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TOXIC SUBSTANCES

SIGNIFICANT NEW USE RULES

The U.S. Environmental Protection Agency's use of its authority under the Toxic Substances Control Act is expanding. Its use of TSCA Section 5 "significant new use rule" (SNUR) authority is clearly on the increase, as most recently demonstrated by the important role that significant new use rules have in Chemical Action Plans. This article describes SNURs, their issuance and legal background, and a few key issues of which regulated entities need to be aware in responding to a proposed or promulgated SNUR.

EPA's SNUR Authority and Key Points Regarding SNURs for Former New Chemicals

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The Toxic Substances Control Act authorizes EPA to take a variety of actions to address concerns with the manufacture, importation, processing, and use of "existing" chemicals. "Existing," of course, refers to those chemicals that are listed on the TSCA Chemical Substance Inventory (public and confidential inventory). One regulatory tool that EPA uses more frequently than others is the issuance of significant new use rules.¹

In several 2009 *Federal Register* notices issuing SNURs, EPA refers to the fact that it has promulgated over 1,000 SNURs. Many of these apply to former "new chemicals" that were the subjects of Premanufacture Notices (PMNs). A not insignificant number of SNURs apply, however, to existing chemicals. According to a 2008 report, 1,309 SNUR actions have been taken on new chemicals—734 of these were in combination with consent orders under TSCA Section 5(e), and 575 were "non-5(e) SNURs" (additional explanation is provided below). A quick count in 40 C.F.R. Section 721, Subpart E, indicates that SNURs have been promulgated on over 300 existing chemicals.

¹ TSCA § 5(a)(1)(B), 15 U.S.C. § 2604(a)(1)(B).

Chemical Action Plans May Lead to SNURs

Recently, EPA has been developing Chemical Action Plans outlining the risks that EPA believes specific chemicals may present, and identifying the risk-mitigation steps EPA wishes to take to address those concerns.² While EPA discusses several potential measures, including chemical testing under TSCA Section 4 and restrictions or bans under TSCA Section 6, it is more likely than not that the regulatory measure by which EPA ultimately may reduce identified risks is through the issuance of SNURs.

There are several issues that companies can encounter when faced with a proposed or promulgated SNUR. There are times, for example, when the “use” that is “significant” is not transparent in the regulations, leaving a company without critical information to determine if its use complies with the SNUR. There are other occasions when entities that have submitted a pre-manufacture notice, but have not been subject to a TSCA Section 5(e) consent order, can monitor EPA’s actions regarding the terms and procedures for developing “expedited” non-5(e) SNURs and ensure that EPA meets its regulatory requirements.

This article, after providing background on when and how SNURs are issued, discusses several issues of which entities should be aware and address when manufacturing, importing, or processing former new chemicals subject to, or proposed to be subject to, a SNUR.

Factors Triggering a SNUR

TSCA Section 5(a) requires manufacturers, importers, and processors of chemicals to provide notice to EPA of any use of a substance that EPA has determined is “a significant new use.”³

A determination that a use is significant and new must be made by rule, known as a SNUR. TSCA does not establish standards or criteria for establishing when a new use is deemed “significant,” but requires EPA to consider “all relevant factors” before promulgating a SNUR. These factors include (a) the projected *volume* of manufacturing and processing of a chemical substance; (b) the extent to which a use *changes the type or form of exposure* of human beings or the environment to a chemical substance; (c) the extent to which a use *increases the magnitude and duration of exposure* of human beings or the environment to a chemical substance; and (d) the reasonably anticipated *manner and methods of manufacturing, processing, distribution* in commerce, and disposal of a chemical substance.⁴ The underscored language demonstrates the breadth and scope of new “use” is indeed seemingly limitless. The significant new “use” that triggers a SNUR may not be a “use” at all, but an increased production volume, in-

creased human or environmental exposure, or change in disposal or manufacturing methods. The inherent breadth of these factors gives EPA enormous discretion to define a new use as “significant” for purposes of addressing potential chemicals risks under its SNUR authority, a reason no doubt TSCA Section 5 authority has become the darling in EPA’s arsenal of TSCA tools.

Extending Section 5(e) Controls

A careful review of SNURs reveals some interesting facts. For some substances, EPA issued final SNURs that set forth the same exposure controls that were negotiated with the initial PMN submitter through TSCA Section 5(e) consent orders. This is because while a Section 5(e) consent order applies only to the original PMN submitter who signs that consent order, a SNUR applies to *all* manufacturers and processors of the chemical substance.⁵

For other substances, EPA determined that, although the manufacturing, processing, and use of the substance as set forth in each respective PMN did not present health and/or environmental risks requiring EPA action, there were other potential uses that EPA determined may cause significant adverse health and/or environmental effects for which SNURs are required. These are referred to as “non-5(e) SNURs.”

EPA must identify the uses it considers “significant new uses” in the specific SNUR for that substance. In developing a chemical-specific SNUR, EPA may incorporate provisions identified in its “generic SNUR” regulations at 40 C.F.R. Part 721, Subpart B. These generic SNUR regulations set forth five categories of general significant new uses. The generic SNUR regulations also contain various regulatory requirements applicable to significant new uses that EPA may select based on the known or suspected effects of the chemical and the conditions of manufacturing and processing. For example, EPA’s generic SNUR regulations designate as a standardized “significant new use” any manner of manufacture, import, or processing where the manufacturer, importer, or processor has not established a worker protection program.⁶ Other general significant new uses include any uses in the absence of a hazard communication program⁷ and various uses in connection with certain industrial, commercial, and consumer activities.⁸

Expedited Process Is Common

To issue a SNUR, EPA can elect to engage in full notice-and-comment rulemaking but generally prefers instead to utilize its expedited process whenever possible. EPA has issued regulations establishing expedited procedures for Section 5(e) SNURs and non-5(e)

² In the toluene diisocyanate (TDI) Chemical Action Plan, for example, EPA stated that based on statements by some in industry that uncured TDI is not used in consumer products, EPA could propose a SNUR designating the use of uncured TDI and its related polyisocyanates in a consumer product as a new use requiring prior notice to EPA. The Chemical Action Plan for TDI and related compounds is available at <http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/tdi.html> (72 DEN A-16, 4/14/11).

³ TSCA § 5(a)(1)(B), 15 U.S.C. § 2604(a)(1)(B).

⁴ TSCA § 5(a)(2), 15 U.S.C. § 2604(a)(2) (emphasis added).

⁵ 60 Fed. Reg. 16311, 16312 (March 29, 1995). See also EPA, Questions and Answers for the New Chemicals Program at 1-62, available at: <http://www.epa.gov/oppt/newchemicals/pubs/qanda-newchemicals.pdf>. (“[A] § 5(e) Consent Order is not binding on any companies that may subsequently manufacture or import the substance other than the submitter who signed the § 5(e) Consent Order. Consequently, after signing a § 5(e) Consent Order with the PMN submitter, EPA generally promulgates a [SNUR], which applies similar restrictions as in the § 5(e) Consent Order to other potential manufacturers and processors.”)

⁶ 40 C.F.R. § 721.63.

⁷ *Id.* § 721.72.

⁸ *Id.* § 721.80.

SNURs.⁹ “5(e) SNURs” must be “based on and be consistent with” the Section 5(e) consent order issued for that substance.¹⁰ Non-5(e) SNURs must satisfy certain concern criteria set forth in the regulations.¹¹ These conditions also apply to any additional uses EPA designates as significant that are not specified in the Section 5(e) consent order.

Under these expedited rulemaking procedures, EPA can publish a “direct final rule” that will become final unless EPA timely receives adverse comment during the comment period.¹² If adverse comments are received, EPA will withdraw the direct final rule and then issue a proposed SNUR. EPA states that it tries to use its expedited procedure “in cases where it does not think comment is likely (e.g., SNURs which put in place restrictions already agreed upon between EPA and a PMN filer).”¹³

When EPA promulgates a SNUR designating a significant new use for a particular chemical substance, manufacturers, importers, and processors of that chemical substance must provide to EPA a significant new use notice (SNUN) at least 90 days before any manufacture, import, or processing for that use.¹⁴ Upon review of a SNUN, EPA can exercise the same authority it may take with respect to a newly filed PMN. Specifically, EPA can obtain health or environmental testing, take action to protect against risks EPA believes to be unreasonable, including regulating the manufacture, processing, distribution, use, or disposal of the substance, or take action to protect against imminent hazards as provided under TSCA Sections 5(e), 5(f), 6, or 7.¹⁵ If EPA does not take any such action in response to the SNUN, it must publish a notice in the *Federal Register* explaining its reasons for failing to take such action.¹⁶

In addition to complying with the SNUR, TSCA Section 12(b) export notification requirements are triggered for substances subject to a proposed or promulgated SNUR. TSCA Section 12(b) requires exporters of chemicals to notify EPA in writing if they are exporting, or intending to export, chemical substances or mixtures that are subject to certain TSCA rules or orders.¹⁷ Specifically, for substances subject to Section 12(b) requirements based on a SNUR, companies are required to submit an export notification to EPA for the first export or intended export to a particular country, unless the substance is being exported at a concentration of less than 1 percent (by weight or volume) or 0.1 percent (by weight or volume) for certain substances identified as carcinogens, in which case it meets the *de minimus* exemption.¹⁸

⁹ *Id.* §§ 721.160, 721.170. See also 54 Fed. Reg. 31298 (July 27, 1989); 60 Fed. Reg. 16311 (March 29, 1995).

¹⁰ 40 C.F.R. § 721.160(b).

¹¹ *Id.*, 40 C.F.R. § 721.170(b).

¹² *Id.* §§ 721.160(c), 721.170(d).

¹³ EPA, Questions and Answers for the New Chemicals Program at 1-64, available at <http://www.epa.gov/oppt/newchemicals/pubs/qanda-newchemicals.pdf>.

¹⁴ 40 C.F.R. § 721.25(a).

¹⁵ TSCA §§ 5(e), 5(f), 6, and 7, 15 U.S.C. §§ 2604(e), 2604(f), 2605, and 2606.

¹⁶ TSCA § 5(g), 15 U.S.C. § 2604(g).

¹⁷ See 40 C.F.R. § 707.60(a).

¹⁸ *Id.* §§ 707.60(c), 707.65.

Steps to Determine Scope of a SNUR When Use Information Is Confidential

In many SNURs, EPA states that it would consider a significant new use of the substance to be triggered when there is: “Aggregate manufacture and importation volume for any use greater than that allowed by the section 5(e) consent order.”¹⁹ A company can in some instances obtain specific SNUR conditions from the manufacturer, but there are circumstances when a company may wish to determine the conditions itself. In these cases, a company would need to obtain a copy of the consent order at issue to understand the applicable aggregate manufacture and importation volumes. If the manufacture and importation volume allowed by a consent order has been claimed as confidential business information,²⁰ there would be no way for a company to know whether the volume it is considering manufacturing or importing is greater than that allowed by the Section 5(e) consent order.

In these cases, EPA’s regulations provide that in circumstances where a person who intends to manufacture, import, or process a chemical substance subject to a SNUR needs to obtain use information, that person may ask EPA whether the use for which the person intends to manufacture, import, or process the substance is a significant new use.²¹ The regulations further state that if EPA determines that the person has a *bona fide* intent (BFI), EPA will advise that person whether the use is a significant new use.²² If the use is not a significant new use, EPA will advise that person what activities would constitute a significant new use. Many SNURs will state specifically that these regulatory provisions apply when determining whether a specific use is subject to this SNUR.

Establishing Bona Fide Intent

To establish a bona fide intent to manufacture, import, or process a chemical substance, EPA’s regulations state that the person must submit to EPA: (1) all materials and statements required under 40 C.F.R. Section 721.6; and (2) the specific use for which the person intends to manufacture, import, or process the chemical substance.²³ The section referred to by EPA in the regulations regarding the bona fide intent procedure, 40 C.F.R. Section 721.6, has been redesignated as 40 C.F.R. Section 721.11.²⁴

The regulatory text indicates that a company will be told either that its use is a significant new use, or that its use is not a significant new use and will be told what activity would constitute a significant new use.²⁵ This presents another problem when the significant new use is production above some volume threshold that has been claimed as confidential business information. This

¹⁹ See, e.g., 40 C.F.R. §§ 721.320, 721.3520, 721.9550 (referencing 40 C.F.R. § 721.80(q)).

²⁰ There are also many instances where the chemical name of a new chemical has been claimed CBI and only a generic name is provided in the Code of Federal Regulations (C.F.R.). In these cases, EPA has established *bona fide* procedures at 40 C.F.R. § 721.11 for companies to ask EPA whether a particular substance is subject to a SNUR.

²¹ *Id.* § 721.1725(b)(1).

²² *Id.* § 721.1725(b)(1)(iv).

²³ *Id.* § 721.1725(b)(1)(ii).

²⁴ 53 Fed. Reg. 28354, 28359 (July 27, 1988).

²⁵ 40 C.F.R. § 721.1725(b)(1).

is because if a notice of bona fide intent is submitted to determine whether proposed importation volumes would be considered a significant new use, EPA will not provide the actual volume that would be considered a significant new use, but rather state only whether the volumes proposed in the BFI notice would be considered a significant new use. Although EPA has considered a procedure under which it would disclose the production volume that would be a significant new use, this procedure has not been implemented.²⁶ The result is that a company currently needs to submit new bona fide intent requests every time projected manufacture/importation volumes change to ensure that the increase does not trigger SNUN requirements. The process is inefficient and fraught with commercial uncertainty. Unless EPA implements a different procedure, however, the best recommendation would be for companies to inform EPA of the likely total annual amount manufactured/imported for a SNUR substance as well as a proposed maximum volume, with the hope that EPA will inform the company whether the volumes fall within the boundaries specified in the consent order and therefore do not represent a significant new use.

Steps Companies Should Take When Non-5(e) SNURs Are Being Developed

EPA is authorized by regulation to issue 5(e) SNURs²⁷ that set forth the same exposure controls that were negotiated with the initial PMN submitter through TSCA Section 5(e) consent orders, or, alternatively, non-5(e) SNURs²⁸ that control potential uses that are not anticipated by the initial PMN submitter, but may cause changes in exposures or releases and/or that EPA determines are significant and thus may be of concern with regard to adverse health and/or environmental effects. EPA states the following regarding its identification of SNUR conditions in a non-5(e) context:

When EPA determines that a substance is a candidate for a significant new use rule under this section, it will notify the person that submitted the premanufacture notice for the substance no later than 7 calendar days before the expiration of the notice review period under § 720.75 of this chapter. In providing this notice, EPA will describe the health or environmental concerns identified under paragraph (b) of this section and the activities under consideration for designation as significant new uses. Such notice may be by telephone, but in this event will be confirmed in writing no later than 30 days after completion of the notice review period.²⁹

²⁶ 68 Fed. Reg. 15061, 15077 (March 28, 2003; 60 DEN A-3, 3/28/03) (“EPA is considering whether to adopt a special procedure for use when CBI production volume is designated as a significant new use. Under such a procedure, a person showing a *bona fide* intent to manufacture or import the substance, under the procedure described in § 721.11, would automatically be informed of the production volume that would be a significant new use. Thus, the person would not have to make multiple *bona fide* submissions to EPA for the same substance to remain in compliance with the SNUR, as could be the case under the procedures in § 721.1725(b)(1).”)

²⁷ 40 C.F.R. § 721.160.

²⁸ *Id.* § 721.170.

²⁹ *Id.* § 721.170(d)(2).

In a *Federal Register* notice announcing revised SNUR requirements, EPA states:

[T]he non-5(e) SNUR process provides interested persons several opportunities for comment. Section 721.170(d)(2) requires EPA to notify the PMN submitter at least 7 days before expiration of the 90-day PMN review period regarding the Agency’s risk concerns and the activities under consideration for designation as a significant new use. In most cases, EPA actually expects to provide this notice many days before the “Day-83” deadline required by section 721.170(d)(2). Of course, once a PMN submitter receives this notice, the submitter may respond to EPA with comments regarding both the risk concerns and the potential regulatory terms or “significant new use” designations.³⁰

The regulations thus provide very clear deadlines that EPA must observe when notifying PMN submitters, orally and/or in writing, if it is considering a non-5(e) SNUR. The details and procedures for how this information is actually communicated by EPA can be murky at times, however. Although EPA has stated that it expects to provide notice “many days before the ‘Day-83’ deadline required by section 721.170(d)(2)” and the purpose of such notice is to allow the submitter to respond to EPA before the SNUR is proposed, there is very little detail provided in EPA documents or actual cases about this process or the consequences of EPA’s non-compliance with it.

Companies should pay close attention to documenting whether and how EPA complies with its regulatory requirements with regard to providing timely oral and written notification of the non-5(e) SNUR terms to “describe the health or environmental concerns” and “the activities under consideration for designation as significant new uses.” At the least, EPA’s non-adherence to these requirements could provide the basis for renegotiation of the underlying terms and conditions of the non-5(e) SNUR or more, including under some circumstances invalidation of the non-5(e) SNUR.

Conclusion

EPA has made clear its intent to use its authority under TSCA in new, different, and more effective ways. EPA’s desire to do so may in part be driven by the political reality that TSCA reauthorization legislation may not be in our future any time soon. As EPA experiments with its TSCA Section 5 authority, regulated entities need to be on the lookout for subtle yet important incremental changes in the way EPA implements its SNUR authority. Submitters need also to be mindful of EPA’s obligations with regard to notification of non-5(e) SNURs, and be especially aware of the notification provisions pertinent to SNUR conditions as the process for providing these notifications are fluid and imprecise. Finally, stakeholders should be urging EPA to revise the process to eliminate the “21 questions” aspect of volume thresholds that are claimed as confidential business information. EPA proposed to eliminate this problem seven years ago, but to date the problem remains unresolved. As SNURs are plainly a tool of EPA choice,

³⁰ 60 Fed. Reg. 16311, 16313 (March 29, 1995).

the time to address this problem and others embedded in the process is now.

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