EPA Responses to interagency Comments Received from OMB on November 6, 2019

November 27, 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.

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 photomicrolithography 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.

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.

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.~~"

COMMENT 5: Page 1. On page 1, and elsewhere in the draft supplemental proposed rule, EPA describes the action it is taking as making inapplicable an existing exemption from notification requirements. EPA may want to instead consider amending the regulation that created the exemption so as to conform to the new statutory requirement. This may allow EPA to avoid using the terminology "make inapplicable the exemption" or "lifting the exemption," which may be confusing under the circumstances (where the statute itself addresses EPA's authority and the regulation has not been amended to conform to it).

Specifically, EPA could consider proposing to revise the regulation (40 CFR 721.45(f)) that provides the exemption from significant new use notification requirements for persons who import or process the chemicals as part of an article. As this draft

acknowledges, EPA's authority to impose such notification requirements is now controlled by a statutory requirement, 16 U.S.C. 2604(a)(5), as a result of TSCA reform in 2016.

If the underlying regulation is amended, EPA can then avoid using the terminology "to make inapplicable the exemption" or to "lift" the exemption, which may be confusing under the circumstances (where the statute itself addresses EPA's authority and the regulation has not been amended to conform to the statute).

> ***EPA Response:*** EPA thanks the reviewer for the comment. EPA will consider future regulatory changes to address any confusion. EPA recognizes that the terminology "make inapplicable the exemption" and "lifting the exemption" can create confusion, and has tried to minimize the use of this terminology and focus the preamble on the fact that EPA will require notification for new imports of articles containing LCPFAC chemical substances as part of a surface coating.

COMMENT 6: Page 1. For ease of understanding, it would be helpful to clarify that making the exemption inapplicable is equivalent to requiring reporting, and not making the exemption inapplicable is equivalent to not requiring reporting. The double negative involved in "making the exemption inapplicable" can lead to unnecessary difficulties in understanding the meaning of document.

> ***EPA Response:*** EPA appreciates the suggestion. EPA will change the language in the summary from "make the article exemption inapplicable for persons" to "require notification of significant new uses from persons." See EPA Response 4 for the complete change.

COMMENT 7: Page 1. It would be helpful to clearly state the extent to which those who "process" LCPFAC as part of an article would or would not be exempt from notification of a significant new use. It appears that the 2015 proposal made the exemption inapplicable (thus, requiring reporting) for those who import or process these chemicals as part of an article, while the proposed supplemental rule would allow the exemption from reporting to be in place for those who "process" the chemicals as part of an article. Clarification of this point, and clear communication of the meaning of "process chemical substances as part of an article" would help the reader understand when these chemicals can be imported/used without reporting.

> ***EPA Response:*** EPA recognizes the need for clarity regarding whether or not processors are subject to the rule. The 2015 proposal did not propose to require reporting from processors of articles. The amended CFR text in the 2015 proposal stated that "The other provision of § 721.45(f), respecting processing a chemical substance as part of an article, remains applicable." This supplemental proposal continues to allow the processing of articles containing LCPFAC chemical substances as part of an article. The reporting requirement is applicable only to manufacturers (including importers). Comment 10 below addressed the instances where EPA has incorrectly stated "processors" and helped provide clarity that processors are not subject to the rule.

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.

COMMENT 9: Page 4. Regarding the following, if this is the case, how will the agency enforce its proposal when finalized?

"persons who import a chemical substance covered under this proposed rule as part of an article would be exempt from TSCA section 13 import certification"

EPA Response: While 19 CFR 12.119 allows EPA to establish section 13 import certification requirements for chemicals in articles, EPA did not propose to require section 13 import certification for the subject chemical substances when part of articles. This is consistent with EPA's past practice of requiring SNUN reporting for chemical substances as part of articles without also requiring import certification or export notification for these chemical substances as part of articles (40 CFR 721.2800; 40 CFR 721.10068).

COMMENT 10: On pages 5, 10, 16, and 18-19, we suggest minor technical edits intended to ensure that EPA is consistently describing the exemptions proposed in the 2015 proposed rule and this draft supplement, both of which address the import of articles (i.e., both proposed to the lift the exemption only as to import) but not the processing of articles. For example, the draft discussion on the top of page 19 suggests that EPA is making the requisite affirmative finding with respect to both import and processing, not only with respect to import. We also provide a minor edit to improve the clarity of the discussion on page 19 (the insertion of "including those").

Page 5. Recommended edit. We suggest checking that the descriptions of the proposed requirements are consistent and accurate.

"EPA proposed to make the exemption from notification requirements for persons who import ~~or process~~ the chemical substance"

Page 10. Recommended edit for consistency with the discussion below, where EPA explains that the exemption still applies as to processing.

> "EPA proposes to make the exemption inapplicable for import of these articles because there is…"

Page 16. Recommended edit. Again, we would check that this is what EPA proposed.

> "…importing ~~or processing~~ the category of articles that contain certain LCPFAC chemical…"

Page 18. Recommended edit and we suggest that EPA double check the descriptions of the scope of this supplement, which appears to only address import (and not processing) of articles.

> "EPA is proposing to make the TSCA section 5(a)(5) finding and make inapplicable the exemption at 40 CFR 721.45(f) for persons who import ~~or process~~ any….

Page 19. Recommended edit.

> "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"

> "Therefore, EPA affirmatively finds under TSCA section 5(a)(5) that notification for import is justified"

"exposures and risks, including those that might exist before those uses would begin."

EPA Response: EPA thanks the reviewer for suggesting these edits to ensure that the proposed exemptions are described consistently and accurately. EPA will make an additional edit at Page 19, line 319. Additionally, EPA will edit the passage at Page 19, line 376, but EPA will not be adding the specific language provided by the reviewer because, given that the SNU does not exist at the time the SNUN is submitted, EPA only

evaluates the potential hazards, exposures, and risks that would be expected to exist before the new use begins.

EPA will make the following changes:

Line 109: In that previously proposed rule, EPA proposed to make the exemption from notification requirements for persons who import ~~or process~~ the chemical substance as part of an article inapplicable for the import of a subset of LCPFAC chemical substances in all articles.

Line 228: EPA proposes to make the exemption inapplicable for import of these articles because there is reasonable potential for exposure to LCPFAC chemical substances, including PFOA, if these chemical substances are part of surface coatings on articles imported into the United States.

Line 319: Rather than making the article exemption inapplicable for any article, as was proposed in the January 21, 2015, proposal (Ref. 1), this action proposes to make a finding under TSCA section 5(a)(5) and make the article exemption at 40 CFR 721.45(f) inapplicable for persons importing ~~or processing~~ the category of articles that contain certain LCPFAC chemical substances as part of a surface coating for a non-ongoing use ~~on articles~~.

Lines 355-356: Based on these considerations, EPA is proposing to make the TSCA section 5(a)(5) finding and make inapplicable the exemption at 40 CFR 721.45(f) for persons who import ~~or process~~ any of a defined set of LCPFAC chemical substances as part of an article where LCPFAC chemical substances have been applied as part of a surface coating for a non-ongoing use.

Line 368: 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.

Line 372: Therefore, EPA affirmatively finds under TSCA section 5(a)(5) that notification for import 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.

Line 376: Existence of the SNUR triggers the submission of a SNUN, thereby allowing EPA to evaluate potential uses (before those uses would begin) whether in the form of an article, or not, for any hazards, exposures and risks~~, including those~~ that might exist ~~before those uses would begin~~.

COMMENT 11: Page 5. Please see recommended edit. Be clear in this paragraph about what the new statutory requirements are as of 2016.

"Additionally, TSCA section 5(a)(5) (15 U.S.C. 2604(a)(5)), as amended in 2016, authorizes EPA to require notification for the import or processing of a"

EPA Response: EPA will make the following change at line 94 to provide greater clarification:

> Additionally, TSCA section 5(a)(5) (15 U.S.C. 2604(a)(5)), as amended in 2016, authorizes EPA to require notification for the import or processing of a chemical substance as part of an article or category of articles under TSCA section 5(a)(1) (15 U.S.C. 2604(a)(1)(A)(ii)) if EPA makes an affirmative finding in a rule under TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.

COMMENT 12: Page 5. Regarding the following text, by category do you mean those articles with LCPFAC in surface coatings? Suggest clarifying.

"part of the category of articles discussed in Unit I.C"

EPA Response: Yes, the intention is to include those articles with LCPFAC as part of a surface coating. EPA will provide the following edit on line 101 for clarification:

> "part of the category of articles, articles that contain certain LCPFAC chemical substances as part of a surface coating, discussed in Unit I.C"

COMMENT 13: Page 5. Regarding the following text, do you mean EPA proposed to keep the exemption from notification requirements?

"proposed to make the exemption from"

EPA Response: EPA did not propose to keep the exemption for notification requirements. Rather, EPA proposed to make the exemption inapplicable, thus requiring notification requirements for articles containing LCPFAC chemical substances. As discussed in response to comment 4, EPA is clarifying its terminology.

COMMENT 14: Page 5. Regarding the following sentence, we presume this would apply to new uses only, not ongoing uses in articles, regardless of whether or not in surface coating. If this is correct, can EPA clarify?

> "EPA is now issuing a supplemental proposal for the import of certain LCPFAC chemical substances as part of a surface coating on articles."

EPA Response: Yes, this is correct; SNURs apply only to new uses. Ongoing uses are outside the scope of the SNUR and not subject to the rule.

COMMENT 15: Page 5. Regarding the following, an explicit statement regarding the impact of this supplemental proposal on the proposed rule should be provided here. In other words, EPA is narrowing the scope of its previous inapplicability of the article exemption. Language to this effect should be provided.

> "EPA proposed to make the exemption from notification requirements for persons who import or process the chemical substance as part of an article inapplicable for the import of a subset of LCPFAC chemical substances in all articles. EPA is now issuing a supplemental proposal for the import of certain LCPFAC chemical substances as part of a surface coating on articles."

EPA Response: EPA appreciates the reviewer's suggestion for greater clarity. To address this comment, EPA will add the following green text at line 112 (please note the red text is an edit from comment 17):

> In that previously proposed rule, EPA proposed to make the exemption from notification requirements for persons who import or process the chemical substance as part of an article inapplicable for the import of a subset of LCPFAC chemical substances in all articles. EPA is now issuing a supplemental proposal for the import of certain LCPFAC chemical substances; this action would make the exemption from notification requirements inapplicable and require significant new use notification reporting for the import of a subset of LCPFAC chemical substances only as part of a surface coating on articles. This supplemental proposal better defines the articles subject to the rule by defining the subject articles as "imported articles where certain LCPFAC chemical substances are part of surface coating on the articles" rather than what was originally proposed, "imports of articles."

COMMENT 16: Page 6. Regarding "ongoing," is there a definition or an explanation for the scope of this term?

EPA Response: See response to comment 3.

COMMENT 17: Page 6. Recommended edit for clarity.

EPA is now issuing a supplemental proposal for the import of certain LCPFAC chemical substances that would make the exemption from notification requirements inapplicable for the import of a subset of LCPFAC chemical substances only as part of a surface coating on articles."

EPA Response: EPA believes this edit appears on page 5 rather than page 6, and will make the recommended changes with some modification at line 111 to read as follows:

> EPA is now issuing a supplemental proposal for the import of certain LCPFAC chemical substances; this action would make the exemption from notification requirements inapplicable and require significant new use notification reporting for the import of a subset of LCPFAC chemical substances only as part of a surface coating on articles.

COMMENT 18: Page 6. Recommended edit:

"which states that articles can be subject to notification requirements as a significant new use ~~provided that~~ only if 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."

EPA Response: EPA will slightly modify this edit so that the language is consistent with the statute.

EPA will make the recommended changes with some modification at line 114 to read as follows:
"which states that articles can be subject to notification requirements as a significant new use ~~provided that~~ ~~only~~ "if the Administrator 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."

COMMENT 19: Page 6. EPA discusses the fact that the rule it proposed in 2015 also would have made inapplicable the exemption with respect to certain articles containing other PFAS chemicals (i.e., ones not addressed by this supplement). Will EPA be issuing a separate supplement to make the requisite affirmative finding under 15 U.S.C. 2604(a)(5) with respect to these articles (which are not addressed by this regulation)?

EPA Response: Page 6 discusses other aspects of the 2015 proposal that are not the subject to supplemental rule. EPA intends to finalize these aspects of the 2015 proposal along with supplemental rule in one final rule. See also EPA's response to comment 21.

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.

COMMENT 21: Page 7. Regarding the following, why is the article exemption for carpets not part of a supplement given the new 2016 requirements? Was the reasonable potential for exposure adequately justified in the original NPRM?

> "are not the subject of this supplemental proposal."

EPA Response: EPA appreciates the question. After the 2016 TSCA amendments, EPA reviewed the new requirements established at TSCA section 5(a)(5) and determined that EPA previously established the reasonable potential for exposure from a category of articles (carpets containing LCPFAC chemical substances) to adequately justify notification. For further clarification: In October 2013, EPA finalized a SNUR that lifted the articles exemption for the import of all carpets containing any LCPFAC chemical substances, with the exception of two LCPFAC chemical substances that were ongoing at the time of the rule (78 FR 62443). In the 2015 proposal, EPA proposed to remove the exemption and require SNUN reporting for these two chemical substances because EPA determined their use to no longer be ongoing. Therefore, while these two substances as part of carpets are not the subject of this supplemental proposal, the Agency intends to include them as part of the final rule.

COMMENT 22: Page 7. EPA discusses the SNUR for the LCPFAC chemicals that it proposed in the 2015 proposed rule. In proposing the SNUR, EPA considered the statutory factors listed in 15 U.S.C. 2604(a)(2). EPA may want to consider whether in this supplement it should expressly request comment on whether and how the amendment being made by this supplement may impact these factors (and/or how the change may otherwise bear on the original proposal).

EPA Response: EPA appreciates the comment. The scope of this SNPRM is limited to the article exemption. EPA is not reconsidering the statutorily required TSCA section 5(a)(2) factors from the 2015 proposal.

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"

COMMENT 24: Page 8. Please describe what this change means re: justification of reasonable potential for exposure.

"Enacted on June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114-182) amended several sections of TSCA and added section 5(a)(5), Article Consideration"

EPA Response: For added clarity, EPA will add the following at lines 152-157:

Enacted on June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114-182) amended several sections of TSCA and added section 5(a)(5), Article Consideration. The Article Consideration requires that EPA find in a rule that the reasonable potential for exposure to a chemical substance through the article or category of articles justifies notification. After considering the reasonable potential for exposure from articles under TSCA section 5(a)(5), EPA is now issuing a supplemental proposal to make inapplicable the exemption for persons who import certain LCPFAC chemical substances when those LCPFAC chemical substances are part of a surface coating on articles.

COMMENT 25: Page 8. Please see recommended edit:

"LCPFAC chemical substances only when those LCPFAC"

EPA Response: EPA prefers to keep the sentence as written. 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.

COMMENT 26: Page 9. It would be helpful to clearly communicate the current understanding of overall extent of ongoing use of LCPFAC by parties that were not involved in the 2010/2015 PFOA Stewardship Program.

EPA Response: LCPFAC chemicals subject to the SNUR are proprietary chemicals manufactured by the companies participating in the 2010/2015 PFOA Stewardship Program. With their phaseout by the end of 2015, those chemicals are no longer available for use, except for any existing stocks of chemicals and any ongoing uses identified during the public comments received on the 2015 proposal. EPA intends to address these issues in response to public comments as part of the final rule and not as part of the supplemental proposal.

COMMENT 27: Page 9. Recommended edit:

"In providing comments on the reasonable potential for exposure to LCPFAC chemical substances in articles, commenters are urged to provide sufficient information for EPA to substantiate any assertions of use and of exposure.

EPA Response: EPA appreciates the edit and will make the recommended change at line 204 to read as follows:

> In providing comments on the reasonable potential for exposure to LCPFAC chemical substances in articles, commenters are urged to provide sufficient information for EPA to substantiate any assertions of use and of exposure.

COMMENT 28: Page 13. Recommended edit suggested because EPA regulations production. As this is degradation, is best to clarify.

"PFOA can also be ~~produced~~ created unintentionally by the degradation of some"

EPA Response: EPA thanks for reviewer for providing this clarification and will make the following edit at line 254:

> PFOA can also be ~~produced~~ created unintentionally by the degradation of some fluorotelomers, which are not manufactured using PFOA but could degrade to PFOA.

COMMENT 29: Page 9. Please be clear about what costs are actually being estimated here. This is not the cost of the overall SNUR as supplemented by this SNPRM; it is only the costs of the specific article reporting requirements in the SNPRM alone. The overall costs of the SNUR would decrease as a result of this supplement because the exemption is lifted for a smaller number of articles.

> "EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential importers of articles containing the chemical substances included in this supplemental proposal in surface coatings."

EPA Response: EPA appreciates the reviewer's recommendation to provide greater clarity about the estimated incremental costs and believes the reviewer meant page 8 instead of page 9. To clearly demonstrate what costs are estimated in this supplemental proposal, EPA will add onto the reviewer's suggested edit to read "when they are part of a surface coating on articles." EPA will make edits at line 179 to read as follows:

> EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential importers of articles containing the chemical substances included in this supplemental proposal when they are part of a surface coating on articles."

COMMENT 30: Page 11. Be clear about whether this has changed from the last proposal.

> "As proposed in the 2015 SNUR NPRM, the article exemption would still apply to LCPFAC chemical substances not listed in Table 1 or Table 2 of this unit, with the exception of the import of carpets, for which the import exemption is already inapplicable (78 FR 62443; October 22, 2013) (FRL-9397-1)."

EPA Response: EPA thanks for reviewer for the comment and will make the recommended revisions for clarity at line 230 to read as follows:

> As proposed in the 2015 SNUR NPRM, the article exemption would still apply to LCPFAC chemical substances not listed in Table 1 or Table 2 of this unit, with the exception of the import of carpets, for which the import exemption is already inapplicable (78 FR 62443; October 22, 2013) (FRL-9397-1).

COMMENT 31: Page 13. Recommended edit:

> "In addition to the subset of LCPFAC chemical substances identified in Table 1, PFOA and its salts would be subject to the proposal."

EPA Response: EPA appreciates the suggestion for greater clarity and will make the following change at line 241:

> In addition to the subset of LCPFAC chemical substances identified in Table 1, PFOA and its salts would be subject to the proposal

COMMENT 32: Page 14, Section B. Why is only PFOA addressed in this section? What about all of the other chemicals listed in table 1? This makes it seem like only PFOA is relevant to this rule, when in reality a number of other chemicals are included.

EPA Response: As indicated in lines 260-273 of Section B on page 14, other LCPFAC, not just PFOA, are discussed in this section and relevant to the rule. In this section, EPA talks about the 2010/2015 PFOA Stewardship Program, which includes PFOA and related chemical substances (LCPFAC chemical substances).

COMMENT 33: Page 15 Section C. Why is the focus only on PFOA? Perhaps expand as written in the Economic Analysis document (Section 2.1):

> "To date, LCPFACs have been linked to a number of health effects, including thyroid disease and impacts on reproductive function (Melzer et al. 2010; Knox et al. 2011). PFOA in particular is likely to be associated with particular human diseases: studies in 2012 established a probable link between exposure to PFOA and testicular and kidney cancer (C8 Science Panel 2012c), ulcerative colitis (C8 Science Panel 2012b), thyroid disease (C8 Science Panel 2012d), preeclampsia (C8 Science Panel 2011), and hypercholesterolemia (C8 Science Panel 2012a)."

EPA Response: EPA appreciates the comment. PFOA is the primary chemical substance studied as part of the LCPFAC class of chemical substances. EPA, however, will expand this section to include additional information on LCPFAC chemical substances more broadly. EPA will edit lines 280-285 as follows, with "Refs X and Y" as placeholders for the Melzer et al. 2010; Knox et al. 2011 citations:

> To date, LCPFACs have been linked to a number of health effects, including thyroid disease and impacts on reproductive function (Refs X and Y). PFOA and its salts, which are considered LCPFAC chemical substances, have been the primary focus of studies related to LCPFAC class of chemical substances. PFOA is persistent, widely present in humans and the environment, has a half-life in humans of 2.3-3.8 years, and can cause adverse effects in laboratory animals, including cancer and developmental and systemic toxicity (Refs. 3, 5, 6, 7, and 8). Human epidemiology data report associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney) (Ref. 9).

COMMENT 34: Page 15 Section C. Same comment as above - what about all of the other chemicals listed in Table 1? Why does this only address PFOA?

EPA Response: PFOA is the primary chemical substance that has been studied as part of the LCPFAC class of chemical substances. EPA, however, will expand this section to include additional information on LCPFAC chemical substances more broadly. EPA will edit lines 280-285 as follows, with "Refs X and Y" as placeholders for the Melzer et al. 2010; Knox et al. 2011 citations:

> To date, LCPFACs have been linked to a number of health effects, including thyroid disease and impacts on reproductive function (Refs X and Y). PFOA and its salts, which are considered LCPFAC chemical substances, have been the primary focus of studies related to LCPFAC class of chemical substances. PFOA is persistent, widely present in humans and the environment, has a half-life in humans of 2.3-3.8 years, and can cause adverse effects in laboratory animals, including cancer and developmental and systemic toxicity (Refs. 3, 5, 6, 7, and 8). Human epidemiology data report associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney) (Ref. 9).

COMMENT 35: Page 15 Section A. It would be helpful to clearly state the extent to which EPA is or is not suggesting that the inclusion of LCPFAC in an article other than as a surface coating would lead to a reasonable potential for exposure, and the basis for that finding.

EPA Response: EPA appreciates the comment. The reasonable potential for exposure to uses other than as part of a surface coating are outside the scope of the supplemental proposed rule. EPA will clarify this point by adding the following text at Line 323:

> EPA is not making a finding on the reasonable potential for exposure from articles that do not contain LCPFAC chemical substances as a surface coating.

COMMENT 36: Page 15, Section A. Regarding the following text, this suggests fish is the only food containing LCPFAC.

> "Multiple pathways of exposure, including through drinking water, food (fish)"

EPA Response: EPA appreciates the commenter bringing this to our attention. The cited source refers to "food" more generally. EPA will edit lines 292-294 as follows (the green edit is a result of comment 37):

> Multiple pathways of exposure, including through drinking water, food ~~(fish)~~, ~~migration from food-packaging paper products,~~ house dust, and release from *treated articles are possible (Ref. 12).*

COMMENT 37: Page 15, Section A. There are currently no authorized uses of LCPFAC chemical substances in food packaging. The use of such substances in food packaging in the US would thus represent use of an unauthorized food additive and would render the food contained in the package adulterated under the FFD&C Act. Recommend deleting the following language "migration from food-packaging paper products"

> ***EPA Response:*** Food packaging is outside the scope of this SNUR and will be deleted. EPA will edit lines 292-294 as follows (the red edit is a result of comment 36):
>
> > Multiple pathways of exposure, including through drinking water, food ~~(fish)~~, ~~migration from food-packaging paper products,~~ house dust, and release from treated articles are possible (Ref. 12).

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)).

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.

COMMENT 40: Page 16, Section A. Regarding the following text, citation or is this a hypothetical? It seems like a reasonable assumption that the coating layer could be degraded. Is EPA assuming for this proposal that this happens all the time? If so, a citation would be helpful. Or should EPA add a clause along the lines of: which can lead to degradation of the coating layer, depending on the circumstances (eg depending upon the stressor and the type of coating matrix).

"which can lead to degradation of the coating layer."

EPA Response: EPA appreciates the comment and will add the following additional language at lines 310-311:

> which can lead to degradation of the coating layer, depending on the circumstances (e.g. depending upon the stressor and the type of coating matrix).

COMMENT 41: Page 16, Section A. Regarding the following text, are LCPFAC always unbound and unicorporated 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.

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.

COMMENT 43: Page 16. Regarding the following, the regulatory text does not include processing. Is this an error? This is included throughout the preamble.

"inapplicable for persons importing or processing the category of articles"

EPA Response: EPA appreciates the comment and will address the error; the error is not in the regulatory text but rather in the preamble text. Processors of articles are not subject to the rule.

EPA will make the following edit at lines 318-319.

inapplicable for persons importing ~~or processing~~ the category of articles

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 citied sources to the reviewers.

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.

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.

COMMENT 47: Page 17. This is the clearest statement yet of what this proposal actually does and should be included much sooner.

"Rather than making the article exemption inapplicable for any article, as was proposed in the January 21, 2015, proposal (Ref. 1), this action proposes to make a finding under TSCA section 5(a)(5) and make the article exemption at 40 CFR 721.45(f) inapplicable for persons importing or processing the category of articles that contain certain LCPFAC chemical substances as part of a surface coating on articles."

EPA Response: EPA appreciates the comment. EPA will restate this passage (with some edits for accuracy) at the end of Line 117 in *Unit I.C C. What Action Is the Agency Taking?* Line 117 will be edited as follows:

> ...from an article or category of articles justifies notification. Rather than making the article exemption inapplicable for any article, as was proposed in the January 21, 2015, proposal (Ref. 1), this action proposes to make a finding under TSCA section 5(a)(5) and make the article exemption at 40 CFR 721.45(f) inapplicable for persons importing ~~or processing~~ the category of articles that contain certain LCPFAC chemical substances as part of a surface coating on articles.

COMMENT 48: Page 17. Regarding the following sentences, it would be helpful to have citations for these 2 sentences.

> "LCPFAC chemical substances have been used in surface coatings for numerous applications given their hydrophobic and lipophobic properties. Examples of LCPFAC coating applications in articles are stain- and water-repellent fabrics and nonstick products (e.g., coatings for cookware)."

EPA Response: EPA appreciates the request for citation. EPA will add a citation to the LCPFAC Action Plan, which is already cited in the FRN. The LCPFAC Action Plan

(https://www.epa.gov/sites/production/files/2016-01/documents/pfcs_action_plan1230_09.pdf) states:

"PFCs are substances with special properties that have thousands of important manufacturing and industrial applications. They impart valuable properties, including fire resistance and oil, stain, grease, and water repellency. For example, they are used to provide nonstick surfaces on cookware and waterproof, breathable membranes for clothing, and are used in many industry segments, including the aerospace, automotive, building/construction, chemical processing, electronics, semiconductors, and textile industries."

Lines 329-332 will now read:

> LCPFAC chemical substances have been used in surface coatings for numerous applications given their hydrophobic and lipophobic properties. Examples of LCPFAC coating applications in articles are stain- and water-repellent fabrics and nonstick products (e.g., coatings for cookware) (Ref. 3).

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.

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.

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.

COMMENT 52: Page 17, Section i., Ref 18. Do the levels released justify 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." For more explanation of TSCA Section 5(a)(5), please refer to the EPA Response to Comment 51.

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.

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.

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.

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.

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.

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).

COMMENT 59: Page 18. EPA discusses its affirmative finding and the reasonable potential for exposure to LCPFAC chemicals. We note that it appears that EPA is making its finding (again, that the reasonable potential for exposure justifies notification) based on exposure from consumer or commercial use of articles. Our comment notes that EPA could consider (and perhaps even request comment on) whether it has statutory authority to make the requisite finding based on exposure from drinking water containing chemicals released during decomposition of articles (or in other ways from articles).

This is the exposure associated with consumer or commercial use of the articles, correct? If it hasn't already, EPA may want to consider whether the statute also provides authority to address exposure from drinking water containing chemicals released during decomposition of articles (or otherwise from articles). *See* https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/exposure-based-policy-under-section (mentioning exposure through groundwater). If appropriate, EPA could request comment (i.e., information) related to the potential for this kind of exposure through articles (and/or perhaps on the scope of its statutory authority). That could help inform future decision making even if the issue is not relevant here.

> ***EPA Response:*** EPA appreciates the comment. The uses subject to the SNUR are not ongoing. If a SNUN were to be submitted for a new use, EPA would then evaluate that new use.

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.

COMMENT 61: Page 18. Regarding the following, if this is the case, why is EPA only limiting this SNUR to surface coatings with LCPFAC. This sentence is confusing.

"However, even when added to an article, LCPFAC can be released over time with use."

EPA Response: EPA thanks the reviewer for this comment and is editing the sentence to focus on the scope of the rule, which is to lift the articles exemption for articles that contain LCPFAC chemical substances as part of a surface coating. EPA will make the following edits at lines 361 through 365:

However, ~~even~~ when added to the surface coating of an article, LCPFAC can be released over time with use. Based on this understanding, upon receipt of a SNUN, EPA intends to evaluate the potential risk of exposure to human health and the environment for any intended significant new use of LCPFAC chemical substances (including as part of a surface coating of an article).

COMMENT 62: Page 18. Regarding the following "(including as part of an article)" Do you mean only as part of a surface coating of an article, or do you really mean any part of an article? Please clarify.

EPA Response: EPA intended to refer only the surface coating of an article. EPA will make the following edits in lines 361 through 365:

However, ~~even~~ when added to the surface coating of an article, LCPFAC can be released over time with use. Based on this understanding, upon receipt of a SNUN, EPA intends to evaluate the potential risk of exposure to human health and the environment for any intended significant new use of LCPFAC chemical substances (including as part of a surface coating of an article).

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.

COMMENT 64: Page 19. Regarding the following "potential for exposure," is this to justify notification?

EPA Response: EPA finds that the reasonable potential for exposure of LCPFAC chemical substances from the import of a new use of an article containing LCPFAC chemical substances as part of a surface coating justifies notification to EPA of the new use prior to import occuring.

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.

COMMENT 66: Page 19. Recommended edits:

"However, ~~even~~ when added to the surface coating of an article, LCPFAC can be released over time with use. Based on this understanding, upon receipt of a SNUN, EPA intends to evaluate the potential risk of exposure to human health and the environment for any intended significant new use of LCPFAC chemical substances (including as part of a surface coating on an article)."

EPA Response: EPA accepts the edits for clarity, with the minor change of "on" to "of" for consistency in the last sentence. EPA will make the following changes at lines 361 through 365:

> However, ~~even~~ when added to the surface coating of an article, LCPFAC can be released over time with use. Based on this understanding, upon receipt of a SNUN, EPA intends to evaluate the potential risk of exposure to human health and the environment for any intended significant new use of LCPFAC chemical substances (including as part of a surface coating of an article).

EPA will also make corresponding changes in the regulatory text at line 675:

> *Changes in this supplemental rule:* (1) Revocation of certain notification exemptions. With respect to imports of carpets, the provisions of § 721.45(f) do not apply to this section. With respect to imports of articles, the provisions of § 721.45(f) also do not apply to a chemical substance identified in paragraphs (b)(2) or (b)(3) of this section when they are part of ~~surface coatings on articles~~ a surface coating of an article. A person who imports a chemical substance identified in paragraph (b)(1) of this section as part of a carpet or who imports a chemical substance identified in paragraphs (b)(2) or (b)(3) of this section as part of a surface coating on an article is not exempt from submitting a significant new use notice. The other provision of § 721.45(f), respecting processing a chemical substance as part of an article, remains applicable.

COMMENT 67: Page 20. Recommended edit:

"substances as part of the surface coating of an article"

EPA Response: EPA accepts the edits for clarity. EPA will make the following changes at lines 411 through 413:

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

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.

COMMENT 69: Page 21. Recommended edit:

> "EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential importers of the chemical substance included in this supplemental proposal in surface coatings of articles (Ref. 2)."

EPA Response: EPA thanks the reviewer for this suggestion and accepts the edits. EPA, however, believes this edit to be on Page 20 rather than Page 21. EPA will make the following changes at lines 398 through 399:

> "EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential importers of the chemical substance included in this supplemental proposal in surface coatings of articles (Ref. 2)."

COMMENT 70: Page 21. Regarding the following, it's not clear what the connection is to asbestos here.

> "Companies manufacturing, importing, or processing asbestos or articles containing asbestos will incur an average cost of $79 for notifying their customers of SNUR regulatory activities."

EPA Response: EPA thanks the commenter for identifying this error and will correct the typo at Lines 407 to 409 as follows:

> "Companies ~~manufacturing,~~ importing~~, or processing~~ ~~asbestos or~~ articles containing ~~asbestos~~ LCPFAC chemical substances as part of a surface coating will incur an average cost of $79 for notifying their customers of SNUR regulatory activities."

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.

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.

COMMENT 73: Page 21. Regarding the following language, this is confusing because the beginning of the sentence assumes that companies are assessing the composition of articles so what other actions is this part referring to? Please clarify. What if the companies don't have resources to do testing? Will EPA do the testing for them?

> "take actions that are commensurate with the company's perceived likelihood that a chemical substance might be a part of an article"

EPA Response: As noted in the first paragraph of section 3.2.7a of the EA: "The supplemental proposed rule does not prescribe steps that an importer must take to identify if a chemical in articles is subject to the supplemental proposed SNUR; therefore, there are a variety of potential actions that a company could take to identify specific substances in its articles, should they choose to do so".

Table 3-7 of the Economic Analysis provides a range of activities that companies may undertake to assess the composition of articles. These activities include: identification of the type of imported article that potentially uses the substance, identification of the suppliers involved, collection of data from suppliers, and chemical testing. As noted in response to comment 72, due to existing regulatory limitations and existing resources to support companies understanding and managing of their supply chains, EPA believes that article importers will incur costs at the lower end of the range provided in Exhibit 3-7 of the EA. Test costs are estimated at an average of $141 per article.

COMMENT 74: Page 27. Please see recommended edits:

> "EPA believes the cost of submitting a SNUN, $10,000, is"

EPA Response: EPA thanks the reviewer for this recommendation and will accept the edit with modification. The following change will be made to line 571:

> EPA believes the cost of submitting a SNUN, $10,000 for small business submitters, is relatively small compared to the cost to a firm of developing and marketing a new chemical new or marketing a new use of the chemical and that the requirement to submit a SNUN generally does not have a significant economic impact.

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.

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.

COMMENT 77: Page 31. It would be helpful if EPA could highlight what changes here are due to this supplemental vs the original proposal

"Therefore, it is proposed that 40 CFR chapter I be amended as follows:"

EPA Response: EPA appreciates the comment. The changes to the regulation text occur at Lines 672-680. Please see the originally proposed and supplemental regulation text below, with the changed language highlighted. Please note that EPA is including a change made in response to comment 66:

From 2015 Proposal: (1) Revocation of certain notification exemptions. With respect to imports of carpets, the provisions of § 721.45(f) do not apply to this section. With respect to imports of articles, the provisions of § 721.45(f) also do not apply to a chemical substance identified in paragraphs (b)(2) or (b)(3) of this section. A person who imports a chemical substance identified in paragraph (b)(1) of this section as part of a carpet or who imports a chemical substance

identified in paragraphs (b)(2) or (b)(3) of this section as part of an article is not exempt from submitting a significant new use notice. The other provision of § 721.45(f), respecting processing a chemical substance as part of an article, remains applicable.

Changes in this supplemental rule: (1) Revocation of certain notification exemptions. With respect to imports of carpets, the provisions of § 721.45(f) do not apply to this section. With respect to imports of articles, the provisions of § 721.45(f) also do not apply to a chemical substance identified in paragraphs (b)(2) or (b)(3) of this section when they are part of ~~surface coatings on articles~~ a surface coating of an article. A person who imports a chemical substance identified in paragraph (b)(1) of this section as part of a carpet or who imports a chemical substance identified in paragraphs (b)(2) or (b)(3) of this section as part of a surface coating on an article is not exempt from submitting a significant new use notice. The other provision of § 721.45(f), respecting processing a chemical substance as part of an article, remains applicable.

COMMENT 78: Page 34. Regarding the following, where is this exemption discussed?

"Import of fluoropolymer dispersions and emulsions, and fluoropolymers as part of articles, containing chemical substances identified in paragraph (b)(3) of this section shall not be considered as a significant new use subject to reporting."

EPA Response: This was discussed in the 2015 proposed rule. In the proposed rule, EPA states that the "import of fluoropolymer dispersions and emulsions, and fluoropolymers as part of articles, containing PFOA or its salts was not determined to be a significant new use because this use is currently ongoing and EPA is not making inapplicable any of the standard exemptions at 40 CFR 721.45 for PFOA." This supplemental action makes no change to EPA's previously proposed exemption. It continues to be included in the reg text, given that it was proposed.

COMMENT 79: Page 35. Regarding the following, i this the key language for this supplemental. Noting that the article exemption does not apply and thus these articles must be notified?

"With respect to imports of articles, the provisions of § 721.45(f) also do not apply to a chemical substance identified in paragraphs (b)(2) or (b)(3) of this section when they are part of surface coatings on articles."

EPA Response: Correct. This is the key language for this supplemental rule. Comment-Response 77 above highlights the changes to this language.

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.

It is uncertain whether any small entities will submit SNUNs as a result of the rule and to which NAICS code they belong. EPA therefore disagrees that the percentage of small entity costs to NAICS code average revenues should be added to the table.

EA COMMENT 2: Please include, if applicable, a sentence said that the costs would not cross the 1% threshold for any size group of any NAICS code identified; this can be checked in the 2012 SUSB.

EPA Response: In response to EA Comment 1, a table of the average small business revenues was added. In the last sentence of the accompanying text to the EA for that response, it was indicated that "EPA therefore cannot conclude whether any small businesses would have a significant impact as a result of this supplemental proposal since the number of SNUNs that submitted is not known" This 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.

EA COMMENT 3: Page 1-1. Regarding the following, where is this explained in the SNPRM? This is not clear and seems to be inconsistent with text elsewhere, including later in this paragraph. See lines 371-375 of the SNPRM (emphasis added): Based on these considerations, EPA is proposing to make the TSCA section 5(a)(5) finding and make inapplicable the exemption at 40 CFR 721.45(f) for persons who import **or process** any of a defined set of LCPFAC chemical substances as part of an article where LCPFAC chemical substances have been applied as part of a surface coating for a non-ongoing use.

> "However, EPA is also proposing that the exemption at CFR 40 721.45(f) remain in effect for persons who *process* chemical substances as part of an article because existing stocks of articles may still contain LCPFAC or PFOA chemical substances."

EPA Response: EPA appreciates the comment. EPA has clarified above that the supplemental rule is only for the import of articles containing LCPFAC chemical substances as part of surface coatings of articles (note: under TSCA, manufacturing includes import). EPA has corrected this error in the SNPRM via several edits above (see Comments 10, 43, and 47). The original proposal also proposed to leave the exemption for processors in place.

EA COMMENT 4: Page 2-1. Recommended edit:

> "PFOA ~~in particular is likely to~~ may be associated with particular human diseases"

EPA Response: EPA thanks the reviewer for this suggestion and will accept the edit. The following change will be made on page 2-1:

> PFOA ~~in particular is likely to~~ may be associated with particular human diseases

EA COMMENT 5: Page 2-7. Regarding the following, again, where is this explained in the rule? This does not appear in the SNPRM and appears to be false. The EA needs updating throughout to be consistent with the SNPRM on this point. See lines 371-375 of the SNPRM (emphasis added): Based on these considerations, EPA is proposing to make the TSCA section 5(a)(5) finding and make inapplicable the exemption at 40 CFR 721.45(f) for persons who import **or process** any of a defined set of LCPFAC chemical substances as part of an article where LCPFAC chemical substances have been applied as part of a surface coating for a non-ongoing use.

> "However, EPA is also proposing that the exemption at 40 CFR 721.45(f) remain in effect for persons who *process* chemical substances as part of an article because existing stocks of articles may still contain LCPFAC or PFOA chemical substances."

EPA Response: EPA appreciates the comment. As noted in EPA's response to EA Comment 3, EPA has clarified that the supplemental rule is only for the import of articles containing LCPFAC chemical substances as part of surface coatings of articles (note: under TSCA, manufacturing includes import). EPA has corrected this error in the SNPRM via several edits above (see Comments 10, 43, and 47). The original proposal also proposed to leave the exemption for processors in place.

EA COMMENT 6: Page 2-8, Section 2-5. What about processing?

EPA Response: EPAB – EPA appreciates the comment. Processors of articles are not subject to the rule. EPA has clarified above that the supplemental rule is only for the import of articles containing LCPFAC chemical substances as part of surface coatings of articles (note: under TSCA, manufacturing includes import). EPA has corrected this error in the SNPRM via several edits above (see Comments 10, 43, and 47). The original proposal also proposed to leave the exemption for processors in place.

EA COMMENT 7: Page 3-1. The following is not consistent with what is described earlier in this document.

> "The SNUR discussed in this report specifies that any manufacture (including import) or processing of LCPFACs for a designated significant new use will require reporting under section 5(a)(1)(A) of TSCA."

EPA Response: EPA appreciates the comment. EPA will edit the text on Page 3-1 to read as follows:

> "The SNUR discussed in this report specifies that ~~any manufacture (including the~~ import~~) or processing~~ of certain LCPFAC~~s~~ chemical substances as part of a

surface coating of articles for a designated significant new use will require reporting under section 5(a)(1)(A) of TSCA."

EA COMMENT 8: Page 3-1. EPA does not assume that industry will select option 1 elsewhere in this document. For example, on page 3-12, this document says "This analysis assumes that no entities are expected to submit a SNUN."

"and EPA's expectation that affected entities would select Option 1"

EPA Response: EPA will update the statement on page 3-12 to say, "This analysis assumes that ~~no~~ few, if any, entities are expected to submit a SNUN."

EA COMMENT 9: Executive Summary, Section 3 and 4. Individual cost components are clearly presented. However, total costs are not presented in one place. This makes it difficult to determine cost impact. All costs should be summarized in one table in the Executive Summary. Industry costs, unit and total, should be summarized in one table in Section 3. Agency costs should be summarized in one table in Section 4.

EPA Response: A summary table of per firm costs was added to the Economic Analysis at page 1-2 of the Executive Summary along with accompanying text on page 1-2:

> The required notification initiates EPA's evaluation of the conditions associated with the intended use within the applicable review period. Manufacturing (including import) or processing for the significant new use is 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. A firm intending to engage in these activities will be required to submit a SNUN, incurring an estimated submission cost of approximately $23,105 for large businesses per chemical, and potentially other minor costs. For small businesses, the estimated cost is approximately $9,905 to complete and submit a SNUN. Exhibit ES-1 summarizes costs incurred per firm. Section 3 provides more detail on these cost calculations[1], ~~and potentially other minor costs~~.
>
> In addition to any firms that may make a SNUN submission, the supplemental proposed SNUR may also affect firms that do not make a submission. By avoiding a significant new use, a firm can avoid submission and testing costs but may incur other compliance costs. The firm may also incur "hidden" costs; for example, it could forego profitable opportunities to use the chemical in an application that would be a significant new use, or limit production volume to avoid a significant new use. The potential hidden costs to the firms that do not make a submission are not quantified.
>
> Costs in this report are estimated at the firm level. Total ~~and reflect the burden of a SNUR on the firms that make a submission. The potential hidden~~ costs of the supplemental proposal ~~to the firms that do not make a submission~~ are not estimated since the number SNUN submissions is unknown. ~~quantified.~~ EPA, however, receives

only a handful of SNUNs each year and ~~per year. The number of firms affected by not making submissions to EPA is unknown;~~ therefore the anticipated number of SNUN submissions as a result of this supplemental proposal is low. ~~, costs are not aggregated across the affected entities.~~

Exhibit ES-1: Compliance Options and Associated Costs Incurred by a Firm Due to the Supplemental Proposed SNUR			
Option[1]		**Costs**	**Quantified Costs per Chemical (2018$)[2]**
1.	Electronic submission of a Significant New Use Notice (SNUN), indicating to EPA that the firm would like to import the chemical as part of an article for a Significant New Use as defined in the SNUR.	Costs of submitting a SNUN, including rule familiarization, CDX registration (for companies that are first-time submitters), form completion, user fee, and any test costs.	$63.34 rule familiarization cost; $23,105 submission cost (including SNUN recordkeeping under 40 CFR 721.40 and fee $16,000 for large businesses). EPA usually receives well under ten SNUNs per year. First time submitters would incur $220.86 for CDX registration and associated activities. Companies importing an article currently used in commerce in the United States would incur a cost $76.32 for notifying consumers of SNUR regulatory activities.
2.	Import in a way that avoids a Significant New Use.	Cost of the profit foregone as a result of not engaging in the commercial activity originally planned (opportunity costs), and recordkeeping.	Opportunity costs are not quantified. Other costs include rule familiarization ($63.34), recordkeeping ($11.45), and customer notification ($76.32) may apply. Costs associated with article importation may include activities such as article identification ($153 to $1,832), supplier identification ($1,121) recordkeeping ($11), collecting data from suppliers ($6 to $611 per article), and testing ($149 per article tested).
Note(s): [1] Firms may be subject to both options at once since submission of a SNUN results in profits foregone as a result of not			

manufacturing, importing, or processing the chemical. [2] Quantified costs are attributable to the SNUR only if a firm would not otherwise follow the specified practices. Costs are detailed in Section 3.2. [3] EPA does not require the development of test data for submission of a SNUN, although a firm may submit test data already in its possession and/or describe any other available data. Because EPA does not require the development of test data, EPA assumes that no firms will incur testing costs as a result of the final SNUR.			

Exhibit 4-1 (Agency costs per SNUN) was added to Section 4, page 4-1 of the EA.

Exhibit 4-1: Agency Cost per SNUN		
Total Annual Agency Cost for PMN/SNUN/MCAN Review (2016$)	**Average Number of Annual PMN, SNUN, and MCAN Submissions**	**Agency Cost per SNUN (2018$)**
$18,933,659	462	$44,000
Source(s): Table 9 - Annual Section 5 PMN/SNUN/MCAN Cost Estimates. EO 12866 Documentation; Draft Submitted to OMB – Technical Background Document (RIN 2070-AK27; Proposed Rule. EPA-HQ-OPPT-2016-0401-0020. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0020. **Note(s):** Agency costs are comprised of both pay and nonpay (i.e. contract) dollars. Costs are inflated to 2018$ using the U.S. Bureau of Labor Statistics Employment Cost Index – Total Compensation: Professional and Related Private Industry, Not Seasonally Adjusted. (Series ID: CIU2010000120000I (B)) (BLS 2019b) (see Appendix A)		

A table could not be included for total costs, as requested by the commenter. It was not possible to estimate the total costs of the rule since the number of SNUNs that would be submitted as a result of the supplemental proposal is not known. This explanation was added to the Economic Analysis in the Executive Summary page ES 1-2

> Costs in this report are estimated at the firm level. Total ~~and reflect the burden of a SNUR on the firms that make a submission. The potential hidden~~ costs of the supplemental proposal ~~to the firms that do not make a submission~~ are not estimated

since the number SNUN submissions is unknown. ~~quantified.~~ EPA, however, receives only a handful of SNUNs each year and ~~per year. The number of firms affected by not making submissions to EPA is unknown;~~ therefore the anticipated number of SNUN submissions as a result of this supplemental proposal is low. ~~, costs are not aggregated across the affected entities.~~

EA COMMENT 10: Section 2. There are various areas of uncertainty and ranges of potential outcomes. Averages, means, or other measure of central tendency limit the analysis.

a. Chemical substances, salts, and aggregate production volumes (Exhibits 2-1, 2-2, and 2- 3)
b. Industries that may Import Articles Containing LCPFACs (Exhibit 2-4)
c. Firms that do not currently import articles using the chemicals, but who may be interested in importing these articles in the future (Section 2.5 Article Importation)
d. Articles that could potentially have LCPFAC chemical substances as part of a surface coating include (Section 2.4 Chemical Uses)
e. State-level and international regulations, as well as voluntary actions by firms may influence the use of a chemical within an article (Section 2.5.2 Activities that may Impact the Use of LCPFACs)

Recommend including a sensitivity analysis or uncertainty analysis. See Table 2, Steps 8 and 9, in the GAO Cost Estimating and Assessment Guide: https://www.gao.gov/new.items/d093sp.pdf.

EPA Response: Table 2 in the GAO Cost Estimating and Assessment Guide indicates that a sensitivity analysis should "test the sensitivity of cost elements to changes in estimating input values and key assumptions". The sources of uncertainty listed in (a) – (e) are not inputs into the estimated industry compliance cost in the Economic Analysis of this Rule, and therefore it is not possible to conduct a sensitivity analysis.

Similarly, Table 2 in the GAO Cost Estimating and Assessment Guide indicates that an uncertainty analysis should "use an acceptable statistical analysis method (e.g., Monte Carlo simulation) to develop a confidence interval around the point estimate." An analysis of this type would require knowing the distributions of the input data (e.g. standard errors), which the available input data used in the EA does not support.

EA COMMENT 11: Section 5. Benefits are not quantified and therefore underestimated. These costs could offset industry costs of complying with the rule and agency cost of implementing the rule. For example, the analysis referenced in Section 6.6 (Executive Order 13045, Protection of Children) should be conducted.

f. This study focuses on unit costs (e.g., per chemical, per agency) so that the total cost across the EPA and industry was not determined. Therefore, the full tangible and intangible impact was underestimated.

g. If the absolute $100M threshold is large relative to the cost, that does not make the impact irrelevant to the protection of children.

Recommend quantifying the most relevant benefits.

EPA Response: Information needed to conduct a quantitated benefits analysis for this rule are not available. Data required would include the amount of LCPFC reduced in the environment, the human health and environmental risk reduction as a result of any reduction in LCPFC exposure, and the monetary value of these reduced risks. These data are not available.

EA COMMENT 12: Appendix. Labor rates in Exhibit A-2 are less than market value for calculation of loaded wage rates. Recommend including rates from GSA schedules to consider a wider range of labor rates that reflects current market wages.

EPA Response: The GSA schedules reflect federal contract labor rates, which may include other ancillary costs (e.g. overhead) in addition to total industry labor compensation (wages and employment benefits). EPA does not believe that GSA schedules are necessarily more representative of the loaded wage rates derived from the Bureau of Labor Statistics presented in Exhibit A-2.