EPA Amends SNUR Regulations to Protect Workers’ Health

On July 5, 2022, the U.S. Environmental Protection Agency (EPA) issued a final rule amending the regulations governing significant new uses of chemical substances under the Toxic Substances Control Act (TSCA) to align with revisions that were made to the Occupational Safety and Health Administration (OSHA) Hazard Communications Standard (HCS) and changes to the OSHA Respiratory Protection...
Standard and the National Institute for Occupational Safety and Health (NIOSH) respirator certification requirements for the respiratory protection of workers from exposure to chemicals. 87 Fed. Reg. 39756. In addition, EPA is amending the regulations governing significant new use rules (SNUR) to address issues that have been identified by EPA and raised by stakeholders through public comments. EPA is also making a minor change to reporting requirements for premanufacture notices (PMN) and other TSCA notifications. EPA states that it “expects these changes to have minimal impact on the costs and burdens of compliance, while updating the significant new use reporting requirements to assist in addressing any potential risks to human health and the environment.”

Changes to 40 C.F.R. Section 721.63, Protection in the Workplace

The final rule updates language pertaining to the respiratory protection requirements listed in 40 C.F.R. Sections 721.63(a)(4), (a)(5), and (a)(6) to be consistent with both OSHA and NIOSH requirements. In 40 C.F.R. Section 721.63(a)(4), which requires that respirators be used in accordance with 30 C.F.R. Part 11, EPA is replacing the reference to 30 C.F.R. Part 11 with a reference to 42 C.F.R. Part 84 to incorporate the most updated NIOSH regulation for testing and certifying respirators. According to EPA, most manufacturers and processors are already subject to and complying with 42 C.F.R. Part 84. EPA states that this change will apply to all previously issued SNURs that contain significant new use requirements pertaining to respiratory protection by clarifying that manufacturers and processors subject to current SNURs can follow updated respiratory protection requirements without triggering a significant new use notice (SNUN) requirement. EPA will include the updated language in the issuance of new SNURs “as appropriate.”

The final rule also updates the NIOSH-certified respirator language in 40 C.F.R. Section 721.63(a)(5). According to EPA, it had been incorporating the updated NIOSH-certified respirator language in newly issued SNURs when it issued the proposed rule in July 2016, and it has continued to do so. EPA states that the final provisions to 40 C.F.R. Section 721.63(a)(5) will standardize the use of the updated NIOSH-certified respirator language and allow EPA to cross-reference the language for new chemical SNURs rather than on an individual basis.

EPA has included language that allows any person subject to SNURs with older respirator requirements in 40 C.F.R. Section 721.63(a)(5) already cited in Subpart E to continue using older-style respirators to avoid triggering a SNUN requirement. EPA also included language in 40 C.F.R. Section 721.63(a)(5) that will allow any person subject to the older respirator requirements to use an equivalent respirator under the newer requirements, provided that the assigned protection factor (APF) of the new respirator is equal to or greater than the respirator cited in Subpart E. EPA notes that the amendment to 40 C.F.R. Section 721.63(a)(6) also updates language for the airborne form of a chemical substance applicable to the respiratory protection requirements in 40 C.F.R. Section 721.63(a)(4). EPA states that it will cite this language when issuing new SNURs.

The final rule also revises 40 C.F.R. Section 721.63 to add language that would make it a significant new use not to implement a hierarchy of controls to protect workers. This revision will require any person subject to an applicable SNUR to determine and
use appropriate engineering and administrative controls before using personal protective equipment (PPE) for worker protection, similar to the requirements in OSHA standards at 29 C.F.R. Section 1910.134(a)(1) and guidance in Appendix B to Subpart I of 29 C.F.R. 1910.

EPA states that based on public comments, it decided to move the language that was proposed at 40 C.F.R. Sections 721.63(a)(1) and 721.63(a)(4) to new paragraphs 40 C.F.R. Sections 721.63(a)(7) and 721.63(a)(8), respectively. According to EPA, these new paragraphs will not affect previously issued SNURs but will only be applicable to SNURs issued or amended after the final rule becomes effective. EPA notes that while it is not updating the language referenced by many existing SNURs, it “continues to affirm that a hierarchy of controls should be applied, and that PPE should be the last option in controlling exposures.” EPA believes that most companies are already following a hierarchy of controls as required by OSHA regulations.

Changes to 40 C.F.R. Section 721.72, Hazard Communication Program

Based on the changes to 29 C.F.R. Section 1910.1200, OSHA’s modified HCS, EPA is making changes to 40 C.F.R. Section 721.72. In March 2012, OSHA modified its HCS to conform to the United Nations’ Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Under EPA’s current regulations, when SNURs are issued with a citation to 40 C.F.R. Section 721.72 in Subpart E for a chemical substance, it is considered a significant new use if the company does not develop a written hazard communication program for the substance in the workplace. According to EPA, manufacturers and processors subject to a SNUR in Subpart E can rely on an existing hazard communication program, such as one established under the OSHA HCS or one based on GHS recommendations, to comply with this significant new use requirement to the extent the hazard communication program contains elements cited for that SNUR from 40 C.F.R. Section 721.72 paragraphs (a) through (h).

EPA is adding new paragraphs (i) and (j) to 40 C.F.R. Section 721.72 that it will use when imposing hazard communication requirements for SNURs issued after the rule becomes effective. The new paragraph (i) will require that a written hazard communication program be developed and implemented for the substance in each workplace in accordance with OSHA HCS 29 C.F.R. Section 1910.1200. The new paragraph (j) describes specific statements and other warnings that could be incorporated in SNURs for substances identified in Subpart E. The specific statements and warnings that could be required would be based on EPA’s risk assessment of the chemical substance and would be consistent with the OSHA HCS and GHS recommendations.

EPA states that it expects that, whenever the statements in paragraphs (g), (h), and (j) are required and the determinations for the SNUR are published, manufacturers and processors subject to the SNUR will also consider if they trigger any other corresponding hazard communication under the OSHA HCS requirements or under GHS recommendations. Any hazard and/or precautionary statements required by the SNUR will include a minimum set of hazard warnings. EPA may also propose
individual SNURs or issue Section 5(e) SNURs under 40 C.F.R. Section 721.160 using other specific statements, signal words, symbols, hazard category, and pictograms as hazard communication requirements.

EPA is updating 40 C.F.R. Section 721.72 paragraphs (a) through (h) to be consistent with both OSHA requirements and GHS recommendations. These changes apply to individual SNURs in Subpart E issued before the effective date of the final rule. EPA is making changes to 40 C.F.R. Section 721.72 paragraphs (a), (c), and (d) to change using the term “material safety data sheet” (MSDS) to “safety data sheet” (SDS) and allow easily accessible electronic versions or other alternatives to maintaining paper copies of the SDS. These changes apply to any previously issued SNUR in Subpart E that cites these paragraphs. EPA is also adding new hazard and precautionary statements, listed in 40 C.F.R. Section 721.72 paragraphs (g) and (h), to make this provision consistent with statements under the OSHA HCS requirements and the GHS recommendations. While the previously issued SNUR precautionary and hazard statements will remain applicable solely for previously issued SNURs, EPA has also identified which of the new statements can be used as alternatives for the previously issued precautionary and hazard statements. According to EPA, manufacturers and processors subject to a previously issued SNUR will have the option to use the prior precautionary and hazard statements or use the new alternative statements that are consistent with the OSHA HCS requirements or GHS recommendations to comply with the SNUR.

EPA is also including language that allows any person subject to a previously issued SNUR containing requirements for 40 C.F.R. Section 721.72 paragraphs (a) through (h) to comply with those requirements by following the requirements of 40 C.F.R. Section 721.72 paragraph (i), which will be applied to SNURs issued after the final rule, and using any statements specified for that substance in the 40 C.F.R. Section 721.72 paragraphs (g) or (h). For example, according to EPA, a person currently subject to a SNUR citing the requirement to establish a hazard communication program as described in 40 C.F.R. Section 721.72 paragraphs (a) through (f) and the requirement for using a hazard statement in paragraph (g)(1)(iii), central nervous system effects, could comply by taking the following steps: establish a hazard communication program according to the requirements in paragraph (i) and use the hazard statement in paragraph (g)(1)(iii), “central nervous system effects,” or the alternative hazard statement (g)(1)(xi), “may cause damage to the central nervous system through prolonged or repeated exposure.”

EPA recommends using a Chemical Abstracts Service Registry Number (CAS RN) to identify the chemical substance in an SDS whenever possible. Only when a CAS number is not available should a different unique numerical identifier be used. According to EPA, because of variations in naming conventions for chemical substances, using CAS numbers makes it easier for the regulated community to identify and report accurately chemical identities. EPA states that the changes for SNUR hazard communications requirements concerning how to identify chemical substances are consistent with OSHA regulations.

**Clarification of the Use of 40 C.F.R. Section 721.80, Industrial Commercial and Consumer Activities**
EPA is also clarifying the significant new use for new chemical SNURs described at 40 C.F.R. Section 721.80(j), which identifies a significant new use as “Use other than as described in the premanufacture notice referenced in subpart E of this part for the substance.” When EPA issues a SNUR using the designation at 40 C.F.R. Section 721.80(j) in Subpart E for a chemical substance and that use described in the PMN is claimed as confidential, EPA cites 40 C.F.R. Section 721.80(j). In identifying the significant new use in Subpart E for certain previously issued SNURs where the use described in the PMN was not claimed confidential, EPA states that it cited 40 C.F.R. Section 721.80(j) and included the PMN use described in the PMN in parentheses. EPA has received public comments in response to proposed SNURs and pre-notice inquiries for SNUNs, stating that manufacturers and processors subject to SNURs find it confusing when EPA cites 40 C.F.R. Section 721.80(j) and then identifies the PMN use in parentheses, making it appear as though the significant new use is the use in the parentheses, where the significant new use is actually use other than the use in parentheses.

To identify better the significant new use, EPA states that it has changed this procedure to cite only 40 C.F.R. Section 721.80(j) when the use described in the PMN is confidential. When the use described in the PMN is not confidential, EPA intends to identify the significant new use in a new chemical SNUR by describing the use, such as in the following example: “A significant new use is any use other than as a pesticide intermediate.”

**Changes to 40 C.F.R. Section 721.91, Computation of Estimated Surface Water Concentrations: Instructions**

When EPA issues a new chemical SNUR citing the significant new uses described in 40 C.F.R. Sections 721.90 (a)(4), (b)(4), and (c)(4), the SNUR requires a SNUN if the results of the equation for computation of estimated surface water concentrations in 40 C.F.R. Section 721.91 exceed the level specified for that SNUR in Subpart E. EPA states that it is revising this requirement to allow manufacturers and processors to account for reductions in surface water concentrations resulting from wastewater treatment. 40 C.F.R. Section 721.91 contains instructions for the computation of estimated surface water concentrations according to the equation specified in 40 C.F.R. Sections 721.90(a)(4), (b)(4), and (c)(4). EPA is revising the instructions at 40 C.F.R. Section 721.91 to allow for a certain percentage of removal of a chemical substance from wastewater after undergoing control technology, applicable to the requirements at 40 C.F.R. Section 721.90. EPA states that when appropriate, it will identify an applicable removal percentage when issuing SNURs. The revised provisions will apply only when a removal percentage has been identified in the SNUR. EPA notes that this change does not apply to existing SNURs where a removal percentage has not been identified.

According to EPA, due to questions and comments from manufacturers and processors expressing confusion around the meaning of the phrase “predictable or purposeful release” at 40 C.F.R. Section 721.90, EPA is making changes to clarify the scope of the term. The phrase is used to qualify significant new uses pertaining to releases to water in 40 C.F.R. Section 721.90. EPA states that “routine or repeated activity that results in releases to water or non-routine releases to water that are not due to emergency conditions are included in the term ‘predictable or
purposeful.” EPA does not intend the phrase “predictable or purposeful release” to limit its strict liability authority under the statute.

Changes to 40 C.F.R. Section 721.11, Applicability Determination When the Specific Chemical Identity Is Confidential

Certain new chemical SNURs have a significant new use designation that is based on confidential business information (CBI) contained in the PMN and therefore, not disclosed in the published SNUR. Currently, for each SNUR containing a significant new use designation considered to be CBI, that SNUR cross-references the bona fide procedure in the specific SNUR in Subpart E for 40 C.F.R. Section 721.1725. Under the bona fide procedures, a manufacturer or processor may request EPA to determine whether a specific use would be a significant new use under the SNUR. The manufacturer or processor must show that it has a bona fide intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the chemical substance. If EPA concludes that the person has shown a bona fide intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the bona fide submission would be a significant new use under the rule.

When the chemical identity in a SNUR is CBI, 40 C.F.R. Section 721.11 provides a means by which bona fide submitters can determine whether their substance is subject to the SNUR. EPA states that chemical identity is not the only information contained in a SNUR that may be claimed as CBI, however. EPA is modifying the bona fide procedure in 40 C.F.R. Section 721.11 of Subpart A so that it applies to all SNURs containing any CBI, including the significant new use. EPA finds it would be more efficient to have a bona fide procedure for determining confidential significant new uses in Subpart A rather than referencing 40 C.F.R. Section 721.1725(b)(1) each time EPA issues a SNUR containing a significant new use designation containing CBI. In addition, EPA is modifying the bona fide procedure that allows EPA to disclose the confidential significant new use designations to a manufacturer or processor who has established a bona fide intent to manufacture (including import) or process a particular chemical substance.

Changes for Submission of SDSs with PMNs, SNUNs, Low Volume Exemptions (LVE), Low Release and Exposure Exemptions (LoREX), and Test Marketing Exemption (TME) Applications

EPA is revising requirements in 40 C.F.R. Sections 720.38, 720.45, and 723.50 to require that any SDS already developed, even if in draft form, must be submitted as part of any notification or exemption application (PMN, SNUN, LVE, LoREX, or TME) under TSCA Section 5. According to EPA, many submitters already submit available SDSs as part of their submission, and the information contained in SDSs “is often useful for EPA’s assessments of chemicals.” EPA notes that the revision does not require submitters to develop an SDS. It only requires a submitter to submit an already-developed SDS as part of a notification under TSCA Section 5, to the extent the SDS is known or reasonably ascertainable by the submitter.

Commentary
We commend EPA for completing its rulemaking to modernize important sections of the SNUR regulations at 40 C.F.R. Part 721. EPA appropriately refers to the OSHA and NIOSH standards for workplace protection and EPA has done so in a way that does not trigger SNUNs for existing activity, while also ensuring consistent requirements on SNURs going forward. EPA also codified a requirement to implement engineering or administrative controls in preference to PPE -- a sensible step that we view as the most common solution for worker protection. An employer using a SNUR substance in the workplace will have to develop and keep records of its evaluation of the feasibility of engineering and administrative controls, but this is most likely a matter of ensuring there is a written record of an evaluation that is already done. EPA is also to be commended for updating its regulations to conform better to GHS standards.

EPA has also updated the method for computing a surface water concentration (SWC) when documenting compliance with a SWC limit. The method at 40 C.F.R. Section 721.91 is now aligned with EPA's standard method it uses during its new chemical risk evaluation. In addition, EPA has clarified the meaning of "predictable or purposeful" releases to water.

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