

Public Review DRAFT: December 9, 2020

Document ID No.: RIN 2070-ZA23

DRAFT

Compliance Guide for Imported Articles Containing Surface Coatings Subject to the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule

This guide was prepared pursuant to Executive Order 13891 and "EPA Guidance; Administrative Procedures for Issuance and Public Petitions" (85 FR 66230, October 19, 2020). The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies. The statements in this document are intended solely as guidance to aid in complying with the EPA regulation "Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule" and the implementing regulations in 40 CFR part 721.

To determine whether EPA has revised this guide and/or to obtain copies, contact EPA's TSCA Hotline at (202) 554-1404 in DC, or consult the EPA's TSCA PFAS website at <u>https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-andpolyfluoroalkyl-substances-pfas</u>. The full text of the implementing regulation can be found at 40 CFR Part 721 and also in the **Federal Register** (85 FR 45109, July 27, 2020) and in the rulemaking docket, identified under EPA docket ID No. EPA-HQ-OPPT-2013-0225 and available online at <u>https://www.regulations.gov</u>.

1 I. Introduction

2 This document is issued by the U.S. Environmental Protection Agency (EPA) as the official compliance guide for

3 imported articles that may contain long-chain perfluoroalkyl carboxylate chemical substances as part of a

4 surface coating. The information in this guide was compiled from and based on the EPA regulation entitled,

5 "Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use

6 Rule," published on July 27, 2020. EPA is continually improving and updating its rules, policies, compliance

7 programs, and outreach efforts. You may determine whether EPA has revised or supplemented the information

- 8 in this guide by consulting EPA's perfluoroalkyl and polyfluoroalkyl substances (PFAS) website at
- 9 <u>https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-</u>
 10 substances-pfas.

11 Contents

25

12 This guide is organized as follows:

- 13 I. Introduction
- 14 II. <u>Regulation Summary</u>
- 15 III. <u>Guidance for Articles Subject to the SNUR</u>
- 16 IV. <u>How to Comply</u>
- 17 V. For More Information
- 18 <u>Appendix: Acronym List</u>

19 Who should use this guide?

You should use this guide if you believe you import long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances as part of a surface coating on articles.¹ How to determine whether you fall into this category is outlined in Section III of this guide. Many of the following types of businesses may be covered by this guide:

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

¹ Manufacturers, importers, and processors of LCPFAC chemical substances that are not a part of a surface coating on articles are subject to the final rule (85 FR 45109, July 27, 2020); however, this compliance guide is specifically for the application of LCPFC chemical substances as surface coatings.

35 What requirements does this guide cover?

- 36 This guide describes the significant new use EPA identified under section 5(a)(2) of the Toxic Substances Control
- 37 Act (TSCA) that covers the import of an article or category of articles with certain LCPFAC chemicals as part of the
- 38 surface coating, as established by EPA's final rule "Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl
- 39 Sulfonate Chemical Substances; Significant New Use Rule" (85 FR 45109, July 27, 2020) and the implementing
- 40 regulations at 40 CFR Part 721.
- 41 Specifically, this guide provides additional clarity on what is meant by a "surface coating," identifies which entities
- 42 are regulated, describes the activities that are required or prohibited, and summarizes the notification 43 requirements of the final SNUR.
- This compliance guide explains your federal compliance obligations with respect to the regulation under TSCA section 5(a)(2) of the import of a subset of LCPFAC chemical substances as part of a surface coating on articles.

46 How do I obtain a copy of the SNUR?

47 A complete copy of the final rule is in the Federal Register (Vol. 85, p. 45109) and in docket EPA-HQ-OPPT-2013-

- 48 0225 at <u>https://www.regulations.gov/</u>, which also includes supporting documents.
- 49 See the section entitled "For More Information" for additional information resources.

50 II. Regulation Summary

51 Regulation Summary

52 On July 27, 2020, EPA finalized a Significant New Use Rule giving the Agency the authority to review an expansive 53 list of products containing certain PFAS before they can be manufactured, sold, or imported in the United States. 54 The SNUR requires notice and EPA review before manufacturing and processing for any use of certain long-chain 55 PFAS (both LCPFAC and perfluoroalkyl sulfonate chemical substances) that have been phased out in the United 56 States. Additionally, pursuant to the SNUR, articles containing certain LCPFAC as a surface coating cannot be 57 imported into the United States without submission of a Significant New Use Notice (SNUN).

58 Importers and processors of a chemical substance as part of an article are generally exempted from SNURs 59 pursuant to 40 CFR 721.45(f), but the exemption can be made inapplicable in a particular SNUR if EPA makes an 60 affirmative finding that there is reasonable potential for exposure to a chemical substance through an article or 61 category of articles (see TSCA section 5(a)(5)). For this SNUR, EPA lifted the imported article exemption at 40 CFR 721.45(f). Importers of certain LCPFAC chemical substances (Table 1) and perfluorooctanoic acid (PFOA) or its salts 62 (see examples in Table 2) as part of a surface coating on articles are subject to the SNUR. The article exemption 63 64 still applies to LCPFAC chemical substances not listed Table 1 including those LCPFAC that are not PFOA or its salts, 65 with the exception of the import of carpets, for which the import exemption is already inapplicable (78 FR 62443, October 22, 2013; FRL-9397-1). 66

The other exemption in 40 CFR 721.45(f), for processing a chemical substance as part of an article, remains applicable. Importers of the following LCPFAC chemical substances as part of a surface coating on articles are subject to the SNUR:

70 Table 1—LCPFAC Chemical Substances Subject to Reporting After December 31, .	70	Table 1-1	LCPFAC Chemica	Substances	Subiect to	Reporting	After	December 31.	2015	
---	----	-----------	----------------	------------	------------	-----------	-------	--------------	------	--

	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-
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- heneicosafluoro-12-iodo-
Perfluorodecylethyl acrylate	17741-60-5	N/A	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11, 12,12,12-heneicosafluorododecyl 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
1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,1 0,10,11,11,12,12-Pentacosafluoro- 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-pentacosafluoro-14-iodo-
3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,1 1,12,12,13,13,14,14,14- Pentacosafluorotetradecan-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-pentacosafluoro-
3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,1 1,12,12,13,13,14,14,15,15,16,16,16- Nonacosafluorohexadecan-1-ol	60699-51-6	N/A	1-Hexadecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12,12,13 ,13,14,14,15,15,16,16,16-nonacosafluoro-
1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,1 0,10,11,11,12,12,13,13,14,14- Nonacosafluoro-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-nonacosafluoro-16-iodo-
Sodium;2-methylpropane-1- sulfonate	68187-47-3	N/A	1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3- [(.gammaomegaperfluoro- 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, .gammaomegaperfluoro
Thiols, C8-20, gamma-omega- perfluoro, telomers with acrylamide	70969-47-0	N/A	Thiols, C8-20, .gammaomegaperfluoro, 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, .gammaomegaperfluoro, 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- [(.gammaomegaperfluoro-C4-20-a lkyl)thio]acetyl] derivs., inner salts
Polyfluoroalkyl betaine (generic)	СВІ	71217	Polyfluoroalkyl betaine (PROVISIONAL)
Modified fluoroalkyl urethane (generic)	СВІ	89419	Modified fluoroalkyl urethane (PROVISIONAL)

Page 4 of 13 DRAFT Compliance Guide for Surface Coatings Subject to the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule

- 71 In addition to the subset of LCPFAC chemical substances identified in the list above, PFOA and its salts are
- 72 subject to the final rule. PFOA and its salts are considered LCPFAC chemical substances. PFOA and examples of
- 73 PFOA salts with CASRNs and chemical names are as follows:

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)

74 Table 2—PFOA and Examples of Its Salts

75 **Ongoing Uses Not Subject to the SNUR**

76 The timing of when a use is commenced is relevant to determining whether a use is an ongoing use not subject to 77 the SNUR. Uses that arose after the January 21, 2015 publication of the proposed rule are significant new uses 78 that require notification and review by EPA. These are distinguished from uses that existed at the time of the 79 publication of the proposed rule. If EPA received public comment on either the 2015 proposed rule or 2020 80 supplemental rule that the use was ongoing at the time of the publication of the proposed rule, and the use was 81 identified as ongoing in the final SNUR, then the use is considered an ongoing use not subject to the SNUR. Uses 82 that were ongoing as of the publication of the proposed rule would not be considered ongoing uses if they ceased 83 by the date of issuance of the final SNUR. The SNUR identified the manufacture, import, or processing of certain 84 LCPFAC chemical substances for the following uses as ongoing:

- Use of LCPFAC chemical substances for use in an antireflective coating, photoresists, or surfactant for use in
 photomicrolithography and other process to produce semiconductors or similar components of electronic or
 other miniaturized devices.
- Use of 2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester (CASRN 27905-45 9) as a coating or component of a hydrophobic and/or oleophobic coating or barrier applied to
- 90 manufactured articles or component of articles using an energy source or plasma deposition methods,
- 91 which include a pulse deposition mode. Examples of such articles include: electronic devices and
- 92 components thereof, medical consumables and bio-consumables, filtration devices and filtration materials,93 clothing, footwear and fabrics.
- Use of Silane, trichloro(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl)-(CASRN 78560-44-8) as a
 surface treatment to make low refractive index resin for optical applications; surface treatment for minerals,
 particles and inorganic surfaces for hydrophobicity; and monomer to make specialty resins hydrophobic.
- Use of Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (CASRN 335-67-1) as a surfactant and
 coating as part of the following articles: stickers, labels, and parts to which those stickers and labels are
- 99 attached.

- Use of 1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3-[(.gamma.-.omega.-perfluoro-C4-16-
- alkyl)thio]propyl]amino] derivs., sodium salts (CASRN 68187-47-3); Thiols, C8-20, .gamma.-.omega. perfluoro, telomers with acrylamide (CASRN 70969-47-0);or Perfluorinated polyamine (generic)
 (ACC274147) as a component in fire extinguishing agent.
- Use of Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (CASRN 335-67-1); Octanoic acid,
 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, sodium salt (1:1) (CASRN 335-95-5); or Octanoic acid,
 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, ammonium salt (1:1) (CASRN 3825-26-1) in automotive
 articles, both in factory assembly and replacement parts.
- Use of Poly(difluoromethylene), .alpha.,.alpha.'-[phosphinicobis(oxy-2,1-ethanediyl)]bis[.omega.-fluoro-, ammonium salt (1:1) (CASRN 65530-70-3); Poly(difluoromethylene), .alpha.-fluoro-.omega.-[2-
- (phosphonooxy)ethyl]-, ammonium salt (1:1) (CASRN 65530-71-4); or Poly(difluoromethylene), .alpha. fluoro-.omega.-[2-(phosphonooxy)ethyl]-, ammonium salt (1:2) (CASRN 65530-72-5) in the manufacturing of
 architectural coatings or wood coatings, at a maximum concentration of 0.1% by weight.
- Use of Poly(difluoromethylene), .alpha.,.alpha.'-[phosphinicobis(oxy-2,1-ethanediyl)]bis[.omega.-fluoro-,
 ammonium salt (1:1) (CASRN 65530-70-3); Poly(difluoromethylene), .alpha.-fluoro-.omega.-[2-
- (phosphonooxy)ethyl]-, ammonium salt (1:1) (CASRN 65530-71-4); or Poly(difluoromethylene), .alpha.-
- 116 fluoro-.omega.-[2-(phosphonooxy)ethyl]-, ammonium salt (1:2) (CASRN 65530-72-5) in the manufacturing of 117 industrial primer coatings for non-spray applications to metal by coil coating application, at a maximum
- concentration of 0.01% by weight.
- Use of Alcohols, C8-14, .gamma.-.omega.-perfluoro (CASRN 68391-08-2) in the manufacture of coatings and
 finishes for a variety of textile, leather, and hard surface treatments, and in the manufacture of wetting
 agents.
- Use of Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, ether with .alpha.-fluoro-.omega.-(2-hydroxyethyl)poly(difluoromethylene) (1:1) (CASRN 65545-80-4) in water-based inks.
- Use of Poly(difluoromethylene), .alpha.-[2-[(2-carboxyethyl)thio]ethyl]-.omega.-fluoro-, lithium salt (1:1)
 (CASRN 65530-69-0) in photo media coatings.
- 126 Use of Ethanol, 2,2'-iminobis-, compd. with .alpha.-fluoro-.omega.-[2-
- 127 (phosphonooxy)ethyl]poly(difluoromethylene) (2:1) (CASRN 65530-63-4); Ethanol, 2,2'-iminobis-, compd.
- with .alpha.,.alpha.'-[phosphinicobis(oxy-2,1-ethanediyl)]bis[.omega.-fluoropoly(difluoromethylene)] (1:1)
 (CASRN 65530-64-5); or Ethanol, 2,2'-iminobis-, compd. with .alpha.-fluoro-.omega.-[2-
- (phosphonooxy)ethyl]poly(difluoromethylene) (1:1) (CASRN 65530-74-7) in paints and coatings, grouts, and
 sealers.
- Use of Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, ether with .alpha.-fluoro-.omega.-(2 hydroxyethyl)poly(difluoromethylene) (1:1) (CASRN 65545-80-4) in paints, coatings, ink jet inks, and ink
 masterbatch.
- Use of 1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3-[(.gamma.-.omega.-perfluoro-C4-16alkyl)thio]propyl]amino] derivs., sodium salts (CASRN 68187-47-3) in adhesives.
- 137 If you are using a LCPFAC chemical substances listed above for the specific use listed, then that use is not subject
- 138 to the SNUR and this guidance does not apply.

¹³⁹ III. Guidance for Articles Subject to the SNUR

140 What is an article?

As defined at 40 CFR 704.3, article means a manufactured item: (1) which is formed to a specific shape or design during manufacture; (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.

147 An imported article must have an end-use function dependent in whole or in part upon a shape or design that 148 was present at the point of import. If the shape and design of an item at the point of import does not serve any 149 function with respect to the item's end use, then the item being imported is not an article.

EXAMPLE: Plastic or metallic blocks or sheets imported and then processed in such a way that they
 entirely lose the shape they had at the point of import (e.g., by being melted down, molded, extruded,
 cut up extensively or into small pieces, or further reacted) would not qualify as articles at the point of
 importation. Conversely, if plastic or metallic sheeting is imported with a specific thickness, the sheeting
 may still be considered an imported article even though the expected end use of the sheeting may
 involve cutting or trimming to a different length or width. However, there must still be a relationship
 between the shape or design of the sheeting and the end use of the sheeting.

157 What are examples of articles subject to the SNUR?

Because the LCPFAC rule is for significant new uses, the following is a non-exhaustive list of potential articlesthat may use LCPFAC chemical substances as part of a surface coating on the article:

• Apparel

- Furniture
- pment
- Outdoor equipment
- Electronic componentsLight bulbs
- Automotive partsCarpets
- Solar panels

- Paper goods
- Luggage
- Construction materials

160 What is not an article?

- 161 Products such as paints, lubricants, and fire-fighting foam are not articles. A paint, however, would be
- 162 considered as part of an article if applied to an article (e.g., paint on a car is considered as part of an article but
 163 paint in a can is not an article under TSCA). Additionally, a lubricant applied to an article would be considered as
 164 part of an article.
- 165 EXAMPLE: A lubricant such as automotive grease would be considered part of an article when already
 166 included within an automobile's engine. When automotive grease is purchased by a consumer at a car
 167 supply store to add to the automobile, that automotive grease would not be considered an article.

168 What is a surface coating?

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

During the public comment period for the 2020 supplemental proposal, several commenters asked EPA to define "surface coating" and to include a definition in the regulatory text. EPA did not finalize a regulatory definition of "surface coating." Rather, EPA is providing additional clarity on what is meant by a "surface coating" in this guidance document

176 coating" in this guidance document.

188

- 177 **EXAMPLE:** If Chemical A is used in furniture varnish that is applied during the production of a piece of
- 178 furniture at a furniture manufacturer, once Chemical A is applied to the furniture, Chemical A is
- 179 considered a surface coating that is part of an article. If a varnish containing Chemical A is purchased at a
 180 hardware store, for use by a consumer to build or refinish a piece of furniture, the container of varnish
- 181 containing Chemical A could be used as a surface coating but not be considered as part of an article.

182 What constitutes a surface coating subject to the SNUR?

183 In the context of the LCPFAC SNUR, EPA considers any LCPFAC (from the list in Table 1 or PFOA and its salts) that 184 meets one of the following two criteria to be a surface coating covered by the SNUR:

- coating on any surface of an article that is in direct contact with humans or the environment during
 the article's normal use or reuse, whether the coating is oriented towards the interior or exterior of
 the article;
- coating on any internal component, even if facing the interior of the article, if that component is in
 contact with humans or the environment during the article's normal use or reuse.

EXAMPLE: An importer of luggage is working with a foreign manufacturer to develop a new product line
 of fabric luggage. In order to protect the luggage against water and stains, the importer would like a
 surface coating protectant applied to the luggage. The foreign manufacturer has three coatings they can
 use: One with Chemical A, another with Chemical B, and another with Chemical C. All three chemicals
 are LCPFAC chemical substances, so the importer must ensure that he complies with the final LCPFAC
 SNUR. While all three chemical substances are LCPFAC chemical substances, they are not all subject to
 the same requirements of the final SNUR.

198Chemical A is CASRN 17741-60-5, which is listed in Table 1 - LCPFAC Chemical Substances Subject to199Reporting After December 31, 2015. Because it is listed in Table 1 and there is no ongoing use for200Chemical A under 40 CFR 721.10536(b)(5), Chemical A is subject to the LCPFAC SNUR when imported in201an article as part of a surface coating. If the importer wishes to import luggage containing Chemical A as202a surface coating, they must first submit a SNUN at least 90 days before they intend to commence203import (see Section V. How to Comply).

204 Chemical B is CASRN 27905-45-9, which is also listed in Table 1 - LCPFAC Chemical Substances Subject to 205 Reporting After December 31, 2015. Chemical B, however, has an ongoing use pursuant to 40 CFR 206 721.10536(b)(5)(ii) for use "as a coating or component of a hydrophobic and/or oleophobic coating or 207 barrier applied to manufactured articles or component of articles using an energy source or plasma 208 deposition methods, which include a pulse deposition mode. Examples of such articles include: 209 electronic devices and components thereof, medical consumables and bio-consumables, filtration 210 devices and filtration materials, clothing, footwear and *fabrics*." Because the use of Chemical B as a 211 coating on fabric is recognized as an ongoing use in the final SNUR, this use of Chemical B is not a 212 significant new use subject to the final SNUR. The foreign manufacturer may use CASRN 27905-45-9 as a 213 surface coating on the fabric luggage without the importer needing to submit a SNUN.

214 Chemical C is CASRN XXXX-XX-X (a hypothetical chemical for this example), which is a LCPFAC chemical 215 substance subject to the final SNUR pursuant to 40 CFR 721.10536(b)(1). Chemical C is not listed in Table 216 1 - LCPFAC Chemical Substances Subject to Reporting After December 31, 2015 and it is not PFOA or a 217 PFOA salt. Only LCPFAC chemical substances that are listed in Table 1 or that are PFOA and its salts are 218 subject to the notification requirements of 40 CFR 721.25 when imported as part of a surface coating of 219 an article (see 40 CFR 721.10536(c)(1)). As such, when imported as part of a surface coating of an article, 220 Chemical C is not subject to the rule and may be used by the foreign manufacturer as a surface coating 221 on the fabric luggage and then imported into the US without the importer needing to submit a SNUN. 222 Chemical C, however, may be subject to the SNUR if manufactured, imported, or processed for another 223 use.

Are surface coatings that have cured or undergone chemical reaction after application subject to the SNUR?

Yes. Articles that have surface coatings that contain certain LCPFAC chemical substances that have been cured or undergone chemical reaction after being applied to an article are subject to the SNUR.

228 Are complex durable goods subject to the SNUR?

Yes. The term "complex durable good" is defined in TSCA section 6(c)(2)(D). Statutory exemptions for
replacement parts for complex durable goods may be granted pursuant to TSCA section 6(c)(2)(D) in some cases,
but only in TSCA section 6(a) risk management rules. Designation as a "complex durable good" under TSCA
section 6 does not affect whether a use is or is not a significant new use under the SNUR. EPA acknowledges that
imported articles may be comprised of multiple components and have a complex supply chain, which may
present greater demands on some importers to ensure that if an article contains certain LCPFAC chemical
substances in surface coatings, a SNUN is submitted to EPA least 90 days before engaging in import.

If an article contains an LCPFAC chemical substance as a surface coating, but the LCPFAC chemical substance is believed to not be released, is the article subject to the SNUR?

Yes. In the final SNUR, EPA affirmatively found that under TSCA section 5(a)(5) that the notification for import is
 justified due to the reasonable potential for exposure to certain LCPFAC chemical substances when part of
 surface coatings on articles. The article is subject to the SNUR regardless of whether or not the *importer* believes

Page 9 of 13

- that no release or exposure will result from an imported article containing a subject LCPFAC chemical substance
- as part of a surface coating, unless that given use is listed as an ongoing use at 40 CFR 721.10536(b)(5). In order
- to import an article containing certain LCPFAC chemical substances in surface coatings, a SNUN needs to be
- submitted to EPA at least 90 days before importation occurs. The submission of a SNUN allows EPA to evaluate
- potential uses (before those uses would begin) for any hazards, exposures, and risks that might exist. See
- 247 Section V. How to Comply for information on submitting a SNUN.

248 Are impurities in surface coatings subject to the SNUR?

No. To the extent the chemical substance subject to the SNUR is only "unintentionally present" at the point of
foreign manufacture, it is exempt from reporting by the importer as an imported impurity (see 40 CFR
721.45(d)). As such, importers are not required to submit a SNUN for a substance based simply on that
substance's presence as an impurity (i.e., a chemical substance is unintentionally present with another chemical
substance (40 CFR 720.3(m)). If a subject LCPFAC chemical substance is only present as an impurity in a surface

coating as part of an article, then it is not subject to the SNUR.

255 Are processors of articles exempted or not covered?

Yes. Processors of articles are not subject to the SNUR. EPA is retaining the exemption at 40 CFR 721.45(f) for
persons who process chemical substances as part of articles because existing stocks of articles still contain
LCPFAC or perfluoroalkyl sulfonate chemical substances. Because the processing of articles containing LCPFAC or
perfluoroalkyl sulfonate chemical substances is ongoing, it cannot be subject to a SNUR. EPA considers recycling
to be a form of processing (85 FR 45109, July 27, 2020).

261

²⁶² IV. Who Must Comply?

263 How can I tell if I am subject to the SNUR?

As an importer of articles, you are subject to the SNUR if you import, for a "significant new use," articles containing a subset of LCPFAC chemical substances as part of a surface coating. The subset of LCPFAC chemical substances for which EPA lifted the articles exemption includes those listed in Table 1 of this guidance document and PFOA or its salts (see examples in Table 2).

The use of the subject LCPFAC chemical substances as part of food packaging or medical devices is not subject to the rule. TSCA section 3(2)(B) excludes any food, food additive, drug, cosmetic, or device regulated under the Federal Food, Drug, and Cosmetic Act from the definition of a chemical substance under TSCA. The Food and

- 271 Drug Administration (FDA), however, has separately issued restrictions on the use of PFAS chemical substances
- in FDA regulated uses. Prior to import, importers should ensure that they are in compliance with all federal and
- 273 state regulations regarding PFAS chemical substances.
- 274 In the final SNUR, published July 27, 2020, EPA also finalized amendments requiring persons to notify EPA at
- 275 least 90 days before commencing: the manufacturing (including importing) or processing of a subset of LCPFAC
- chemical substances for any use that was not ongoing after December 31, 2015; the manufacturing (including
- 277 importing) or processing of all other LCPFAC chemicals substances for which there were no ongoing uses as of

Page 10 of 13

January 21, 2015 (the date of the original 2015 proposal); and the import of perfluoroalkyl sulfonate chemical
substances as part of carpets. These additional amendments, however, are not the subject of this compliance
guide.

V. How to Comply

282 What should I do to comply?

Under section 5(a) of TSCA and 40 CFR part 721, if EPA promulgates a SNUR, then a manufacturer (including importer) or processor wishing to engage in a designated significant new use must submit a SNUN to EPA at least 90 days before engaging in the new use. This notification provides EPA the opportunity to evaluate and make a determination on the new use and, if necessary, take action to prohibit or limit the activity if EPA finds that the significant new use presents unreasonable risk of injury to health or the environment.

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what data may be useful in evaluating a significant new use. EPA can also help the regulated community confirm whether or not they are subject to the rule and if a SNUN is required. As part of this optional pre-notice consultation, EPA would discuss specific information it believes may be useful in evaluating a significant new use.

- 292 Submitting a SNUN that fails to include sufficient information to permit a reasoned evaluation may increase the
- likelihood that EPA will either respond with a determination that the information available to the Agency is
- insufficient to permit a reasoned evaluation of the health and environmental effects of the significant new use
- or, alternatively, that in the absence of sufficient information, the manufacturing (including importing),
- processing, distribution in commerce, use, or disposal of the chemical substance may present an unreasonablerisk of injury to health or the environment.

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

301 SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the

- Agency in accordance with the procedures set forth in 40 CFR 721.25 and 40 CFR 720.40. For more information
- 303 on submitting a SNUN and the e-PMN software, visit: <u>https://www.epa.gov/reviewing-new-chemicals-under-</u>
- 304 <u>toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa</u>. Additionally, you can talk to a specialist via
 305 the TSCA Hotline by e-mail at <u>tsca-hotline@epa.gov</u> or by telephone, (202) 554-1404.

306 Import Certification and Export Notification

The final LCPFAC SNUR does not require TSCA section 13 import certification for the subject chemical substances when part of articles (i.e., not as part of a surface coating on articles). Considering that the use of these chemicals in articles covered by this SNUR are no longer ongoing, EPA determined that it is not necessary to

310 include TSCA section 13 import requirements in the SNUR. This is consistent with EPA's past practice of making

- 311 the exemption at 40 CFR 721.45(f) inapplicable without also requiring import certification or export notification
- for these chemical substances as part of articles (40 CFR 721.2800; 40 CFR 721.10068). With or without an
- 313 import certification requirement, it is the importer that is "responsible for [e]nsuring that chemical importation

Page 11 of 13

complies with TSCA just as domestic manufacturers are responsible for [e]nsuring that chemical manufacture
 complies with TSCA" (40 CFR 707.20(b)(1)).

316 Under TSCA section 12(b) and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify

317 EPA if they export or intend to export a chemical substance or mixture, including as part of an article, for which,

318 among other things, a rule has been proposed or promulgated under TSCA section 5. Pursuant to these export

319 notification requirements, persons exporting a substance that is the subject of a SNUR must submit a one-time

320 notice to EPA each calendar year for the first export or intended export to a particular country.

321 Compliance Date

322 The final LCPFAC SNUR, which lifts the articles exemption for a subset of LCPFAC chemical substances as part of a 323 surface coating on articles, is effective September 25, 2020. The import of certain LCPFAC chemical substances as 324 part of a surface coating on an article are prohibited from commencing without submission of a SNUN and 325 subsequent approval by EPA. This final rule requires persons to notify EPA at least 90 days before commencing 326 the import of these chemical substances for the significant new uses described in this guidance. The final SNUR 327 precludes the commencement of such importing until EPA has conducted a review of the notice, made an 328 appropriate determination on the notice, and taken such actions as are required in association with that 329 determination.

330 What happens if the Agency discovers a violation?

In accordance with section 15 of TSCA, it is unlawful to fail or refuse to comply with any requirement under TSCA, or with any rule promulgated under TSCA. Therefore, any failure to comply with the final rule would be a violation of section 15 of TSCA. In addition, under section 15 of TSCA, it is unlawful for any person to: (1) Fail or refuse to establish or maintain records as required by the final rule or other regulations promulgated under this chapter; (2) fail or refuse to permit access to or copying of records, as required by TSCA; or (3) fail or refuse to permit entry or inspection as required by section 11 of TSCA.

Violators of the final LCPFAC SNUR may be subject to both civil and criminal liability. Under the penalty provision
of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty for each violation.
Each day in violation of the final rule could constitute a separate violation. Knowing or willful violations could lead
to the imposition of criminal penalties for each day of violation and imprisonment. In addition, other remedies
are available to EPA under TSCA.

³⁴² VI. For More Information

Additional information is available at <u>https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-</u>
 management-and-polyfluoroalkyl-substances-pfas. The regulations can be found in the Federal Register ((85 FR
 45109, July 27, 2020) at <u>https://www.regulations.gov/document?D=EPA-HQ-OPPT-2013-0225-0232</u> or at docket
 EPA-HQ-OPPT-2013-0225 at <u>https://www.regulations.gov</u>.

347 Where can I go if I have questions or need further assistance?

Please contact EPA's TSCA Hotline with questions by telephone at (202) 554-1404, by fax at (585) 232-3111 or by email at <u>tsca-hotline@epa.gov</u>.

350 Appendix

351 Acronym List

352	CASRN	Chemical Abstracts Service Registry Number
353	CFR	Code of Federal Regulations
354	EPA	U.S. Environmental Protection Agency
355	FR	Federal Register
356	LCPFAC	long-chain perfluoroalkyl carboxylate
357	NAICS	North American Industrial Classification System
358	PFAS	perfluoroalkyl and polyfluoroalkyl substances
359	SNUN	Significant New Use Notice
360	SNUR	Significant New Use Rule
361	TSCA	Toxic Substances Control Act