PFAS Significant New Use Rule or When Articles Are Not Exempt

An article is generally defined as a manufactured item which is formed to a specific shape or design, and which has an end use function dependent upon its shape or design, and which does not release, or otherwise result in exposure to, a hazardous chemical under normal conditions of use. If the shape and design of an item does not serve any function with respect to the item's end use, then the item is not an article.

Most environmental regulatory programs exempt articles. As such, they do not have to be included in environmental reports, e.g., the TRI Form R, submitted to regulatory agencies. Even the federal Toxic Substances Control Act (TSCA) exempts articles, that is, until September 25, 2020, the effective date of a final TSCA rule published in the Federal Register on July 27, 2020. This Significant New Use Rule or SNUR, codified as 40 CFR 721.10536, is based on the 2016 TSCA Amendments, known as the Frank R. Lautenberg Chemical Safety for the 21st Century Act. A provision of the latter states that articles can be subject to notification requirements as a significant new use if EPA makes an affirmative finding that reasonable potential for exposure to a chemical from an article justifies notification.

As of September 25, the SNUR requires persons to notify EPA at least 90 days before beginning import of any of a subset of Perfluoralkyl and Polyfluoroalkyl Substances (PFAS), specifically 26 long-chain perfluoroalkyl carboxylate (LCPFAC) chemical constituents of a surface coating on articles. In short, articles containing these LCPFACs as a surface coating cannot be imported into the United States without submitting to EPA a Significant New Use Notice (SNUN).

A surface coating is material applied typically in a thin layer to a surface as a protective, decorative, or functional film. Although frequently referring to paint, the term also refers to applied films, e.g., varnishes, sealants, adhesives, inks, maskants, and temporary protective coatings. A lubricant applied to an article would be considered a surface coating. In accordance with draft EPA guidance, a surface coating can be either exterior and interior of an article or both. If the coating of the article is at all exposed to humans or to the environment it is subject to this SNUR. Even if the importer believes that no release or exposure will result from an article with the subject LCPFAC as part of a surface coating, he or she must still submit a SNUN unless the given use is listed as ongoing at 40 CFR 721.10536(b)(5).

Unfortunately, there is no *de minimis* for LCPFACs specified in Part 721 of the TSCA rules. Indeed, only in Part 707, regarding exports, is a *de minimis* level specified, *viz.*, less than 1.0 % by weight or volume, except less than 0.1 % for known or potential human carcinogens. However, based on the draft EPA guidance (see link at bottom of this discussion), if the LCPFAC is present in the surface coating only as an impurity, a SNUN is not required.

Importantly, articles with surface coatings, containing these LCPFACs, that have been cured or undergone chemical reaction after being applied are subject to this SNUR. Even when LCPFACs are bound within the matrix of a coating, they can still be released over time and present a reasonable potential for exposure.

The SNUR also requires notification to EPA at least 90 days prior to: 1) manufacturing, importing, or processing any of a subset of LCPFAC chemical substances for any use that was not ongoing after December 31, 2015; 2) manufacturing, importing, or processing perfluorooctanoic acid (PFOA) or its salts, which are considered LCPFAC chemical substances, and all other LCPFAC chemicals for which there were no ongoing uses as of January 21, 2015; and, 3) importing any perfluoroalkyl sulfonate chemical substances as part of carpets. The

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discussion herein, however, focuses primarily on LCPFACs which are part of the surface coating on imported articles.

As mentioned above, LCPFACs are part of a large group of environmentally persistent and human health compromising chemicals referred to as PFAS. Typically these have long, complicated chemical names. Therefore, the shorter Chemical Abstract Service (CAS) numbers are generally a better identifier. The term LCPFAC refers to a category of PFAS characterized by a long chain of perfluorinated carboxylate groups in the chemical structure, specifically chemicals with chains of seven to 20 carbon atoms with attached fluorine atoms. The particular category of LCPFACs covered by this rule also includes the salts and precursors of these perfluorinated carboxylates. The CAS Numbers of the 26 LCPFACs subject to this SNUR are as follows:

335-66-0	335-67-1	335-93-3	335-95-5	507-63-1	678-39-7
865-86-1	2043-53-0	2043-54-1	2395-00-8	3825-26-1	17741-60-5
27905-45-9	30046-31-2	39239-77-5	60699-51-6	65510-55-6	68187-47-3
68391-08-2	70969-47-0	125476-71-3	1078712-88-5	and	1078715-61-3.

In addition, there are three LCPFACs for which the CAS Numbers have been classified as confidential business information. The generic names of these are: Polyfluoroalkyl Betaine, Modified Fluoroalkyl Urethane, and Perfluorinated Polyamine.

It should be emphasized that a SNUR only covers new uses, not ongoing uses. Thus any ongoing uses of the above LCPFACs are not subject to this SNUR. E.g., the use of CAS 68187-47-3 {1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3-[(.gamma.-.omega.-perfluoro-C4-16-alkyl)thio]propyl]amino] derivs., sodium salts}, CAS 70969-47-0 {Thiols, C8-20, .gamma.-.omega.-perfluoro, telomers with acrylamide}, or Generic Perfluorinated Polyamine as a component in fire extinguishing agents is not regulated under this SNUR. Similarly, use of CAS 335-67-1 {Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-}, CAS 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)}, or CAS 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)} in automotive articles, both in factory assembly and replacement parts, is not subject to notification.

In addition, because existing stocks of articles still contain PFAS, EPA is retaining the TSCA exemption at 40 CFR 721.45(f) for processing articles, which includes recycling. Since such processing of articles containing LCPFACs is ongoing, it cannot be subject to a SNUR.

At this time, EPA is not making inapplicable any of the standard exemptions at 40 CFR 721.45 for fluoropolymer dispersions and emulsions, and fluoropolymers as part of articles. However, EPA may issue a future SNUR on the manufacture, import, and processing of fluoropolymer dispersions and emulsions and articles containing fluoropolymers. Such issuance is almost certain under a new administration.

EPA acknowledges that articles to be imported may consist of multiple components (e.g., "complex durable goods") and have a complex supply chain, which present greater demands on some importers to ensure compliance if articles contain regulated LCPFACs in surface coatings.

What to do? Plan ahead, perform due diligence, and document findings. Long before importing an article, persons should determine what, if any, surface coatings have been applied. While not specifically required by the SNUR, importing parties may take additional steps to determine if the subject LCPFACs are part of the surface coating of articles being considered for import. Such

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determination may involve collecting and reviewing information (e.g., Technical and/or Safety Data Sheets) from suppliers along the supply chain, and/or testing samples of the article itself.

Unless testing of the chemical substance is required under Section 4 of TSCA, persons submitting a SNUN are required to include only information in their possession or control and to describe any other information known or reasonably ascertainable. Nevertheless, as a general matter, EPA recommends that SNUN submitters include information that would permit a reasoned evaluation of risks posed by the chemical substance during its life (import to disposal). An incomplete SNUN will only delay importation of the article.

The draft of the EPA Guidance Document "Compliance Guide for Imported Articles Containing Surface Coatings Subject to the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule," dated December 9, 2020, can be accessed here: https://www.epa.gov/sites/production/files/2020-12/documents/draft_lcpfac-snur_surface-coating-compliance-guide_2020-12-09.pdf