

Response to Public Comments

Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule RIN 2070-AJ99

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Office of Pollution Prevention and Toxics

Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency

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American Coatings Association (ACA)	0225-0069
Outdoor Power Equipment Institute (OPEI)	0225-0070
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Fire Fighting Foam Coalition (FFFC)	0225-0074
Dynax Corporation	0225-0075
Semiconductor Industry Association (SIA)	0225-0076
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Brooks Automation	0225-0080
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Superfund Program, Sources, Transport, Exposure & Effects of PFASs (STEEP) et al.	0225-0211

Bryan Cave Leighton Paisner LLP (BCLP)	0225-0212
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3M Company	0225-0231

Note: Each comment summary is followed by the end portion of one or more Federal Docket Management System ID numbers. The numbers identify the public comments used to compile the comment summary. Some commenters appear more than once if multiple comments were submitted during the two comment periods. The comments were submitted to the rulemaking docket during the comment period for the proposed rule (Docket # EPA-HQ-OPPT-2013-0225).

68 **List of Abbreviations**

69 CASRN – Chemical Abstracts Service Registry Number

70 CBI - Confidential Business Information

71 CDR – Chemical Data Reporting

72 CPcat – Chemical/Product Categorical Data

73 ECHA – European Chemical Agency

74 EPA – Environmental Protection Agency

75 LCPFAC – Long-Chain Perfluoroalkyl Carboxylate

76 NHANES – National Health and Nutrition Examination Survey

77 NIH – National Institute of Health

78 PFAS – Per- and Polyfluoroalkyl substances

79 PFCs – Perfluorinated Chemicals

80 PFOA – Perfluorooctanoic acid

81 PTFE – Polytetrafluoroethylene

82 Ref – Reference

83 SDS – Safety Data Sheets

84 SNUN – Significant new use notices

85 SNUR – Significant New Use Rule

86 TRI – Toxic Release Inventory

87 TSCA – Toxic Substances Control Act

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94 **Response to Comments: Long-Chain Perfluoroalkyl Carboxylate and**
95 **Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule**
96 **RIN 2070-AJ99**

97

98 **Introduction**

99 This document is an addendum to Unit XII of the final significant new use rule (SNUR)
100 under the Toxic Substances Control Act (TSCA) section 5(a) for Long-Chain Perfluoroalkyl
101 Carboxylate (LCPFAC) and Perfluoroalkyl Sulfonate Chemical Substances, identified by docket
102 identification number EPA-HQ-OPPT-2013-0225.

103 Public comment was taken on the proposed rule published on January 21, 2015. On
104 March 16, 2015, EPA extended the 60-day comment period by an additional 90 days. During the
105 150-day comment period, 56 unique comments were received from different groups. On March
106 3, 2020, EPA issued a supplement to the 2015 proposed rule. During the 45-day public comment
107 period, EPA received an additional 37 comments. In total, EPA received 93 comments on the
108 proposed and supplemental SNUR. Commenters provided feedback on many provisions of the
109 rule. The supplemental to the proposed rule also contained a request for comment on the future
110 consideration of a safe harbor provision for SNURs or a de minimis threshold for justifying the
111 SNUR notification requirement for articles.

112 EPA is: 1.) Finalizing an amendment to a SNUR for LCPFAC chemical substances by
113 designating as a significant new use manufacturing (including importing) or processing of a
114 subset of LCPFAC chemical substances for any use that was no longer ongoing after December
115 31, 2015; 2.) Finalizing an amendment to a SNUR for LCPFAC chemical substances by
116 designating as a significant new use manufacturing (including importing) or processing of all
117 other LCPFAC chemicals substances for any use that was no longer ongoing after January 21,
118 2015; 3.) Finalizing an amendment to make inapplicable the exemption for persons who import a
119 subset of LCPFAC chemical substances as part of surface coatings on articles; and 4.) Finalizing
120 an amendment to a SNUR for perfluoroalkyl sulfonate chemical substances that will make
121 inapplicable the exemption for persons who import perfluoroalkyl sulfonate chemical substances
122 as part of carpets.

123 EPA received several ongoing use claims. EPA reviewed all ongoing use claims,
124 requested additional information from commenters to substantiate ongoing use claims, and has
125 recognized and excluded from the definition of 'significant new uses' certain ongoing activities.
126 The semiconductor and small electronic component manufacturing industries represent the
127 largest portion of stakeholders with ongoing uses. Additionally, there continue to be uses of
128 LCPFAC and PFAS chemical substances in firefighting foams, coatings, automotive articles,
129 waterproofing emulsions, and other uses as noted in the final SNUR.

130 Additionally, EPA received several comments stating that the lack of LCPFAC CAS
131 numbers and the generic identification of PFOA and its salts provide insufficient information for
132 entities to understand what chemicals the rule encompasses. TSCA section 26(c) expressly
133 recognizes that an action may be taken with respect to a category of chemical substances or
134 mixtures based on chemical structure, and EPA believes the most precise way to identify the
135 chemicals subject to this SNUR is through the chemical structure definition.

136 In the March 3, 2020 supplement to the proposed rule, EPA requested comment on
137 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 below.

Several commenters raised concern over the issue of impurities, stating that the impurity levels of perfluorooctanoic acid (PFOA) and its precursors cannot be completely eliminated and thus should not be subject to the SNUR. Additionally, commenters noted that there are fluorinated substances that do not fall into the scope of the SNUR, but which may degrade into in-scope LCPFAC substances, and requested that those fluorinated substances not be subject to the SNUR. Several commenters also requested that EPA consider promulgating TSCA §6(a) rules to directly restrict perfluorinated chemicals and complete development of a detailed risk assessment to determine if PFAS chemical substances present an unreasonable risk.

A. General Comment

1. Comment Summary: Several commenters supported the rule or EPA’s efforts to minimize harm from LCPFAC chemical substances.

Sources: 0225-0050, 0225-0057, 0225-0065, 0225-0074, 0225-0082, 0225-0093, 0225-0199, 0225-0200, 0225-0202, 0225-0203, 0225-0213, 0225-0218, 0225-0223, 0225-0230

Response: EPA appreciates the supporting comments. This action is one of the many tools the Agency is using as part of the Per- and Polyfluoroalkyl Substances (PFAS) Action Plan to adequately address the growing concerns related to PFAS. Aggressively addressing Per and Polyfluoroalkyl (PFAS) is an ongoing and high priority effort for EPA. EPA’s PFAS Action Plan commits the Agency to take important steps that will enhance how the Agency researches, monitors, detects and addresses PFAS. Over the past year, EPA has made significant progress under the Action Plan to help states and local communities address PFAS. For more information on EPA’s work on PFAS, please visit: <https://www.epa.gov/pfas>.

2. Comment Summary: Several commenters requested that EPA consider banning or 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 presents an unreasonable risk.

Sources: 0225-0056, 0225-0082, 0225-0195, 0225-0201, 0225-0224

Response: Section 6(a) of TSCA 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 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, EPA worked with the eight major fluoropolymer and telomere manufacturers to voluntarily phase-out the production of LCPFAC chemical substances (Ref. 1). As such, the reduced supply of long-chain perfluorinated chemicals has led industries to more quickly transition to safer chemical substances, as noted in both public commenters 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 intended significant new use of the regulated chemical substances and, if necessary, an opportunity to 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 section 6(a) rule would better regulate LCPFAC and PFAS chemical substances, EPA will consider taking further regulatory action.

B. Uses Subject to the Rule

3. Comment Summary: 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.

Source: 0225-0047, 0225-0049, 0225-0055, 0225-0058, 0225-0059, 0225-0061, 0225-0062, 0225-0065, 0225-0066, 0225-0067, 0225-0068, 0225-0069, 0225-0070, 0225-0071, 0225-0072, 0225-0073, 0225-0076, 0225-0077, 0225-0078, 0225-0080, 0225-0081, 0225-0089, 0225-0090, 0225-0091, 0225-0092, 0225-0093, 0225-0094, 0225-0095, 0225-0096, 0225-0097, 0225-0098, 0225-0099, 0225-0100, 0225-0106, 0225-0108, 0225-0109, 0225-0111, 0225-0204, 0225-0207, 0225-0208, 0225-0209, 0225-0212, 0225-0214, 0225-0220, 0225-0221, 0225-0222

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. Exclusions from the definition of 'significant

new uses' are included with the regulation amendment at § 721.10536 b(5) thru b(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 claim was reviewed and use 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 § 721.10536.

During the public comment for the supplemental rule, 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 C.F.R. § 880.6250), gowns (21 C.F.R. § 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 regulation. 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 review the

need to promulgate future rules as necessary. As a result of public comments received, EPA recognizes manufacture, import, or processing of the following uses 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 photomicrolithography 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.

4. Comment Summary: Several commenters requested that EPA maintain the current designations in 40 C.F.R. § 721.9582 for existing paragraphs (a)(1) and (a)(3)(ii).

Sources: 0225-0058, 0225-0067, 0225-0068, 0225-0081, 0225-0090, 0225-0091, 0225-0095

Response: In the proposed (80 FR 2885; January 21, 2015) (FRL– 9915–63) and previously finalized (78 FR 62443; October 22, 2013) (FRL–9397-1) LCPFAC and Perfluoroalkyl Sulfonate Chemical Substances SNURs, EPA maintained the current designations in 40 C.F.R. § 721.9582 for existing paragraphs (a)(1) and (a)(3)(ii), stating that the chemical substances listed in Table 2 and Table 3 of 40 C.F.R. § 721.9582 shall not be considered as a significant new use subject to reporting for use as a component of a photoresist substance, including a photo acid generator or surfactant, or as a component of an anti-reflective coating, used in a photomicroolithography process to produce semiconductors or similar components of electronic or other miniaturized devices. These paragraphs are maintained because these uses continue to be ongoing. If EPA has reason to believe that the manufacturing or import of these substances of concern are no longer ongoing, EPA would consider taking regulatory action and designating these uses as a significant new use.

5. Comment Summary: Several commenters believe that all fluoropolymer resins made with LCPFACs, including dispersions and emulsions made with LCPFACs, should be subject to the SNUR. One commenter stated that they were unaware of any continuing purchase of fluoropolymer dispersions and emulsions made with PFOA. Additionally, one comment stated that the continued import of fluoropolymer dispersions and emulsions, and fluoropolymers as part of articles will put U.S. fluoropolymer manufacturers and processors at a significant competitive disadvantage to a foreign competitor, given that it provides no incentive to foreign manufacturers to eliminate LCPFACs from their processes and products.

Source: 0225-0051, 0225-0054, 0225-0064, 0225-0223, 0225-0219, 0225-0223

Response: EPA proposed excluding fluoropolymer dispersions and emulsions made with LCPFACs because EPA thought this use to be ongoing. Comments received during the public comment period have substantiated the ongoing use of fluoropolymer dispersions and emulsions made with PFOA or any of its salts. Currently ongoing uses of LCPFACs cannot be included in the SNUR. EPA will continue to monitor uses of LCPFACs and consider promulgating future SNURs for discontinued or other non-ongoing uses.

6. Comment Summary: One commenter stated the SNUR should include fluoropolymers made with LCPFACs (as defined in EPA's proposed § 721.10536 (b)(1)) rather than limit the applicability of the SNUR to the fluorinated compounds listed in EPA's proposed § 721.10536 (b)(3) Table 2. – PFOA and Examples of Its Salts.

Source: 0225-0051

Response: In both the proposed and final SNUR, EPA has included fluoropolymers made with LCPFACs (as defined in EPA's proposed § 721.10536 (b)(1)) and believes that the commenter misinterpreted the regulation text.

7. Comment Summary: Several commenters stated that the processing of articles should be subject to the SNUR. One commenter stated that allowing recycling, which is a form of processing, may create an unintentional loophole for processors to create new products without first submitting a significant new use notice. On the other hand, one commenter proposed that the processing of existing inventories of fluoropolymers made with LCPFACs is ongoing and should not be subject to the SNUR, thereby allowing existing inventories to be depleted. Additionally, the comment stated that the market for recycled fluoropolymers is worldwide and proposed to allow the use and import of recycled fluoropolymers made with LCPFACs in cases where the fluoropolymers were originally manufactured prior to the date of the proposed SNUR, thus allowing polymer recycling activities to continue.

Source: 0225-0051, 0225-0082, 0225-0215, 0225-0216, 0225-0217, 0225-0225, 0225-0226

Response: The processing of articles containing LCPFAC chemical substances is an ongoing use. EPA cannot regulate any ongoing use under a section 5(a)(2) Significant New Use Rule. Thus, the continued processing of existing inventories of fluoropolymers made with LCPFACs and the recycling of fluoropolymers is recognized as ongoing in the final rule and would not be subject to a significant new use notice. EPA received public comments stating that there is ongoing use of preexisting stocks of perfluorinated chemical substances. These ongoing uses have been recognized in the regulation text.

EPA recognizes the importance and impact of recycling, which contributes to American

prosperity and the protection of our environment. As a result of the phaseout of LCPFAC chemicals through the 2010/2015 PFOA Stewardship Program, EPA expects the amount of articles that contains LCPFAC to decline over time. While EPA did partially lift the article exemption at 40 CFR 721.45(f), the other provision of 40 CFR 721.45(f), respecting processing a chemical substance as part of an article, which includes recycling, remains applicable. EPA acknowledges concerns over potential loopholes created by the retention of processing in 40 CFR 721.45(f) and has not ruled out a later proposal to address concerns related to domestic processors of articles.

In the 2020 supplement to the proposed rule, EPA stated that, “as to processors, it is EPA's understanding that there is no ongoing manufacturing or processing of LCPFAC chemical substances in the U.S.” EPA would like to clarify that statement. EPA does not believe there is continued domestic manufacturing of LCPFAC chemical substances and the subsequent processing of those chemicals. EPA, however, is aware of the continued processing of existing stocks of LCPFAC chemical substances and the processing of LCPFAC chemical substances as part of articles.

8. Comment Summary: One commenter requested that EPA “make clear that the SNUR does not restrict products consisting of perfluoroalkyl chemical substances with perfluorinated carbon chain lengths less than seven carbons.”

Source: 0225-0210

Response: This rule is for long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances. 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 (see Unit II. Chemical Substances Subject to this Rule).

9. Comment Summary: One commenter stated that they have two low volume exemptions (LVEs) for chemical substances subject to the rule.

Source: 0225-0060

Response: EPA appreciates the comment. Uses of a chemical substance that falls under the terms of an approved LVE are ongoing uses so long as the chemical substance is being actively manufactured or processed for that use. Accordingly, EPA has recognized the ongoing use of these chemical substances above in Comment Response #3 and in the regulatory text.

C. Lifting the Articles Exemption

10. Comment Summary: 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 stated that EPA “should explicitly exempt manufacturers that import articles containing a substance unless EPA has made an affirmative finding of exposure following the requirements of TSCA.” 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. Another commenter stated that EPA must be able to show that exposure from an article “is likely to occur under environmental conditions or actual conditions of use” and “is likely to occur at levels of toxicological significance.” One commenter stated that EPA had not made the affirmative finding specifically for the use of LCPFAC substances in semiconductor fabrication equipment and infrastructure.

Source: 0225-0205, 0225-0206, 0225-0208, 0225-0209, 0225-0218, 0225-0219, 0225-0220, 0225-0221, 0225-0231

Response: EPA believes that the reasonable potential for exposure has been addressed through the studies cited in supplement to the proposed rule. 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. EPA's decision to finalize a SNUR for a particular chemical substance is not based on an extensive evaluation of the hazard, exposure, or potential risk associated with that chemical substance. 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 is consistent with the statutory language requiring a reasonable potential for exposure (rather than a certainty of exposure). EPA has defined the category of articles subject to notification to be “articles that contain LCPFAC chemical substances as part of a surface coating,” EPA is not required to individually make an affirmative finding for specific industries or specific types or articles. TSCA section 5(a)(5) only states that EPA must make the finding for an article or category of articles.

11. Comment Summary: Several commenters requested that EPA broaden the scope to include all imported articles containing LCPFAC or long-chain perfluoroalkyl sulfonate chemical substances. One commenter asked EPA to ensure the final rule is as protective as was originally envisioned. One of the commenters suggested the inclusion of articles such as food-grade paper products. One commenter stated that they failed to “see how the [EPA] has made the determination that there is reasonable potential of exposure from LCPFAC chemicals from articles with surface coatings yet not from other items imported containing such chemicals.” One comment requested that the SNUR broadly encompass all LCPFAC uses that could result in

human or environmental exposure and that EPA use its full authority under TSCA sections 5(e) and 5(f) to prohibit these uses in the event that a SNUN was submitted.

Sources: 0225-0050, 0225-0082, 0225-0205, 0225-0211, 0225-0215, 0225-0216, 0225-2017, 0225-0225, 0225-0226

Response: In the 2015 proposal (80 FR 2885; January 21, 2015) (FRL-9915-63), 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 the 2016 TSCA amendments, 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. While EPA is aware of instances where LCPFAC chemicals are used in products or 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.

Although the Agency has the authority to lift the exemption for importers and processors of all PFAS as part of an article or category of articles, such a broad action is not possible at this time because it was not proposed and there are ongoing uses of certain PFAS as part of articles. Because there are ongoing uses of PFAS imported and processed as part of articles, EPA is unable to designate these as significant new uses subject to a SNUR. With regards to food contact substances in food contact articles, these products are regulated by the United States Food and Drug Administration.

12. Comment Summary: Several commenters asked that EPA better define or provide clarification on the definition of a “surface coating.” Two commenters asked that a definition of a surface coating be included in the regulation text. Additionally, commenters asked EPA to provide examples of what may be considered new uses of articles containing LCPFAC chemical substances as part of a surface coating. Some commenters question if interior surfaces of articles would be subject to the rule or asked that the scope of the definition only apply to surface coatings that the user could be directly exposed to. One commenter stated that they were “concerned that EPA intends to regulate importers of articles including when the chemicals in those articles may not come into contact with the user.” One commenter stated that when a coating is “inextricably adhered to a coated surface or are treated or cured in such a manner that the coating components are chemically modified (and are no longer identifiable by their original chemical identities)” that the coating should no longer be considered a LCPFAC surface coating.

Source: 0225-0207, 0225-0208, 0225-0209, 0225-0214, 0225-0222

Response: EPA appreciates the comments. 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. EPA does not intend to finalize a regulatory definition of “surface coating.” Rather, EPA will be issuing guidance within a reasonable timeframe of the final rule. 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.

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. 2, 3, 4, and 5), even when adhered to surfaces in accordance with practices reported in patents (Refs. 3 and 4), and hence, present the reasonable potential for exposure to the chemical substance through the category of articles subject to the rule.

This broad interpretation 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 and data to review. If EPA receives a SNUN, EPA will evaluate the potential releases from the article and with information specific to that article.

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.

13. Comment Summary: Two comments asked that replacement parts be exempt from the final rule.

Source: 0225-0078, 0225-0220

Response: EPA appreciates the comment and recognizes the importance of replacement parts. However, EPA is not adopting any broad exemptions from the SNUR without substantiation of specific ongoing use. If EPA received such substantiation, EPA provided an exemption in the final rule.

14. Comment Summary: One commenter asked EPA to confirm that the chemicals listed by CASRNs in the amended §721.10536(b)(2) and (b)(3) are the only chemicals applicable to surface coatings of articles.

Source: 0225-0207

Response: With regards to articles, this SNUR requires notification to EPA before the importation of articles containing LCPFAC chemical substances listed at the amended 40 CFR 721.10536(b)(2) and (b)(3) when they are part of a surface coating of an article. This SNUR also requires notice for all LCPFAC chemical substances at 40 CFR 721.10536 when imported in carpets. Additionally, EPA is finalizing an amendment to a SNUR at 40 CFR 721.9582 for perfluoroalkyl sulfonate chemical substances that will make inapplicable the exemption for persons who import perfluoroalkyl sulfonate chemical substances as part of carpets.

D. Safe Harbor

15. Comment Summary: 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. One commenter opposing a safe harbor provision stated that a safe harbor provision “would allow a significant new use to commence through the import of an article containing LCPFAC chemical substances without requiring that EPA be notified and have a chance to review a SNUN for that use.” 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.

Source: 0225-0204, 0225-0208, 0225-0209, 0225-0214, 0225-0215, 0225-0216, 0225-0218, 0225-0219, 0225-0223, 0225-0226, 0225-0227, 0225-0228, 0225-0229

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.

E. Establishing a De Minimis Threshold

16. Comment Summary: 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.”

Source: 0225-0204, 0225-0206, 0225-0207, 0225-0208, 0225-0209, 0225-0210, 0225-0214, 0225-0215, 0225-0216, 0225-0217, 0225-0220, 0225-0221, 0225-0222, 0225-0225, 0225-0226, 0225-0227, 0225-0228, 0225-0229

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.

EPA believes that section 5(a)(5) actions should be applied on a case-by-case basis. Each time

EPA considers requiring notification under 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 (80 FR 2885; January 21, 2015) and the 2020 supplement to the proposed rule (85 FR 12479; March 3, 2020). 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, 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.

F. Economic Analysis

17. Comment Summary: Several commenters stated that EPA underestimated the economic impacts of costs of compliance with the SNUR. One commenter stated that the estimated cost of a notification seemed unlikely to cover the cost of generating relevant data, substantiating a specific case for manufacturing (importing), or using or placing on the market substances of concern (including articles in which these may be contained). One commenter stated that the cost of testing one article is “approximately \$150 per product tested.” Another commenter stated that the “complete and documented investigation” of articles that might contain LCPFAC chemical substances would be “essentially impossible.” Lastly, one comment suggested that EPA improve the Economic Analysis to better include regulatory alternatives.

Source: 0225-0056, 0225-0208, 0225-0214, 0225-0222, 0225-0227

Response: The SNUR Economic Analysis estimated the impact of the Rule as \$23,000 (for large businesses) and \$10,000 for small businesses. These costs are per SNUN submission and include rule familiarity, SNUN submission, and recordkeeping. If a SNUN is submitted and there are

future testing requirements or limits placed on the use or marketing of a chemical substance subject to the SNUR, the impact of those procedures would be a result of that further action and not this SNUR. Included in those procedures would be an assessment of the costs and benefits of those actions.

18. Comment Summary: One commenter asked if EPA had made a forecast of the number of notifications and the resources required to process SNUNs.

Source: 0225-0056

Response: EPA does not make a forecast of the number of notifications. However, as indicated in the Economic Analysis, historically, the number of SNUN submissions has been very low. EPA has, over the years, promulgated SNURs that cover a total of more than 1,000 chemicals. In response, the Agency receives only a handful of SNUNs per year. For example, the number of SNUNs received was six in Federal fiscal year (FY) 2007, eight in FY2008, seven in FY2009, two in FY2010, and ten in FY2011. EPA accounts, however, for both industry and Agency costs and burdens of submissions on a per unit basis. These are estimated in the Economic Analysis for the SNUR (Ref. 6).

G. Other Comments

19. Comment Summary: 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 other chemicals this rule encompasses. They believe that EPA must define the universe of covered chemicals that would be subject to the regulation.

Source: 0225-0066, 0225-0078, 0225-0089, 0225-0220

Response: TSCA section 26(c) expressly recognizes that an action may be taken with respect to a category or 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 number and unique chemical identity) to generate the specific structure for any potentially reportable substance, which they can 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. 7). 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 at: https://www.epa.gov/sites/production/files/2020-04/documents/tri_non-cbi_pfas_list_2_19_2020_final_clean.pdf (Ref. 8).

20. Comment Summary: 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 or a Certificate of Analysis 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. One commenter recommended that EPA establish impurity levels for short-chain fluorotelomer-based products of 25 ppb PFOA and 1000 ppb of a combination of PFOA-related substances.

Source: 0225-0051, 0225-0052, 0225-0064, 0225-0081, 0225-0083, 0255-0092, 0225-0093, 0225-0107, 0225-0210, 0225-0218, 0225-0219, 0225-0222

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 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.

21. Comment Summary: EPA received one comment stating there is ongoing production of certain LCPFAC chemicals as a byproduct of short-chain perfluorinated chemicals, which are recycled and used in another commercial process.

Source: CBI

Response: EPA appreciates the comment. This process is not subject to the notification requirements of 40 CFR 721.25 given the exemption at 40 CFR 721.45(e) for manufacturers, importers, or processors of chemical substances only as a byproduct which are used only by public or private organizations that extract component chemical substances from it for commercial purposes.

22. Comment Summary: One commenter stated that the continued importation of dispersions containing LCPFACs potentially continues to allow the release of LCPFACs into the environment and potentially places EPA in conflict with EPA’s own enforcement of the Clean Water Act.

Source: 0225-0064

Response: Based on public comments received, EPA recognizes that some chemical substances subject to the final SNUR are currently being imported into the United States. Currently ongoing uses of LCPFACs cannot be included in the SNUR and have been expressly recognized as such and excluded from the final rule. EPA will continue to monitor uses of LCPFACs and consider promulgating future SNURs for discontinued or other non-ongoing uses.

On February 20, 2020, EPA issued preliminary determinations to regulate PFOA and PFOS in drinking water. EPA, however, does not have reason to believe that the continued, limited importation of dispersions containing LCPFACs will have significant releases into the environment. If EPA has reason to believe that the import of these substances of concern will be released into the environment, EPA would consider taking regulatory action.

23. Comment Summary: One commenter claimed continued use of C8 substances for outdoor and safety equipment and claims that alternative C6 substances do not serve as an adequate alternative for the high performance applications. They additionally state that more C6 chemical substances have to be used and reapplied often, which has an increased environmental impact.

Source: 0225-0077

Response: EPA acknowledges the comment and continues to review C6 and C8 fluorinated chemicals. EPA received public comments stating that there are ongoing uses of a select number of C8 substances for outdoor and safety equipment and these ongoing uses have been recognized in the regulation text.

24. Comment Summary: One commenter requested that EPA build a database of all the fluoropolymer manufacturers who have converted from LCPFCs to EPA compliant materials.

Source: 0225-0064

Response: EPA acknowledges the comment. Through the 2010/2015 PFOA Stewardship Program, a voluntary risk reduction program, EPA worked with the eight major fluoropolymer and telomer manufacturers to voluntarily phase-out the production of those chemical substances of concern (Ref. 1). The companies participating in the PFOA Stewardship Program were global companies with business operations in United States and other countries. Under the PFOA Stewardship Program, each of the companies committed to work toward a global phaseout of PFOA and related chemicals, both for U.S. operations and for the company's global business. The companies that took part in the 2010/2015 PFOA Stewardship program were: Arkema, Asahi, BASF Corporation, Clariant, Daikin, Dyneon, DuPont, and Solvay Solexis. EPA, however, does not intend to build a database of all fluoropolymer manufacturers who have converted from LCPFCs.

25. Comment Summary: One commenter indicated that a chemical substance had been incorrectly categorized as a LCPFAC compound and associated with a previously finalized SNUR (78 FR 62443).

Source: 0225-0079

Response: EPA has updated the inventory accordingly.

26. Comment Summary: One commenter stated that because three chemical substances listed on

Table 1 of the Proposed SNUR are listed as Confidential Business Information (CBI), there is no clear way to determine if the product is regulated.

Source: 0225-0083

Response: The identities of these chemical substances have been withheld in accordance with EPA CBI practices. CBI is broadly defined as proprietary information, considered confidential to the submitter, the release of which would cause substantial business injury to the owner. Companies generally request CBI for confidential proprietary information believed to give other companies an advantage in the marketplace, such as details of their manufacturing processes and formulas. Given the chemical structure definition used in this rule, manufacturers will be able to determine if their product is subject to the SNUR and will provide this information to downstream users as required by the rule.

27. Comment Summary: One commenter requested a standard definition of "ongoing use."

Source: 0225-0083

Response: Ongoing uses are recognized uses which were occurring as of the date of publication of the proposed rule, unless otherwise noted. To establish a significant new use, EPA must determine that the use is not ongoing. In order to identify current uses of LCPFAC and PFAS chemical substances, EPA reviewed published literature including IHS' Chemical Economics Handbook (formerly of SRI Consulting), National Institute of Health's (NIH) Household Product Database, EPA's Chemical/Product Categorical Data (CPcat) database, the Consumer Product Information Database, the most recent data available from EPA's Chemical Data Reporting program (CDR), general web searches, Safety Data Sheets (SDSs), European Chemical Agency (ECHA) reports and risk assessments, the Danish Ministry of the Environment Surveys of Chemicals in Consumer products, and other information from manufacturing company websites.

28. Comment Summary: One commenter asked that we work to align our regulatory standards with others, notably the EU.

Source: 0225-0083

Response: EPA acknowledges the comment. EPA continues to work with other countries to coordinate regulatory processes, via methods such as the North American Notification Consultation (NAN-C) Process. Additionally, EPA is a US representative of the OECD/UNEP Global Perfluorinated Chemicals (PFC) Group.

29. Comment Summary: One commenter stated that the data from the National Health and

Nutrition Examination Survey (NHANES), upon which EPA relies for its claim that PFOA is “widely present in humans,” is extremely out of date and fundamentally mischaracterizes any potential exposure to these substances today.

Source: 0225-0231

Response: EPA acknowledges the comment. EPA expects the presence of PFOA in humans and the environment to decline over time because the manufacture and processing of PFOA and other LCPFAC chemical substances have declined or ceased. The most recent NHANES data reflects EPA’s expectation and can be found at <https://www.cdc.gov/exposurereport>. While the current potential exposure to LCPFAC chemical substances has decreased, EPA is concerned about future exposures. If reinitiated, EPA believes that additional use of these chemical substances in consumer products could potentially significantly increase human exposure, and that such exposures should not occur without notice and review by EPA.

30. Comment Summary: One commenter requested that EPA clarify whether a SNUN needs to be submitted for specific product categories, for a specific use/application, and/or for each specific chemical. They asked if a SNUN could be submitted for a group of LCPFAC chemicals.

Source: 0225-0207

Response: TSCA requires that SNUNs be submitted for specific chemical substances. SNUNs can include multiple requested significant new uses that have been identified by EPA in the corresponding SNUR; each will be assessed by the Agency.

31. Comment Summary: One commenter stated that it is not clear which assessment criteria will apply to SNUNs and under what circumstances EPA will take regulatory action towards the submitters, to ensure that the overall objectives of protecting health and environment are met.

Source: 0225-0056

Response: Given that each SNUN submission is unique and requires a case-by-case review, EPA does not provide general assessment criteria or indicate specific actions the agency may take to protect against any unreasonable risks prior to conducting that review. When possible, SNUN submitters should provide detailed information on human exposure and environmental releases, any test data that will aid in a reasoned evaluation of potential risks posed by the chemical substance, potential benefits of the chemical substance, and information on risks posed by the chemical substances compared to risks posed by potential substitutes.

32. Comment Summary: One commenter stated that there are no SNURs that apply to short-chain PFAS and asked the EPA impose restrictions on the reintroduction of substances in this category that are no longer in commercial production or are planned to be manufactured for new uses.

Source: 0225-0225

Response: EPA appreciates the comment. EPA will continue to engage with interested stakeholders and consider future SNURs for short-chain PFAS as appropriate.

33. Comment Summary: One commenter recommended a separate engagement or rulemaking process to obtain a wider perspective and set expectations for article SNURs. One commenter expressed concern that this supplemental proposal lays the groundwork for how EPA will regulate articles with SNURs into the future.

Source: 0225-0207, 0225-2014

Response: EPA appreciates the comment. EPA will continue to engage with interested stakeholders when the Agency issues SNURs that lift the articles exemption. In this rule, as has been the case historically, EPA considered lifting the articles exemption on a case-specific basis, taking into consideration the unique applications and qualities of a given chemical substance or class of chemical substances. Since the passage of the Lautenberg Act, EPA has issued two SNURs that require significant new use notification for the import of articles. The first SNUR to lift the articles exemption was the SNUR restricting the discontinued uses of asbestos (84 FR 17345, April 25, 2019). The LCPFAC SNUR is the second SNUR to require significant new use notifications for the import of articles.

34. Comment Summary: Two commenters asked that EPA update the SNUR to not only include articles that contain LCPFAC chemical substances in the final coating content but articles that were manufactured with the use of LCPFAC chemical substances. One commenter suggested that for imports that claim they are “long-chain PFAS-free” must not contain LCPFAC chemical substances or be manufactured using LCPFAC chemical substances.

Source: 0225-0212, 0225-0223

Response: EPA appreciates the comment. EPA will continue to engage with interested stakeholders and consider future amendments to the articles exemption but EPA is not finalizing requirements that articles certify that they were not made with the use of LCPFAC chemicals at this time.

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