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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2013-0225; FRL-10003-21]

RIN 2070-AJ99

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: EPA is supplementing a proposed significant new use rule (SNUR) issued under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances to make inapplicable the exemption for persons who import a subset of LCPFAC chemical substances as part of surface coatings on articles. This subset of LCPFAC chemical substances also includes the salts and precursors of these perfluorinated carboxylates. 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.

DATES: Comments must be received on or before [INSERT DATE 45 DAYS AFTER DATE

OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2013-0225, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Tyler Lloyd, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-4016; email address: lloyd.tyler@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (including import), process, or distribute in commerce chemical substances and mixtures. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Apparel Manufacturing (NAICS code 315).
- Electrical Equipment, Appliance, and Component Manufacturing (NAICS code 335).
- Merchant Wholesalers, Durable Goods (NAICS codes 423).
- Merchant Wholesalers, Nondurable Goods (NAICS 424).
- Furniture and Home Furnishings Stores (NAICS codes 442).
- Electronics and Appliance Stores (NAICS codes 443).
- Building Material and Garden Equipment and Supplies Dealers (NAICS code 444).
- Clothing and Clothing Accessories Stores (NAICS code 448).
- Sporting Goods, Hobby, Musical Instrument, and Book Stores (NAICS code 449).
- General Merchandise Stores (NAICS code 450).
- Non-store Retailers (NAICS code 451).

This action may affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in

support of import certification appears at 40 CFR part 707, subpart B. Additionally, persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b); see also 40 CFR part 707, subpart D and 40 CFR 721.20). Under the existing TSCA import certification and export notification rules, 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, and persons who export or intend to export a chemical substance as part of an article would be exempt from the TSCA section 12(b) export notification requirements. See Unit V. for more information on the applicability of the import certification and export notification requirements.

If you have any questions regarding the applicability of this action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Is the Agency's Authority for Taking this Action?

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human

beings or the environment to a chemical substance.

- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)). TSCA furthermore prohibits such manufacturing or processing 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 (15 U.S.C. 2604(a)(1)(B)(ii)). 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. This supplemental proposal proposes to exercise EPA's authority under TSCA section 5(a)(5) to require notification for the import of the subject chemical substances as part of the category of articles, articles that contain certain LCPFAC chemical substances as part of a surface coating, discussed in Unit I.C. As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. What Action Is the Agency Taking?

In the **FEDERAL REGISTER** of January 21, 2015 (80 FR 2885) (FRL-9915-63) (Ref.

1), EPA proposed a SNUR for long-chain perfluoroalkyl carboxylate (LCPFAC) and perfluoroalkyl sulfonate chemical substances. As stated in the previous proposal, the LCPFAC chemical substances also include the salts and precursors of these perfluorinated carboxylates. In that previously proposed rule, EPA proposed to make the exemption from notification requirements for persons who import 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.” EPA is issuing this supplemental proposal to be responsive to the article consideration provision at TSCA section 5(a)(5), added with the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114-182), which states that articles can be subject to notification requirements as a significant new use 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. 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 the category of articles that contain certain LCPFAC chemical substances as part of a surface coating on articles. As to processors, it is EPA’s understanding that there is no ongoing manufacturing or processing of

LCPFAC chemical substances in the U.S. Based on that understanding, EPA does not expect that there would be any future such processing, and EPA therefore is not proposing that this Supplemental Proposed Rule apply to processors. EPA seeks comment on this approach.

In the proposed rule issued in the **FEDERAL REGISTER** of January 21, 2015 (Ref. 1), EPA also proposed: 1) an amendment to a SNUR for LCPFAC chemical substances by designating as a significant new use manufacturing (including importing) or processing of a subset of LCPFAC chemical substances for any use that was no longer ongoing after December 31, 2015; 2) an amendment to a SNUR for LCPFAC chemical substances by designating as a significant new use manufacturing (including importing) or processing of all other LCPFAC chemicals substances for any use that was no longer ongoing after January 21, 2015; and 3) an amendment to a SNUR for perfluoroalkyl sulfonate chemical substances that would make inapplicable the exemption from notification requirements for persons who import perfluoroalkyl sulfonate chemical substances as part of carpets. These other amendments, as proposed on January 21, 2015 (Ref. 1), are not the subject of this supplemental proposal. EPA is considering the comments received on the January 21, 2015, proposal (Ref. 1) and will respond to them with publication of the final rule.

During the public comment period for the rule proposed in the **FEDERAL REGISTER** of January 21, 2015 (Ref. 1), EPA received comments about ongoing uses of LCPFAC and perfluorooctanoic acid (PFOA) chemical substances and requests that EPA modify the proposed SNUR to specifically recognize and exclude from the significant new uses certain ongoing activities. EPA received public comments claiming several ongoing uses. EPA continues to review these claims of ongoing use to understand whether these uses remain ongoing. EPA intends to undertake further outreach to commenters to confirm and better understand the

ongoing uses. In the final rule, EPA will recognize and exclude from the significant new uses any ongoing activities for these chemicals. The final rule would take final action on both the previously proposed rule and this supplemental proposal. For further background information for this supplemental proposal, consult the proposal issued in the **FEDERAL REGISTER** of January 21, 2015 (Ref. 1) and the corresponding docket for this rulemaking (EPA-HQ-OPPT-2013-0225).

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 articles for a significant new use, consistent with the requirements at 40 CFR 721.25, to notify EPA at least 90 days before commencing such import. 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 the 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.

D. Why Is the Agency Taking this Action?

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. As a precondition to authorizing EPA to “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),” this provision requires that EPA affirmatively find in a rule under section 5(a)(2) 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.

If finalized as proposed, the January 21, 2015, proposed SNUR would require timely advance notice to EPA of any future import of LCPFAC chemical substances for new uses that may produce changes in human and environmental exposures, and would ensure that an appropriate determination (relevant to the risks associated with such importing, processing, and use) has been issued prior to the commencement of such importing. The proposed SNUR is furthermore necessary to ensure that manufacturing (including importing) or processing for the significant new use cannot proceed until EPA has responded to the circumstances by taking the required actions under TSCA sections 5(e) or 5(f) in the event that EPA determines any of the following: (1) that the significant new use presents an unreasonable risk under the conditions of use (without consideration of costs or other non-risk factors, and including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA); (2) that the information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the significant new use; (3) that, in the absence of sufficient information, the manufacturing (including importing), processing, distribution in commerce, use, or disposal of the substance, or any combination of such activities, may present an unreasonable

risk (without consideration of costs or other non-risk factors, and including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA); or (4) that there is substantial production and sufficient potential for environmental release or human exposure (as defined in TSCA section 5(a)(3)(B)(ii)(II)).

The rationale and objectives for this supplemental proposal are explained in Unit III.

E. What are the Estimated Incremental Impacts of this Action?

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. This analysis (Ref. 2), which is available in the docket, is discussed in Unit IX., and is briefly summarized here.

In the event that a SNUN is submitted, costs are estimated to be approximately \$23,000 per SNUN submission for large business submitters and about \$10,000 for small business submitters. The rule may also affect firms that plan to import or process articles that may be subject to the SNUR. Although there are no specific requirements in the rule for these firms, they may choose to undertake some activity to assure themselves that they are not undertaking a significant new use. In the accompanying Economic Analysis for this SNUR (Ref. 2), EPA provides example steps (and their respective costs) that an importer or processor might take to identify LCFPAC chemical substances in articles. These can include gathering information through agreements with suppliers, declarations through databases or surveys, or use of a third-party certification system. Additionally, importers may require suppliers to provide certificates of testing analysis of the products or perform their own laboratory testing of certain articles. EPA is unable to predict, however, what, if any, particular steps an importer might take; thus, potential total costs were not estimated.

F. Do You Have Comments or Information About Ongoing Uses?

EPA welcomes comment on all aspects of this supplemental proposal. EPA based its understanding of the use profile of these chemicals on the published literature, company progress reports submitted during the 2010/2015 PFOA Stewardship Program, the 2016 CDR submissions, market research, and review of Safety Data Sheets. To confirm EPA's understanding, the Agency is requesting public comment on all aspects of this supplemental proposal. 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. 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.

G. Additional Considerations for Comment

TSCA section 5(a)(5) provides that the EPA 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.” (Emphasis added.) Thus, Congress provided EPA with considerable discretion to determine (1) what is a “reasonable” potential for exposure; (2) what kind of reasonable potential “justifies” notification; and (3) whether, in EPA’s discretion (“*may* require”), to require notification in a case in which such a reasonable potential exists. By making notification contingent on the existence of a “reasonable” potential for exposure, TSCA section 5(a)(5) implies that there is some category of less than reasonable potentials for exposure that could not give rise to notification.

EPA requests comment on whether or not the Agency should affirmatively establish an explicit threshold at which, or explicit criteria for determining whether, a significant new use exhibits a reasonable potential for exposure that justifies notification. While TSCA section 5(a)(5) does not establish a specific threshold or specific criteria for making this determination and does not require EPA to affirmatively establish such a threshold or such criteria, EPA may establish a threshold, or criteria, for determining reasonable potential for exposure if appropriate.

EPA seeks comment on whether EPA could adopt a de minimis threshold for determining “reasonable potential for exposure” and if so, how that de minimis threshold could be established. For example, the United States Court of Appeals for the District of Columbia Circuit has recognized that “[u]nless Congress has been extraordinarily rigid, there is likely a basis for an implication of de minimis authority to provide exemption when the burdens of regulation yield a gain of trivial or no value.” *Alabama Power Co. v. Costle*, 636 F.2d 323, 360-61 (D.C. Cir. 1980).

In *Alabama Power*, the Court has recognized that “[c]ategorical exemptions from statutory commands may . . . be permissible as an exercise of agency power, inherent in most statutory schemes, to overlook circumstances that in context may fairly be considered de minimis. It is commonplace, of course, that the law does not concern itself with trifling matters, and this principle has often found application in the administrative context. Courts should be reluctant to apply the literal terms of a statute to mandate pointless expenditures of effort.” 636 F.2d at 360 (citations omitted). “The ability . . . to exempt de minimis situations from a statutory command is not an ability to depart from the statute, but rather a tool to be used in implementing the legislative design.” *Id.* Courts have continued to recognize that authority to create de minimis exemptions may be implied where “the burdens of regulation yield a gain of trivial or no value.”

Env'tl. Def. Fund, Inc. v. EPA, 82 F.3d 451, 466 (D.C. Cir. 1996) (internal quotation marks omitted); *see also, e.g., Ass'n of Admin Law Judges v. FLRA*, 397 F.3d 957, 961-62 (D.C. Cir. 2005). As an application of the statutory requirements in the context of this specific Significant New Use Rule, EPA could set a specific threshold level for the content of the LCPFAC below which reporting would not be required (in percentage of the product composition for example). EPA requests comment both on how this threshold level could be determined, and on what such levels might be. Establishment of a threshold could be based on one or more of the following rationales: (1) below the selected threshold level, there is no “reasonable potential for exposure” within the meaning of section 5(a)(5) (i.e., the risk of exposure is very low); and (2) below the selected threshold level, there is a “reasonable potential for exposure” (or, alternatively, there may be such a potential), but the potential does not “justif[y] notification” (i.e., potential for risk is very low in light of the low level of LCPFAC present in the surface coating). EPA is seeking comment on whether there would be reasonable potential for exposure under typical conditions of use of the article as contrasted with laboratory experiments designed to release the LCPFAC under laboratory conditions.

Alternatively, EPA could establish or use specific criteria to determine whether or not the “reasonable potential for exposure” justifies notification. For example, EPA could receive from importers information on the level of LCPFAC in the product or in the surface coating, and determine the level is low enough to not meet the “reasonable potential for exposure” notification requirement. EPA notes also that a person’s exposure to LCPFAC could be impacted by whether or not the article itself is used as a stand-alone product or incorporated into another product, and as such receiving such information could also be of help to the Agency. Another consideration could be that EPA requests information on the method by which the LCPFAC is

incorporated into the surface coating and whether that method changes the likelihood of release from the article. EPA seeks comment on the above discussion and on criteria that the Agency could use to determine whether or not the “reasonable potential for exposure” justifies notification. EPA seeks detailed input on these potential criteria, as well as other suggestions for criteria that could be implemented to help ensure that the notification is justified.

We invite robust comment on these and other possible thresholds or criteria that could be implemented by EPA in a final rule.

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

H. What should I consider as I prepare my comments for EPA?

When submitting your comments, keep the following items in mind:

1. *Submitting CBI.* It is EPA's policy to include all comments received in the public docket without change or further notice to the commenter and to make the comments available on-line at www.regulations.gov, including any personal information provided, unless a comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that is claimed to be CBI. For CBI information in a disk or CD

ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2, subpart B.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www2.epa.gov/dockets/commenting-epa-dockets#tips>.

II. Chemical Substances Subject to this Proposed Rule

A. What Chemicals Are Covered by this Supplemental Proposal?

This supplemental proposal would modify the requirements for a subset of LCPFAC chemical substances at 40 CFR 721.10536 by making the exemption at 40 CFR 721.45(f) inapplicable for persons who import LCPFAC chemical substances listed in this unit and PFOA or its salts (see the second bulleted list of this unit) as part of an article in which these LCPFAC chemical substances have been applied as part of a surface coating. The subset of LCPFAC chemical substances also includes the salts and precursors of these perfluorinated carboxylates. 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. As proposed in the 2015 SNUR NPRM, the article exemption would still apply to LCPFAC chemical substances not listed in 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). The other provision of 40 CFR 721.45(f), respecting processing a chemical substance as part of

an article, remains applicable. These LCPFAC chemical substances are:

- Perfluorooctyl iodide (CAS Registry No. (CASRN) 507-63-1; TSCA Chemical Inventory Name: Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-8-iodo-)
- Tetrahydroperfluoro-1-decanol (CASRN 678-39-7; TSCA Chemical Inventory Name: 1-Decanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-)
- Perfluoro-1-dodecanol (CASRN 865-86-1; TSCA Chemical Inventory Name: 1-Dodecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafuoro-)
- Perfluorodecyl iodide (CASRN 2043-53-0; TSCA Chemical Inventory Name: Decane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-10-iodo-)
- 1,1,2,2-Tetrahydroperfluorododecyl iodide (CASRN 2043-54-1; TSCA Chemical Inventory Name: Dodecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10-heneicosafuoro-12-iodo-)
- Perfluorodecylethyl acrylate (CASRN 17741-60-5; TSCA Chemical Inventory Name: 2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafuorododecyl ester)
- 1,1,2,2-Tetrahydroperfluorodecyl acrylate (CASRN 27905-45-9; TSCA Chemical Inventory Name: 2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester)
- 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12-Pentacosafuoro-14-iodotetradecane (CASRN 30046-31-2; TSCA Chemical Inventory Name: Tetradecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12-pentacosafuoro-14-iodo-)
- 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14-Pentacosafuorotetradecan-1-ol (CASRN 39239-77-5; TSCA Chemical Inventory Name: 1-Tetradecanol,

3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-pentacosafuoro-)

- 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-Nonacosafluorohexadecan-1-ol (CASRN 60699-51-6; TSCA Chemical Inventory Name: 1-Hexadecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-nonacosafuoro-)
- 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14-Nonacosafuoro-16-iodohexadecane (CASRN 65510-55-6; TSCA Chemical Inventory Name: Hexadecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14-nonacosafuoro-16-iodo-)
- Sodium;2-methylpropane-1-sulfonate (CASRN 68187-47-3; TSCA Chemical Inventory Name: 1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3-[(.gamma.-.omega.-perfluoro- C4-16-alkyl)thio]propyl]amino] derivs., sodium salts)
- 1,1,2,2-Tetrahydroperfluoroalkyl (C8-C14) alcohol (CASRN 68391-08-2; TSCA Chemical Inventory Name: Alcohols, C8-14, .gamma.-.omega.-perfluoro)
- Thiols, C8-20, gamma-omega-perfluoro, telomers with acrylamide (CASRN 70969-47-0; TSCA Chemical Inventory Name: Thiols, C8-20, .gamma.-.omega.-perfluoro, telomers with acrylamide)
- Silicic acid (H_4SiO_4), sodium salt (1:2), reaction products with chlorotrimethylsilane and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-1-decanol (CASRN 125476-71-3; TSCA Chemical Inventory Name: Silicic acid (H_4SiO_4), sodium salt (1:2), reaction products with chlorotrimethylsilane and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-1-decanol)
- Thiols, C4-20, gamma-omega-perfluoro, telomers with acrylamide and acrylic acid,

sodium salts) (CASRN 1078712-88-5; TSCA Chemical Inventory Name: Thiols, C4-20, .gamma.-.omega.-perfluoro, telomers with acrylamide and acrylic acid, sodium salts)

- 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(2-((gamma-omega-perfluoro-C4-20-alkyl)thio)acetyl) derivs., inner salts (CASRN 1078715-61-3; TSCA Chemical Inventory Name: 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-[2-[(.gamma.-.omega.-perfluoro-C4-20-alkyl)thio]acetyl] derivs., inner salts)
- Polyfluoroalkyl betaine (generic) (CASRN is CBI; EPA Accession No. 71217; TSCA Chemical Inventory Name: Polyfluoroalkyl betaine (PROVISIONAL))
- Modified fluoroalkyl urethane (generic) (CASRN is CBI; EPA Accession No. 89419; TSCA Chemical Inventory Name: Modified fluoroalkyl urethane (PROVISIONAL))
- Perfluorinated polyamine (generic) (CASRN is CBI; EPA Accession No. 274147; TSCA Chemical Inventory Name: Perfluorinated polyamine (PROVISIONAL))

The term LCPFAC refers to the long-chain category of perfluoroalkyl carboxylate chemical substances with perfluorinated carbon chain lengths equal to or greater than seven carbons and less than or equal to 20 carbons. The category of LCPFAC chemical substances also includes the salts and precursors of these perfluorinated carboxylates. See Unit II.A. of the proposed rule (Ref. 1) for further discussion of the LCPFAC category. In addition to the subset of LCPFAC chemical substances identified in the list above, PFOA and its salts would be subject to the proposal. PFOA and its salts are considered LCPFAC chemical substances. PFOA and examples of PFOA salts with CASRNs and chemical names are as follows:

- Pentadecafluorooctanoyl fluoride (CASRN 335-66-0; TSCA Chemical Inventory Name: Octanoyl fluoride, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-)

- Perfluorooctanoic acid (CASRN 335-67-1; TSCA Chemical Inventory Name: Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (PFOA))
- Silver perfluorooctanoate (CASRN 335-93-3; TSCA Chemical Inventory Name: Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, silver (+) salt (1:1))
- Sodium perfluorooctanoate (CASRN 335-95-5; TSCA Chemical Inventory Name: Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, sodium salt (1:1))
- Potassium perfluorooctanoate (CASRN 2395-00-8; TSCA Chemical Inventory Name: Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, potassium salt (1:1))
- Ammonium perfluorooctanoate (CASRN 3825-26-1; TSCA Chemical Inventory Name: Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, ammonium salt (1:1) (APFO))

B. What Are the Uses and Production Volumes of LCPFAC Chemical Substances?

PFOA, a member of the LCPFAC category, is a synthetic (man-made) chemical that does not occur naturally in the environment. The ammonium salt of PFOA was manufactured in U.S. for use primarily as an aqueous dispersion agent in the manufacture of fluoropolymers. Chemical Data Reporting (CDR) rule requires manufacturers (including importers) to report for PFOA if they meet 2,500 pounds production volume threshold at a single site. The last time PFOA manufacture was reported to EPA as part of this collection effort was for the 2016 reporting period. PFOA can also be created unintentionally by the degradation of some fluorotelomers, which are not manufactured using PFOA but could degrade to PFOA. Fluorotelomers are used to make polymers that impart soil, stain, grease, and water resistance to coated articles. Some fluorotelomer based products are also used as high-performance surfactants in products where an even flow is essential, such as paints, coatings, cleaning products, and fire-fighting foams for use

on liquid fuel fires (Ref. 3).

Through the 2010/2015 PFOA Stewardship Program, a voluntary risk reduction program, eight major manufacturers and processors of LCPFAC chemical substances committed to voluntarily work toward a phase-out of LCPFAC chemical substances (Ref. 4). All participating companies have met the PFOA Stewardship Program goals and have ceased the manufacture (including import) of the chemical substances listed in Tables 1 and 2 of this unit. As such, the reduced supply of long-chain perfluorinated chemicals has led industries to transition to replacement chemical substances for many uses, as noted in both public comments and industry communication. However, there are still a number of ongoing uses of these chemical substances by companies not participating in the PFOA Stewardship Program. EPA became aware of these uses through public comments identifying several ongoing uses. In the final rule, EPA will recognize and exclude from the significant new uses any confirmed ongoing activities for these chemicals. Ongoing uses identified by EPA are not significant new uses of LCPFAC chemical substances and therefore would not be subject to this rule and would not require a significant new use notice submission to the Agency.

The accompanying economic analysis for this supplemental proposed rule (Ref. 2) details which chemicals listed in Tables 1 and 2 of this unit were reported under the CDR rule (40 CFR 711) as manufactured (including imported) for 2015, the final year of the Stewardship Program (see Exhibits 2-1, 2-2, and 2-3 of the Economic Analysis). The production volumes have been withheld to protect confidential business information.

C. What Are the Potential Health Effects of LCPFAC Chemical Substances?

To date, PFOA has ~~LCPFACs have~~ been linked to a number of health effects, including thyroid disease and impacts on reproductive function (Refs. 5 and 6). 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, 7,-8, 9, and 10). 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. 11).

III. Rationale and Objectives

A. Rationale

This supplemental proposal presents the basis for the reasonable potential for exposure to LCPFAC chemical substances from this category of articles for purposes of TSCA section 5(a)(5). LCPFAC chemical substances have been found in the blood of the general human population, as well as in wildlife, indicating that exposure to these chemical substances is widespread (Ref. 3, 12, and 13). Multiple pathways of exposure, including through drinking water, food, house dust, and release from treated articles are possible (Ref. 14).

In the absence of a regulation, manufacture or processing for the significant new uses proposed on January 21, 2015 (Ref. 1), may begin at any time, without prior notice to EPA. As explained in the January 21, 2015, proposal (Ref. 1), EPA is concerned that commencement of the manufacture (including import) or processing for any new uses, including resumption of past uses, of LCPFAC chemical substances could increase the magnitude and duration of exposure to humans.

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical is not based on an extensive

evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the existence of a SNUR requires a notice, upon receipt of which EPA would conduct an assessment. If a person decides to begin importing any of these chemicals for a significant new use, the notice to EPA allows the Agency to evaluate the use according to the specific parameters and circumstances surrounding the conditions of use.

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

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 the category of articles that contain certain LCPFAC chemical substances as part of a surface coating for a non-ongoing use. EPA defines “articles where certain LCPFAC chemical substances are part of surface coating on articles” as the category of articles subject to this rule, 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 is not making a finding on the reasonable potential for exposure from articles that do not contain LCPFAC chemical substances as a surface coating.

i. Reasonable potential for exposure of LCPFAC from surface coatings.

A coating is a material applied in a thin layer to a surface as a protective, decorative, or functional film. This term often refers to paints such as lacquers or enamels, but also refers to films applied to other materials including, but are not limited to, paints, varnishes, sealants, adhesives, inks, maskants, and temporary protective coatings. 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).

The release of LCPFAC chemical substances from coatings on articles has been well-documented in the scientific literature. LCPFAC chemical substances can be released continuously over years from treated jackets, furniture, and carpets into the air due to volatilization (Refs. 17, 18, and 19) and due to degradation of commercial LCPFAC coatings by simple abiotic reaction with water (Ref. 20). Stone and tile sealants have been shown to contain extractable amounts of LCPFAC chemical substances and, for homes without carpeting, could be an indoor source of these chemical substances (Ref. 21).

Given the reasonable potential for exposure to LCPFAC chemical substances from articles that have LCPFAC chemical substances as part of a surface coating, EPA is proposing to require notification for the import of articles that have LCPFAC chemical substances as part of a surface coating. As noted in Section 1F, EPA is also seeking robust comment on implementing a *de minimis* threshold, an alternative threshold, or other criteria to assist in determining whether

the reasonable potential for exposure justifies notification to EPA. EPA is also seeking comment on a safe harbor provision.

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 cites these studies (Refs. 17, 18, 19, 20, and 21) to support the Agency's conclusion that there is reasonable potential for exposure from the category of articles that contain certain LCPFAC chemical substances as part of a surface coating.

ii. Proposed finding.

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 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. The defined subset are the chemical substances phased out through the 2010/2015 PFOA Stewardship Program, shown in Table 1 and Table 2 of Unit II.

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. 22). However, when added to the surface coating of an article, LCPFAC can be released over time with use (Refs. 3 and 20). Studies on the degradation of fluorotelomer-based polymers show that these polymers are subject to hydrolysis, photolysis and biodegradation, with half-lives of a few days to hundreds of years (Ref. 23). In addition, research by EPA on degradation of fluorotelomers and fluoropolymers has shown that some urethanes and acrylates biodegrade; however, half-lives and kinetics are not yet well-defined (Ref. 16). These studies have shown that the perfluorinated

portion of some polymers is released as the polymer is degraded by microbial or abiotic processes to form telomer alcohols or other intermediates and that they eventually form LCPFAC. 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).

Given that the release of LCPFAC chemical substances from surface coatings on articles has been shown to occur and that these releases can be expected to result in exposure to the users of articles, EPA has reason to anticipate that importing 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 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. 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 that might exist.

A person who imports any of the chemical substances identified in this supplemental proposed SNUR for a significant new use as part of a surface coating on an article would be subject to the significant new use notification requirements. No person would be able to begin importing, as part of a surface coating for an article, any of the LCPFAC chemical substances identified in this supplemental proposed SNUR, for a significant new use without first submitting a SNUN to EPA.

B. Objectives

Based on the considerations in Unit III.A., EPA wants to achieve the following objectives with regard to the significant new uses of LCPFAC chemical substances that are designated in the January 21, 2015, proposal (Ref. 1), including the articles identified in this supplemental proposal:

1. EPA would receive notice of any person's intent to import the chemical substances for the described significant new use before that activity begins.

2. EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins importing the chemical substances for the described significant new use.

3. EPA would be able to either determine that the significant new use is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.

IV. Economic Analysis

A. SNUNs

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). In the event that a SNUN is submitted, average costs are estimated at approximately \$23,000 per SNUN submission for large business submitters and about \$10,000 for small business submitters. These estimates include the cost to prepare and submit the SNUN (averaging about \$7,300), and the payment of a user fee. Businesses that submit a SNUN would be subject to either a \$16,000 user fee required by 40 CFR 700.45(c)(2)(ii), or, if they are a small business, a reduced user fee of \$2,800 (40 CFR 700.45(c)(1)(ii)). Businesses that submit a SNUN are also estimated to incur average costs of \$63 for rule familiarization. First time

submitters will incur an average cost of \$123 for CDX registration and associated activities. Companies importing articles containing LCPFAC chemical substances as part of a surface coating will incur an average cost of \$79 for notifying their customers of SNUR regulatory activities. EPA's complete economic analysis is available in the public docket for this rule (Ref. 2).

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 types of articles that may contain the subject chemical substance in a surface coating. This is because while some firms have an understanding of the contents of the articles they import or process other firms do not. EPA acknowledges that importers and processors of articles may have varying levels of knowledge about the chemical content of the articles that they import or process. These parties may need to become familiar with the requirements of the rule. And while not required by the SNUR, these parties may take additional steps to determine whether the subject chemical substances are part of the articles that they are considering for import or processing. This determination may involve activities such as gathering information from suppliers along the supply chain, and/or testing samples of the article itself. Costs vary across the activities chosen and the extent of familiarity a firm has regarding the articles it imports or processes. Cost ranges are presented in Understanding the Costs Associated with Eliminating Exemptions for Articles in SNURs (Ref. 24). Based on available information, EPA believes that article importers or processors that choose to investigate their products would incur costs at the lower end of the ranges presented in the Economic Analysis. For those companies choosing to undertake actions to assess the composition of the articles they import or process, EPA expects that importers would take actions that are commensurate with the company's

perceived likelihood that a chemical substance might be a part of an article for the significant new uses identified in Units II. and III., and the resources it has available. Example activities and their costs are provided in the accompanying Economic Analysis of this supplemental proposal (Ref. 2).

B. Export Notification

Under TSCA section 12(b) and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which, among other things, a rule has been proposed or promulgated under TSCA section 5. For persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical, depending on the number of required notifications (i.e., the number of countries to which the chemical is exported).

V. Scientific Standards, Evidence, and Available Information

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science, as applicable. These information sources supply information relevant to whether a particular use would be a significant new use, based on relevant factors including those listed under TSCA section 5(a)(2). Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to promulgate a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use; as such, the January 2015 proposed rule (Ref. 1) and this supplemental proposal are not based on an evaluation of expected risks.

The clarity and completeness of the data, assumptions, methods, quality assurance, and

analyses employed in EPA's decision are documented, as applicable and to the extent necessary for purposes of the January 2015 proposed rule and this supplemental proposal, in Unit II. and in the references cited throughout the two preambles. Considering the extent to which the various information, procedures, measures, methods, protocols, methodologies or models used in EPA's decision have been subject to independent verification or peer review, EPA believes that their use is appropriate in this rule. EPA recognizes, based on the available information, that there is variability and uncertainty in whether any particular significant new use would actually present an unreasonable risk. For precisely this reason, EPA is proposing to require notice and review for these uses at such time as they are known more definitely.

VI. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule. Proposed Rule. **Federal Register**. 80 FR 2885, January 21, 2015 (FRL-9915-63).
2. EPA. Economic Analysis of the Supplemental Proposal to the Significant New Use Rule for Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical Substances. January 23, 2020.
3. EPA. Long-Chain Perfluorinated Chemicals Action Plan. December 30, 2009.

Accessed at: https://www.epa.gov/sites/production/files/2016-01/documents/pfcs_action_plan1230_09.pdf.

4. EPA. Risk Management for Per- and Polyfluoroalkyl Substances (PFASs) under TSCA. Accessed at: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfass>.

5. Melzer, David, et al. "Association between serum perfluorooctanoic acid (PFOA) and thyroid disease in the US National Health and Nutrition Examination Survey." *Environmental health perspectives* 118.5 (2010): 686-692.

6. Knox, Sarah S., et al. "Implications of early menopause in women exposed to perfluorocarbons." *The Journal of Clinical Endocrinology & Metabolism* 96.6 (2011): 1747-1753.

7. Butt, Craig M., et al. "Levels and trends of poly-and perfluorinated compounds in the arctic environment." *Science of the Total Environment* 408.15 (2010): 2936-2965.

8. Houde, Magali, et al. "Biological monitoring of polyfluoroalkyl substances: a review." *Environmental Science & Technology* 40.11 (2006): 3463-3473.

9. Calafat, Antonia M., et al. "Polyfluoroalkyl chemicals in the US population: data from the National Health and Nutrition Examination Survey (NHANES) 2003–2004 and comparisons with NHANES 1999–2000." *Environmental Health Perspectives* 115.11 (2007): 1596.

10. Lau, Christopher, et al. "Perfluoroalkyl acids: a review of monitoring and toxicological findings." *Toxicological Sciences* 99.2 (2007): 366-394.

11. EPA. Health Effects Support Document for Perfluorooctanoic Acid (PFOA). EPA 822-R-16-003. May 2016.

12. EPA. Perfluoroalkyl Sulfonates; Significant New Use Rule; Final Rule. **Federal**

Register. 67 FR 11008, March 11, 2002 (FRL-6823-6).

13. 3M Company. The Science of Organic Fluorochemistry. St. Paul, Minnesota, February 5, 1999.

14. Strynar, Mark J., and Andrew B. Lindstrom. "Perfluorinated compounds in house dust from Ohio and North Carolina, USA." *Environmental Science & Technology* 42.10 (2008): 3751-3756.

15. Bohnet, Matthias. Ulmann's Encyclopedia of Industrial Chemistry. Wiley-Vch, 2003.

16. Plastics Industry Association. Guide to the Safe Handling of Fluoropolymer Resins. Fifth Addition. 2018.

17. Knepper, Thomas P., et al. "Understanding the exposure pathways of per-and polyfluoroalkyl substances (PFASs) via use of PFASs-containing products—risk estimation for man and environment." *Texte* 47 (2014): 2014.

18. Gremmel, Christoph, et al. "Systematic determination of perfluoroalkyl and polyfluoroalkyl substances (PFASs) in outdoor jackets." *Chemosphere* 160 (2016): 173-180.

19. Liu, Xiaoyu, et al. "Determination of fluorotelomer alcohols in selected consumer products and preliminary investigation of their fate in the indoor environment." *Chemosphere* 129 (2015): 81-86.

20. Washington, J.W., T.M. Jenkins. 2015. Abiotic hydrolysis of fluorotelomer polymers as a source of perfluorocarboxylates at the global scale. *Environmental Science & Technology*. 49. 14129-14135.

21. Guo, Zhishi, et al. "Perfluorocarboxylic acid content in 116 articles of commerce." Research Triangle Park, NC: US Environmental Protection Agency (2009).

22. EPA. Significant New Uses of Chemical Substances; Certain Chemicals; Final Rule.

Federal Register. 49 FR 35014, September 5, 1984 (FRL-2541-8).

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

24. U.S. EPA. Understanding the Costs Associated with Eliminating Exemptions for Articles in SNURs. May 1, 2013.

VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

The Office of Management and Budget (OMB) designated this to be a significant regulatory action and it was submitted to OMB for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of Executive Order 12866.

EPA prepared an economic analysis of the potential costs and benefits associated with this action. A copy of the economic analysis, entitled “Economic Analysis of the Supplemental Proposal to the Significant New Use Rule for Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical Substances” (Ref. 2), is available in the docket and is briefly summarized in Unit IV.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is expected to be subject to the requirements for regulatory actions specified

in Executive Order 13771 (82 FR 9339, February 3, 2017). EPA prepared an analysis of the estimated costs and benefits associated with this action (Ref. 2), which is available in the docket and is summarized in Unit I.E.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with existing chemical SNURs are already approved under OMB control number 2070-0038 (EPA ICR No. 1188); and the information collection activities associated with export notifications are already approved under OMB control number 2070-0030 (EPA ICR No. 0795). If an entity were to submit a SNUN to the Agency, the annual burden is estimated to be less than 100 hours per response, and the estimated burden for export notifications is less than 1.5 hours per notification. In both cases, burden is estimated to be reduced for submitters who have already registered to use the electronic submission system.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR, part 9, and included on the related collection instrument, or form, as applicable.

D. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, I certify that promulgation of this SNUR would not have a significant economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows.

A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a “significant new use.” By definition of the word “new” and based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. Since this SNUR will require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be. However, 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 handful of notices per year. During the six-year period from 2005-2010, only three submitters self-identified as small in their SNUN submission (Ref. 2). Based on this, EPA believes that few SNUN submissions will occur as a result of the rule. EPA believes the cost of submitting a SNUN, \$10,000 for small business submitters, is relatively small compared to the cost of developing and marketing a chemical new to a firm or marketing a new use of the chemical and that the requirement to submit a SNUN generally does not have a significant economic impact.

Therefore, EPA believes that the potential economic impact of complying with this proposed SNUR is not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published as a final rule on August 8, 1997 (62 FR 42690) (FRL-5735-4), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities.

E. Unfunded Mandates Reform Act (UMRA)

Based on EPA’s experience with proposing and finalizing SNURs, State, local, and

Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted by this rulemaking. As such, the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C. 1531-1538, do not apply to this action.

F. Executive Order 13132: Federalism

This action will not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have any effect on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this action does not address environmental health or safety risks, and EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of the Executive Order.

I. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This action is not a significant energy action as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have any effect on energy supply, distribution, or use.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve any technical standards and is therefore not subject to considerations under section 12(d) of NTTAA, 15 U.S.C.272 note.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). This action does not affect the level of protection provided to human health or the environment.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 20, 2020.

Andrew R. Wheeler,

Administrator.

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

PART 721--[AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. Revise § 721.10536 to read as follows:

§ 721.10536 Long-chain perfluoroalkyl carboxylate chemical substances.

(a) *Definitions.* The definitions in § 721.3 apply to this section. In addition, the following definition applies:

Carpet means a finished fabric or similar product intended to be used as a floor covering. This definition excludes resilient floor coverings such as linoleum and vinyl tile.

(b) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified in this paragraph, where $5 < n < 21$ or $6 < m < 21$, are subject to reporting under this section for the significant new uses described in paragraph (b)(4)(i) and (b)(4)(iv) of this section.

(i) $\text{CF}_3(\text{CF}_2)_n\text{-COO M}$ where $\text{M} = \text{H}^+$ or any other group where a formal dissociation can be made.

(ii) $\text{CF}_3(\text{CF}_2)_n\text{-CH=CH}_2$.

(iii) $\text{CF}_3(\text{CF}_2)_n\text{-C(=O)-X}$, where X is any chemical moiety.

(iv) $\text{CF}_3(\text{CF}_2)_m\text{-CH}_2\text{-X}$, where X is any chemical moiety.

(v) $\text{CF}_3(\text{CF}_2)_m\text{-Y-X}$, where Y = non-S, non-N heteroatom and where X is any chemical moiety.

(2) The chemical substances listed in Table 1 of this paragraph are subject to reporting under this section for the significant new uses described in paragraph (b)(4)(ii) of this section.

Table 1 to paragraph (b)—LCPFAC Chemical Substances Subject to Reporting After December 31, 2015

Chemical Name	CAS Registry No. (CASRN)	EPA Accession No.	TSCA Chemical Inventory Name
Perfluorooctyl iodide	507-63-1	N/A	Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-8-iodo-
Tetrahydroperfluoro-1-decanol	678-39-7	N/A	1-Decanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-
Perfluoro-1-dodecanol	865-86-1	N/A	1-Dodecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafuoro-
Perfluorodecyl iodide	2043-53-0	N/A	Decane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-10-iodo-
1,1,2,2-Tetrahydroperfluorododecyl iodide	2043-54-1	N/A	Dodecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heneicosafuoro-12-iodo-
Perfluorodecylethyl acrylate	17741-60-5	N/A	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafuorododecyl ester
1,1,2,2-Tetrahydroperfluorodecyl acrylate	27905-45-9	N/A	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester
1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12-Pentacosafuoro-14-iodotetradecane	30046-31-2	N/A	Tetradecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12-pentacosafuoro-14-iodo-
3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-Pentacosafuorotetradecan-1-ol	39239-77-5	N/A	1-Tetradecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-pentacosafuoro-
3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16-Nonacosafuorohexadecan-1-ol	60699-51-6	N/A	1-Hexadecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16-nonacosafuoro-
1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14-Nonacosafuoro-16-iodohexadecane	65510-55-6	N/A	Hexadecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14-nonacosafuoro-16-iodo-
Sodium;2-methylpropane-1-	68187-47-3	N/A	1-Propanesulfonic acid, 2-

sulfonate			methyl-, 2-[[1-oxo-3-[(.gamma.-.omega.-perfluoro- C4-16-alkyl)thio]propyl]amino] derivs., sodium salts
1,1,2,2-Tetrahydroperfluoroalkyl (C8-C14) alcohol	68391-08-2	N/A	Alcohols, C8-14, .gamma.-.omega.-perfluoro
Thiols, C8-20, gamma-omega-perfluoro, telomers with acrylamide	70969-47-0	N/A	Thiols, C8-20, .gamma.-.omega.-perfluoro, telomers with acrylamide
Silicic acid (H ₄ SiO ₄), sodium salt (1:2), reaction products with chlorotrimethylsilane and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptafluoro-1-decanol	125476-71-3	N/A	Silicic acid (H ₄ SiO ₄), sodium salt (1:2), reaction products with chlorotrimethylsilane and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptafluoro-1-decanol
Thiols, C4-20, gamma-omega-perfluoro, telomers with acrylamide and acrylic acid, sodium salts)	1078712-88-5	N/A	Thiols, C4-20, .gamma.-.omega.-perfluoro, telomers with acrylamide and acrylic acid, sodium salts
1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(2-((gamma-omega-perfluoro-C4-20-alkyl)thio)acetyl) derivs., inner salts	1078715-61-3	N/A	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-[2-[(.gamma.-.omega.-perfluoro-C4-20-alkyl)thio]acetyl] derivs., inner salts
Polyfluoroalkyl betaine (generic)	CBI	71217	Polyfluoroalkyl betaine (PROVISIONAL)
Modified fluoroalkyl urethane (generic)	CBI	89419	Modified fluoroalkyl urethane (PROVISIONAL)
Perfluorinated polyamine (generic)	CBI	274147	Perfluorinated polyamine (PROVISIONAL)

(3) The chemical substances identified as perfluorooctanoic acid (PFOA) and its salts, including those listed in Table 2 of this paragraph, are subject to reporting under this section for the significant new uses described in paragraph (b)(4)(iii) of this section.

Table 2 to paragraph (b)—PFOA and Examples of Its Salts

Chemical Name	CAS Registry No. (CASRN)	TSCA Chemical Inventory Name
Pentadecafluorooctanoyl fluoride	335-66-0	Octanoyl fluoride, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-

Perfluorooctanoic acid	335-67-1	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (PFOA)
Silver perfluorooctanoate	335-93-3	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, silver (+) salt (1:1)
Sodium perfluorooctanoate	335-95-5	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, sodium salt (1:1)
Potassium perfluorooctanoate	2395-00-8	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, potassium salt (1:1)
Ammonium perfluorooctanoate	3825-26-1	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, ammonium salt (1:1) (APFO)

(4) Significant new uses:

(i) The significant new use for chemical substances identified in paragraph (b)(1) of this section are: Manufacture (including import) or processing for use as part of carpets or to treat carpets (e.g., for use in the carpet aftercare market).

(ii) The significant new use for chemical substances identified in paragraph (b)(2) of this section are: Manufacture (including import) or processing for any use after December 31, 2015.

(iii) The significant new use for chemical substances identified in paragraph (b)(3) of this section are: Manufacture (including import) or processing for any use. 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.

(iv) The significant new use for chemical substances identified in paragraph (b)(1) of this section, except for those chemicals identified in Table 1 of paragraph (b)(2) of this section are: Manufacture (including import) or processing for any use other than that use already covered by paragraph (b)(4)(i) of this section.

(c) *Specific requirements.* (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 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.

(2) [Reserved]

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