

## PRE-PUBLICATION NOTICE

On Monday, June 22, 2020, Andrew R. Wheeler, the EPA Administrator, signed the following document:

Action: Final Rule.  
Title: Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate  
Chemical Substances; Significant New Use Rule  
FRL #: 10010-44  
Docket ID #: EPA-HQ-OPPT-2013-0225

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 721**

**[EPA-HQ-OPPT-2013-0225; FRL-10010-44]**

**RIN 2070-AJ99**

**Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical**

**Substances; Significant New Use Rule**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** Under the Toxic Substances Control Act (TSCA), the Environmental Protection Agency (EPA) is finalizing amendments to the significant new use rule (SNUR) for long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances that were proposed on January 21, 2015; an amendment to a SNUR for perfluoroalkyl sulfonate chemical substances that was proposed on January 21, 2015; and an amendment to make inapplicable the exemption for persons who import a subset of LCPFAC chemical substances as part of surface coatings on articles, which was proposed on March 3, 2020. This final rule requires persons to notify EPA at least 90 days before commencing the manufacture (including import) or processing of these chemical substances for the significant new uses described in this notice. The required significant new use notification initiates EPA's evaluation of the conditions of use associated with the significant new use. Manufacturing (including import) or processing for the significant new use are 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. As with any SNUR, this final rule excludes ongoing uses. Ongoing uses

cannot be subject to a SNUR.

**DATES:** This final rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2013-0225, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket 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](mailto: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](mailto: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 in the class of long-chain perfluoroalkyl carboxylate (LCPFAC) and perfluoroalkyl sulfonate chemical substances. 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:

- Manufacturers (including importers) of one or more of subject chemical substances (NAICS codes 325 and 324110); e.g., chemical manufacturing and petroleum refineries.
- Fiber, yarn, and thread mills (NAICS code 31311).
- Carpet and rug mills (NAICS code 314110).
- Home furnishing merchant wholesalers (NAICS code 423220).
- Carpet and upholstery cleaning services (NAICS code 561740).
- Manufacturers of computer and other electronic products, appliances, and components (NAICS codes 324 and 335).
- Manufacturers of surgical and medical instruments (NAICS 339112).
- Merchant wholesalers (NAICS codes 423 and 424).
- Stores and retailers (NAICS codes 442, 442, 444, 448, 451, 454).
- Providers of other support services (NAICS code 561990).

Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities.

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 final 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). TSCA section 5(a)(2) (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 the following factors:

- 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)(B)(i) 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)(A)(ii) (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. 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), EPA

proposed a SNUR for Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances (Ref. 1). In the **Federal Register** of March 3, 2020 (85 FR 12479) (FRL-10003-21) (Ref. 2), EPA supplemented the 2015 proposed SNUR 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 (Lautenberg 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.

EPA's response to public comments received on both the 2015 proposed rule and the 2020 supplemental proposed rule are provided in a Response to Comments document that is available in the docket and summarized in Unit XII. (Ref. 3). Please consult the **Federal Register** documents of January 21, 2015 (Ref. 1) and March 3, 2020 (Ref. 2) for further background information for this final rule.

This final SNUR will require persons to notify EPA at least 90 days before commencing:

1. The manufacturing (including importing) or processing of a subset of LCPFAC chemical substances for any use that was not ongoing after December 31, 2015;
  2. The manufacturing (including importing) or processing of all other LCPFAC chemicals substances for which there were no ongoing uses as of January 21, 2015 (the date of the original 2015 proposal);
  3. The import of a subset of LCPFAC chemicals as part of a surface coating on articles;
- and
4. The import of perfluoroalkyl sulfonate chemical substances as part of carpets.

This final SNUR will preclude the commencement of such manufacturing and processing



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 the **Federal Register** of April 24, 1990 (55 FR 17376; FRL-3658-5), EPA 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. 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 would be 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. This rule was published on January 21, 2015 and contains two significant new use dates. The first significant new use date is the date that the 2015 proposed rule published and applies to: the manufacturing or processing of all LCPFAC chemical substances, other than those listed in the list of LCPFAC chemical substances in Unit II.; the import of articles containing a subset of LCPFAC chemical substances as part of a surface coating; and the import of perfluoroalkyl sulfonate chemical substances as part of carpets. The second significant new use date is December 31, 2015, for the manufacturing or processing of a subset of LCPFAC chemical substances, those listed in the list of LCPFAC chemical substances in Unit II. for any use. The chemical substances listed in the list of LCPFAC chemical substances in Unit II. correspond to the chemical substances that the principal manufacturers and processors of LCPFAC chemical substances participating in the 2010/2015 PFOA Stewardship Program agreed to phaseout by the end of 2015. Ongoing uses are described in the Response to Comment for this rule (Unit XII. and Ref. 3) and are reflected in updates to the regulatory text.

In the supplement to the proposed rule (Ref. 2), EPA requested 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. Additionally, EPA requested 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 appreciates the comments received. In this final rule, EPA is not finalizing a de minimis threshold for determining “reasonable potential for exposure” or a safe harbor provision. EPA will, however, continue to engage with interested stakeholders on these two issues. A further discussion of the comments received relating to a de minimis threshold and a safe harbor provision are included in the Response to Comment for this rule (Unit XII. and Ref. 3).

*D. Why Is the Agency Taking this Action?*

These SNUR amendments are necessary to ensure that EPA receives timely advance notice of any future manufacturing (including importing) and processing of LCPFAC and perfluoroalkyl sulfonate chemical substances for new uses that may produce changes in human and environmental exposures. Additionally, section 7352 of the National Defense Authorization Act of 2020 mandates that EPA take final action on the 2015 proposal no later than June 22, 2020.

The rationale and objectives for this rule 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 manufacturers (including importers) and processors of the chemical substances included in this final rule. This Economic Analysis (Ref. 4), 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 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. 4), EPA provides example steps (and their respective costs) that an importer 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. EPA is unable to predict, however, what, if any, particular steps an importer might take; thus, potential total costs were not estimated. Importers may require suppliers to provide certificates of testing analysis of the products or perform their own laboratory testing of certain articles. An estimate of article testing cost is provided in Exhibit 3-7 of the Economic Analysis. While testing costs will vary depending on the specific chemical being tested for, the complexity of the article and sample preparation required, and the exact fees of the laboratory chosen for the analysis, an average of \$150 per article tested is given in the Exhibit.

## **II. Chemical Substances Subject to this Rule**

This final SNUR modifies the requirements for a subset of LCPFAC chemical substances in the existing SNUR at 40 CFR 721.10536 by:

1. Designating manufacturing (including importing) or processing of LCPFAC chemical substances listed in the list of LCPFAC chemical substances in this unit for any use that was no longer ongoing after December 31, 2015, as a significant new use; and
2. Designating manufacturing (including importing) or processing of perfluorooctanoic acid (PFOA) or its salts, which are considered LCPFAC chemical substances, and all other

LCPFAC chemical substances for any use not ongoing as of January 21, 2015, the date on which the proposed rule was published, as a significant new use.

For this final SNUR, EPA is also making the exemption at 40 CFR 721.45(f) inapplicable for persons who import LCPFAC chemical substances listed in the list of LCPFAC chemical substances in this unit and PFOA or its salts (see examples in this unit) as part of a surface coating on articles because there is reasonable potential for exposure to LCPFAC chemical substances, including PFOA, if these chemical substances are incorporated as surface coatings in articles and then imported. As was originally proposed in 2015, the article exemption still applies to LCPFAC chemical substances not listed in this unit or that are not PFOA or its salts, 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-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-).

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

- 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-Nonacosafuoro-16-iodohexadecane (CASRN 65510-55-6; TSCA Chemical Inventory Name: Hexadecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-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<sub>4</sub>SiO<sub>4</sub>), 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<sub>4</sub>SiO<sub>4</sub>), 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 perfluorinated 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 2015 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 are subject to the final rule. 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)).

EPA is also amending the existing SNUR at 40 CFR 721.9582 for perfluoroalkyl sulfonate chemical substances to make the exemption at 40 CFR 721.45(f) inapplicable for persons who import perfluoroalkyl sulfonate chemical substances as part of carpets, which is being finalized as proposed. The perfluoroalkyl sulfonate chemical substances for which EPA is

modifying an existing SNUR are currently listed in 40 CFR 721.9582(a)(1). In this rule, which is consistent with the proposal and 40 CFR 721.9582, the term perfluoroalkyl sulfonates refers to a category of perfluorinated sulfonate chemical substances of any chain length. In the 2015 proposed rule, as was past practice, perfluoroalkyl sulfonates chemical substances were referred to as “PFAS” chemical substances. EPA, however, recognizes that the acronym PFAS is now used for “perfluoroalkyl and polyfluoroalkyl substances.” Moving forward, EPA will use PFAS as an acronym for perfluoroalkyl and polyfluoroalkyl substances.

### **III. Rationale and Objectives**

#### *A. Rationale*

##### *1. Known Exposures to LCPFAC and Perfluoroalkyl Sulfonate Substances.*

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



drinking water, food, house dust, and release from treated articles, are possible (Ref. 18).

Perfluoroalkyl sulfonate chemical substances degrade ultimately to perfluoroalkylsulfonic acid (PFASA), which can exist in the anionic form under certain environmental conditions (Ref. 15). PFASA is highly persistent in the environment and has a tendency to bioaccumulate (Ref. 15). While most studies of perfluoroalkyl sulfonate chemical substances to date have focused primarily on perfluorooctane sulfonate (PFOS), structure-activity relationship analysis indicates that the results of those studies are applicable to the entire category. Available test data have raised concerns about their potential developmental, reproductive, and systemic toxicity (Refs. 5, 6, 13, and 19).

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 or processing for any new uses, including resumption of past uses, of LCPFAC and perfluoroalkyl sulfonate chemical substances could increase the magnitude and duration of exposure to humans and the environment.

The manufacture of LCPFAC chemical substances listed in Unit II. was discontinued after December 31, 2015, as committed by the principal manufacturers and processors of LCPFAC chemical substances participating in the 2010/2015 PFOA Stewardship Program. Given that these chemical substances have been discontinued, EPA expects the presence of LCPFAC chemical substances in humans and the environment to decline over time as has been observed in the past when production and use of other persistent chemicals have ceased (Ref. 20). At this time, EPA is aware, and has provided an exemption for, the processing of select chemical substances listed in Unit II. that continues from the use of existing stocks for specific

uses. The processing of existing stocks of these LCPFAC chemical substances is expected to decline over time as stocks of these chemicals are depleted. Similarly, EPA also expects ongoing uses of other LCPFAC chemicals substances to decline because the manufacture and processing for those uses have declined or ceased, as indicated by industry communication, market research, information submitted to EPA under the Chemical Data Reporting (CDR) rule, and comments received related to the proposed rule (Ref. 1) and supplement to the proposed rule (Ref. 2). In addition, EPA expects the presence of perfluoroalkyl sulfonate chemical substances to decline in humans and the environment because perfluoroalkyl sulfonates are no longer imported as part of carpets. EPA is concerned that the manufacturing or processing of these chemical substances for significant new uses could be reinitiated in the future. If reinitiated, EPA believes that such use could significantly increase the magnitude and duration of exposure to humans and the environment to these chemical substances.

### *2. Identification of Significant New Uses.*

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 use of a chemical substance is not based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, EPA's determination that a use constitutes a significant new use requires a notice, upon receipt of which EPA would conduct an assessment. If a person decides to begin manufacturing or processing 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.

### *3. Basis for Lifting the Article Exemption.*

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, which states that EPA “may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles” if EPA affirmatively finds in a rule under section 5(a)(2) that the reasonable potential for exposure to the chemical substance through the article or category of articles justifies notification. In the 2015 proposal (Ref. 1), 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. After careful consideration, and in order to align the 2015 proposed rule with the new requirements under TSCA, EPA issued a supplemental proposal to require submission of a significant new use notice for the import of a subset of LCPFAC chemical substances “as part of a surface coating on articles” as opposed to “all articles.” The supplemental proposal better defined the articles subject to the rule by defining the subject articles by the category: “imported articles where certain LCPFAC chemical substances are part of a surface coating on the articles.” While the 2020 supplemental and the 2015 proposed SNUR differ in language, EPA believes that the difference in impact will be minimal. LCPFAC chemical substances can be applied to articles as a surface coating. By lifting the articles exemption for articles that contain certain LCPFAC chemical substances as part of a surface coating, EPA believes that it has captured the majority of all article applications of these chemical substances. Other than instances where LCPFAC chemicals may be used to manufacture fluoropolymer membranes, EPA is unaware of any other uses of LCPFAC chemical substances in articles other than as a surface coating. EPA may propose future SNURs for the import of other articles containing LCPFAC chemical substances as appropriate.

Products such as paints and coatings, lubricants, and fire-fighting foam are not articles.

As defined at 40 CFR 704.3, article means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design. Examples of articles that could contain LCPFAC chemical substances as part of a surface coating include, but are not limited to, apparel, outdoor equipment, automotive parts, carpets, furniture, and electronic components.

As detailed in the March 3, 2020 supplemental proposal (Ref. 2), given that the release of LCPFAC chemical substances from surface coatings on articles has been shown to occur and that these releases can reasonably be expected to result in exposure to the users of articles and the general public (Refs. 21, 22, 23, 24, and 25), EPA has reason to anticipate that importing articles that have certain LCPFAC chemical substances as part of a surface coating would create a reasonable potential for exposure to these LCPFAC chemical substances, and that EPA should have an opportunity to review the use before such use could occur. Therefore, in light of the evidence before EPA (including the studies referenced below), 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 on articles. If a person wants to recommence a significant new use, existence of the SNUR ensures the submission of a SNUN, thereby allowing EPA to evaluate potential uses (before those uses would begin) for any hazards, exposures and risks that might exist.

During the public comment period for the supplemental proposal (Ref. 2), several

commenters questioned if EPA had adequately shown the reasonable potential for exposure from articles containing LCPFAC chemical substances as part of a surface coating or the risks associated with such potential exposure. One commenter asked that EPA provide linking data between presence of LCPFAC chemical substances in the general population and the release of LCPFAC chemical substances from coatings. EPA believes that the reasonable potential for exposure has been addressed through the studies cited in both this final rule and the supplement to the proposed rule (Refs. 2, 5, 23, 25, and 26). EPA has provided support that there is a reasonable potential for exposure through the citation of peer-reviewed literature, which documents that LCPFAC chemical substances either have the reasonable potential to migrate from articles or that LCPFAC chemical substances do migrate from articles. In order to require notification for the import or processing of an article under TSCA section 5, it is not necessary to definitively show or illustrate the mechanisms by which exposure to a chemical substance through an article may occur. Since the use designated as a significant new use does not currently exist, EPA defers a detailed consideration of potential exposures related to that use until there is a specific condition of use and data to review.

EPA's standard for an affirmative finding that there is a reasonable potential for exposure is in line with the intent of TSCA, as amended by the Lautenberg Act. Consistent with the statutory language requiring a reasonable potential for exposure (rather than a certainty of exposure), Congress did not intend for promulgation of a SNUR to require an exposure assessment or evidence that exposure to the substance through the article or category of articles will in fact occur. 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 a SNUR 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." (Ref. 27).

As stated in the supplemental proposal, 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. During the public comment period for the 2020 supplemental proposal (Ref. 2), several commenters asked EPA to define "surface coating" and to include a definition in the regulatory text. EPA is providing additional clarity on what is meant by a "surface coating" here and in the Response to Comment for this rule (Ref. 3) and does not intend to finalize a regulatory definition of "surface coating." EPA is not defining this term due to the many different ways that LCPFAC chemical substances could be applied to an article as part of a surface coating and how a given article could move through the supply chain from manufacture to disposal. EPA believes that this approach ensures that EPA will have the opportunity to conduct a detailed consideration of potential exposures related to these uses when there is a specific condition of use to review. If EPA receives a SNUN, EPA will evaluate the potential releases from the article with information specific to that article.

In the context of the LCPFAC SNUR, EPA considers any LCPFAC (from the list in Unit II. or PFOA and its salts) containing coating on any surface of any article to be covered by the SNUR. Regardless of whether they are applied to the interior facing surface or the exterior surface of an article, they are still a surface coating. The general nature of a coating is that a

coating, at one point or another, is applied to a surface. Additionally, EPA considers all coating layers and their chemical components, even when they are not the outermost layer of an article, to be included as part a “surface coating.” TSCA section 5(a)(2)(D) contemplates that EPA will consider its ability to review the reasonably anticipated, whole life-cycle impact (e.g., “manufacturing, processing, distribution in commerce, and disposal”) of a significant new use of a chemical substance. The potential for exposure to the chemical substance, including when it is in an article, may be larger during disposal or recycling than during the use of the chemical substance. Further, chemical substances that are ‘internal’ or applied to the ‘interior surface’ of an article may still result in exposure when used by consumers (Ref. 28). It is for these reasons that EPA considers that the rule broadly encompasses all articles with certain LCPFAC containing coatings on any surface, even if the user does not directly come into contact with the coating on the outer surface of the article.

Articles that have surface coatings that contain certain LCPFAC chemical substances that have been cured or undergone chemical reaction after being applied to an article are subject to this rule. Even when LCPFAC are bound within the matrix of the coating, they can still be released from the coating over time and present a reasonable potential for exposure. These surface coatings have been unambiguously shown to be a source of LCPFAC in the environment (Refs. 23, 25 29, and 30), even when adhered to surfaces in accordance with practices reported in patents (Refs. 23 and 25), and hence, present the reasonable potential for exposure to the chemical substance through the category of articles subject to the rule.

As noted in Unit V. of the proposed rule (Ref.1), EPA is retaining the exemption at 40 CFR 721.45(f) for persons who process chemical substances as part of articles because existing stocks of articles still contain LCPFAC or perfluoroalkyl sulfonate chemical substances. EPA

considers recycling to be a form of processing (Ref. 31). Because the processing of articles containing LCPFAC or perfluoroalkyl sulfonate chemical substances is ongoing, it cannot be subject to a SNUR. If EPA finds reason to believe that the processing of articles containing LCPFAC or perfluoroalkyl sulfonate chemical substances has ceased, EPA may issue a future SNUR on the processing of articles that contain these chemical substances. See Comment-Response 7 in the Response to Comment document for additional discussion of the ongoing processing of these chemical substances (Ref. 3).

#### *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 and perfluoroalkyl sulfonate chemical substances that are designated in the January 21, 2015, proposal (Ref. 1) and the March 3, 2020, supplemental proposal (Ref. 2):

1. EPA would receive notice of any person's intent to manufacture (including import) or process 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 manufacturing or processing 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. Significant New Use Determination**

According to TSCA section 5(a)(2), 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:

1. The projected volume of manufacturing and processing of a chemical substance.
2. The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
3. The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
4. 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 to determine what would constitute a significant new use of the LCPFAC and perfluoroalkyl sulfonate chemical substances subject to this final rule, as discussed in this unit. EPA considered relevant information about the toxicity of these substances, trends in blood levels, likely human exposures and environmental releases associated with possible uses, and the four factors listed in TSCA section 5(a)(2).

As discussed in Unit III.A., since the manufacture (including import) and processing of LCPFAC and perfluoroalkyl sulfonate chemical substances for these uses has been discontinued in the United States, exposure will decrease over time. EPA expects their presence in humans and the environment to decline over time. If any of the new uses of LCPFAC and perfluoroalkyl sulfonate chemical substances were to resume after having been phased out, EPA believes that such uses could both change the type and form and increase the magnitude and duration of human and environmental exposure to the substances, constituting a significant new use. Based on consideration of the statutory factors discussed herein, EPA has determined the following uses are significant new uses:

- Manufacturing (including importing) or processing of LCPFAC chemical substances listed in the list of LCPFAC chemical substances in Unit II. for any use that is no longer ongoing after December 31, 2015.

- Manufacturing (including importing) or processing of PFOA or its salts for any use not ongoing as of the date on which the proposed rule was published (Ref. 1).

- Manufacturing (including importing) or processing of all other LCPFAC chemical substances for any use not ongoing as of January 21, 2015, the date on which the proposed rule was published (Ref. 1).

EPA believes any new use of certain LCPFAC chemical substances as part of a surface coating of an article could increase the duration and magnitude of human and environmental exposure to the chemical substances, as discussed in the March 3, 2020, supplement to proposed SNUR (Ref. 2). Based on these considerations, EPA has determined that: Importing LCPFAC chemical substances listed in the list of LCPFAC chemical substances in Unit II. and PFOA or its salts (See Unit I. for examples of PFOA salts) as part of a surface coating of an article, for uses not ongoing as of the date on which the 2015 proposed rule was published (Ref. 1), constitutes a significant new use and warrants making the exemption at 40 CFR 721.45(f) inapplicable to importers of such articles.

Evidence supports that there is a reasonable potential for exposure to the chemical substances subject to this SNUR through their importation as part of a surface coating of an article. EPA should have an opportunity to review such uses before they can resume. Persons subject to this SNUR are required to notify EPA at least 90 days prior to commencing manufacture (including import) or processing of the chemical substances for the new use. This required notification provides EPA with the opportunity to evaluate any intended significant new

use of the regulated chemical substances and, if necessary, an opportunity to protect against potential unreasonable risks.

EPA has determined that the import of fluoropolymer dispersions and emulsions and articles containing fluoropolymers in articles is not a significant new use because, at the time of the 2015 proposed rule, EPA believed this use to be ongoing and did not propose to include this use in the SNUR. Ongoing uses cannot be subject to a SNUR. Since proposing the SNUR in 2015, EPA has received comment that the use fluoropolymer dispersions and emulsions made with PFOA has ceased. Because EPA did not propose and take comment on lifting the exemption for the import of fluoropolymer dispersions and emulsions, and fluoropolymers as part of articles, EPA has not included it in this final rule. At this time, EPA is not making inapplicable any of the standard exemptions at 40 CFR 721.45 for fluoropolymer dispersions and emulsions, and fluoropolymers as part of articles. Yet, EPA may issue a future SNUR on the manufacture and processing of fluoropolymer dispersions and emulsions and articles containing fluoropolymers.

In a previous rule (78 FR 62443, October 22, 2013; FRL-9397-1), EPA designated all uses of the perfluoroalkyl sulfonate chemicals identified in 40 CFR 721.9582 as significant new uses, except the ongoing uses specified in 40 CFR 721.9582 (a)(3) through (a)(5). The Agency has determined that the manufacture (including import) and processing of any of the perfluoroalkyl sulfonate chemical substances subject to this rule have been discontinued, including the importing of these chemical substances as part of carpets. EPA believes any new use of perfluoroalkyl sulfonate chemicals substances as part of carpets could increase the duration and magnitude of human and environmental exposure to the chemical substances, as discussed in the January 21, 2015, proposed SNUR (Ref. 1). The category of articles subject to

the SNUR has not been modified since the 2015 proposed rule; therefore, EPA does not need to modify any of its considerations in order to make the finding under section 5(a)(5). Based on the information provided in the 2015 proposed SNUR, EPA affirmatively finds under TSCA section 5(a)(5) that notification for import is justified by the reasonable potential for exposure to perfluoroalkyl sulfonate chemicals as part of carpets. Based on these considerations, EPA has determined that: Importing perfluoroalkyl sulfonate chemicals identified in 40 CFR 721.9582 as part of carpets, which were not ongoing as of January 21, 2015, the date on which the proposed rule was published (Ref. 1), constitutes a significant new use and warrants making the exemption at 40 CFR 721.45(f) inapplicable to importers of carpets.

#### **V. Applicability of the General Provisions**

The general provisions for SNURs appear under 40 CFR part 721, subpart A, and they apply to this rule except as modified by the rule. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. However, EPA is making the exemption at 40 CFR 721.45(f) inapplicable to persons who import LCPFAC chemical substances listed in the list of LCPFAC chemical substances in Unit II. and PFOA or its salts as part of a surface coating of an article (See Unit I. for examples of PFOA salts). Additionally, EPA is making the exemption at 40 CFR 721.45(f) inapplicable to persons who import perfluoroalkyl sulfonate chemicals substances listed in 40 CFR 721.9582 as part of carpets. As a result, persons subject to the provisions of this final rule would not be exempt from submitting a significant new use notice if they import those LCPFAC chemical substances, including PFOA or its salts, as part of a surface coating of an article or if they import perfluoroalkyl sulfonate chemical substances as part of carpets. However, EPA is retaining the exemption at 40 CFR

721.45(f) for persons who process chemical substances as part of an article because existing stocks of articles may still contain LCPFAC or perfluoroalkyl sulfonate chemical substances. Provisions relating to user fees appear at 40 CFR part 700. Additionally, TSCA, as amended by the Lautenberg Act, makes the provision at 40 CFR 721.45(h) inapplicable.

According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as described in 40 CFR part 720 for submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A), at least to the extent there is no conflict with the provisions at part 721. In addition, the information submission requirements of TSCA sections 5(b) and 5(d)(1) and the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5) apply to SNURs.

Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such other regulatory action as is required by TSCA section 5(a)(3) before the manufacturing (including importing) or processing for the significant new use can commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's finding.

Persons who export or intend to export a chemical substance identified in the proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. In accordance with 40 CFR 707.60(b), this final SNUR does not trigger notice of export for articles. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Such persons must certify that the shipment of the chemical substance complies

with all applicable rules and orders under TSCA, including any SNUR requirements. The TSCA section 13 import certification requirement applies to articles containing a chemical substance or mixture if so required by the Administrator by a specific rule under TSCA. At this time, EPA is not requiring import certification for these chemical substances as part of articles. The EPA policy on import certification appears at 40 CFR part 707, subpart B.

## **VI. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule**

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376) (FRL-3658-5) (Ref. 32), EPA has decided that the intent of TSCA section 5(a)(1)(B) best served by designating a use as a significant new use as of the date of publication of the proposed rule (including the posting of a pre-publication copy of the rule) rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish significant new uses, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who began commercial manufacture or processing of LCPFAC and perfluoroalkyl sulfonate chemical substances after the proposal was published on January 21, 2015, must cease such activity before the effective date of this final rule. These persons would have to comply with all applicable SNUR notice requirements and wait to resume the commercial manufacture or processing of the subject chemical substances until EPA has made a determination. 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 would be 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. Public commenters on the proposed

rule and the supplement to the proposal identified ongoing uses, which have been captured in the Response to Comments in Unit XII. (Ref. 3) and are not covered by this SNUR. Ongoing uses cannot be subject to a SNUR.

## **VII. Development and Submission of Information**

EPA recognizes that TSCA section 5 does not usually require developing new information (e.g., generating test data) before submission of a SNUN; however, there is an exception: development of information is required where the chemical substance subject to the SNUR is also subject to a rule, order, or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)). Also pursuant to TSCA section 4(h), which pertains to reduction of testing of vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies or NAMs), if available, to generate any recommended test data. EPA encourages dialogue with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h).

In the absence of a TSCA section 4 test rule covering the chemical substance, persons are required to submit only information in their possession or control and to describe any other information known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25, and 40 CFR 720.50). However, as a general matter, EPA recommends that SNUN submitters include information that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacturing (including importing), processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific information it believes may be useful in evaluating a significant new use.

Submitting a SNUN that does not itself include information sufficient to permit a reasoned evaluation may increase the likelihood that EPA will either respond with a determination that the information available to the Agency is insufficient to permit a reasoned evaluation of the health and environmental effects of the significant new use or, alternatively, that in the absence of sufficient information, the manufacturing (including importing), processing, distribution in commerce, use, or disposal of the chemical substance may present an unreasonable risk of injury to health or the environment.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs and define the terms of any potentially necessary controls if the submitter provides detailed information on human exposure and environmental releases that may result from the significant new uses of the chemical substance.

### **VIII. SNUN Submissions**

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what information may be useful in evaluating a significant new use. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the chemical substance. According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 40 CFR 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

### **IX. Economic Analysis**



#### *A. SNUNs*

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substance included in this final rule (Ref. 4). 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 \$7,100), 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)). The costs of submission of SNUNs will not be incurred by any company unless a company decides to pursue a significant new use as defined in this final SNUR. EPA's complete economic analysis is available in the public docket for this rule (Ref. 4).

#### *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 each calendar year 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).

#### *C. Import of Chemical Substances as Part of an Article*

In making inapplicable the exemption relating to persons who import certain LCPFAC chemical substances as part of the surface coating of an article, this action may affect firms that

plan to import types of articles that may contain the subject chemical substances in a surface coating. This is because while some firms have an understanding of the contents of the articles they import other firms do not. EPA acknowledges that importers of articles may have varying levels of knowledge about the chemical content of the articles that they import. 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. 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. Cost ranges are presented in Understanding the Costs Associated with Eliminating Exemptions for Articles in SNURs (Ref. 33). Based on available information, EPA believes 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 those companies choosing to undertake actions to assess the composition of the articles they import, EPA expects that importers will 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 final rule (Ref. 4).

## **X. Alternatives**

Before proposing this SNUR, EPA considered the following alternative regulatory action:  
Promulgate a TSCA section 8(a) Reporting Rule.

Under a TSCA section 8(a) rule, EPA could, among other things, generally require

persons to report information to the Agency when they manufacture (including import) or process a chemical substance for a specific use or any use. However, for LCPFAC and perfluoroalkyl sulfonate chemical substances, the use of TSCA section 8(a) rather than SNUR authority would have several limitations. First, if EPA were to require reporting under TSCA section 8(a) instead of TSCA section 5(a), that action would not ensure that EPA receives timely advance notice of future manufacturing (including importing) or processing of LCPFAC chemical substances (including as part of an article and components thereof) for new uses that may produce changes in human and environmental exposures. Nor would action under 8(a) ensure that an appropriate determination (relevant to the risks of such manufacturing (including importing) or processing) has been issued prior to the commencement of such manufacturing (including importing) or processing. Furthermore, a TSCA section 8(a) rule would not ensure that manufacturing (including importing) or processing for the significant new use cannot proceed until EPA has taken 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 manufacture (including import), 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)).

In view of the health concerns about LCPFAC and perfluoroalkyl sulfonate chemical substances if used for a significant new use, EPA believes that a TSCA section 8(a) rule for this substance would not meet EPA's regulatory objectives at this time.

## **XI. 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), the 2020 supplemental proposal (Ref. 2), and this final rule 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, the 2020 supplemental proposal, and this final rule, in Unit III. and in the references cited throughout the three 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 definitively.

## **XII. Response to Public Comment**

The Agency reviewed and considered all comments received related to the 2015 proposed rule (Ref. 1) and the 2020 supplement to the proposed rule (Ref. 2). Copies of all comments are available in the docket for this action (EPA-HQ-OPPT-2013-0225). Responses to all comments received are in the document titled: “Response to Comments on the Proposed Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule (SNUR)” (Ref. 3), which is also available in the docket. Six primary comments, covering the majority of the issues raised by the comments received, are included below.

*1. Comment:* Several commenters claimed ongoing uses of LCPFAC, PFOA, or perfluoroalkyl sulfonate chemical substances and requested that EPA modify the proposed SNUR to specifically recognize and exclude from the definition of 'significant new uses' certain ongoing activities that do not appear to have been previously identified by the Agency to be ongoing. Some commenters reiterated ongoing uses that EPA had already identified as ongoing. One commenter suggested that EPA should define ongoing uses “in a manner that is not company specific.” Several commenters requested that EPA designate “use in semiconductor processing, manufacturing or semiconductor component assembly” as not a significant new use for LCPFAC chemical substances and maintain the exemption under 40 CFR 721.45(f) for all on-going uses in the semiconductor industry. Two commenters asked EPA to exempt medical supplies or other equipment that may be used during the COVID-19 public health emergency. See the Response to Comment document (Ref. 3) for the specific Docket IDs for these comments.

*Response:* EPA reviewed all ongoing use claims, requested additional information from commenters to clarify the claims, and has recognized and excluded from the definition of 'significant new uses' certain ongoing activities for certain chemicals. Exclusions from the definition of 'significant new uses' are included with the regulation amendment at 40 CFR 721.10536(b)(5) thru (17), found under List of Subjects in 40 CFR Part 721.

While reviewing ongoing use claims, EPA found chemical substances that did not fall within the scope of the SNUR. Additionally, during communication with commenters that supplied ongoing use claims, EPA discovered that in some instances commenters had ceased the use of their reported chemical substance. Accordingly, EPA has not recognized and excluded from the definition of 'significant new uses' ongoing use claims that fall outside the scope of the SNUR, have ceased by the date of issuance of the final rule, or were unable to be substantiated.

During the comment response process, EPA reached out to one commenter who was unable to supply substantiation of their claim, yet stated that their ongoing use claim was captured in communication from the supplier directly with EPA. As such, their ongoing use claim was reviewed and has been addressed in the comment submitted by commenter's supplier.

With regards to the use of LCPFAC chemical substances by the semiconductor industry, it has not been EPA's practice to identify an industry as a whole when recognizing ongoing uses. Commenters stated that LCPFAC chemical substances used in the semiconductor industry may be present in surfactants, coatings, seals, gaskets, hoses, motors, electrical wiring, tools, robots, parts, ancillary equipment, and other components but were unable to provide specific information such as a Safety Data Sheet or other documentation to support their claim. EPA was only able to verify ongoing uses within the semiconductor industry in a subset of the claims made, which have been recognized in 40 CFR 721.10536.

During public comment for the supplemental rule (Ref. 2), EPA received two comments stating ongoing uses of LCPFAC chemical substances used in medical supplies, medical equipment, and for pharmaceutical or biopharmaceutical research applications that may be important to the COVID-19 pandemic response. EPA agrees that ongoing uses, especially ones critical to COVID-19 pandemic response, should not be restricted by this SNUR. TSCA section 3(2)(B) excludes devices regulated under the Federal Food, Drug, and Cosmetic Act from the definition of a chemical substance under TSCA. Gloves (21 CFR 880.6250), gowns (21 CFR 880.6265), and masks are all listed separately as devices in FDA's regulations and such devices would not be covered by this SNUR. However, it is important to note that other face masks, gloves, and personal protective equipment that are marketed to the general public for general, non-medical purposes, would be covered by the SNUR if the use is not ongoing. As with other verified ongoing uses, EPA has also exempted the ongoing uses of certain LCPFAC chemical substances used in pharmaceutical and biopharmaceutical research from this rule. EPA, however, has not broadly exempted all uses of LCPFAC chemical substances used in pharmaceutical and biopharmaceutical research because only a select number of applications are ongoing.

When possible, EPA has made explicit chemical and use specific exclusions from the definition of 'significant new uses' rather than broad industry or categorical exclusions. As reflected by the exclusions in the final rule, ongoing activities include manufacturing (including import) or processing of these chemical substances. EPA will continue to work with industry to phase out LCPFAC, PFOA and its salts, and perfluoroalkyl sulfonate chemical substances and will review the need to promulgate future rules as necessary. As a result of public comments received, EPA recognizes manufacture, import, or processing of certain LCPFAC chemical substances for the following uses as ongoing:

- Use of LCPFAC chemical substances for use in an antireflective coating, photoresists, or surfactant for use in photomicroolithography and other process to produce semiconductors or similar components of electronic or other miniaturized devices.
- Use of 2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester (CASRN 27905-45-9) as a coating or component of a hydrophobic and/or oleophobic coating or barrier applied to manufactured articles or component of articles using an energy source or plasma deposition methods, which include a pulse deposition mode. Examples of such articles include: electronic devices and components thereof, medical consumables and bio-consumables, filtration devices and filtration materials, clothing, footwear and fabrics.
- Use of Silane, trichloro(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl)- (CASRN 78560-44-8) as a surface treatment to make low refractive index resin for optical applications; surface treatment for minerals, particles and inorganic surfaces for hydrophobicity; and monomer to make specialty resins hydrophobic.
- Use of Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (CASRN 335-67-1) as a surfactant and coating as part of the following articles: stickers, labels, and parts to which those stickers and labels are attached.
- Use of 1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3-[(gamma.-omega.-perfluoro-C4-16-alkyl)thio]propyl]amino] derivs., sodium salts (CASRN 68187-47-3); Thiols, C8-20, gamma.-omega.-perfluoro, telomers with acrylamide (CASRN 70969-47-0); or Perfluorinated polyamine (generic) (ACC274147) as a component in fire extinguishing agent.
- Use of Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (CASRN 335-67-1); Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, sodium salt (1:1) (CAS No. 335-95-5); or Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, ammonium salt (1:1)



(CASRN 3825-26-1) in automotive articles, both in factory assembly and replacement parts.

- Use of Poly(difluoromethylene), .alpha.,.alpha.'-[phosphinicobis(oxy-2,1-ethanediyl)]bis[.omega.-fluoro-, ammonium salt (1:1) (CASRN 65530-70-3); Poly(difluoromethylene), .alpha.-fluoro-.omega.-[2-(phosphonooxy)ethyl]-, ammonium salt (1:1) (CASRN 65530-71-4); or Poly(difluoromethylene), .alpha.-fluoro-.omega.-[2-(phosphonooxy)ethyl]-, ammonium salt (1:2) (CAS No. 65530-72-5) in the manufacturing of architectural coatings or wood coatings, at a maximum concentration of 0.1% by weight.

- Use of Poly(difluoromethylene), .alpha.,.alpha.'-[phosphinicobis(oxy-2,1-ethanediyl)]bis[.omega.-fluoro-, ammonium salt (1:1) (CASRN 65530-70-3); Poly(difluoromethylene), .alpha.-fluoro-.omega.-[2-(phosphonooxy)ethyl]-, ammonium salt (1:1) (CASRN 65530-71-4); or Poly(difluoromethylene), .alpha.-fluoro-.omega.-[2-(phosphonooxy)ethyl]-, ammonium salt (1:2) (CAS No. 65530-72-5) in the manufacturing of industrial primer coatings for non-spray applications to metal by coil coating application, at a maximum concentration of 0.01% by weight.

- Use of Alcohols, C8-14, .gamma.-.omega.-perfluoro (CASRN 68391-08-2) in the manufacture of coatings and finishes for a variety of textile, leather, and hard surface treatments, and in the manufacture of wetting agents.

- Use of Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, ether with .alpha.-fluoro-.omega.-(2-hydroxyethyl)poly(difluoromethylene) (1:1) (CASRN 65545-80-4) in water-based inks.

- Use of Poly(difluoromethylene), .alpha.-[2-[(2-carboxyethyl)thio]ethyl]-.omega.-fluoro-, lithium salt (1:1) (CASRN 65530-69-0) in photo media coatings.

- Use of Ethanol, 2,2'-iminobis-, compd. with .alpha.-fluoro-.omega.-[2-

(phosphonooxy)ethyl]poly(difluoromethylene) (2:1) (CASRN 65530-63-4); Ethanol, 2,2'-iminobis-, compd. with .alpha.,.alpha.'-[phosphinicobis(oxy-2,1-ethanediyl)]bis[.omega.-fluoropoly(difluoromethylene)] (1:1) (CASRN 65530-64-5); or Ethanol, 2,2'-iminobis-, compd. with .alpha.-fluoro-.omega.-[2-(phosphonooxy)ethyl]poly(difluoromethylene) (1:1) (CASRN 65530-74-7) in paints and coatings, grouts, and sealers.

- Use of Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, ether with .alpha.-fluoro-.omega.-(2-hydroxyethyl)poly(difluoromethylene) (1:1) (CASRN 65545-80-4) in paints, coatings, ink jet inks, and ink masterbatch.

- Use of 1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3-[(.gamma.-.omega.-perfluoro-C4-16-alkyl)thio]propyl]amino] derivs., sodium salts (CASRN 68187-47-3) in adhesives.

2. *Comment:* Several commenters believe that the lack of LCPFAC CAS numbers and the generic identification of PFOA and its salts provide insufficient information for entities to understand what chemicals the rule encompasses. They believe that EPA must define the universe of covered chemicals that would be subject to the regulation. See the Response to Comment document (Ref. 3) for the specific Docket IDs for these comments.

- *Response:* TSCA section 26(c) expressly recognizes that an action may be taken with respect to a category of chemical substances or mixtures based on chemical structure, and EPA believes the most precise way to identify the chemicals subject to this SNUR is through the chemical structure definition. Downstream customers should have sufficient information from suppliers (i.e., CAS registry number and unique chemical identity) to generate the specific structure for any potentially reportable substance and compare to the LCPFAC category definition.

As a convenience to the regulated community, EPA has made available in the public

docket an illustrative list of chemical substances subject to the rule (Ref. 34). As part of that list, EPA has provided specific examples of chemicals that meet the various components of the LCPFAC category definition. The list is not exhaustive, but rather provides a guide to help readers determine whether this rule applies to them.

Additionally, Congress added certain active LCPFAC chemical substances to the Toxics Release Inventory (TRI) list. These chemicals were added to the TRI list under section 7321(b)(1) of the National Defense Authorization Act of fiscal year 2020. TRI added both LCPFAC and perfluoroalkyl sulfonate chemical substances that were identified as active in commerce on the TSCA inventory that was published in February 2019. While this list includes only LCPFAC chemicals on the active inventory, it may assist the regulated community in determining whether or not a given chemical substance is subject to this rule. The list can be found on EPA's website and a citation is included in Unit XIII. (Ref. 35).

*3. Comment:* Several commenters provided 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. Some comments supported the establishment of a threshold while others opposed the idea of a de minimis threshold. One commenter recommended a standard default de minimis threshold of 0.1% for articles for all SNURs. One commenter did not have an opinion on the establishment of a threshold or as a de minimis exemption but did state that they were "interested in EPA establishing a characterization of the 'reasonable potential for exposure' what might be 'reasonably ascertainable' with specific criteria for determining this." See the Response to Comment document (Ref. 3) for the specific Docket IDs for these comments.

*Response:* EPA appreciates the comments received. EPA is not establishing a de minimis

threshold for determining “reasonable potential for exposure” in this final rule. EPA will, however, continue to engage with interested stakeholders on this issue and continue to consider whether guidance for applying this standard may be appropriate in the future, whether as a general matter or, for instance, as applied to specific categories of substances or potential exposures.

As a general proposition, EPA believes that TSCA section 5(a)(5) actions should be considered on a case-by-case basis. Each time EPA considers requiring notification under TSCA section 5(a)(5), EPA will have to consider whether the “reasonable potential for exposure” to the chemical substance through the article or category of articles justifies notification. Since the use designated as a significant new use does not currently exist, EPA is deferring a detailed consideration of potential exposures related to that use until there is a specific condition of use and data to review. If EPA receives a SNUN, EPA would evaluate the potential releases from the article and with information specific to that article.

TSCA section 5(a)(5) does not establish an explicit threshold that an exposure must meet in order to be considered a “reasonable potential for exposure” or to “justify notification.” Rather, 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 there is evidence that a chemical substance is or may be released from an article such that there is a reasonable potential of exposure to the chemical substance, EPA thinks the Agency can reasonably find the statutory criterion to be met in most or all cases.

For this final rule, EPA believes that the reasonable potential for exposure was adequately demonstrated by the studies cited in both the 2015 proposed rule (Ref. 1) and the 2020 supplement to the proposed rule (Ref. 2). The studies cited during the rulemaking process represent the exposures that could result from the significant new uses subject to the SNUR. In showing that releases have been documented from articles using LCFAC chemical substances as a surface coating (Refs. 21, 22, 23, 24, and 25), EPA asserts that the statutory standard has been met to show that there is reasonable potential for exposure from these significant new uses. EPA also concludes, on the record before it, that this reasonable potential for exposure justifies notification.

*4. Comment:* Several commenters provided 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. Some comments supported the establishment of a safe harbor provision while others opposed the idea of a safe harbor provision. One commenter recommended that EPA “establish a rebuttable presumption that a SNUN is not required for an imported article if the foreign supplier of that article certifies in writing that the article (including all components of the article) was not manufactured using any of the substances identified in the Supplemental Proposal.” Another commenter asked that EPA allow importers to rely on supplier/manufacture certifications for purposes of compliance. Related to the idea of a safe harbor provision, several commenters emphasized complex supply chains that comprise many industries and the difficulties this would pose when determining if an article contains a subject chemical substance. See the Response to Comment document (Ref. 3) for the specific Docket IDs for these comments.

*Response:* EPA appreciates the comments received. EPA is not establishing a safe harbor

provision in this final rule. 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 process. EPA provided notice to importers in the 2015 proposed rule and again provided notice of the proposed requirements in the 2020 supplemental proposal. A safe harbor approach undermines the regulatory process for what uses are allowed by permitting a manufacturer to claim a use was ongoing at the time the SNUR was issued. For this final rule, EPA does not believe there should be a safe-harbor provision for uses not identified as ongoing uses in the SNUR, particularly since notice of the requirements of this action were provided five years ago. As part of the public comment period for the proposed rule and supplemental to the proposed rule, EPA received comments of ongoing uses of LCPFAC chemical substances as part of a surface coating on articles and has recognized those uses as ongoing because ongoing uses are not subject to SNURs. Similarly, a general safe-harbor provision may provide incentives for importers to not submit comments to EPA during the public comment period regarding ongoing uses not recognized in a proposed rule, because an importer who fails to submit such comments, and thus to acknowledge such uses, would be more easily able to claim that it did not realize the subject chemical substance was in its product. An importer could potentially use a safe harbor provision to justify a lack of involvement in a rule making because the importer would have the opportunity to identify chemicals later. The importer could avoid participation early on because he could wait to see if anyone else submitted comments and even if there are no comments on his chemical use, he has the alternative to use the safe harbor to challenge the rule.

While EPA acknowledges that imported articles may have a complex supply chain, the most effective method to ensure that certain LCPFAC chemical substances in this SNUR are not present in the surface coating of imported articles is to encourage importers to know with

specificity the contents of what they are importing and to work with their foreign manufacturers to ensure that an article does not contain certain LCPFAC chemical substances in surface coatings.

Even though 19 CFR 12.119 allows EPA to establish TSCA section 13 import certification requirements for chemicals in articles, EPA did not propose to require TSCA section 13 import certification for the subject chemical substances when part of articles. Considering the use of these chemicals in articles covered by this SNUR are no longer ongoing, requiring TSCA section 13 import certification seems an unnecessary requirement to include in the SNUR. This is consistent with EPA's past practice of making the exemption at 40 CFR 721.45(f) inapplicable without also requiring import certification or export notification for these chemical substances as part of articles (40 CFR 721.2800; 40 CFR 721.10068). With or without an import certification requirement, it is the importer that is “responsible for [e]nsuring that chemical importation complies with TSCA just as domestic manufacturers are responsible for [e]nsuring that chemical manufacture complies with TSCA.” 40 CFR 707.20(b)(1).

EPA is not establishing a rebuttable presumption for this rule as one commenter suggested. EPA, however, may consider the factors discussed in EPA’s import policy that may obviate or mitigate penalties for violations with the import of articles, as described at 40 CFR 707.20(c)(1)(iii). The language at 40 CR 707.20(c)(1)(iii) states that “[...] EPA realizes that sometimes importers may not have actual knowledge of the chemical composition of imported mixtures. In these cases, the importer should attempt to discover the chemical constituents of the shipment by contacting another party to the transaction (e.g., his principal or the foreign manufacturer). This person may be able to identify the components of the mixture, or at least state that the substances comply with TSCA. The greater the effort an importer makes to learn

the identities of the imported substances and their compliance with TSCA, the smaller his chance of committing a violation by importing a noncomplying shipment. If a shipment is ultimately determined to have violated TSCA, the good faith efforts of the importer to verify compliance, as evidenced by documents contained in his files, may obviate or mitigate the assessment of a civil penalty under section 16 of TSCA.”

EPA recognizes the complexities of imports. EPA will take into consideration compliance certification and other documents demonstrating that the importer relied on the supplier. EPA will also continue to engage with interested stakeholders on how to ensure compliance with this and future rules. Additionally, EPA maintains the TSCA Hotline and responds to questions from industry. responds to industry questions.

5. *Comment:* Several commenters raised concern over the issue of impurities, stating that the impurity levels of PFOA and its salts cannot be completely eliminated. Additionally, commenters reported that fluorinated substances that do not fall into the scope of the SNUR may degrade into in-scope LCPFAC substances. One commenter stated that their imported article contained residual LCPFAC from the use of polytetrafluoroethylene (PTFE) production, outside the US; the commenter further indicated that their PTFE supplier is currently working to develop an LCPFAC-free product, but at this time the use is ongoing. Also, a comment stated that it is not possible for end users to determine the presence of a given chemical substance, making it difficult for determining "intended use" vs. "impurity".

As a result of the impurity concerns, multiple commenters requested that EPA require suppliers to provide Certificate of Compliance to importers. One comment suggested that the SNUR include all fluoropolymer resins “made with” LCPFACs and exempt such products “made



without” LCPFACs, even if such products may nevertheless bear trace amounts of LCPFACs due to cross-contamination, to encourage importers to demonstrate compliance by obtaining Certificates of Compliance from their overseas suppliers. See the Response to Comment document (Ref. 3) for the specific Docket IDs for these comments.

*Response:* To the extent the chemical substance subject to the SNUR is only “unintentionally present” at the point of foreign manufacture, it is already exempt from reporting by the importer as an imported impurity. See 40 CFR 721.45(d). As such, importers are not required to submit a SNUN for or report on a substance based simply on that substance's presence as an impurity (i.e., a chemical substance is unintentionally present with another chemical substance, 40 CFR 720.3(m)). Additionally, the impurity exemption at 40 CFR 721.45(d) includes domestic manufacture and processing.

EPA is aware of the issues related to perfluorinated chemical impurities and polymer degradation. Given that the Agency did not propose to require a certification procedure, it does not agree that a certification procedure should be specified and incorporated into the final rule. However, the Agency continues to study this issue and has not ruled out a later proposal to require import certification for these chemical substances as part of articles.

With or without an import certification requirement, it is the importer that is “responsible for [e]nsuring that chemical importation complies with TSCA just as domestic manufacturers are responsible for [e]nsuring that chemical manufacture complies with TSCA.” 40 CFR 707.20(b)(1).

With regards to providing an additional exemption to importers on the basis of being unable to determine the presence of a given chemical substance, or an inability to determine whether a use is "intended " vs. an "impurity", any exemption would create a safe-harbor for

importers based on lack of knowledge, thus creating incentives for foreign suppliers to deliberately withhold information from importers. This could greatly reduce the efficacy of this SNUR.

*6. Comment:* Several commenters requested that EPA consider promulgating TSCA section 6(a) rules to directly restrict perfluoroalkyl and polyfluoroalkyl substances (PFAS) and complete planned development of a detailed assessment to determine if PFAS chemical substances presents an unreasonable risk. See the Response to Comment document (Ref. 3) for the specific Docket IDs for these comments.

*Response:* TSCA section 6(a) states that “[i]f the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment” the Administrator shall take action under TSCA section 6(a). While EPA appreciates the commenters request to promulgate a rule in accordance with this provision, EPA is not doing so at this time. Rather, at this time EPA believes that a rule under TSCA section 5(a)(2), in conjunction with the 2010/2015 PFOA Stewardship Program, is an effective method to protect human health and the environment from any risks posed by LCPFAC and perfluoroalkyl sulfonate chemical substances.

Through the 2010/2015 PFOA Stewardship Program, a voluntary risk reduction program, eight major fluoropolymer and telomer manufacturers and processors committed to voluntarily work toward a phase-out of LCPFAC chemical substances (Ref. 36). As such, the reduced supply of long-chain perfluorinated chemicals has led industries to more quickly transition to alternative chemical substances, as noted in both public comments and industry communication. For persons subject to this SNUR, they are required to notify EPA at least 90 days prior to

commencing manufacture or processing of these chemical substances. This required notification provides EPA with the opportunity to evaluate any significant new use of the regulated perfluorinated chemical substances and, if necessary, protect against potential unreasonable risks. EPA continues to review the manufacturing, import, and processing of the ongoing uses of these substances of concern. If EPA has reason to believe that either a use of these chemical substances is no longer ongoing or that a TSCA section 6(a) rule would better regulate LCPFAC and perfluoroalkyl sulfonate chemical substances, EPA will consider taking further regulatory action.

### **XIII. References**

The following is a list of the documents that are specifically referenced in this document. The docket includes these documents, as well as other information considered by EPA that are not listed below, including documents that are referenced within the documents that are included in the docket. For assistance in locating docket items, 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. Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule. Supplemental Proposal. **Federal Register**. 85 FR 12479, March 3, 2020 (FRL-10003-21).

3. EPA. Response to Comments on the Proposed Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule (SNUR). June 19, 2020.

4. EPA. Economic Analysis of the Final Significant New Use Rule for Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical Substances. June 19, 2020.

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

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

67 FR 72854, December 9, 2002 (FRL-6823-6).

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of Their Occurrence and Fate. *Journal of Environmental Monitoring*. 13: 20-31. 2011.

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18. 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.

19. EPA. Perfluoroalkyl Sulfonates; Proposed Significant New Use Rule; Proposed Rule. **Federal Register**. 67 FR 11014, March 11, 2002 (FRL-6823-7).

20. Kato, K. et al. Trends in Exposure to Polyfluoroalkyl Chemicals in the U.S. Population: 1999-2008. *Environmental Science and Technology*. 45: 8037-8045. 2011.

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

22. 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.

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33. EPA. Understanding the Costs Associated with Eliminating Exemptions for Articles in SNURs. November 12, 2014.

34. EPA. Illustrative List of LCPFACs Update September 17, 2014.

35. EPA. Chemicals Added to the Toxics Release Inventory Pursuant to Section 7321 of the National Defense Authorization Act. April 1, 2020. Accessed at: [https://www.epa.gov/sites/production/files/2020-04/documents/tri\\_non-cbi\\_pfas\\_list\\_2\\_19\\_2020\\_final\\_clean.pdf](https://www.epa.gov/sites/production/files/2020-04/documents/tri_non-cbi_pfas_list_2_19_2020_final_clean.pdf).

36. EPA. 2010/2015 PFOA Stewardship Program Final Report. Accessed at: [https://www.epa.gov/sites/production/files/2017-02/documents/2016\\_pfoa\\_stewardship\\_summary\\_table\\_0.pdf](https://www.epa.gov/sites/production/files/2017-02/documents/2016_pfoa_stewardship_summary_table_0.pdf).

#### **XIV. 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*

This action is a significant regulatory action that was submitted to the Office of Management and Budget (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 Significant New Use Rule for Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical Substances” (Ref. 4), is available in the docket and is briefly summarized in Unit XI.

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

This is a regulatory action subject to Executive Order 13771 (82 FR 9339, February 3, 2017). Details on the estimated costs and benefits of this final rule can be found in EPA’s analysis (Ref. 4), 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 lower 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. 4). Based on this, EPA believes that few SNUN submissions will occur as a result of the rule. EPA believes the total cost of submitting a SNUN, \$10,000 for small business submitters, is relatively small compared to annual revenues of the companies and does not have a significant economic impact as compared to the cost of developing and marketing a chemical new to a firm or marketing a new use of the chemical. This estimate does not include any costs associated with importer’s identification of chemicals associated with the SNUR.

While EPA does not have estimates on the cost of developing and marketing a new chemical, it has identified a mean reformulation cost of \$31,700 and a maximum of \$114,000, which is well above the \$10,000 SNUN costs.

Therefore, EPA believes that the potential economic impact of complying with this final SNUR is not expected to be significant or adversely impact 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 final rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

#### *J. National Technology Transfer and Advancement Act (NTTAA)*

Since this action does not involve any technical standards, section 12(d) of NTTAA, 15 U.S.C. 272 note, does not apply to this action.

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

This final rule does not invoke special consideration of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations.

#### *L. Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801-808, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).



**List of Subjects in 40 CFR Part 721**

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

Dated: June 22, 2020.

Andrew Wheeler,

*Administrator.*

Therefore, 40 CFR chapter I is 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 § 721.9582:

a. Redesignate paragraph (a) as (b).

b. Add new paragraph (a).

c. Add new paragraph (b)(2)(v).

d. Add paragraph (c).

The amendments read as follows:

**§ 721.9582 Certain perfluoroalkyl sulfonates.**

*(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) \* \* \*

(2) \* \* \*

(v) Import as part of carpets.

\* \* \* \* \*

*(c) Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (c).

*(1) Revocation of certain notification exemptions.* With respect to imports of carpets, the provisions of § 721.45(f) do not apply to this section. A person who imports a chemical

substance identified in this section as part of a carpet 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) The provision at § 721.45(h) does not apply to this section.

(3) [Reserved]

3. 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; and

(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—LCPFAC Chemical Substances Subject to Reporting After December 31, 2015**

<b>Chemical Name</b>	<b>CAS Registry No. (CASRN)</b>	<b>EPA Accession No.</b>	<b>TSCA Chemical Inventory Name</b>
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-heneicosafluoro-
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-Tetrahydroperfluorodecyl 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-heneicosafluoro-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-heneicosafluorodecyl 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-
3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-Nonacosafuorohexadecan-1-ol	60699-51-6	N/A	1-Hexadecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-nonacosafuoro-
1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,1	65510-55-6	N/A	Hexadecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9



3,14,14-Nonacosafuoro-16-iodohexadecane			,9,10,10,11,11,12,12,13,13,14,14-nonacosafuoro-16-iodo-
Sodium;2-methylpropane-1-sulfonate	68187-47-3	N/A	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	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 <sub>4</sub> SiO <sub>4</sub> ), 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	125476-71-3	N/A	Silicic acid (H <sub>4</sub> SiO <sub>4</sub> ), 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)	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—PFOA and Examples of Its Salts**

<b>Chemical Name</b>	<b>CAS Registry No. (CASRN)</b>	<b>TSCA Chemical Inventory Name</b>
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 is: 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 is: 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 is: Manufacture (including import) or processing for any use. Import or processing 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 is: Manufacture (including import) or processing for any use other than the use already covered by

paragraph (b)(4)(i) of this section.

(5) Manufacturing (including importing) or processing of certain chemical substances identified in paragraph (b)(1), paragraph (b)(2), and paragraph (b)(3) of this section for the following specific uses shall not be considered as a significant new use subject to reporting under this section:

(i) Use in an antireflective coating, photoresists, or surfactant for use in photomicroolithography and other processes to produce semiconductors or similar components of electronic or other miniaturized devices.

(6) Use of 2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester (CAS No. 27905-45-9) as a coating or component of a hydrophobic and/or oleophobic coating or barrier applied to manufactured articles or components of articles using an energy source or plasma deposition methods, which include a pulse deposition mode. Examples of such articles include: electronic devices and components thereof, medical consumables and bio-consumables, filtration devices and filtration materials, clothing, footwear and fabrics.

(7) Use of Silane, trichloro(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl)- (CAS No. 78560-44-8) as a surface treatment to make low refractive index resin for optical applications; surface treatment for minerals, particles and inorganic surfaces for hydrophobicity; and monomer to make specialty resins hydrophobic.

(8) Use of Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (CAS No. 335-67-1) as a surfactant and coating, as part of articles: stickers, labels, and parts to which those stickers and labels are attached.

(9) Use of 1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3-[(.gamma.-.omega.-perfluoro-C4-16-alkyl)thio]propyl]amino] derivs., sodium salts (CAS No. 68187-47-3); Thiols, C8-20,

.gamma.-.omega.-perfluoro, telomers with acrylamide (CAS No. 70969-47-0); or Perfluorinated polyamine (generic) (ACC274147) as a component in fire extinguishing agent.

(10) Use of Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (CAS No. 335-67-1); Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, sodium salt (1:1) (CAS No. 335-95-5); or Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, ammonium salt (1:1) (CAS No. 3825-26-1) for use in automotive articles, both in factory assembly and replacement parts.

(11) Use of Poly(difluoromethylene), .alpha.,.alpha.'-[phosphinicobis(oxy-2,1-ethanediyl)]bis[.omega.-fluoro-, ammonium salt (1:1) (CAS No. 65530-70-3); Poly(difluoromethylene), .alpha.-fluoro-.omega.-[2-(phosphonooxy)ethyl]-, ammonium salt (1:1) (CAS No. 65530-71-4); or Poly(difluoromethylene), .alpha.-fluoro-.omega.-[2-(phosphonooxy)ethyl]-, ammonium salt (1:2) (CAS No. 65530-72-5) for use in the manufacturing or processing of

(i) architectural coatings or wood coatings, at a maximum concentration of 0.1% by weight.

(ii) industrial primer coatings for non-spray applications to metal by coil coating application, at a maximum concentration of 0.01% by weight.

(12) Use of Alcohols, C8-14, .gamma.-.omega.-perfluoro (CAS No. 68391-08-2) in the manufacture or processing of coatings and finishes for a variety of textile, leather, and hard surface treatments, and in the manufacture of wetting agents.

(13) Use of Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, ether with .alpha.-fluoro-.omega.-(2-hydroxyethyl)poly(difluoromethylene) (1:1) (CAS No. 65545-80-4) in water-based inks.

(14) Use of Poly(difluoromethylene), .alpha.-[2-[(2-carboxyethyl)thio]ethyl]-.omega.-fluoro-, lithium salt (1:1) (CAS No. 65530-69-0) in photo media coatings.

(15) Use of Ethanol, 2,2'-iminobis-, compd. with .alpha.-fluoro-.omega.-[2-(phosphonooxy)ethyl]poly(difluoromethylene) (2:1) (CAS No. 65530-63-4); Ethanol, 2,2'-iminobis-, compd. with .alpha.,.alpha.'-[phosphinicobis(oxy-2,1-ethanediyl)]bis[.omega.-fluoropoly(difluoromethylene)] (1:1) (CAS No. 65530-64-5); or Ethanol, 2,2'-iminobis-, compd. with .alpha.-fluoro-.omega.-[2-(phosphonooxy)ethyl]poly(difluoromethylene) (1:1) (CAS No. 65530-74-7) in paints and coatings, grouts, and sealers.

(16) Use of Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, ether with .alpha.-fluoro-.omega.-[2-(hydroxyethyl)poly(difluoromethylene)] (1:1) (CAS No. 65545-80-4) in paints, coatings, ink jet inks, and ink masterbatch.

(17) Use of 1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3-[(.gamma.-.omega.-perfluoro-C4-16-alkyl)thio]propyl]amino] derivs., sodium salts (CAS No. 68187-47-3) in adhesives.

(c) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (c).

(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) The provision at § 721.45(h) does not apply to this section.

(3) [Reserved]