyfluoroalkyl substances (PFAS) “in grease-resistant food packaging can leach into food and increase dietary exposure (Ref. 18).” While food-contact products are regulated under the Federal Food, Drug and Cosmetic Act and not TSCA. Similarly, PFAS can-could potentially be released from other similar packaging with PFAS coating that would be subject to TSCA.~~

Follow-up Comment 53: See previous comments on referrals to non-TSCA uses. Suggest edits to instead discuss what that similar TSCA use is.

EPA Follow-up Response: EPA appreciates the comment and will remove the citations to non-TSCA uses. See EPA Follow-up Response 49.

COMMENT 54: Page 17, Section i. Regarding the following sentence, while it is true that PFAS compounds may migrate from coated articles, none of these would be LCPFAC chemicals.

“Similarly, PFAS can be released from other packaging with PFAS coating.”

EPA Response: EPA appreciates the comment and will edit the sentence to make the relevance clearer. As described in the response to comment 53, EPA will make the following edit at line 341:

~~Similarly, PFAS can-could potentially be released from other similar packaging with PFAS coating that would be subject to TSCA.~~

Follow-up Comment 54: see comments above for 53.

EPA Follow-up Response: See response for Follow-up Comment 53.

COMMENT 55: Page 17, Section i. Regarding the following language, this is not a normal use scenario, nor is it a release under typical use. Is there any data to suggest release from stone and tile sealants in a typical home?

“extractable amounts of LCPFAC chemical substances”

EPA Response: EPA is unaware of data that suggest the release of LCPFAC chemicals from stone and tile sealants in a typical home. LCPFAC chemicals have been widely detected in a range of products and also in a wide range of media (drinking water, food, indoor air, dust, and soil). Given the past ubiquitous use of these chemicals and relative abundance in exposure media, it is difficult to assess the particular source of these chemicals in homes or understand the particular mechanism of release. Studies, such as the one cited, use extractable amounts of LCPFAC chemical substances from products under controlled laboratory conditions as a proxy for potential real-world exposure.

Follow-up Comment 55: Based on EPA's response we suggest deleting line 342-344 as there are no data to suggest releases from stone and tile is a potentially important source of exposure.

EPA Follow-up Response: EPA appreciates the request. While EPA does not have data from the release of LCPFAC chemicals from stone and tile sealants in a typical home, EPA does cite the laboratory test on stone and tile sealants as sufficient evidence to demonstrate migration of LCPFAC chemical substances and thus show reasonable potential for exposure from surface coatings. EPA will retain the language at line 342-344.

COMMENT 56: Page 17, Section i. Regarding the following language, “reasonable potential”, please also address how this potential exposure justifies notification.

EPA Response: Please see responses to comments 50 and 51.

Follow-up Comment 56: Reasonable potential should still be addressed.

EPA Follow-up Response: EPA believes that the reasonable potential for exposure has been addressed through the studies cited in the SNPRM. As stated in Follow-up Comment 39, Congress did not intend for promulgation of a SNUR to require an exposure assessment or evidence that exposure to the substance through the article or category of articles will in fact occur. Rather, EPA must show that there is reasonable potential for exposure to justify notification. In showing that releases have been documented from articles using LCPFAC chemical substances as a surface coating, EPA has provided sufficient evidence to show that there is reasonable potential for exposure from certain LCPFAC chemical substances. If EPA receives a SNUN, EPA would then evaluate the potential releases from the article with information specific to that particular use and article.

COMMENT 57: Page 18. Regarding the following, the standard is not the assumption in the CFR definition of “article.” Instead, the amendments to TSCA require the agency to 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.” What is EPA standard for an affirmative finding? It might also be useful to articulate any factors the agency considered or generally considers for “reasonable potential for exposure.” These things should be explained at the begging discussion of “III. Rational and Objectives” section.

“The article exemption at 40 CFR 721.45(f) is based on an assumption that people and the environment will generally not be exposed to chemical substances in articles (Ref. 20).”

EPA Response: EPA notes that the article exemption at 40 CFR 721.45(f) is distinct from TSCA Section 5(a)(5), although the basis for lifting the article exemption at 40 CFR 721.45(f) and making the affirmative finding under TSCA section 5(a)(5) are conceptually similar – both relate to the potential exposure to the chemical substance from the article. Therefore, EPA thinks retaining the explanation related to 40 CFR 721.45(f) is important.

EPA has made the affirmative finding under TSCA section 5(a)(5), based on the reasonable potential for exposure as shown through research on LCPFAC chemical substances, which EPA explains in Unit III. The studies relied upon in the SNPRM are suitable for concluding there is reasonable potential for exposure from the category of articles that contain certain LCPFAC chemical substances as part of a surface coating.

EPA’s standard for an affirmative finding is in line with the intent of TSCA, as amended by the Lautenberg Act. The Senate Congressional Record states that the language added at section 5(a)(5) “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.” (see: <https://www.congress.gov/congressional-record/2016/06/07/senate-section/article/S3511-1>).

EPA does not suggest that the reasonable potential for exposure to a compound indicates unreasonable risk. Rather, this SNUR requires notice of a new use; this notification then requires EPA to evaluate the particular use and determine whether or not any risk management measures are warranted.

For more explanation of TSCA Section 5(a)(5), please refer to the EPA Response to Comment 51.

Follow-up Comment 57: Regarding the highlighted text, it would be helpful for EPA to address this.

EPA Follow-up Response: EPA appreciates the comment. When determining if there is reasonable potential for exposure from articles, EPA considers a number of factors. These factors may differ on a case-by-case basis as appropriate for a given chemical substance or article. For this SNPRM, EPA considered whether the chemical substance

could migrate or be released from the article and thus result in exposures. To determine whether this was the case, EPA conducted a literature search on the migration of LCPFAC chemical substances from an article. EPA relied heavily on existing EPA resources and research on articles containing LCPFAC chemical substances. After conducting this review of available information, EPA worked to define the category or category of articles for which the potential exposure was reasonable. For this, EPA considered existing research showing under what circumstances and which types of uses resulted in release of LCPFAC chemical substances from articles, and identified articles containing LCPFAC as part of a surface coating as reasonably presenting a potential exposure.

COMMENT 58: Page 18. Please provide the supporting reference for this statement "LCPFAC can be released over time with use"

EPA Response: Studies on the degradation of fluorotelomer-based polymers show that these polymers are subject to hydrolysis, photolysis and biodegradation. Studies have shown half-lives of a few days to hundreds of years. In addition, research by EPA on degradation of fluorotelomers and fluoropolymers has shown that some urethanes and acrylates biodegrade; however, half-lives and kinetics of the fluorotelomers are not yet well-defined (Washington et al. (Ref. 16)) These studies have shown that the perfluorinated portion of some polymers is released as the polymer is degraded by microbial or abiotic processes to form telomer alcohols or other intermediates and that they eventually form LCPFAC. EPA will add references to the Long-Chain Perfluorinated Chemicals Action Plan (Ref. 3) and Washington et al. (Ref. 16) at line 362 as follows:

However, even when added to an article, LCPFAC can be released over time with use (Refs. 3 and 16).

Follow-up Comment 58: Recommend adding this response language (explanation) to the preamble.

EPA Follow-up Response: EPA will add the additional explanation to the preamble and will make the following edit at line 362:

However, even when added to an article, LCPFAC can be released over time with use (Refs. 3 and 16). Studies on the degradation of fluorotelomer-based polymers show that these polymers are subject to hydrolysis, photolysis and biodegradation, with half-lives of a few days to hundreds of years (Ref. [Washington et al. 2014 – new reference]). In addition, research by EPA on degradation of fluorotelomers and fluoropolymers has shown that some urethanes and acrylates biodegrade; however, half-lives and kinetics are not yet well-defined (Ref. 16). These studies have shown that the perfluorinated portion of some polymers is released as the polymer is degraded by microbial or abiotic processes to form telomer alcohols or other intermediates and that they eventually form LCPFAC.

Washington, John W., et al. "Decades-scale degradation of commercial, side-chain, fluorotelomer-based polymers in soils and water." *Environmental science & technology* 49.2 (2015): 915-923.

COMMENT 60: Page 18. Regarding the following language, would importers of articles need to know whether or not the LCPFAC is in the surface coating or somewhere else in the article? Is there easy testing to determine this? Has EPA included the costs of testing for surface coatings (vs full article) in the economic analysis?

“Articles that could potentially have LCPFAC chemical substances as part of a surface coating include, but are not limited to: furniture, medical garments, safety equipment, outdoor apparel or equipment, automobile components, aerospace components, electronics, heavy machinery, and household appliances.”

EPA Response: Section 3.2.7 of the Economic Analysis states that importers of articles are responsible for knowing whether a LCPFAC chemical is used in the surface coating or anywhere else in the imported article. Although there are no specific requirements in the supplemental proposal to make this determination, importers may choose to undertake a range of activities to ensure that they are not undertaking a new use. Importers have varying levels of knowledge about the chemical content of articles that they import. Examples of these activities are in Section 3.2.7 of the EA and include testing or gathering information from suppliers. Test costs are estimated at an average of \$141 per article and include testing for the entire article (including surface coatings). The total number of articles that would be tested is not known.

Follow-up Comment 60: Since the rule would apply only to where the chemical is in a surface coating, does the testing cost differentiate between presence vs presence in the coating? We presume importers would want to check the coating only as only if its in the coating would the regulation apply. Is that testing possible?

EPA Follow-up Response: Testing cost does not differentiate between presence vs presence in the coating. Any testing conducted would likely include identification of the chemical on any part of the article, including surface coatings. The Economic Analysis, therefore, does not distinguish any cost differential in testing for the presence of the chemical. The testing costs of \$141 per article are based on averages that are meant to provide a benchmark. Since testing is not required, it is not possible to estimate actual costs of testing.

Testing is one option that an importer may use to determine whether or not an imported article is subject to the SNUR. Because EPA is not requiring testing or prescribing a testing method for detecting LCPFAC chemicals in articles, EPA cannot say that an importer would only test the surface coating. A test that shows there is no LCPFAC chemical substances in the article would also indicate that the article does not contain a surface coating with LCPFAC.

COMMENT 63: Page 18. Regarding the following, it's not clear the citations reflect normal use of all these articles and that EPA has provided proof of reasonable release to justify notification. The discussion does not match this strong statement.

“researched and confirmed and that these releases can reasonably be expected to result in exposure to the users of articles”

EPA Response: EPA appreciates the comment and will provide clarification.

EPA will make the following change to Lines 366-371:

Given that the release of LCPFAC chemical substances from surface coatings on articles has been ~~researched and confirmed~~ shown to occur and that these releases can reasonably be expected to result in exposure to the users of articles, EPA has reason to anticipate that importing ~~or processing~~ articles that have certain LCPFAC chemical substances as part of a surface coating would create the potential for exposure to these LCPFAC chemical substances, and that EPA should have an opportunity to review the intended use before such use could occur.

Follow-up Comment 63: Regarding the highlighted text, where is this addressed?

EPA Follow-up Response: EPA appreciates the comment and understands that the reviewer is asking for proof of reasonable release to justify notification. As described in Response to Follow-up comment #57, to determine whether LCPFAC chemicals can be released, EPA conducted a literature search on the migration of LCPFAC chemical substances from articles. EPA relied heavily on existing EPA resources and research on articles containing LCPFAC chemical substances. As a result of this review of available information, EPA identified a number of studies demonstrating the release of LCPFAC chemical substances from articles (See FRN Refs 13, 14, 15, 19).

Furthermore, as stated in Follow-up Comment 39, Congress did not intend for 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. Instead, to establish a requirement for notification to the Agency, the statutory standard is to demonstrate a reasonable *potential* for exposure. Evaluation of the release and estimated subsequent exposure from a specific use would occur during review of any SNUN received.

COMMENT 65: Page 19. Regarding the following “notification is justified,” based on what? Any reasonable exposure?

EPA Response: Section 5(a)(5) does not establish a threshold that an exposure must meet in order to be considered a “reasonable potential for exposure” and thus “justify notification.” For more explanation of TSCA Section 5(a)(5), please refer to the EPA Response to Comment 51. Please see also response to Comment 39 for studies demonstrating that surface coatings have been unambiguously shown to be a source of LCPFAC in the environment, and hence, present the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule.

Follow-up Comment 65: This is not answered.

EPA Follow-up Response: EPA appreciates the comment and the opportunity to clarify. EPA emphasizes that the notification is justified by establishing that there is

reasonable potential for exposure, the basis of which has been addressed above in response to Follow-up Comment(s) 39, 44, 45, 51, and 63.

COMMENT 68: Page 20. Regarding the following language, not containing or used differently (eg not in surface coating). Suggest that EPA clarify this.

“not containing the chemical substances included in this SNUR, may appear to”

EPA Response: EPA appreciates the comment. First, EPA would like to address an error in the quoted language. The language at lines 411-413 should be edited as follows:

In making inapplicable the exemption relating to persons who import certain chemical substances as part of an article, this action may affect firms that plan to import or process ~~types of articles that may contain the subject chemical substance similar articles that while not containing the chemical substances included in this SNUR, may appear to.~~

Secondly, after following up with the commenter, the commenter clarified their question as follows:

“If they import PFAS as part of an article, wouldn't the exemption be inapplicable only if the PFAS is in a surface coating? Is it even feasible for an importer or processor to know all the chemicals in a product and where those chemicals might be located within the product? What is the burden for these groups to know need to have an awareness of any PFAS and where in the product they may or may not be located?”

EPA appreciates the clarified comment and ~~directs the commenter to EPA's response to comment 60.~~

Follow-up Comment 68: Regarding the highlighted redline, Need to add “in a surface coating”

Regarding the highlighted response, comment 60 doesn't address the questions.

EPA Follow-up Response: EPA will make the change for clarity and will add “in a surface coating” to the edited text. See edit below.

Regarding the question on the details of the articles exemption, EPA directs the reviewer to Follow-up Response to Comment 2: EPA's understanding is that LCPFAC chemical substances in articles are only used as part of a surface coating. While there may be uses EPA is unaware of for LCPFAC chemical substances in an article other than as part of a surface coating, they are not the subject of this SNUR.

EPA will edit the language at lines 411-413 to read as follows:

In making inapplicable the exemption relating to persons who import certain chemical substances as part of an article, this action may affect firms that plan to import or process ~~types of articles that may contain the subject chemical substance similar articles that while not containing the chemical substances included in this SNUR, may appear to.~~ ~~chemical substances included in this SNUR, may appear to.~~

COMMENT 71: Page 21. Regarding the following, isn't it more than part of the article but also as a surface coating? Is it realistic to expect parties to be able to differentiate this? Has EPA incorporated costs of testing all articles to see if LCPFAC are in the surface coatings?

“are part of the articles that they are considering for import or processing.”

EPA Response: For the purpose of the rule, a coating is considered part of the article. In the Economic Analysis, when referring to the presence of LCPFAC in an article, there is no distinction between a coating and other parts of the article. Any testing that would be conducted would include identification of the chemical on any part of the article, including surface coatings. It is important to point out that testing is not required.

Follow-up Comment 71: Regarding the highlighted text, shouldn't there be a distinction since the rule only applies if the chemistry is in the surface coating, not simply present in the article. There needs to be a way for testers to differentiate the location of the chemical in the article.

EPA Follow-up Response: While EPA believes that testing would identify the presence of LCPFCs anywhere on the article, including the surface coating, testing is not required for this rule. EPA does not prescribe the steps that an importer must take to identify these LCPFCs in the articles as a new use. An importer could undertake several activities to assist in the identification of the chemical in the articles, as noted section 3.2.7 of the Economic Analysis:

- 1) **Understand applicable requirements (per-firm cost).** All importers will read and understand the SNUR, within the context of the company's products. This burden is derived in Section 3.2.1 of this report.
- 2) **Identify the type of imported articles that potentially use the chemicals subject to this SNUR (per-firm cost).** This determination may be done based on an understanding of the uses of the subject chemical substances (e.g., those described in Section 2.4 of this analysis) and the application of any *a priori* knowledge of the material and its manufacture to assess the probability whether each regulated substance may be present.
- 3) **Identify all suppliers involved (per-firm cost).** The importer may choose to identify all suppliers from whom the articles identified in the previous step are imported, and as appropriate, to make them aware of the importer's potential notice obligations respecting the regulated chemical substances.
- 4) **Collect data from suppliers (per-article cost).** Importers may choose to obtain verification from suppliers identified in Step 3 that the regulated chemical substance is or is not found in the article. This may be accomplished through, for example, agreements with suppliers, declarations through databases or surveys, or by using a third-party certification system.

- 5) **Chemical testing (per-article cost).** Importers may choose to assess imported articles for chemical content. This could involve requiring suppliers to provide certificates of analysis/laboratory reports for a lot or batch of the material produced. Importers may perform their own laboratory testing of certain articles (or components of articles) to determine if they use the restricted substance.
- 6) **Recordkeeping (per-firm cost).** The importer may choose to keep records confirming the activities completed.

COMMENT 72: Page 21, why does EPA believe that article importers or processors will incur costs at the lower end of the range in the EA?

EPA Response: The rationale for this assumption is explained in Section 3.2.7 of the Economic Analysis: “Given existing regulatory limitations both internationally and within the United States, industry-wide processes, resources that support companies in understanding and managing their supply chains, and the evidence showing minimal worldwide availability of the LCPFACs regulated under the supplemental proposed SNUR, EPA believes that article importers will incur costs at the lower end of the ranges presented in Exhibit 3-7 as a result of this rule. However, firms with less knowledge about the chemical content of the articles they import may choose to undertake more extensive action to identify the chemicals substances located within the articles and may incur larger costs than firms with more understanding of their supply chains. For those companies choosing to undertake actions to assess the composition of the articles they import, EPA expects that in all likelihood, these importers will take actions that are commensurate with the company’s perceived likelihood that a chemical substance might be a part of an article, and the resources it has available.” EPA will seek public comment on this assumption. EPA will add the following at line 204:

[...] substantiate any assertions of use. **Additionally, EPA requests comment on the assumption that article importers that choose to investigate their products will incur costs at the lower end of the ranges presented in the Economic Analysis for this supplemental proposed rule.**

Follow-up Comment 72: Regarding the highlighted text, this doesn’t seem to support it being low end as EPA states that if a firm has less knowledge of their article the costs may be larger. Revisions to text should be made to be more balanced unless EPA knows for sure that all importers know what is in their articles.

EPA Follow-up Response: EPA appreciates the comment and will make the following edits to provide clarity:

...EPA believes that the majority of article importers will incur costs at the lower end of the ranges presented in Exhibit 3-7, as a result of this rule. **However,** Firms with less knowledge about **the chemical content of the articles they import may choose to undertake actions to help in identifying the presence of LCPFC chemicals in the articles. These actions may result in additional costs for the firms that are noted in Section 3.2.7 of the Economic Analysis. Potential costs (presented in Exhibit 3-7) are likely to be at the lower end of the ranges for most**

importers due the fact that these LCPFAC chemical substances (see Table 1) have been phased out as part of PFOA Stewardship Program and that there are no known global manufacturers of these specific LCPFAC chemical substances resulting in low likelihood that importation of articles subject to the rule would occur.

COMMENT 75: Page 27. What is an approximate of this cost for a small business?

“compared to the cost of developing and marketing a chemical new to a firm or marketing a new use of the chemical”

EPA Response: Costs of developing and marketing a new chemical range depending on the industry and the market for the chemical. While EPA does not have an approximate cost of developing and marketing a new chemical for small businesses, it is assumed that these costs would be much higher than the estimated \$10,000 SNUN submission cost for small business submitters. EPA welcomes comment on any available estimates of these costs.

Follow-up Comment 75: Regarding the highlighted text, what is the basis for this assumption? Understood that the approximate cost is not known but does EPA have a range that supports this assumption?

EPA Follow-up Response: While EPA does not have estimates on the cost of developing and marketing a new chemical, one study released in 2006 by Cheminfo Services study (for Environment Canada) estimates a mean reformulation cost of \$31,700 and a maximum of \$114,000, which is well above the \$10,000 SNUN costs. The costs of developing a new chemical would likely be much higher due to more extensive R&D, equipment and production, product testing, and marketing.

COMMENT 76: Page 27. What is the basis for this? Is the assumption that it will not cross the 1% threshold for any size group of any NAICs code identified?

“that the requirement to submit a SNUN generally does not have a significant economic impact.”

EPA Response: EPA believes the SNUR generally will not result in a significant economic impact. The estimated costs are \$23,000 per SNUN submission for large business submitters and about \$10,000 for small business submitters. It is important to point out that the costs are only incurred when a SNUN is submitted. The costs are relatively low. A one percent impact would only occur only for businesses below \$1 million in annual revenues. In terms of impact on a substantial number of entities, as noted on page 27, “EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a small number of significant new use notices per year. During the six-year period from 2005-2010, only three submitters self-identified as small in their SNUN submission.” Based on this, EPA believes that few SNUN submissions will occur as a result of the rule.

Follow-up Comment 76: Regarding the highlighted text, are there any potential small businesses impacted by this rule with a revenue below \$1 million in annual revenues?

EPA Follow-up Response: EPA has no way of predicting which companies (if any) would submit a SNUN. The costs for the submitter would only occur if a SNUN is submitted. Based on historical data provided in our initial response to this comment and the fact that LCPFCs have been regulated globally and manufacturing phased out in the United States, EPA believes the number of SNUNs submitted will be very low.

EA COMMENT 1: Please include a table in the RFA section with the average small revenue for the NAICS codes identified and the small entity cost as a percentage.

EPA Response: EPA agrees with the comment on adding a table in the RFA section of the Economic Analysis of average small business revenue for the affected NAICS codes. The table and accompanying text was added to Section 6.1, page 6-1 beginning at the second paragraph:

Exhibit 6-1 presents the average small business revenue for each 3-digit NAICS code represented by industries potentially affected by the rule. These average revenues are for illustrative purposes. It is not known how many firms will submit a SNUN and which NAICS code they would comprise. EPA, therefore, cannot conclude whether any small businesses would have a significant impact as a result of this supplemental proposal.

Exhibit 6-1: Average Small Business Revenue for Potentially Affected Entities		
NAICS	NAICS Description	Average Small Business Revenue (millions, 2018\$)^{1,2}
315	Apparel Manufacturing	\$2.21
335	Electrical Equipment, Appliance, and Component Manufacturing	\$21.38
423	Merchant Wholesalers, Durable Goods	\$5.38
424	Merchant Wholesalers, Nondurable Goods	\$9.71
442	Furniture and Home Furnishings Stores	\$1.21
443	Electronics and Appliance Stores	\$1.05
444	Building Material and Garden Equipment and Supplies Dealers	\$1.72
448	Clothing and Clothing Accessories Stores	\$0.84
449	Sporting Goods, Hobby, Musical Instrument, and Book Stores	\$0.81
450	General Merchandise Stores	\$0.69
451	Non-store Retailers	\$1.60
Source(s): U.S. Census Bureau (2015); U.S. Small Business Administration (2019); U.S. Bureau of Economic		

Analysis (2019)

Note(s):

¹ Revenues are inflated to 2018\$ using the Bureau of Economic Analysis Implicit Price Deflator for Gross Domestic Product

² Average small business revenues are estimated using the U.S. Census Statistics of U.S. Businesses (SUSB). The SUSB divides firms into revenue brackets according to the firm's annual receipts and employment size. To estimate revenues for just the small entities, average revenues were calculated only for the SUSB revenue or employment brackets where the upper bound is less than the SBA small business threshold. Note that this approach will result in a conservative estimate for small firm revenues, as it excludes the small firms with the largest revenues from the estimates.

Follow-up EA Comment 1: Regarding the highlighted text, in these statements, EPA appears to be stating that it does not know the small entity impact (or whether it would be substantial) and cannot know whether there is a significant impact. These two elements are crucial to establish a factual basis to be able to support an RFA certification.

EPA Follow-up Response: Similar to the response to comment #76 While EPA cannot predict the number of SNUNs submitted or by which type of companies. EPA believes the SNUR will not result in a significant economic impact. The estimated costs are \$23,000 per SNUN submission for large business submitters and about \$10,000 for small business submitters. It is important to point out that the costs are only incurred when a SNUN is submitted. The costs are relatively low. A one percent impact would only occur only for businesses below \$1 million in annual revenues. In terms of impact on a substantial number of entities, as noted on page 27, "EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a small number of significant new use notices per year. During the six-year period from 2005-2010, only three submitters self-identified as small in their SNUN submission." In addition, LCPFCs have been both regulated globally, and manufacturing has been phased out in the United States. Based on this, EPA believes that few SNUN submissions will occur as a result of the rule. Likely there would not be a substantial number of small businesses submitting SNUNs as a result of the Rule.