

EPA Publishes Finalized PFAS Significant New Use Rule

The U.S. Environmental Protection Agency on June 22, 2020, released the prepublication version of final regulations establishing "significant new use rules" for long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances, a subset of per- and polyfluoroalkyl substances (PFAS). The final rule requires companies to provide the EPA with notice and an opportunity to evaluate new uses of LCPFAC chemical substances before commencing the manufacture, import, or production of such substances. The rule is intended to give the EPA control over the amount of PFAS introduced to the general environment.

Background

Per- and polyfluoroalkyl substances are man-made compounds historically used in a variety of products including cookware, water-repellant fabrics, cleaning products, and fire-fighting foam. While certain PFAS compounds are no longer manufactured in the United States, many compounds are imported into the country. PFAS compounds contain strong chemical bonds which prevent the chemical from breaking down over time. The EPA regulates new introductions of PFAS chemicals into the environment to lessen their bioaccumulation in groundwater and soil. Under the authority of the Toxic Substances Control Act, the EPA may impose restrictions on, and require reporting, testing, and recordkeeping for, the use of PFAS. 15 U.S.C. § 2603–05. Under Section 5(a)(1) of TSCA, the EPA may regulate uses of chemical substances by promulgating significant new use rules and requiring a 90-day notice before the use commences. 15 U.S.C. § 2604. This 90-day period gives the EPA the opportunity to impose conditions of use as the agency sees fit, which companies must meet before beginning use of a regulated chemical.

On January 21, 2015, the EPA [issued a proposed rule](#) for two subsets of PFAS substances: LCPFAC chemical substances and perfluorooctanoic acid (PFOA) or its salts, which the EPA considers LCPFAC chemical substances. 80 FR 2285. The proposal was designed to grant the EPA authority to evaluate and impose conditions on the manufacturing, importing, processing, and distributing of certain LCPFAC substances. The EPA proposed an amendment on March 3, 2020, to cover the import of articles with surface coating containing the listed substances and to update the existing proposal for the import of carpets containing perfluoroalkyl sulfonate chemical substances. The EPA's March 3, 2020, proposed amendment also requested comments on whether the EPA should adopt a *de minimis* threshold to assist in determining what constitutes a "reasonable potential for exposure," and whether the EPA should adopt a safe harbor provision for companies currently importing articles who can prove their use was ongoing prior to the effective date of the final rule.

Discussion of Final Rule

The EPA's final rule imposes notice requirements on new uses, designates new uses of chemicals, and waives the exemption of article and carpet imports. Specifically, the final rule:

Requires Notice and Opportunity for the EPA's Evaluation and Potential Prohibition of Uses

The rule imposes three main requirements on companies before commencement of a designated new use:

1. Provide the EPA at least 90-days' prior notice of the new use.
2. Allow the EPA to evaluate and impose conditions on the new use.
3. Refrain from commencing the new use until the EPA publishes a determination on the notice in the Federal Register.

Designates New Uses of Chemical Substances

The rule modifies the requirements for a subset of PFAS chemical substances already regulated under [40 C.F.R. 721.10536](#). The modifications include the following:

- Designate as a significant new use the manufacturing, importing, or processing of certain LCPFAC chemicals listed for any new use not ongoing as of December 31, 2015.
- Designate as a significant new use the manufacturing, importing, or processing of PFOA or its salts and all other LCPFAC chemicals for any new use not ongoing as of January 21, 2015.

The rule does not apply to uses of these chemicals which were ongoing at the time the EPA released the proposed rule and which are still ongoing when the final rule takes effect. However, persons who began the commercial manufacture (including importing) or processing of LCPFAC and perfluoroalkyl sulfonate chemical substances after January 21, 2015 (date of publication of the proposed rule), must cease these activities before the effective date of the final rule and submit a significant new use notice to the EPA and wait to resume the commercial manufacturing or processing of the chemical substances until the EPA has made a determination.

Makes the Exemption for Certain Imported Articles Inapplicable

The final rule explicitly removes the exemption in the prior regulations (40 C.F.R. 721.45(f)) for the import of articles containing listed chemicals as part of their surface coating, and extends the requirements of the proposed rule to such articles. Here, "articles" includes only those items which have a defined shape. This provision is intended to apply to apparel, outdoor equipment, furniture, etc., as the EPA believes these items provide greater exposure of LCPFAC and PFOA chemicals to humans and the environment. This provision does not apply to paint, coatings, lubricants, and firefighting foam, or to companies who process articles because of an existing stock.

Makes the Exemption for Carpets Containing PFAS Inapplicable

The final rule amends the existing regulations for perfluoroalkyl sulfonate chemical substances, found at 40 C.F.R. 721.9582, to invalidate the exemption for imports of carpets containing those chemical substances. Many uses of perfluoroalkyl sulfonate chemical substances in carpets remained ongoing at the time the EPA finalized the existing regulations and, as such, were not subject to the rule. The EPA has now determined these formerly ongoing uses of those chemical substances have been discontinued. Through this final rule, the EPA extends the notice and review requirements in the existing regulations to any new or resumed imports of perfluoroalkyl sulfonate chemical substances in carpets.

The final rule does not include either a *de minimis* threshold for determining "reasonable potential for exposure" or a safe harbor provision. Although the agency sought comments on these issues, the EPA determined that significant new uses should be reviewed on a case-by-case basis and threshold "reasonable potential exposures" determined at that time instead of adopting a *de minimis* threshold. The EPA also declined to adopt a safe harbor provision, reasoning that such a provision would discourage importers from participation in a rulemaking by identifying chemicals late or using the safe harbor provision as a means of challenging the rule in lieu of public comments.

Implications

The rule will become effective 60 days after publication in the Federal Register. Companies with preexisting import/export certifications should closely examine the applicability of the final rule on their operations. This rule is likely to affect manufacturers and importers of fiber, thread, yarn, carpet, home furnishings, electronic products, and surgical and medical equipment as well as merchant wholesalers, stores, and retailers.

The author recognizes the contributions of Summer Associate Anna Laird to this update.

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