

Toxic Substances Control Act (TSCA) – Significant New Use Rules (SNURs) Region: USA

WHY IS THIS ALERT IMPORTANT?

If your company uses chemicals that are identified by the United States Environmental Protection Agency (EPA) as being subject to the Toxic Substances Control Act (TSCA) Significant New Use Rule (SNUR), then this regulatory alert will provide you with an important change to the SNUR regulations.

To better align with revisions that were made to the Occupational Safety and Health Administration (OSHA) Hazard Communications Standard (HCS), the EPA amended the regulations governing significant new uses of chemical substances under TSCA. This revision also considers changes to the OSHA Respiratory Protection Standard and the National Institute for Occupational Safety and Health (NIOSH) respirator certification requirements as well as other changes.

Non-compliance to the SNUR regulations and its amendment may result in penalties and fines, such as imprisonment up to 15 years and fines up to \$1,000,000, as well as impacts to the production and supply chain of chemical substances.

INTENDED AUDIENCE

This Regulatory Alert is intended for IAEG members and their suppliers who manufacture, import, process or use certain substances in the United States.

BACKGROUND ON REGULATION

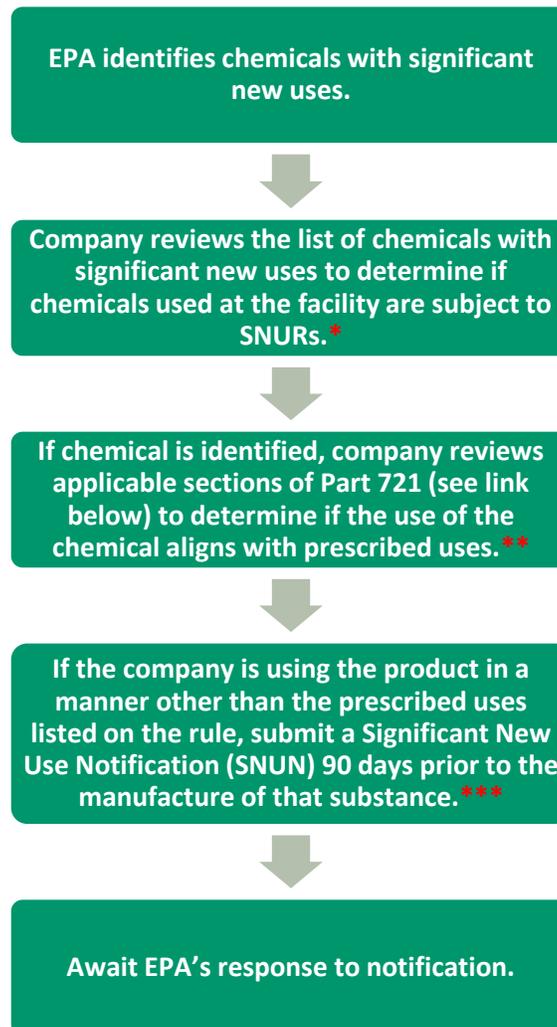
Part 721 of the Code of Federal Regulations (CFR) identifies uses of chemical substances which EPA has determined as significant new uses under the authority of section 5(a)(2) of TSCA. The SNUR also specifies procedures for manufacturers and processors to report on those significant new uses. The flow diagram shown on the next page provides an overview of the steps taken to address the regulation.

Under Section 5(a) of TSCA, the US EPA determines whether using a particular chemical substance under specific conditions may pose an unreasonable risk to human health and/or the environment. Following this, a SNUR may be issued in the Federal Register, where certain uses of the substance may be designated as 'significant new uses'. The SNURs will enable the management of risk for activities relating to the substances by prohibiting or limiting the activity.

Substances manufactured or processed in small quantities for scientific experimentation, analysis and chemical research qualify for general exemptions (specified in [Section 721.45 of the CFR](#)). Additionally, substances used for test marketing purposes may also be exempted upon application.

Further details can be found in the 'Regulatory Obligations' section of this Alert, and the flow diagram on the next page, which illustrates steps taken to address the regulation.

Flow Chart



Part 721: [Significant New Uses of Chemical Substances](#).

* The [list](#) of chemicals with significant new uses.

** This step of the process is impacted by the amendment to the SNUR regulations (published: 5 July 2022). See the 'What's New' section below for further details.

*** Where a significant new use of a chemical is considered confidential business information (CBI), and another company intends to manufacture or process the chemical substance for commercial purposes, then the company must submit a *bona fide* notice to the EPA. This notice is used to declare that the company has a genuine commercial need (intent to manufacture or import) for the chemical with CBI. If the EPA believes that the company's intent is valid, they will search the full TSCA chemical substance inventory, which contains a list of chemicals regulated by the TSCA (existing substances), including non-

confidential and confidential substances. Following this, a written determination is provided to the company by the EPA on the TSCA Inventory status for the chemical substance. Further details can be found on [Section 720.25 of the CFR](#).

What's New

In line with the changes to the Occupational Safety and Health Administration (OSHA) Hazard Communications Standard (HCS), and OSHA and National Institute for Occupational Safety and Health (NIOSH) respiratory standards, the EPA amended the requirements for SNURs on 5 July 2022. The main aim was to better protect the health of workers.

The SNUR regulations amendments (published: 5 July 2022) include:

» **Changes to protection in the workplace:**

The language concerning respiratory protection requirements at 40 CFR 721.63(a)(4), (a)(5), and (a)(6) was updated to be consistent with both the OSHA and NIOSH requirements. The reference to 30 CFR Part 11 was replaced with a reference to [42 CFR Part 84](#) to incorporate the most updated NIOSH regulation for testing and certifying respirators. The NIOSH recommends that any respirator user, who still uses filters produced and approved under 30 CFR Part 11, replaces the filters to those approved under 42 CFR Part 84 (enhanced filter penetration requirements). These changes apply to all previously issued SNURs that contain significant new use requirements pertaining to respiratory protection. Manufacturers and processors subject to current SNURs can follow updated respiratory protection requirements without triggering a SNUN requirement. The amended provisions to 40 CFR 721.63(a)(5) will standardize the use of the updated NIOSH-certified respirator language, and allow the EPA to cross-reference the language for new chemical SNURs rather than on an individual basis. All the newly added NIOSH-certified respirator language can be found starting at point (xvi) under 40 CFR 721.63(a)(5) [see [Attachment A](#)].

» **Changes to Hazard Communication Program:**

The Hazard Communication Program requirements (40 CFR 721.72) was updated to align with the OSHA HCS (Hazard Communications Standard) – only applies to SNURs issued after 5 July 2022. This has resulted in new hazard and precautionary statements, and identification (by the EPA) of OSHA statements that must be on the label and SDS.

» **Changes to computation of estimated surface water concentrations:**

A SNUR with specific significant new uses described in 40 CFR Sections 721.90(a)(4), (b)(4), and (c)(4) requires a SNUN when the surface water concentration of the substance exceeds the level specified for that SNUR. 40 CFR 721.91, which sets out the methodology to calculate the surface water concentration, was amended to allow manufacturers and processors to account for reductions in the concentrations resulting from control technology (e.g., wastewater treatment).

» **Changes to applicability determination when the specific chemical identity is confidential:**

The *bona fide* notice procedures in [40 CFR 721.11](#) were amended to authorize the EPA to disclose the confidential significant new use designations to a manufacturer or processor who has established a *bona fide* intent/notice.

- » **Changes for submission of Safety Data Sheets (SDSs) with Pre-Manufacture Notice (PMN), SNUNs, Low Volume Exemptions (LVEs), Low Release and Exposure Exemptions (LoREXs), and Test Marketing Exemption (TME):**

The requirements in 40 CFR 720.38, 720.45 and 723.50 were updated to require any SDS that is already developed (draft or otherwise) to be submitted as part of any notification or exemption application (PMN, SNUN, LVEs, LoREXs, or TME) under Section 5 of TSCA. Submitters are not required to develop a SDS, but instead provide an already-developed SDS to the extent the SDS is known or reasonably ascertainable by the submitter. Therefore, the ‘changes for submission of SDSs’ are applicable to other processes/areas within TSCA other than SNUNs, including PMN, LVEs, LoREXs and TME.

A comparison table highlighting the changes prior to and after the amendments to the SNUR regulations is provided on [Attachment A](#) for ease of reference. Further details regarding the amendment to the SNUR regulations can be found on the Federal Register Final Rule (see ‘Useful Links’ section).

RELEVANT DATE

- » SNUR regulations amendment effective: 6 September 2022

REGULATORY OBLIGATIONS

Companies intending to manufacture, import or process a substance, which is subject to a SNUR for an activity that is designated as a significant new use, are required to notify the EPA (via a SNUN) at least 90 days before commencing the activity. The EPA will then evaluate the intended use and, if necessary, prohibit or limit the activity before it occurs.

In many cases, the EPA will need to respond to a SNUN by amending the SNUR to allow companies other than the SNUN submitter, such as the submitter's processor customers, to engage in the newly approved use(s). Before the EPA amends the SNUR, even after a manufacturer submits a SNUN and the review period expires, processors and other manufacturers of the substance are still legally required to submit their own SNUN before engaging in the significant new use.

With respect to the SNUR regulations amendments (published: 5 July 2022), companies must review their existing SNURs to assess whether the changes impact their business, and make any necessary changes to comply with the updated regulatory obligations. The key updates include:

- » Aligning current SNURs to updated respiratory protection requirements provided in 40 CFR 721.63(a)(4), (a)(5), and (a)(6).
- » Using the new hazard and precautionary statements, and identification of OSHA statements on the label and SDS according to 40 CFR 721.72.
- » Altering the computation of discharges of chemicals to surface water as described in 40 CFR 721.91 to determine whether a SNUN is needed.
- » Submission of an already-developed SDS (even if in a draft form) with a new substance notification or exemption application (e.g., PMN, SNUN, LVEs, LoREXs and TME) as specified in 40 CFR 720.38, 720.45 and 723.50.

RISKS TO AEROSPACE AND DEFENSE

Penalties for non-compliance include imprisonment 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. 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 thus subjecting the company to fines and penalties. Production may be impacted while restricted new uses are being reviewed by the EPA.

USEFUL LINKS

[Attachment A](#)

[TSCA](#)

[TSCA SNURs](#)

[TSCA SNURs Amendment \(Published: 5 July 2022\)](#)

[TSCA Inventory](#)

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