

## International Trade Alert

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### EPA Proposes New Controls for Chemicals Used in Petroleum Refining: Will They Affect Your Operations?

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Companies involved in petroleum refining operations or that import chemical substances used in such operations should be aware of a recent regulatory proposal issued by U.S. EPA under the Toxic Substances Control Act (TSCA) that could impact their operations. On January 23, 2013, EPA proposed what is referred to as a significant new use rule, or "SNUR," for four chemical substances used in chemical manufacturing and petroleum refineries. **The SNURs would require persons who intend to manufacture, import, or process any of the four chemical substances for certain prescribed new uses to notify EPA at least 90 days before commencing that activity.** 78 Fed. Reg. 4806. EPA would evaluate the reported new use and, if necessary, may prohibit or limit the activity before it occurs. The four SNURs were originally issued as direct final SNURs in September of 2012 but, because the Agency received adverse comments on the SNURs, they are now being issued in proposed form on which EPA will accept comments until February 22, 2013.

**What chemical substances are affected?** The chemical substances for which EPA has proposed SNURs are identified in EPA's notice as pentane, 1,1,1,2,3,3-hexafluoro-4-(1,1,2,3,3,3-hexafluoropropoxy) (PMN number P-07-204; CAS number 870778-34-0), to be used as a heat transfer fluid, and partially fluorinated alcohol substituted glycols (PMN numbers P-10-58, P-10-59, and P-10-60), to be used as intermediates (P-10-58 and P-10-59) and as a surface active agent (P-10-60).

**What is a significant new use?** TSCA authorizes EPA to determine that a particular use of a chemical substance is a "significant new use," triggering a requirement for regulated entities to submit a significant new use notice (SNUN) at least 90 days prior to manufacturing, importing, or processing the chemical substance for that use. TSCA § 5(a)(2). Persons subject to the SNURs must follow regulatory procedures mirroring those required for EPA's evaluation of new chemical substances in connection with submissions of premanufacture notices (PMNs). Upon receiving a SNUN from a person seeking to use the chemical substance for the significant new use, EPA may take regulatory action to control the activities covered by the SNUN, including through the use of consent orders. In this way, EPA is able to impose binding conditions not only on the original submitter of a PMN, but also on the subsequent manufacture, import, or processing of the chemical substance for the significant new use by other individuals.

**Why have these chemicals triggered SNURs?** Under TSCA, EPA determines whether the use of a chemical substance constitutes a "significant new use" based on the following factors:

- The projected volume of manufacturing and processing of a chemical substance;
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance;
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance;
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance; and,
- Any other factors EPA finds to be relevant to the determination of "significant new use."

In its proposed SNUR, EPA explains why the PMNs for the four chemical substances triggered the SNURs:

- **Pentane, 1,1,1,2,3,3-hexafluoro-4-(1,1,2,3,3,3-hexafluoropropoxy):** During its review of the PMN for this substance to be used as a heat transfer fluid, EPA identified concerns for neurotoxicity and liver effects associated with exposure to the substance. Although worker exposure is normally abated by the use of impervious gloves, and EPA has therefore not determined that the use of the substance would pose an unreasonable risk, EPA has determined that the use of the substance without such protections, or in any manner other than as described in the amended PMN, could cause serious health effects.

- **Partially fluorinated alcohol substituted glycols:** During its review of the three PMNs for these substances, EPA identified concerns for potential incineration and decomposition of the products of the substances, which could bioaccumulate or biomagnify and prove toxic to humans and animals. EPA has determined that these chemicals may be produced in substantial quantities and may result in significant or substantial human exposure to the substances and their potential degradation products, and that the use of these chemicals could present an unreasonable risk of injury to human health and the environment. EPA therefore issued a consent order for these chemicals, requiring submission of testing on the chemical substance P-10-60 and analysis of raw materials. The consent order further restricts the use of substances P-10-58 and P-10-59 as intermediates to make substance P-10-60. The proposed SNUR designates the absence of the protective measures required in the consent order.

**Reporting Requirements.** In accordance with the proposed reporting obligations, any manufacturer, importer, or processor that intends to undertake an activity that qualifies as a significant new use of the covered substances would be **required to notify EPA at least 90 days prior to undertaking the activity.** EPA would review and evaluate the data submitted and, if necessary, utilize the appropriate authorities available under TSCA to regulate the manufacture, import, or processing of the new use of the subject chemical.

**Immediate Compliance.** EPA has determined that the date of the original publication of the direct final rule (September 21, 2012) will be used to determine whether a use of one of the four chemical substances subject to these SNURs is a significant new use. Therefore, **persons who commence commercial manufacturing, import, and/or processing of any of the four chemical substances for the significant new use will be required to cease that activity before the effective date of the final rule resulting from this proposal.** Such activities could be resumed only after the person had complied with all applicable SNUR notification requirements, and only after expiration of the applicable SNUR review period. However, EPA has provided for compliance with the SNURs prior to the effective date of the final rule; advance compliance with the conditions set forth at 40 C.F.R. § 721.45(h) will render an individual exempt from the requirements of the SNUR. In addition, the SNUR requirements are subject to existing significant new use exemptions, including, for example, for persons who import the chemical for a significant new use in small quantities solely for research and development.

#### **What Does This Mean for Your Company?**

- All U.S. companies that manufacture, import, or process any of the four chemical substances subject to these SNURs should carefully evaluate whether planned activities involving the manufacture, import, or processing of these chemicals might qualify as a significant new use subject to the proposed reporting requirements.
- **Companies that may be subject to the SNUR requirements should consider submitting comments on the SNURs to EPA by February 22, 2013.**
- **Following the close of the comment period on the SNURs, companies that may be subject to the SNUR requirements upon the effective date of the final rule should:**

- Determine whether the company's activities qualify for an exemption;
- Review internal compliance policies and, if necessary, amend policies and procedures to adapt to the proposed requirements;
- Assess whether to provide appropriate personnel with additional compliance training in advance of the effective date of the final rule;
- Allocate resources to accommodate any increased compliance needs; and
- Track issuance of the final rule, at which point the SNUR requirements will take effect.

Contact the attorneys in Venable's [International Trade and Customs Group](#) or [Environmental Group](#) for additional details on how the proposed new reporting requirements may impact your company, or for assistance in the development of comments on the proposal. Venable can also assist companies in reviewing and updating internal compliance programs in light of the newly proposed requirements.