

*** EO 12866 Review Draft – Deliberative – Do Not Cite, Quote or Release During the Review***

RIN2070-AJ99_EO12866_LCPFAC-SNUR_SNPRM_FRDocument_2019-09-16.docx_v4

Draft document as submitted for review under EO 12866/13563.

BILLING CODE 6560-50-P

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT- 2013-0225; FRL-10003XXXX-XX]

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RIN 2070-AJ99

Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical

Substances; Significant New Use Rule; Supplemental Proposal

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

Commented [A3]: EPA typesetting ed

~~ACTION:~~ ACTION: Supplemental notice of proposed rulemaking.

Commented [A4]: EPA typesetting ed

~~SUMMARY:~~ SUMMARY: EPA is supplementing a proposed significant new use rule (SNUR)

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issued under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances to make inapplicable the exemption for persons who import a subset of LCPFAC chemical substances as part of surface coatings on articles. This subset of LCPFAC chemical substances also includes the salts and precursors of these perfluorinated carboxylates. This supplemental proposal would require importers to notify EPA at least 90 days before commencing the import of these chemical substances in certain articles for the significant new use described in this document. The required significant new use notification would initiate EPA's evaluation of the conditions of use associated with the intended significant new use. Manufacturing (including import) or processing for the significant new use would be prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination. In a January 21, 2015, proposed LCPFAC SNUR, EPA proposed to require notification of significant new uses from persons who import a subset of LCPFAC

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

Commented [A7]: Follow-up Comment #4

37 ~~DATES: DATES:~~ Comments must be received on or before ~~[insert date 60]~~45 days after date of
38 ~~publication in the Federal Register]. [INSERT DATE 60 DAYS AFTER DATE OF~~
39 ~~PUBLICATION IN THE FEDERAL REGISTER].~~

Commented [A8]: Comment #4
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Commented [A11]: Agency change given new deadline outline in the Defense Authorization Bill: "Not later than June 22, 2020, the Administrator shall take final action on the proposed rule entitled "Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule" (80 Fed. Reg. 2885 (January 21, 2015))."

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

- 42 • *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions
43 for submitting comments. Do not submit electronically any information you consider to be
44 Confidential Business Information (CBI) or other information whose disclosure is restricted by
45 statute.
- 46 • *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics

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47 (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC
48 20460-0001.

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

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

53 **FOR FURTHER INFORMATION CONTACT: FOR FURTHER INFORMATION**

54 **CONTACT:** *For technical information contact:* Tyler Lloyd, Chemical Control Division

Commented [A14]: EPA typesetting ed

55 (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200
56 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-4016;
57 email address: lloyd.tyler@epa.gov.

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

61 **SUPPLEMENTARY INFORMATION:**

62 **I. Executive Summary**

63 *A. Does this Action Apply to Me?*

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

68 Potentially affected entities may include:

69 • Apparel Manufacturing (NAICS code 315).

- 70 • Electrical Equipment, Appliance, and Component Manufacturing (NAICS code 335).
- 71 • Merchant Wholesalers, Durable Goods (NAICS codes 423).
- 72 • Merchant Wholesalers, Nondurable Goods (NAICS 424).
- 73 • Furniture and Home Furnishings Stores (NAICS codes 442).
- 74 • Electronics and Appliance Stores (NAICS codes 443).
- 75 • Building Material and Garden Equipment and Supplies Dealers (NAICS code 444).
- 76 • Clothing and Clothing Accessories Stores (NAICS code 448).
- 77 • Sporting Goods, Hobby, Musical Instrument, and Book Stores (NAICS code 449).
- 78 • General Merchandise Stores (NAICS code 450).
- 79 • Non-store Retailers (NAICS code 451).

80 This action may affect certain entities through pre-existing import certification and export
81 notification rules under TSCA. Persons who import any chemical substance governed by a final
82 SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements
83 and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28.
84 Those persons must certify that the shipment of the chemical substance complies with all
85 applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in
86 support of import certification appears at 40 CFR part 707, subpart B. Additionally, persons who
87 export or intend to export a chemical substance that is the subject of a proposed or final SNUR
88 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b); see
89 also 40 CFR part 707, subpart D and 40 CFR 721.20). Under the existing TSCA import
90 certification and export notification rules, persons who import a chemical substance covered
91 under this proposed rule as part of an article would be exempt from TSCA section 13 import
92 certification, and persons who export or intend to export a chemical substance as part of an

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93 article would be exempt from the TSCA section 12(b) export notification requirements. See Unit
94 V. for more information on the applicability of the import certification and export notification
95 requirements.

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

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

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

Commented [A15]: Comment #38

- 106 • The projected volume of manufacturing and processing of a chemical substance.
- 107 • The extent to which a use changes the type or form of exposure of human beings or
108 the environment to a chemical substance.
- 109 • The extent to which a use increases the magnitude and duration of exposure of human
110 beings or the environment to a chemical substance.
- 111 • The reasonably anticipated manner and methods of manufacturing, processing,
112 distribution in commerce, and disposal of a chemical substance.

113 In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to
114 consider any other relevant factors. ~~Once EPA determines that a use of a chemical substance is a~~
115 significant new use, TSCA section 5(a)(1) requires persons to submit a significant new use

Commented [A16]: Follow-up Comment #38

116 notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process
117 the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)). TSCA furthermore prohibits
118 such manufacturing or processing from commencing until EPA has conducted a review of the
119 notice, made an appropriate determination on the notice, and taken such actions as are required
120 in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). Additionally, TSCA section
121 5(a)(5) (15 U.S.C. 2604(a)(5)), as amended in 2016, authorizes EPA to require notification for
122 the import or processing of a chemical substance as part of an article or category of articles under
123 TSCA section 5(a)(1) (15 U.S.C. 2604(a)(1)(A)(ii)) if EPA makes an affirmative finding in a
124 rule under TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) that the reasonable potential for
125 exposure to the chemical substance through the article or category of articles subject to the rule
126 justifies notification. This supplemental proposal proposes to exercise EPA's authority under
127 TSCA section 5(a)(5) to require notification for the import of the subject chemical substances as
128 part of the category of articles, articles that contain certain LCPFAC chemical substances as part
129 of a surface coating, discussed in Unit I.C. As described in Unit V., the general SNUR provisions
130 are found at 40 CFR part 721, subpart A.

131 *C. What Action Is the Agency Taking?*

132 In the Federal Register ~~FEDERAL REGISTER~~ of January 21, 2015 (80 FR 2885)
133 (FRL-9915-63) (Ref. 1), EPA proposed a SNUR for long-chain perfluoroalkyl carboxylate
134 (LCPFAC) and perfluoroalkyl sulfonate chemical substances. As stated in the previous proposal,
135 the LCPFAC chemical substances also include the salts and precursors of these perfluorinated
136 carboxylates. In that previously proposed rule, EPA proposed to make the exemption from
137 notification requirements for persons who import ~~or process~~ the chemical substance as part of an
138 article inapplicable for the import of a subset of LCPFAC chemical substances in all articles.

Commented [A17]: Comment #11

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Commented [A20]: EPA edit for grammatical error

Commented [A21]: Comment #10, #7

Commented [A22R21]: Having read this comment and seeing this change in context, if EPA's main justification for this supplemental is because of what is perceived as a new ability to regulate articles, coming from the Lautenberg 5a5 language, it is very unclear why EPA is only focusing on importers and not processors of articles. The Lautenberg language treats the processors and importers of articles similarly, yet the EPA difference is not explained. If it is not adequately explained, this differential treatment could be challenged by importers as arbitrary.

Please also check the reg text as that does refer to processing.

Commented [A23R21]: EPA appreciates the comment. While the Lautenberg amendments added the language at 5(a)(5), EPA already had and exercised its authority to require notification on imported articles. In the 2015 proposed rule, EPA only proposed to lift the articles exemption for imported articles and not for processors of articles. EPA proposed to only lift the articles exemption for imported articles because EPA believes that the recycling (which is considered processing under TSCA) of articles containing LCPFAC chemical substances is an ongoing use. Ongoing uses cannot be subject to a SNUR.

EPA is now issuing this supplemental based on the language added at 5(a)(5) and is again only proposing to require notification on the import of articles.

The reg text, which refers to lifting the articles exemption is as follows.

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.

In the reg text cited above, EPA is lifting the exemption for the import of articles but the exemption for processing remains applicable.

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139 EPA is now issuing a supplemental proposal for the import of certain LCPFAC chemical
140 substances. this action would make the exemption from notification requirements inapplicable
141 and require significant new use notification reporting for the import of a subset of LCPFAC
142 chemical substances only as part of a surface coating on articles. This supplemental proposal
143 better defines the articles subject to the rule by defining the subject articles as “imported articles
144 where certain LCPFAC chemical substances are part of surface coating on the articles” rather
145 than what was originally proposed. “imports of articles.” EPA is issuing this supplemental
146 proposal to be responsive to the article consideration provision at TSCA section 5(a)(5), added
147 with the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L.
148 114-182), which states that articles can be subject to notification requirements as a significant
149 new use provided that if the Administrator EPA makes an affirmative finding in a rule that the
150 reasonable potential for exposure to a chemical from an article or category of articles justifies
151 notification. Rather than making the article exemption inapplicable for any article, as was
152 proposed in the January 21, 2015, proposal (Ref. 1), this action proposes to make a finding under
153 TSCA section 5(a)(5) and make the article exemption at 40 CFR 721.45(f) inapplicable for
154 persons importing the category of articles that contain certain LCPFAC chemical substances as
155 part of a surface coating on articles. As to processors, it is EPA’s understanding that there is no
156 processing of LCPFAC ongoing. Based on that understanding, EPA is not proposing that this
157 Supplemental Proposed Rule apply to processors. EPA seeks comment regarding this
158 understanding.

Commented [A24]: Comment #17

Commented [A25]: Comment #15

Commented [A26]: Comment #18

Commented [A27]: Comment #47

Commented [A28]: Added per 2/11 Principals call

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159 In the proposed rule issued in the Federal Register **FEDERAL REGISTER** of January
160 21, 2015 (Ref. 1), EPA also proposed: 1) an amendment to a SNUR for LCPFAC chemical
161 substances by designating as a significant new use manufacturing (including importing) or

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162 processing of a subset of LCPFAC chemical substances for any use that was no longer ongoing
163 after December 31, 2015; 2) an amendment to a SNUR for LCPFAC chemical substances by
164 designating as a significant new use manufacturing (including importing) or processing of all
165 other LCPFAC chemicals substances for any use that was no longer ongoing after January 21,
166 2015; and 3) an amendment to a SNUR for perfluoroalkyl sulfonate chemical substances that
167 would make inapplicable the exemption from notification requirements for persons who import
168 perfluoroalkyl sulfonate chemical substances as part of carpets. These other amendments, as
169 proposed on January 21, 2015 (Ref. 1), are not the subject of this supplemental proposal. EPA is
170 considering the comments received on the January 21, 2015, proposal (Ref. 1) and will respond
171 to them with publication of the final rule.

172 During the public comment period for the rule proposed in the [Federal Register](#)
173 ~~FEDERAL REGISTER~~ of January 21, 2015 (Ref. 1), EPA received comments about ongoing
174 uses of LCPFAC and perfluorooctanoic acid (PFOA) chemical substances and requests that EPA
175 modify the proposed SNUR to specifically recognize and exclude from the significant new uses
176 certain ongoing activities. EPA received public comments claiming several ongoing uses. EPA
177 continues to review these claims of ongoing use to understand whether these uses remain
178 ongoing. EPA intends to undertake further outreach to commenters to confirm and better
179 understand the ongoing uses. In the final rule, EPA will recognize and exclude from the
180 significant new uses any ongoing activities for these chemicals. The final rule would take final
181 action on both the previously proposed rule and this supplemental proposal. For further
182 background information for this supplemental proposal, consult the proposal issued in the
183 [Federal Register](#) ~~FEDERAL REGISTER~~ of January 21, 2015 (Ref. 1) and the corresponding
184 docket for this rulemaking (EPA-HQ-OPPT-2013-0225).

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Commented [A31]: EPA typesetting ed

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185 This supplemental proposal to the proposed SNUR would require persons who intend to
186 import these LCPFAC chemical substances as part of a certain surface coating on articles for a
187 significant new use, consistent with the requirements at 40 CFR 721.25, to notify EPA at least 90
188 days before commencing such import. This supplemental proposal to the proposed SNUR would
189 furthermore preclude the commencement of import of such articles until EPA has conducted a
190 review of the notice, made an appropriate determination on the notice, and taken such actions as
191 are required in association with that determination. As discussed in the Federal Register Federal
192 Register of April 24, 1990 (55 FR 17376), EPA has decided that the intent of the TSCA section
193 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of
194 publication of the proposed rule rather than as of the effective date of the final rule. This rule was
195 proposed on January 21, 2015. Uses arising after the publication of the proposed rule are
196 distinguished from uses that exist at publication of the proposed rule. The former would be new
197 uses, the latter ongoing uses, except that uses that are ongoing as of the publication of the
198 proposed rule would not be considered ongoing uses if they have ceased by the date of issuance
199 of a final rule.

Commented [A32]: Comment #23

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Commented [A34]: Comment #3

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

201 Enacted on June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century
202 Act (Pub. L. 114-182) amended several sections of TSCA and added section 5(a)(5), Article
203 Consideration. The Article Consideration As a precondition to authorizing EPA to “require
204 notification under this section for the import or processing of a chemical substance as part of an
205 article or category of articles under paragraph (1)(A)(ii).” this provision requires that EPA
206 affirmatively find in a rule under section 5(a)(2) that the reasonable potential for exposure to a
207 chemical substance through the article or category of articles justifies notification. After

Commented [A35]: Comment #24

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208 considering the reasonable potential for exposure from articles under TSCA section 5(a)(5), EPA
209 is now issuing a supplemental proposal to make inapplicable the exemption for persons who
210 import certain LCPFAC chemical substances when those LCPFAC chemical substances are part
211 of a surface coating on articles.

212 If finalized as proposed, the January 21, 2015, proposed SNUR would require timely
213 advance notice to EPA of any future import of LCPFAC chemical substances for new uses that
214 may produce changes in human and environmental exposures, and would ensure that an
215 appropriate determination (relevant to the risks associated with such importing, processing, and
216 use) has been issued prior to the commencement of such importing. The proposed SNUR is
217 furthermore necessary to ensure that manufacturing (including importing) or processing for the
218 significant new use cannot proceed until EPA has responded to the circumstances by taking the
219 required actions under TSCA sections 5(e) or 5(f) in the event that EPA determines any of the
220 following: (1) that the significant new use presents an unreasonable risk under the conditions of
221 use (without consideration of costs or other non-risk factors, and including an unreasonable risk
222 to a potentially exposed or susceptible subpopulation identified as relevant by EPA); (2) that the
223 information available to EPA is insufficient to permit a reasoned evaluation of the health and
224 environmental effects of the significant new use; (3) that, in the absence of sufficient
225 information, the manufacturing (including importing), processing, distribution in commerce, use,
226 or disposal of the substance, or any combination of such activities, may present an unreasonable
227 risk (without consideration of costs or other non-risk factors, and including an unreasonable risk
228 to a potentially exposed or susceptible subpopulation identified as relevant by EPA); or (4) that
229 there is substantial production and sufficient potential for environmental release or human
230 exposure (as defined in TSCA section 5(a)(3)(B)(ii)(II)).

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

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

233 EPA has evaluated the potential costs of establishing SNUR reporting requirements for
234 potential importers of articles containing the chemical substances included in this supplemental
235 proposal **when they are part of a surface coating on articles.** This analysis (Ref. 2), which is
236 available in the docket, is discussed in Unit IX., and is briefly summarized here.

Commented [A36]: Comment #29

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

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

251 EPA welcomes comment on all aspects of this supplemental proposal. EPA based its
252 understanding of the use profile of these chemicals on the published literature, company progress
253 reports submitted during the 2010/2015 PFOA Stewardship Program, the 2016 CDR

254 submissions, market research, and review of Safety Data Sheets. To confirm EPA’s
255 understanding, the Agency is requesting public comment on all aspects of this supplemental
256 proposal. In providing comments on the reasonable potential for exposure to LCPFAC chemical
257 substances in articles, commenters are urged to provide sufficient information for EPA to
258 substantiate any assertions of use and of exposure. Additionally, EPA requests comment on the
259 assumption that article importers that choose to investigate their products will incur costs at the
260 lower end of the ranges presented in the Economic Analysis for this supplemental proposed rule.

Commented [A37]: Comment #27

Commented [A38]: Comment #72

261 G. Additional Considerations for Comment

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262 EPA also requests comment on whether or not the Agency should affirmatively establish
263 an explicit threshold at which, or explicit criteria for determining whether, a significant new
264 use exhibits a reasonable potential for exposure that justifies notification. While TSCA section
265 5(a)(5) does not establish a specific threshold or specific criteria for making this determination
266 and does not require EPA to affirmatively establish such a threshold or such criteria, EPA may
267 establish a threshold, or criteria, for determining reasonable potential for exposure if appropriate.

Commented [A39]: Note new language and edits from lines 258-337 or so.

Commented [A40R39]: Suggested revisions for section in redline

Commented [A41]: We seek affirmative confirmation from EPA OGC and DOJ that with the language requesting comment in this section, EPA would be able to finalize any of these options (re: (1) a threshold or criteria for reasonable potential for exposure, and (2) a safe harbor) in a final rule while complying with the APA’s notice and comment requirements (i.e., the logical outgrowth test would be satisfied).

Commented [A42R41]:

Commented [A43R41]: We moved this text, see response below

268 The statutory text TSCA section 5(a)(5) provides that the EPA Administrator “may
269 require notification under this section for the import or processing of a chemical substance as
270 part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an
271 affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the
272 chemical substance through the article or category of articles subject to the rule justifies
273 notification.” (Emphasis added.) Thus, Congress provided EPA with considerable discretion to
274 the statutory text allows EPA to determine (1) what is a “reasonable” potential for exposure; (2)
275 what kind of reasonable potential “justifies” notification; and (3) whether, in EPA’s discretion
276 (“may require”), to require notification in a case in which such a reasonable potential exists. By

Commented [A44]: From EPA Change #2 on EPA Responses to interagency Comments Received from OMB and SBA by phone 12/19/19

Commented [A45]: General comment – the prior version of this discussion needed to be more robust to ensure that the agency could actually act on the comments, in the final rule, to make changes to the proposal in such a way as to establish such a threshold or criteria

To this end, some language largely borrowed from another EPA rulemaking is provided below.

Commented [A46R45]: Suggested revisions for section in redline.

Commented [A47R45]: We moved this text, see response below

277 making notification contingent on the existence of a “reasonable” potential for exposure. TSCA
278 section 5(a)(5) implies that there is some category of less than reasonable potentials for exposure
279 that could not give rise to notification.

280 EPA requests comment on whether or not the Agency should affirmatively establish an
281 explicit threshold at which, or explicit criteria for determining whether, a significant new use
282 exhibits a reasonable potential for exposure that justifies notification. While TSCA section
283 5(a)(5) does not establish a specific threshold or specific criteria for making this determination
284 and does not require EPA to affirmatively establish such a threshold or such criteria, EPA may
285 establish a threshold, or criteria, for determining reasonable potential for exposure if appropriate.

286 EPA seeks comment on whether For example, EPA could adopt a de minimis threshold
287 for determining “reasonable potential for exposure” and if so, how that de minimis threshold
288 could be established. For example, ~~the~~ the United States Court of Appeals for the District of
289 Columbia Circuit has recognized that “[u]nless Congress has been extraordinarily rigid, there is
290 likely a basis for an implication of de minimis authority to provide exemption when the burdens
291 of regulation yield a gain of trivial or no value.” *Alabama Power Co. v. Costle*, 636 F.2d 323,
292 360-61 (D.C. Cir. 1980). In this instance, not only has Congress not been rigid, but Congress has
293 afforded to EPA considerable discretion in TSCA section 5(a)(5). The statutory text provides that
294 the EPA Administrator “may require notification under this section for the import or processing
295 of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if
296 the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable
297 potential for exposure to the chemical substance through the article or category of articles subject
298 to the rule justifies notification.” (Emphasis added.) The statutory language represents the
299 opposite of a mandate requiring EPA to require notification for import or processing with respect

Commented [A48]: We seek affirmative confirmation from EPA OGC and DOJ that with the language requesting comment in this section, EPA would be able to finalize any of these options (re: (1) a threshold or criteria for reasonable potential for exposure, and (2) a safe harbor) in a final rule while complying with the APA’s notice and comment requirements (i.e., the logical outgrowth test would be satisfied).

Commented [A49R48]:

Commented [A50R48]: It is difficult to completely insulate a final rule from a vulnerability that isn’t a logical outgrowth of a proposal. And here it is particularly hard to speculate on the extent of any such vulnerability when the details of what a future final rule might contain are so uncertain. It’s not only unclear what the final rule might say but what the record basis would be. However, the fact that EPA is not proposing in this supplemental proposal a specific de minimis level or standard for including articles in a significant new use does, in EPA’s view, increase the probability of logical outgrowth problems.

EPA would need more supporting information in the record and the opportunity to analyze that information to justify any specific threshold in the final rule. Because the SNUR only covers uses that are not ongoing, conducting that analysis would be a challenge.

The NDAA provided a statutory deadline of June 22, 2020 for the final LCPFAC SNUR.

Commented [A51]: From EPA Change #2 on EPA Responses to interagency Comments Received from OMB and SBA by phone 12/19/19

Commented [A52]: General comment – the prior version of this discussion needed to be more robust to ensure that the agency could actually act on the comments, in the final rule, to make changes to the proposal in such a way as to establish such a threshold or criteria.

To this end, some language largely borrowed from another EPA rulemaking is provided below.

Commented [A53R52]: Suggested revisions for section in redline.

Commented [A54]: This discussion (except for the particular application to section 5(a)(5)) is generally borrowed from EPA’s proposed rule at <https://www.federalregister.gov/documents/2019/08/14/2019-17018/protection-of-stratospheric-ozone-adjustments-to-the-allowance-system-for-controlling-hfc>

Commented [A55R54]: Suggested revisions for section in redline.

Commented [A56]: We moved this up to the first paragraph of section G.

300 ~~to a chemical substance for which there is any conceivable potential for exposure. Instead of~~
301 ~~providing that EPA “shall” require notification, or that notification is or could be triggered based~~
302 ~~upon “any” potential for exposure, section 5(a)(5) instead provides that EPA “may” require~~
303 ~~notification, and that notification is or could be triggered based upon the “reasonable” potential~~
304 ~~for exposure—which, moreover, must “justify” notification, as determined by EPA. The~~
305 ~~statutory text allows EPA to determine (1) what is a “reasonable” potential for exposure; (2) to~~
306 ~~determine what kind of reasonable potential “justifies” notification; and (3) whether, in EPA’s~~
307 ~~discretion (“may require”), to require notification in a case in which such a reasonable potential~~
308 ~~exists.~~

Commented [A57]: EPA accepted the addition of the same 5(a)(5) language with emphasis added in the previous paragraph, and we are not saying anywhere in the supplemental proposal that TSCA requires that EPA “shall” require notification for “any” potential exposure. Rather, EPA is providing in this preamble the rationale for proposing there is a reasonable potential for exposure from imported articles that justifies notification. This language is redundant and potentially confusing.

309 In *Alabama Power*, the Court ~~concluded~~has recognized that “[c]ategorical exemptions
310 from statutory commands may . . . be permissible as an exercise of agency power, inherent in
311 most statutory schemes, to overlook circumstances that in context may fairly be considered de
312 minimis. It is commonplace, of course, that the law does not concern itself with trifling matters,
313 and this principle has often found application in the administrative context. Courts should be
314 reluctant to apply the literal terms of a statute to mandate pointless expenditures of effort.” 636
315 F.2d at 360 (citations omitted). “The ability . . . to exempt de minimis situations from a statutory
316 command is not an ability to depart from the statute, but rather a tool to be used in implementing
317 the legislative design.” *Id.* Courts have continued to recognize that authority to create de minimis
318 exemptions may be implied where “the burdens of regulation yield a gain of trivial or no value.”
319 *Env’tl. Def. Fund. Inc. v. EPA*, 82 F.3d 451, 466 (D.C. Cir. 1996) (internal quotation marks
320 omitted); *see also, e.g., Ass’n of Admin Law Judges v. FLRA*, 397 F.3d 957, 961-62 (D.C. Cir.
321 2005). ~~In this case, by making notification contingent on the existence of a “reasonable”~~
322 ~~potential for exposure, section 5(a)(5) implies that there is some category of less than reasonable~~

Commented [A58]: We kept this language – we moved it up a line 265-268

Commented [A59]: This was not the court holding, rather it dicta. The word “recognized” was used in the previous paragraph and EPA suggests using it here for consistency and clarity.

323 ~~potentials for exposure that could not give rise to notification.~~

Commented [A60]: We moved this up to the first paragraph of this section.

324 ~~As another alternative, and as~~As an application of the statutory requirements in the
325 context of this specific Significant New Use Rule, EPA could set a specific threshold level for
326 ~~the content of the LCPFAC below which reporting would not be required (for example, 0.1%,~~
327 ~~0.5%, or 1% in percentage of the product composition for example). EPA requests comment both~~
328 ~~on how this threshold level could be determined, and on what such levels might be.~~
329 ~~Establishment of a threshold~~ Such an action could be based on one or more of the following
330 ~~rationales: (1) below the selected threshold level, there is no “reasonable potential for exposure”~~
331 ~~within the meaning of section 5(a)(5), because (i.e., the risk of exposure is very low); and (2)~~
332 ~~below the selected threshold level, there is a “reasonable potential for exposure” (or,~~
333 ~~alternatively, there may be such a potential), but the potential does not “justif[y] notification.”~~
334 ~~within the meaning of section 5(a)(5), given that the concomitant (i.e., potential for risk is very~~
335 ~~low in light of considerations of the reasonable potential for exposure being so low, due to the~~
336 ~~low level of LCPFAC present in the surface coating); that notification is not justified when one~~
337 ~~considers the potential for risk. While some studies discussed in Section III show the release of~~
338 ~~LCPFAC from articles, many of those studies were laboratory-based and did not represent a~~
339 ~~natural environment. EPA is also interested in considering the reasonable potential for exposure~~
340 ~~in a natural environment that represents typical exposures. EPA is seeking comment on whether~~
341 ~~there would be reasonable potential for exposure under typical conditions of use of the article as~~
342 ~~contrasted with laboratory experiments designed to release the LCPFAC under laboratory~~
343 ~~conditions.~~

Commented [A61]: Studies such as those cited examine the release of LCPFAC chemical substances from products under controlled laboratory conditions as a proxy for potential real-world exposure. EPA believes that it is reasonable to conclude that if LCPFAC chemicals are released from articles in controlled experiments, there is a reasonable potential for exposure under normal use conditions.

Commented [A62]: EPA rejects this edit because the use designated as a significant new use does not currently exist. Thus, EPA defers a detailed consideration of potential exposures related to that use until there is a specific condition of use and data to review.

Commented [A63]: Added per 2/11 Principals call

344 ~~Additionally~~As another alternative, Alternatively, EPA could use establish or use specific
345 criteria to determine whether or not the “reasonable potential for exposure” justifies notification.

346 For example, EPA could receive from importers information on the level of ~~For instance, in the~~
347 ~~context of this particular Significant New Use Rule, these criteria could be linked to aspects such~~
348 ~~as: the LCPFAC level in the product or ; the LCPFAC level in the surface coating, and determine~~
349 ~~the level is low enough to not meet the “reasonable potential for exposure” notification~~
350 ~~requirement. EPA notes also that a person’s exposure to LCPFAC could be impacted by ;~~
351 ~~whether or not the article itself is used as a stand-alone product or incorporated into another~~
352 ~~product, and as such receiving such information could also be of help to the Agency. Another~~
353 ~~consideration could be that EPA requests information on the (for instance, LCPFAC may be in~~
354 ~~the surface coating of a chip that is within the motherboard of a computer or printer); and/or the~~
355 ~~method by which the LCPFAC is incorporated into the surface coating and its whether that~~
356 ~~method changes the impact on the likelihood of release from the article. EPA seeks comment on~~
357 ~~the above discussion and on criteria that the Agency could use to determine whether or not the~~
358 ~~“reasonable potential for exposure” justifies notification.- detailed input on these potential~~
359 ~~criteria, as well as other suggestions for criteria that could be implemented to help ensure that the~~
360 ~~notification is justified.~~

361
362 We invite robust comment on these and other possible thresholds or criteria that could be
363 implemented by EPA in a final rule.

364 ~~Additionally-Finally, EPA notes that diverse importers of articles could be affected by~~
365 ~~this rule, and that some may be unfamiliar with the SNUR process and may not identify at the~~
366 ~~time of this rulemaking that they have an ongoing use of a LCPFAC. -EPA requests comment on~~
367 ~~whether or not the Agency should include a safe harbor provision for importers of articles that~~
368 ~~can demonstrate their the use was ongoing prior to the effective date of this rule. -EPA is aware,~~

Commented [A64]: Added per 2/11 Principals call

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Commented [A65]: Suggest EPA provide some examples of safe harbor provisions in other contexts and how could be applied here (similar to legal language added above) and how considered by courts

Commented [A66R65]: Suggested revisions in redline

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369 ~~including from comments received on the 2015 proposal, that some importers have knowledge~~
370 ~~that there may be some LCPFAC and other polyfluoroalkyl substances (PFAS) compounds~~
371 ~~within an article. However, because these chemistries often occur in complex mixtures, and it is~~
372 ~~possible that these mixtures change over time, there is not perfect knowledge of which LCPFAC~~
373 ~~may or may not be in products that are current ongoing uses. EPA requests that commenters~~
374 ~~provide support either for or against adding a safe harbor provision to this rule, including~~
375 ~~discussion of the text of section 5(a)(5) and how the discretion granted therein could be exercised~~
376 ~~to allow for a safe harbor provision. EPA also requests specific language that could be used in~~
377 ~~structuring such a safe harbor provision.~~

Commented [A67]: This discussion also should be made more robust.

Commented [A68R67]: Suggested revisions in redline.

Commented [A69]: From EPA Responses to interagency Comments Received from OMB and SBA by phone 12/19/19

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

379 1. Submitting CBI. ~~1. Submitting CBI.~~ It is EPA's policy to include all comments
380 received in the public docket without change or further notice to the commenter and to make the
381 comments available on-line at www.regulations.gov, including any personal information
382 provided, unless a comment includes information claimed to be CBI or other information whose
383 disclosure is restricted by statute. Do not submit this information to EPA through regulations.gov
384 or e-mail. Clearly mark the part or all of the information that is claimed to be CBI. For CBI
385 information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD
386 ROM as CBI and then identify electronically within the disk or CD ROM the specific
387 information that is claimed as CBI. In addition to one complete version of the comment that
388 includes information claimed as CBI, a copy of the comment that does not contain the
389 information claimed as CBI must be submitted for inclusion in the public docket. Information so
390 marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2,
391 subpart B.

Commented [A70]: EPA typesetting ed

392 ~~2. Tips for preparing your comments.~~ *2. Tips for preparing your comments.* When

Commented [A71]: EPA typesetting ed

393 preparing and submitting your comments, see the commenting tips at

394 <http://www2.epa.gov/dockets/commenting-epa-dockets#tips>.

395 II. Chemical Substances Subject to this Proposed Rule

396 A. What Chemicals Are Covered by this Supplemental Proposal?

397 This supplemental proposal would modify the requirements for a subset of LCPFAC
398 chemical substances at 40 CFR 721.10536 by making the exemption at 40 CFR 721.45(f)
399 inapplicable for persons who import LCPFAC chemical substances listed in Table 1 of this unit
400 and PFOA or its salts (see Table 2 of this unit) as part of an article in which these LCPFAC
401 chemical substances have been applied as part of a surface coating. The subset of LCPFAC
402 chemical substances also includes the salts and precursors of these perfluorinated carboxylates.

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

Commented [A72]: Comment #10

406 proposed in the 2015 SNUR NPRM, the article exemption would still apply to LCPFAC
407 chemical substances not listed in Table 1 or Table 2 of this unit, with the exception of the import
408 of carpets, for which the import exemption is already inapplicable (78 FR 62443; October 22,
409 2013) (FRL-9397-1). The other provision of 40 CFR 721.45(f), respecting processing a chemical
410 substance as part of an article, remains applicable.

Commented [A73]: Comment #30

411 Table 1—LCPFAC Chemical Substances Subject to Reporting

Commented [A74]: EPA typesetting ed of Table 1 (change to font 12pt and single space)

Chemical Name	CAS Registry No. (CASRN)	EPA Accession No.	TSCA Chemical Inventory Name
Perfluorooctyl iodide	507-63-1	N/A	Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-8-iodo-

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Tetrahydroperfluoro-1-decanol	678-39-7	N/A	1-Decanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10, 10-heptadecafluoro-
Perfluoro-1-dodecanol	865-86-1	N/A	1-Dodecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10, 11,11,12,12,12-heneicosafuoro-
Perfluorodecyl iodide	2043-53-0	N/A	Decane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8- heptadecafluoro-10-iodo-
1,1,2,2-Tetrahydroperfluorododecyl iodide	2043-54-1	N/A	Dodecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9, 9,10,10-heneicosafuoro-12- iodo-
Perfluorodecylethyl acrylate	17741-60-5	N/A	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10, 11,11,12,12,12- heneicosafuorododecyl ester
1,1,2,2-Tetrahydroperfluorodecyl acrylate	27905-45-9	N/A	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10, 10-heptadecafluorodecyl ester
1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12-Pentacosafuoro-14-iodotetradecane	30046-31-2	N/A	Tetradecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9, 9,10,10,11,11,12,12- pentacosafuoro-14-iodo-
3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-Pentacosafuorotetradecan-1-ol	39239-77-5	N/A	1-Tetradecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10, 11,11,12,12,13,13,14,14,14- pentacosafuoro-
3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-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, 11,11,12,12,13,13,14,14,15,15,1 6,16,16-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	65510-55-6	N/A	Hexadecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9, 9,10,10,11,11,12,12,13,13,14,14 -nonacosafuoro-16-iodo-
Sodium;2-methylpropane-1-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 ₄ SiO ₄), sodium salt (1:2), reaction products with chlorotrimethylsilane and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-1-decanol	125476-71-3	N/A	Silicic acid (H ₄ SiO ₄), sodium salt (1:2), reaction products with chlorotrimethylsilane and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-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)

412

413 **Table 1—LCPFAC Chemical Substances Subject to Reporting**

Chemical Name	CAS Registry No. (CASRN)	EPA Accession No.	TSCA Chemical Inventory Name
Perfluorooctyl iodide	507-63-1	N/A	Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-8-iodo-
Tetrahydroperfluoro-1-decanol	678-39-7	N/A	1-Decanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-
Perfluoro-1-dodecanol	865-86-1	N/A	1-Dodecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-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-

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Chemical Name	CAS Registry No. (CASRN)	EPA Accession No.	TSCA Chemical Inventory Name
1,1,2,2-Tetrahydroperfluorododecyl iodide	2043-54-1	N/A	Dodecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10-heneicosaffluoro-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-heneicosaffluorododecyl 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-Pentacosaffluoro-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-pentacosaffluoro-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-Pentacosaffluorotetradecan-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-pentacosaffluoro-
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-Nonacosaffluorohexadecan-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-nonacosaffluoro-
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-Nonacosaffluoro-16-iodohexadecane	65510-55-6	N/A	Hexadecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14-nonacosaffluoro-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 (H4SiO4), 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 (H4SiO4), 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,	1078712-88-5	N/A	Thiols, C4-20, gamma-omega-perfluoro, telomers with acrylamide and acrylic acid, sodium salts

Chemical Name	CAS Registry No. (CASRN)	EPA Accession No.	TSCA Chemical Inventory Name
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)

414

415 The term LCPFAC refers to the long-chain category of perfluoroalkyl carboxylate
 416 chemical substances with perfluorinated carbon chain lengths equal to or greater than seven
 417 carbons and less than or equal to 20 carbons. The category of LCPFAC chemical substances also
 418 includes the salts and precursors of these perfluorinated carboxylates. See Unit II.A. of the
 419 proposed rule (Ref. 1) for further discussion of the LCPFAC category. [In addition to the subset](#)
 420 [of LCPFAC chemical substances identified in Table 1](#), PFOA and its salts would be subject to
 421 the proposal. PFOA and its salts are considered LCPFAC chemical substances. PFOA and
 422 examples of PFOA salts with CASRNs and chemical names are shown in Table 2 of this unit.

Commented [A75]: Comment #31

423 **Table 2—PFOA and Examples of Its Salts**

Commented [A76]: EPA typesetting ed of Table 2 (change to font 12pt and single space)

Chemical Name	CAS Registry No. (CASRN)	TSCA Chemical Inventory Name
Pentadecafluorooctanoyl fluoride	335-66-0	Octanoyl fluoride, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-
Perfluorooctanoic acid	335-67-1	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (PFOA)
Silver perfluorooctanoate	335-93-3	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, silver (+) salt (1:1)

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

424 **Table 2—PFOA and Examples of Its Salts**

Chemical Name	CAS Registry No. (CASRN)	TSCA Chemical Inventory Name
Pentadecafluorooctanoyl fluoride	335-66-0	Octanoyl fluoride, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-
Perfluorooctanoic acid	335-67-1	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (PFOA)
Silver perfluorooctanoate	335-93-3	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, silver (+) salt (1:1)
Sodium perfluorooctanoate	335-95-5	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, sodium salt (1:1)
Potassium perfluorooctanoate	2395-00-8	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, potassium salt (1:1)
Ammonium perfluorooctanoate	3825-26-1	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, ammonium salt (1:1) (APFO)

425

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

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427 PFOA, a member of the LCPFAC category, is a synthetic (man-made) chemical that does
 428 not occur naturally in the environment. The ammonium salt of PFOA was manufactured in U.S.
 429 for use primarily as an aqueous dispersion agent in the manufacture of fluoropolymers. Chemical
 430 Data Reporting (CDR) rule requires manufacturers (including importers) to report for PFOA if
 431 they meet 2,500 ~~pounds lbs~~ production volume threshold at a single site. The last time PFOA
 432 manufacture was reported to EPA as part of this collection effort was for the 2016 reporting
 433 period. PFOA can also be ~~produced created~~ unintentionally by the degradation of some
 434 fluorotelomers, which are not manufactured using PFOA but could degrade to PFOA.

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435 Fluorotelomers are used to make polymers that impart soil, stain, grease, and water resistance to
436 coated articles. Some fluorotelomer based products are also used as high-performance surfactants
437 in products where an even flow is essential, such as paints, coatings, cleaning products, and fire-
438 fighting foams for use on liquid fuel fires (Ref. 3).

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

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

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

459 ~~To date, PFOA has LCPFACs have been linked to a number of health effects, including~~
460 ~~thyroid disease and impacts on reproductive function (Refs. 5 and 6). PFOA and its salts, which~~
461 ~~are considered LCPFAC chemical substances, have been the primary focus of studies related to~~
462 ~~LCPFAC class of chemical substances.~~ PFOA is persistent, widely present in humans and the
463 environment, has a half-life in humans of 2.3-3.8 years, and can cause adverse effects in
464 laboratory animals, including cancer and developmental and systemic toxicity (Refs. 3, ~~5-7, 6-8,~~
465 ~~7-9, and 8-10~~). Human epidemiology data report associations between PFOA exposure and high
466 cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders,
467 pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney) (Ref. ~~9~~
468 ~~11~~).

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Commented [A79]: This is confusing as the reference is for just PFOA yet the sentence suggests all LCPFAC are 'linked' to these health effects. This simply is not true. Suggest deleting this sentence as below references are more specific to PFOA and don't make broad vague statements (eg what does linked mean to a scientist?) the effect is also captured below with reference 11 which is a more robust EPA document

Commented [A80R79]: EPA appreciates the comment. Rather than remove these references, EPA will amend the sentence to reflect that the references pertain to PFOA.

Commented [A81]: Comment #33
Refs X and Y

Commented [A82]: EPA typesetting ed

469 III. Rationale and Objectives

470 A. Rationale

471 This supplemental proposal presents the basis for the reasonable potential for exposure to
472 LCPFAC chemical substances from this category of articles for purposes of TSCA section
473 5(a)(5). LCPFAC chemical substances have been found in the blood of the general human
474 population, as well as in wildlife, indicating that exposure to these chemical substances is
475 widespread (Ref. 3, ~~10-12, 11-13~~). Multiple pathways of exposure, including through drinking
476 water, food (~~fish~~), ~~migration from food packaging paper products~~, house dust, and release from
477 treated articles are possible (Ref. ~~12-14~~).

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Commented [A84]: Comment #37

478 In the absence of a regulation, manufacture or processing for the significant new uses
479 proposed on January 21, 2015 (Ref. 1), may begin at any time, without prior notice to EPA. As
480 explained in the January 21, 2015, proposal (Ref. 1), EPA is concerned that commencement of

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481 the manufacture (including import) or processing for any new uses, including resumption of past
482 uses, of LCPFAC chemical substances could increase the magnitude and duration of exposure to
483 humans.

484 Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2),
485 EPA's decision to propose a SNUR for a particular chemical is not based on an extensive
486 evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the
487 existence of a SNUR requires a notice, upon receipt of which EPA would conduct an assessment.
488 If a person decides to begin importing any of these chemicals for a significant new use, the
489 notice to EPA allows the Agency to evaluate the use according to the specific parameters and
490 circumstances surrounding the conditions of use.

491 In most cases, LCPFAC chemical substances are not incorporated into the article and
492 bound to the article matrix but are rather added or applied as a coating or as part of coating aid.
493 Surface coatings are subject to mechanical and/or chemical or photolytic stress, which can lead
494 to degradation of the coating layer, depending on the circumstances (e.g. depending upon the
495 stressor and the type of coating matrix). As an unbound, unincorporated component of a surface
496 coating (Refs. 15 and 16), LCPFAC chemical substances can thereby be released from the
497 coating as a result of this degradation of the coating layer. Additionally, because LCPFAC
498 chemical substances used in this category of articles are coating the surface, if the underlying
499 substrate of the article is degraded and released, the LCPFAC surface coating could be released
500 at the same time.

501 Rather than making the article exemption inapplicable for any article, as was proposed in
502 the January 21, 2015, proposal (Ref. 1), this action proposes to make a finding under TSCA
503 section 5(a)(5) and make the article exemption at 40 CFR 721.45(f) inapplicable for persons

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Commented [A86]: Comment #40

Commented [A87]: Comment #41
Refs. Q and R

504 importing ~~or processing~~ the category of articles that contain certain LCPFAC chemical
505 substances as part of a surface coating ~~for a non-ongoing use on articles~~. EPA defines “articles
506 where certain LCPFAC chemical substances are part of surface coating on articles” as the
507 category of articles subject to this rule, based on the reasonable potential for exposure as shown
508 through research on LCPFAC chemical substances. This category of articles is expected to
509 exhibit reasonable potential for exposure to LCPFAC chemical substances, as elaborated herein.
510 EPA is not making a finding on the reasonable potential for exposure from articles that do not
511 contain LCPFAC chemical substances as a surface coating.

Commented [A88]: Comment #43

Commented [A89]: Comment #10

Commented [A90]: Comment #35

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

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

Commented [A91]: EPA typesetting ed

514 A coating is a material applied in a thin layer to a surface as a protective, decorative, or
515 functional film. This term often refers to paints such as lacquers or enamels, but also refers to
516 films applied to other materials including, but are not limited to, paints, varnishes, sealants,
517 adhesives, inks, maskants, and temporary protective coatings. LCPFAC chemical substances
518 have been used in surface coatings for numerous applications given their hydrophobic and
519 lipophobic properties. Examples of LCPFAC coating applications in articles are stain- and water-
520 repellent fabrics and nonstick products (e.g., coatings for cookware) (Ref. 3).

Commented [A92]: Comment #48

521 The release of LCPFAC chemical substances from coatings on articles has been well-
522 documented in the scientific literature. LCPFAC chemical substances can be released
523 continuously over years from treated jackets, furniture, and carpets into the air due to
524 volatilization (Refs. 13-17, 14-18, and 15-19) and due to degradation of commercial LCPFAC
525 coatings by simple abiotic reaction with water (Ref. 16-20). ~~Research on non-stick coatings on~~
526 ~~cookware and food contact paper (e.g., popcorn bags) has shown LCPFACs to be released into~~

Commented [A93]: Follow-up Comment #49

527 the gas phase under normal cooking temperatures (Ref. 17-21). A 2017 study showed that per-
528 and polyfluoroalkyl substances (PFAS) (including long-chain fluorotelomer alcohols) in grease-
529 resistant food packaging can leach into food stated that per- and polyfluoroalkyl substances
530 (PFAS) “in grease-resistant food packaging can leach into food and increase dietary exposure
531 (Ref. 18-22).” While food-contact products are regulated under the Federal Food, Drug and
532 Cosmetic Act and not TSCA, (Ref. 18).” Similarly, PFAS can could potentially be released from
533 other similar packaging with PFAS coating that would be subject to TSCA. Stone and tile
534 sealants have been shown to contain extractable amounts of LCPFAC chemical substances and,
535 for homes without carpeting, are a potentially important could be an indoor source of these
536 chemical substances (Ref. 19-23,21).

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

544 Articles that could potentially have LCPFAC chemical substances as part of a surface
545 coating include, but are not limited to: furniture, medical garments, safety equipment, outdoor
546 apparel or equipment, automobile components, aerospace components, electronics, heavy
547 machinery, and household appliances. EPA cites these studies (Refs. 17, 18, 19, 20, and 21) to
548 support the Agency’s conclusion that there is reasonable potential for exposure from the category
549 of articles that contain certain LCPFAC chemical substances as part of a surface coating.

Commented [A94]: Comment #49, #54, #53

Commented [A95]: Comment #53

Commented [A96]: EPA response 55 is clear that there is no data to suggest releases from stone in a normal home environment. As such this language is misleading as there is nothing to suggest a potentially important exposure. Extraction of LCPFAC from stone in a laboratory does not tell us anything about meaningful home exposures.

Commented [A97R96]: EPA accepts the edit

Commented [A98]: Follow-up citation change

Commented [A99]: Note new text

Commented [A100R99]: EPA accepts the added language

Commented [A101]: Follow-up comment #45 (one of two)

Commented [A102]: @@@

Commented [A103]: (Refs. 13, 14, 15, 16, and 17) in EPA response 2 document

550 ~~ii. Proposed finding.~~ ~~ii. Proposed finding.~~ Commented [A104]: EPA typesetting ed

551 Based on these considerations, EPA is proposing to make the TSCA section 5(a)(5)
552 finding and make inapplicable the exemption at 40 CFR 721.45(f) for persons who import ~~of~~
553 ~~process any~~ of a defined set of LCPFAC chemical substances as part of an article where Commented [A105]: Comment #10, #7

554 LCPFAC chemical substances have been applied as part of a surface coating for a non-ongoing
555 use. The defined subset are the chemical substances phased out through the 2010/2015 PFOA
556 Stewardship Program, shown in Table 1 and Table 2 of Unit II.

557 The article exemption at 40 CFR 721.45(f) is based on an assumption that people and the
558 environment will generally not be exposed to chemical substances in articles (Ref. 20-24-22).

559 However, ~~even~~ when added to ~~the surface coating of~~ an article, LCPFAC can be released over Commented [A106]: Comment #61, #66

560 time with use (Refs. 3 and 16-20). ~~Studies on the degradation of fluorotelomer-based polymers~~ Commented [A107]: Comment #58

561 ~~show that these polymers are subject to hydrolysis, photolysis and biodegradation, with half-lives~~

562 ~~of a few days to hundreds of years (Ref. 23). In addition, research by EPA on degradation of~~

563 ~~fluorotelomers and fluoropolymers has shown that some urethanes and acrylates biodegrade;~~

564 ~~however, half-lives and kinetics are not yet well-defined (Ref. 16). These studies have shown~~

565 ~~that the perfluorinated portion of some polymers is released as the polymer is degraded by~~

566 ~~microbial or abiotic processes to form telomer alcohols or other intermediates and that they~~

567 ~~eventually form LCPFAC.~~ Based on this understanding, upon receipt of a SNUN, EPA intends to Commented [A108]: Follow-up Comment #58

568 evaluate the potential risk of exposure to human health and the environment for any intended

569 significant new use of LCPFAC chemical substances (including as ~~part of a surface coating of an~~

570 ~~article~~). Commented [A109]: Comment #61 #62, #66

571 Given that the release of LCPFAC chemical substances from surface coatings on articles Commented [A110]: Comment #63

572 has been ~~researched and confirmed shown to occur~~ and that these releases can ~~reasonably~~ be Commented [A111]: Suggest deletion as many of the examples (extraction, digestion) are not real world exposures. We are allowing EPA to maintain the reasonable potential for exposure language but its not clear the data support this sentence which refers to day to day use.

Commented [A112R111]: EPA accepts the edit

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573 expected to result in exposure to the users of articles, EPA has reason to anticipate that importing
574 ~~or processing~~ articles that have certain LCPFAC chemical substances as part of a surface coating
575 would create the potential for exposure to these LCPFAC chemical substances, and that EPA
576 should have an opportunity to review the intended use before such use could occur. Therefore,
577 EPA affirmatively finds under TSCA section 5(a)(5) that notification for import is justified by
578 the reasonable potential for exposure to certain LCPFAC chemical substances when part of
579 surface coatings for the articles identified in this SNUR. Existence of the SNUR triggers the
580 submission of a SNUN, thereby allowing EPA to evaluate potential uses (before those uses
581 would begin) whether in the form of an article, or not, for any hazards, exposures and risks that
582 might exist before those uses would begin.

Commented [A113]: Comment #10, #7

Commented [A114]: Comment #10

Commented [A115]: Comment #10

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

589 *B. Objectives*

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

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

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

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

602 **IV. Economic Analysis**

603 *A. SNUNs*

604 EPA has evaluated the potential costs of establishing SNUR reporting requirements for
605 potential importers of the chemical substance included in this supplemental proposal in surface
606 coatings of articles (Ref. 2). In the event that a SNUN is submitted, average costs are estimated
607 at approximately \$23,000 per SNUN submission for large business submitters and about \$10,000
608 for small business submitters. These estimates include the cost to prepare and submit the SNUN
609 (averaging about \$7,300), and the payment of a user fee. Businesses that submit a SNUN would
610 be subject to either a \$16,000 user fee required by 40 CFR 700.45(c)(2)(ii), or, if they are a small
611 business, a reduced user fee of \$2,800 (40 CFR 700.45(c)(1)(ii)). Businesses that submit a
612 SNUN are also estimated to incur average costs of \$63 for rule familiarization. First time
613 submitters will incur an average cost of \$123 for CDX registration and associated activities.
614 Companies manufacturing, importing, or processing asbestos or articles containing asbestos
615 LCPFAC chemical substances as part of a surface coating will incur an average cost of \$79 for
616 notifying their customers of SNUR regulatory activities. EPA's complete economic analysis is
617 available in the public docket for this rule (Ref. 2).

618 In making inapplicable the exemption relating to persons who import certain chemical

Commented [A116]: Comment #69

Commented [A117]: Comment #70

619 substances as part of the surface coating of an article, this action may affect firms that plan to
620 import or process types of articles that may contain the subject chemical substance in a surface
621 coating. similar articles that while not containing the chemical substances included in this
622 SNUR, may appear to. This is because while some firms have an understanding of the contents
623 of the articles they import or process other firms do not. EPA acknowledges that importers and
624 processors of articles may have varying levels of knowledge about the chemical content of the
625 articles that they import or process. These parties may need to become familiar with the
626 requirements of the rule. And while not required by the SNUR, these parties may take additional
627 steps to determine whether the subject chemical substances are part of the articles that they are
628 considering for import or processing. This determination may involve activities such as gathering
629 information from suppliers along the supply chain, and/or testing samples of the article itself.
630 Costs vary across the activities chosen and the extent of familiarity a firm has regarding the
631 articles it imports or processes. Cost ranges are presented in Understanding the Costs Associated
632 with Eliminating Exemptions for Articles in SNURs (Ref. ~~21-25~~ 24). Based on available
633 information, EPA believes that article importers or processors that choose to investigate their
634 products would incur costs at the lower end of the ranges presented in the Economic Analysis.
635 For those companies choosing to undertake actions to assess the composition of the articles they
636 import or process, EPA expects that importers would take actions that are commensurate with
637 the company’s perceived likelihood that a chemical substance might be a part of an article for the
638 significant new uses identified in Units II. and III., and the resources it has available. Example
639 activities and their costs are provided in the accompanying Economic Analysis of this
640 supplemental proposal (Ref. 2).

641 *B. Export Notification*

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Commented [A119]: Follow-up Comment #68
@@@

Commented [A120]: Comment #68

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

649 **V. Scientific Standards, Evidence, and Available Information**

650 EPA has used scientific information, technical procedures, measures, methods, protocols,
651 methodologies, and models consistent with the best available science, as applicable. These
652 information sources supply information relevant to whether a particular use would be a
653 significant new use, based on relevant factors including those listed under TSCA section 5(a)(2).
654 Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's
655 decision to promulgate a SNUR for a particular chemical use need not be based on an extensive
656 evaluation of the hazard, exposure, or potential risk associated with that use; as such, the January
657 2015 proposed rule (Ref. 1) and this supplemental proposal are not based on an evaluation of
658 expected risks.

659 The clarity and completeness of the data, assumptions, methods, quality assurance, and
660 analyses employed in EPA's decision are documented, as applicable and to the extent necessary
661 for purposes of the January 2015 proposed rule and this supplemental proposal, in Unit II. and in
662 the references cited throughout the two preambles. Considering the extent to which the various
663 information, procedures, measures, methods, protocols, methodologies or models used in EPA's
664 decision have been subject to independent verification or peer review, EPA believes that their

665 use is appropriate in this rule. EPA recognizes, based on the available information, that there is
666 variability and uncertainty in whether any particular significant new use would actually present
667 an unreasonable risk. For precisely this reason, EPA is proposing to require notice and review for
668 these uses at such time as they are known more definitely.

669 **VII. References**

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

676 1. EPA. Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical
677 Substances; Significant New Use Rule. Proposed Rule. **Federal Register** (80 FR 2885, January
678 21, 2015) (FRL-9915-63).

679 2. EPA. Economic Analysis of the Supplemental Proposal to the Significant New Use
680 Rule for Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical
681 Substances. **MONTH DAY, 2019.**

682 3. EPA. Long-Chain Perfluorinated Chemicals Action Plan. December 30, 2009.
683 Accessed at: [https://www.epa.gov/sites/production/files/2016-](https://www.epa.gov/sites/production/files/2016-01/documents/pfcs_action_plan1230_09.pdf)
684 [01/documents/pfcs_action_plan1230_09.pdf](https://www.epa.gov/sites/production/files/2016-01/documents/pfcs_action_plan1230_09.pdf)

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

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689 [thyroid disease in the US National Health and Nutrition Examination Survey." *Environmental*](#)
690 [health perspectives 118.5 \(2010\): 686-692.](#)
- 691 [6. Knox, Sarah S., et al. "Implications of early menopause in women exposed to](#)
692 [perfluorocarbons." *The Journal of Clinical Endocrinology & Metabolism* 96.6 \(2011\): 1747-](#)
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- 696 [8. 6: Houde, Magali, et al. "Biological monitoring of polyfluoroalkyl substances: a](#)
697 [review." *Environmental Science & Technology* 40.11 \(2006\): 3463-3473.](#)
- 698 [9. 7- Calafat, Antonia M., et al. "Polyfluoroalkyl chemicals in the US population: data](#)
699 [from the National Health and Nutrition Examination Survey \(NHANES\) 2003–2004 and](#)
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701 [1596.](#)
- 702 [10. 8: Lau, Christopher, et al. "Perfluoroalkyl acids: a review of monitoring and](#)
703 [toxicological findings." *Toxicological Sciences* 99.2 \(2007\): 366-394.](#)
- 704 [11. 9: EPA. Health Effects Support Document for Perfluorooctanoic Acid \(PFOA\). EPA](#)
705 [822-R-16-003. May 2016.](#)
- 706 [12. 10: USEPA. "Perfluoroalkyl Sulfonates; Significant New Use Rule, Final Rule." 67](#)
707 [FR 11008, March 11, 2002.](#)
- 708 [13. 11: 3M Company. *The Science of Organic Fluorochemistry*. St. Paul, Minnesota,](#)
709 [February 5, 1999.](#)
- 710 [14. 12: Strynar, Mark J., and Andrew B. Lindstrom. "Perfluorinated compounds in house](#)

711 dust from Ohio and North Carolina, USA." *Environmental Science & Technology* 42.10 (2008):
712 3751-3756.

713 [15. Bohnet, Matthias. *Ulmann's Encyclopedia of Industrial Chemistry*. Wiley-Vch, 2003.](#)

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717 polyfluoroalkyl substances \(PFASs\) via use of PFASs-containing products—risk estimation for
718 man and environment." *Texte* 47 \(2014\): 2014.](#)

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722 products and preliminary investigation of their fate in the indoor environment." *Chemosphere*
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724 [20. 16. Washington, J.W., T.M. Jenkins. 2015. Abiotic hydrolysis of fluorotelomer
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728 fluorotelomer alcohols released from nonstick cookware and microwave popcorn bags
729 *Environmental Science & Technology* 41.4 \(2007\): 1180-1185.](#)

730 [22. 18. Schaidt, Laurel A., et al. "Fluorinated Compounds in US Fast Food Packaging."
731 *Environmental Science & Technology Letters* 4.3 \(2017\): 105-111.](#)

732 [21. 23. 49. Guo, Zhishi, et al. "Perfluorocarboxylic acid content in 116 articles of
733 commerce." Research Triangle Park, NC: US Environmental Protection Agency \(2009\).](#)

Commented [A121]: Follow-up comment #45 (one of two)
keep

Commented [A122]: Follow-up comment #49
Remove references

@@@ In follow-up comment #45 (one of two), there is reference to
ref 21 (ref 17), but this is not longer in the document

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734 ~~22, 24, 20~~. U.S. EPA. Significant New Uses of Chemical Substances; Certain Chemicals.
735 49 FR 35014, September 5, 1984 (FRL-2541-8).

736 ~~23~~. [Washington, John W., et al. "Decades-scale degradation of commercial, side-chain,
737 fluorotelomer-based polymers in soils and water." Environmental science & technology 49.2
738 \(2015\): 915-923.](#)

Commented [A123]: Follow-up Comment #58

739 ~~24, 25, 21~~. U.S. EPA. Understanding the Costs Associated with Eliminating Exemptions
740 for Articles in SNURs. May 1, 2013.

741

742 VIII. Statutory and Executive Order Reviews

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

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

747 The Office of Management and Budget (OMB) designated this to be a significant
748 regulatory action and it was submitted to OMB for review under Executive Orders 12866 (58 FR
749 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in
750 response to OMB recommendations have been documented in the docket for this action as
751 required by section 6(a)(3)(E) of Executive Order 12866.

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

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

758 This action is expected to be subject to the requirements for regulatory actions specified
759 in Executive Order 13771 (82 FR 9339, February 3, 2017). EPA prepared an analysis of the
760 estimated costs and benefits associated with this action (Ref. 2), which is available in the docket
761 and is summarized in Unit I.E.

762 *C. Paperwork Reduction Act (PRA)*

763 This action does not impose any new information collection burden under the PRA, 44
764 U.S.C. 3501 *et seq.* Burden is defined in 5 CFR 1320.3(b). The information collection activities
765 associated with existing chemical SNURs are already approved under OMB control number
766 2070-0038 (EPA ICR No. 1188); and the information collection activities associated with export
767 notifications are already approved under OMB control number 2070-0030 (EPA ICR No.
768 0795). If an entity were to submit a SNUN to the Agency, the annual burden is estimated to be
769 less than 100 hours per response, and the estimated burden for export notifications is less than
770 1.5 hours per notification. In both cases, burden is estimated to be reduced for submitters who
771 have already registered to use the electronic submission system.

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

778 *D. Regulatory Flexibility Act (RFA)*

779 Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, I certify that promulgation of

780 this SNUR would not have a significant economic impact on a substantial number of small
781 entities. The rationale supporting this conclusion is as follows.

782 A SNUR applies to any person (including small or large entities) who intends to engage
783 in any activity described in the rule as a “significant new use.” By definition of the word “new”
784 and based on all information currently available to EPA, it appears that no small or large entities
785 presently engage in such activities. Since this SNUR will require a person who intends to engage
786 in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will
787 occur unless someone files a SNUN to pursue a significant new use in the future or forgoes
788 profits by avoiding or delaying the significant new use. Although some small entities may decide
789 to conduct such activities in the future, EPA cannot presently determine how many, if any, there
790 may be. However, EPA’s experience to date is that, in response to the promulgation of SNURs
791 covering over 1,000 chemical substances, the Agency receives only a handful of notices per year.
792 During the six-year period from 2005-2010, only three submitters self-identified as small in their
793 SNUN submission (Ref. 2). Based on this, EPA believes that few SNUN submissions will occur
794 as a result of the rule. EPA believes the cost of submitting a SNUN, \$10,000 for small business
795 submitters, is relatively small compared to the cost of developing and marketing a chemical new
796 to a firm or marketing a new use of the chemical and that the requirement to submit a SNUN
797 generally does not have a significant economic impact.

798 Therefore, EPA believes that the potential economic impact of complying with this
799 proposed SNUR is not expected to be significant or adversely impact a substantial number of
800 small entities. In a SNUR that published as a final rule on August 8, 1997 (62 FR 42690) (FRL-
801 5735-4), the Agency presented its general determination that proposed and final SNURs are not
802 expected to have a significant economic impact on a substantial number of small entities.

Commented [A124]: This language was agreed to be included here on the Dec. 19, 2019 call. This is also included in the agency's Follow-Up response to comment 76.

Commented [A125R124]: EPA appreciates the addition of the agreed upon language.

Commented [A126]: Comment #74

803 *E. Unfunded Mandates Reform Act (UMRA)*

804 Based on EPA’s experience with proposing and finalizing SNURs, State, local, and
805 Tribal governments have not been impacted by these rulemakings, and EPA does not have any
806 reason to believe that any State, local, or Tribal government would be impacted by this
807 rulemaking. As such, the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C.
808 1531-1538, do not apply to this action.

809 *F. Executive Order 13132: Federalism*

810 This action will not have federalism implications as specified in Executive Order 13132
811 (64 FR 43255, August 10, 1999), because it will not have substantial direct effect on States, on
812 the relationship between the national government and the States, or on the distribution of power
813 and responsibilities among the various levels of government.

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

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

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

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

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826 *I. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy*

827 *Supply, Distribution, or Use*

828 This action is not a significant energy action as defined in Executive Order 13211 (66 FR
829 28355, May 22, 2001), because it is not likely to have any effect on energy supply, distribution,
830 or use.

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

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

834 *K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority*

835 *Populations and Low-Income Populations*

836 This action will not have disproportionately high and adverse human health or
837 environmental effects on minority or low-income populations as specified in Executive Order
838 12898 (59 FR 7629, February 16, 1994). This action does not affect the level of protection
839 provided to human health or the environment.

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

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

843

844 Dated:

845

846

Commented [A127]: EPA typesetting ed

847 **Alexandra Dapolito Dunn,**

Commented [A128]: EPA typesetting ed

848 *Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

849

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

851 **PART 721--[AMENDED]**

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

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

854 2. Revise § 721.10536 to read as follows:

855 **§ 721.10536 Long-chain perfluoroalkyl carboxylate chemical substances.**

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

858 *Carpet* means a finished fabric or similar product intended to be used as a floor covering.

859 This definition excludes resilient floor coverings such as linoleum and vinyl tile.

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

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

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

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

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

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

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

873 **Table 1—LCPFAC Chemical Substances Subject to Reporting After December 31, 2015**

Commented [A129]: EPA typesetting ed (size 12 font and single spacing)

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

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sulfonate			methyl-, 2-[[1-oxo-3-(γ - ω -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, γ - ω -perfluoro
Thiols, C8-20, γ - ω -perfluoro, telomers with acrylamide	70969-47-0	N/A	Thiols, C8-20, γ - ω -perfluoro, telomers with acrylamide
Silicic acid (H ₄ SiO ₄), sodium salt (1:2), reaction products with chlorotrimethylsilane and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-1-decanol	125476-71-3	N/A	Silicic acid (H ₄ SiO ₄), sodium salt (1:2), reaction products with chlorotrimethylsilane and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-1-decanol
Thiols, C4-20, γ - ω -perfluoro, telomers with acrylamide and acrylic acid, sodium salts)	1078712-88-5	N/A	Thiols, C4-20, γ - ω -perfluoro, telomers with acrylamide and acrylic acid, sodium salts
1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(2-((γ - ω -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-((γ - ω -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)

874

875 **Table 1—LCPFAC Chemical Substances Subject to Reporting After December 31, 2015**

Chemical Name	CAS Registry No. (CASRN)	EPA Accession No.	TSCA Chemical Inventory Name
Perfluorooctyl iodide	507-63-1	N/A	Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8- heptadecafluoro-8-iodo-
Tetrahydroperfluoro-1-decanol	678-39-7	N/A	1-Decanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10-

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Chemical Name	CAS Registry No. (CASRN)	EPA Accession No.	TSCA Chemical Inventory Name
Perfluoro-1-dodecanol	865-86-1	N/A	heptadecafluoro- 1-Dodecanol; 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafuoro-
Perfluorodecyl iodide	2043-53-0	N/A	Decane; 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-10-iodo-
1,1,2,2-Tetrahydroperfluorododecyl iodide	2043-54-1	N/A	Dodecane; 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10-heneicosafuoro-12-iodo-
Perfluorodecylethyl acrylate	17741-60-5	N/A	2-Propenoic acid; 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafuorododecyl ester
1,1,2,2-Tetrahydroperfluorodecyl acrylate	27905-45-9	N/A	2-Propenoic acid; 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester
1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12-2-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-Pentacosafuorotetradecan-1-ol	39239-77-5	N/A	1-Tetradecanol; 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-pentacosafuoro-
3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16-Nonacosafuorohexadecan-1-ol	60699-51-6	N/A	1-Hexadecanol; 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-nonacosafuoro-
1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14-Nonacosafuoro-16-iodohexadecane	65510-55-6	N/A	Hexadecane; 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14-nonacosafuoro-16-iodo-
Sodium;2-methylpropane-1-sulfonate	68187-47-3	N/A	1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3-[(γ - ω -perfluoro-C4-16-alkyl)thio]propyl]amino] derivs., sodium salts
1,1,2,2-	68391-08-2	N/A	Alcohols, C8-14, γ - ω -

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Chemical Name	CAS Registry No. (CASRN)	EPA Accession No.	TSCA Chemical Inventory Name
Tetrahydroperfluoroalkyl (C8-C14) alcohol			perfluoro
Thiols, C8-20, gamma-omega-perfluoro, telomers with acrylamide	70969-47-0	N/A	Thiols, C8-20, gamma-omega-perfluoro, telomers with acrylamide
Silicic acid (H ₄ SiO ₄), sodium salt (1:2), reaction products with chlorotrimethylsilane and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-1-decanol	125476-71-3	N/A	Silicic acid (H ₄ SiO ₄), sodium salt (1:2), reaction products with chlorotrimethylsilane and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-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)

876

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

880 **Table 2—PFOA and Examples of Its Salts**

Chemical Name	CAS Registry No. (CASRN)	TSCA Chemical Inventory Name
Pentadecafluorooctanoyl	335-66-0	Octanoyl fluoride,

Commented [A130]: EPA typesetting ed (size 12 font and single spacing)

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)

881

882 **Table 2—PFOA and Examples of Its Salts**

Chemical Name	CAS Registry No. (CASRN)	TSCA Chemical Inventory Name
Pentadecafluorooctanoyl fluoride	335-66-0	Octanoyl fluoride, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-
Perfluorooctanoic acid	335-67-1	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (PFOA)
Silver perfluorooctanoate	335-93-3	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, silver (+) salt (1:1)
Sodium perfluorooctanoate	335-95-5	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, sodium salt (1:1)
Potassium perfluorooctanoate	2395-00-8	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, potassium salt (1:1)
Ammonium perfluorooctanoate	3825-26-1	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, ammonium salt (1:1) (APFO)

883

884 (4) Significant new uses:

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

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

890 (iii) The significant new use for chemical substances identified in paragraph (b)(3) of this

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891 section are: Manufacture (including import) or processing for any use. Import of fluoropolymer
892 dispersions and emulsions, and fluoropolymers as part of articles, containing chemical
893 substances identified in paragraph (b)(3) of this section shall not be considered as a significant
894 new use subject to reporting.

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

899 (c) *Specific requirements. (1) Revocation of certain notification exemptions.* With respect
900 to imports of carpets, the provisions of § 721.45(f) do not apply to this section. With respect to
901 imports of articles, the provisions of § 721.45(f) also do not apply to a chemical substance
902 identified in paragraphs (b)(2) or (b)(3) of this section when they are part of **surface coatings on**
903 **articles a surface coating of an article.** A person who imports a chemical substance identified in
904 paragraph (b)(1) of this section as part of a carpet or who imports a chemical substance identified
905 in paragraphs (b)(2) or (b)(3) of this section as part of a surface coating on an article is not
906 exempt from submitting a significant new use notice. The other provision of § 721.45(f),
907 respecting processing a chemical substance as part of an article, remains applicable.

908 (2) [Reserved]

Commented [A131]: Comment #66