

Regulatory Alert

Global Environmental and Chemical Regulations, Policies, and Standards

Alert 34



Significant New Use Rule: Per- and Poly-Fluoroalkyl Chemical Substances Designated as Inactive on the TSCA Inventory

Region: USA

WHY IS THIS ALERT IMPORTANT?

Under the Toxic Substances Control Act (TSCA), the Environmental Protection Agency (EPA) finalized a significant new use rule (SNUR) on 11 January 2024 targeting [329 perfluoroalkyl and polyfluoroalkyl substances \(PFAS\)](#) that have not been manufactured, imported, or processed for many years. These PFAS are consequently designated as “inactive” on the [TSCA Chemical Substance Inventory](#). The SNUR became effective on 11 March 2024, 60 days after publication in the [Federal Register](#).

EPA is taking this action to increase regulatory oversight of PFAS and prevent companies from starting or resuming manufacturing or importing these 329 inactive PFAS. Under the SNUR, impacted entities must inform the EPA at least 90 days before starting any production, importation, or processing of the chemical substance for a significant new use. Upon receiving the notification, EPA will conduct a review and inform required actions. Reviews conducted by EPA will assess if use might pose unreasonable risks to health and/or the environment and prevent future unsafe environmental releases.

INTENDED AUDIENCE

This Regulatory Alert is intended for IAEG members and their suppliers who intend to manufacture, import, process, use, or sell any of the 329 inactive PFAS.

EXECUTIVE SUMMARY

EPA has determined that 329 PFAS are not currently being manufactured or used in the US and designated them as inactive on the TSCA Inventory¹. The SNUR, effective as of 11 March 2024, prevents these 329 PFAS from re-entering the marketplace and environment unless EPA first completes a full risk review and issues a determination. Specific exemptions are available for articles, byproducts, and exports only.

¹ These 329 PFAS are also not subject to an existing SNUR.

BACKGROUND ON REGULATION

The SNUR on the 329 inactive PFAS is a key component of the comprehensive approach outlined in EPA's [PFAS Strategic Roadmap: EPA's Commitments to Action 2021–2024](#). This SNUR is designed to prevent the unauthorized manufacturing, importing, or processing of significant new uses.²

Under the authorization of [TSCA section 5\(a\)\(2\)](#), EPA has the power to classify the use of a chemical substance as a "significant new use." After such a classification, [TSCA section 5\(a\)\(1\)](#) mandates that individuals must submit a significant new use notice (SNUN) to EPA at least 90 days before the manufacturing, importing, or processing of the chemical substance for that use. These activities can only begin after EPA has examined the SNUN, made a fitting determination, and carried out actions concerning that determination.

APPLICABILITY

The EPA defines the category of PFAS included in the final rule as those that:

- » are designated as inactive on the TSCA Inventory
- » are not already subject to a SNUR
- » meet the PFAS definition used by EPA's Office of Pollution Prevention and Toxics, in which PFAS must contain at least one of the following three structures:
 - R-(CF₂)-CF(R')R'', where both the CF₂ and CF moieties are saturated carbons
 - R-CF₂OCF₂-R', where R and R' can either be F, O, or saturated carbons
 - CF₃C(CF₃)R'R'', where R' and R'' can either be F or saturated carbons

EPA has listed the inactive PFAS that meet these criteria except for 30 PFAS that have been claimed as Confidential Business Information and have generic names that do not contain fluor or fluorine.³

RELEVANT DATES

- » Effective: 11 March 2024

REGULATORY OBLIGATIONS

The SNUR prevents companies from starting or resuming manufacturing or importing these 329 inactive PFAS. The EPA has determined the significant new uses to be the manufacture (including import) or processing of inactive PFAS for any use except:

- » importing or processing of the inactive PFAS-containing articles
- » manufacture (including import) or processing of the inactive PFAS:
 - as impurities
 - as byproducts not used for commercial purposes
 - as byproducts that are burned as a fuel or disposed of as a waste (including in a landfill or for enriching soil), or from which component chemical substances are extracted for commercial purposes

² In the absence of this final SNUR, manufacturing, importation, or processing of any of the 329 PFAS could commence any time after a manufacturer submits a Notice of Activity under Section 8 of TSCA. At that point, the substance would be considered 'active' on the TSCA Inventory. This would occur without the necessary prior notification under Section 5, denying EPA the opportunity to review and address any potential risks associated with the proposed new use.

³ EPA states that there is a "need to take additional steps to list the 30 inactive PFAS that are not subject to an existing SNUR and whose generic name do not contain 'fluor' or 'fluorine.'"

- in small quantities solely for research and development
- for test marketing purposes
- for use as a non-isolated intermediate
- solely for export from the United States as described in 40 CFR 720.30(e) or 721.3, except where the Administrator has made a finding described in [TSCA section 12\(a\)\(2\)](#)

General provisions for SNURs are described in [40 CFR part 721, subpart A](#). The provisions describe persons subject to the rule, recordkeeping requirements, and exemptions to reporting requirements. Further details can also be found in IAEG's [Alert 24](#) on SNURS.

EPA suggests that entities intending to submit a significant new use notification (SNUN) should engage in preliminary discussions with the agency. Such conversations can provide sufficient time to conduct any tests that may assist in evaluating the risks associated with the substance. SNUN submitters are subject to the same regulations and procedures as those submitting a Pre-Manufacture Notice. This includes submitting data on health and environmental effects, as stipulated in [40 C.F.R. Section 720.50](#). In addition, companies exporting any of the 329 inactive PFAS will be subject to the export notification requirement under TSCA Section 12(b).

RISKS TO AEROSPACE AND DEFENSE

Criminal penalties for knowing or willful violations include imprisonment of up to 15 years and/or a fine of up to \$250,000. A convicted organization may be subject to a fine of up to \$1,000,000. There are also civil penalties, which are now up to \$48,512 maximum per day. If your company does not have a review process in place to identify chemicals that are subject to SNURs, the potential exists for companies to use restricted chemicals in a manner not allowed by the regulation, subjecting the company to fines and penalties. Production may be impacted while the EPA reviews restricted new uses.

USEFUL LINKS

[PFAS Strategic Roadmap: EPA's Commitments to Action 2021–2024](#)

[SNUR on Inactive PFAS](#)

[TSCA requirements for exporting chemicals](#)

[List of “inactive” PFAS subject to SNURs](#)

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