

**Before the United States  
Environmental Protection Agency  
Significant New Use Rules  
83 Fed. Reg. 52,179 (Oct. 16, 2018); Docket EPA-HQ-OPPT-2017-0575**

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**Comments of the Chemical Users Coalition**

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The Chemical Users Coalition (“CUC”) appreciates the opportunity to provide these comments regarding EPA’s October 16, 2018 Federal Register notice proposing Significant New Use Rules (“SNURs”) for 13 chemical substances that were found “not likely to present an unreasonable risk” following the Premanufacture Notification (“PMN”) review process set forth in Section 5 of the amended Toxic Substances Control Act (“TSCA”).<sup>1</sup>

CUC is an association of companies from diverse industries interested in chemical regulatory policy from the perspective of entities that typically acquire and use, rather than manufacture or import, chemical substances.<sup>2</sup> CUC encourages regulators seeking to develop and implement requirements to protect health and the environment to do so in a manner that enables the regulated community’s ability to pursue technological innovation simultaneously with sustainable economic development in the United States. This is particularly important in the area of chemical regulatory policy, which necessarily addresses how core technologies and products can be adapted to address emerging information about health and environmental risk. Thus, CUC supports the successful implementation of the 2016 TSCA amendments when done in a manner that assures the various TSCA programs are both effective and efficient.

CUC’s comments to these proposed SNURs are consistent with comments the Coalition submitted previously encouraging EPA’s efforts to permit more timely review of PMNs.<sup>3</sup> CUC considers the approach taken for the proposed SNURs for 13 chemical substances found “not likely to present an unreasonable risk” under the conditions of use described in the PMNs to be generally consistent with the requirements of the amendments to Sections 5(a)(3) and 5(e) of TSCA (concerning the review and regulation of new chemicals and new uses) as well as the terms of Section 5(a)(2) (the authority to promulgate SNURs). To the extent this approach also represents potential improvements in the Agency’s ability to provide more timely review of PMNs, CUC supports the approach.

CUC’s members continue to encourage the Agency’s efforts in this regard. Accordingly, CUC’s comments on the 13 proposed SNURs focus on EPA’s approach to issuing follow-up

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<sup>1</sup> Significant New Use Rules on Certain Chemical Substances, 83 Fed. Reg. 52,179 (Oct. 16, 2018); *Chemicals Determined Not Likely to Present an Unreasonable Risk Following Pre-Manufacture Notification Review*, EPA, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely> (last updated Oct. 25, 2018).

<sup>2</sup> The members of CUC are Airbus S.A.S., The Boeing Company, General Electric Company, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, and United Technologies Corporation.

<sup>3</sup> Comments of the Chemical Users Coalition regarding New Chemicals Review Program (Jan. 19, 2018), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2017-0585-0066&attachmentNumber=2&contentType=pdf>.

SNURs, but do not address the specific chemical substances (or the particular reporting “triggers”) at issue in these proposed SNURs. CUC recommends EPA exercise this approach to issuing “follow-up” SNURs judiciously by issuing such SNURs only when needed, and when doing so to consider the potential impact of SNURs issued in this manner on processors and downstream users of such substances.

### **EPA’s Issuance of Follow-Up SNURs**

As discussed in CUC’s prior comments concerning the New Chemical Review process, CUC commends EPA for its efforts to provide timely review of PMNs and to enable the market entry of new and innovative chemical substances which, under the conditions of the intended uses proposed, will not present an unreasonable risk.<sup>4</sup> CUC agrees in general with EPA’s decision to designate the chemical substances covered by these proposed SNURs as not likely to present an unreasonable risk “based on EPA’s risk assessment for the chemical substances under intended conditions of use described in the PMN and EPA’s issuance of a proposed SNUR to address certain reasonably foreseen uses.”<sup>5</sup> However, CUC encourages EPA to make explicit in the preamble to the final SNURs that the SNURs are an essential part of the “not likely to present an unreasonable risk” determination for these substances, as this information provides insight into the Agency’s reasoning for issuing these SNURs. Such clarity should be provided in the preamble to the proposals for any future SNURs for which the basis of the determination is similar.

EPA’s approach as demonstrated by these SNURs allows the Agency to address potential concerns which *might* arise only if alternative uses that are not described in the PMN (and which have not yet been determined to present unreasonable risks) are reported to be under consideration by a future submitter of a Significant New Use Notification (“SNUN”). This allows the Agency to exercise its discretion to require that EPA receive a SNUN prior to the commencement of previously unreported conditions of use, and to do so without gratuitously imposing obstacles on intended conditions of use reported in a PMN that are not likely to present an unreasonable risk.

Although CUC is in general agreement with EPA’s approach of making findings of not likely to present an unreasonable risk for PMNs where the proposed uses in the PMNs present no unreasonable risk, and to subsequently issue SNURs to address concerns that could arise if one or more alternative conditions of use become foreseeable, CUC nevertheless encourages EPA to take a risk-based approach to identifying what changes in the conditions of use will constitute significant new uses, and to consider the potential burden on downstream users when designating potential new uses to be significant.<sup>6</sup> Section 5(a)(2) of TSCA requires EPA to consider “all

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<sup>4</sup> *Id.*

<sup>5</sup> Chemicals Determined Not Likely to Present an Unreasonable Risk Following Pre-Manufacture Notification Review, EPA, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely> (last updated Oct. 25, 2018) (referencing EPA TSCA Section 5(a)(3) Determinations for Premanufacture Notice for P-16-0192, P-16-0354, P-16-0355, P-16-0380, P-16-0381, P-16-0382, P-16-0383, P-16-0384, P-16-0385, P-16-0483, P-16-0484, P-16-0575, P-16-0581).

<sup>6</sup> Although TSCA forbids EPA from considering costs and other non-risk factors when determining whether a significant new use presents an unreasonable risk, TSCA explicitly requires EPA to consider “*all relevant factors*” when designating a new use as significant. Compare 15 U.S.C. § 2604(a)(3) with 15 U.S.C. § 2604(a)(2).

relevant factors” when designating a new use as significant, including (1) the projected manufacturing or processing volume of a chemical substance; (2) the “type or form of exposure of human beings or the environment” to the chemical substance; (3) the “magnitude and duration of exposure of human beings or the environment” to the environment; and (4) the “reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal” of the chemical substance.<sup>7</sup>

Clearly, Congress intended that the Agency exercise its authority to require Significant New Use reporting when material changes occur in the conditions of use of a substance that can affect exposure (i.e., human exposure and environmental releases)—factors for determining potential risks. CUC specifically requests that, when considering the criteria laid out in Section 5(a)(2) of TSCA for identifying significant new uses, EPA also evaluate the exposure-oriented criteria in light of the hazards presented by the PMN substance, and hence, the potential risks of the designated new uses. Substances which have been identified in the PMN review process as not likely to present an unreasonable risk should not routinely become the subject of follow-up SNURs (especially in the absence of any hazard concerns being identified in the course of the review of the PMN). It would be wasteful of EPA resources to require and receive SNURs that report on new uses for all substances which have been identified as not likely to present an unreasonable risk, unless changes in exposure also would be expected to increase the concerns for potential risks presented during such new uses. Imposing such reporting requirements routinely on all PMN substances that have completed review merely to capture new use information (or to identify and “track” new uses) is beyond the scope of EPA’s authority to issue SNURs and will impose an unnecessary impediment to innovation. Moreover, other provisions of TSCA, such as Section 8, provide a mechanism for tracking substances after substances enter commerce when there are not identified concerns with regard to potential risks.

### **Impact on Downstream Users**

SNURs issued for substances that were found “not likely to present an unreasonable risk” during the PMN review period will impose substantial application fees on manufacturers and processors of chemical substances subject to such rules. The fees imposed for the submission of SNURs under the recently issued TSCA fees rule are considerable.<sup>8</sup> Because EPA may consider “any relevant factors” in designating a new use as significant, CUC encourages EPA, prior to issuing a “follow-up” SNUR, to take into account the burden imposed by the recent sizeable increase in SNUN fees, and limit such SNURs to those situations in which changes in the conditions of use are likely to affect exposures and potential risks of concern.

CUC also asks that EPA consider the impact of the issuance of follow-up SNURs on downstream users of chemical substances in particular. Specifically, downstream users often must struggle to figure out when a product they use is covered by a SNUR. This is particularly true when the proposed SNUR provides only the generic name of a confidential chemical substance (without a CAS number), or when the proposed SNUR covers the use of a chemical

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<sup>7</sup> 15 U.S.C. § 2604(a)(2); 83 Fed. Reg. at 52,181.

<sup>8</sup> Fees for the Administration of Toxic Substances Control Act, 83 Fed. Reg. 52,694 (Oct. 17, 2018) (imposing a fee of \$16,000 for the submission of a SNUN by a non-small business entity). Moreover, these fees are more than six times higher than the fees that were in place when EPA first made public the New Chemicals Framework.

substance in an article. A downstream user could unwittingly begin a new use after the cutoff date designated by a proposed SNUR without knowing that the chemical substance at issue is the subject of the proposed SNUR unless the supplier (or a downstream formulator/distributor) voluntarily advises its customers of the presence of the substance in a confidential formulation.<sup>9</sup> This is exacerbated when EPA proposes a SNUR for a substance that is not yet listed on the Inventory, and the manner in which the substance is eventually listed on the Inventory is only by an accession number or by another tool intended to mask specific chemical identity.

These difficulties are especially pronounced when the SNUR proposes to require reporting on the manufacture or processing of an article in which the chemical substance at issue is present. The presence of a particular chemical in an article which is a product already in commerce may not be readily disclosed by the manufacturer or processor, nor discernable by a distributor or end user. As a Coalition of chemical substance processors and users, CUC encourages EPA before issuing final SNURs in the case of the 13 substances identified in the immediate example, and before proposing additional SNURS for other PMN substances considered to be eligible for “not likely to present” determinations, to carefully consider the burdens and compliance risks imposed on such downstream processors and users as a result of EPA’s issuance of a SNUR—especially when the specific chemical identities and intended uses have been claimed as confidential by the PMN submitter (such as several SNURs among those recently proposed).<sup>10</sup>

For these reasons, CUC requests that EPA consider how it can implement a notification requirement that will address the gap between when a proposed SNUR is issued, and when manufacturer notification requirements under 40 CFR § 721.5 come into effect with the publication of the final SNUR. To that end, CUC recommends: (a) EPA issue such follow-up SNURs expeditiously, and (b) resume its practice of issuing a written communication to the PMN submitter (previously, “drop, follow-up letter”) prior to the end of the review period which specifically advises the PMN submitter of any concerns EPA might have related to the PMN substance and of the Agency’s intent to issue a SNUR to require reporting of any new conditions of use that could increase exposures to the PMN substance before they may be undertaken. Such correspondence also should request the PMN submitter provide a copy of the letter to any of the PMN submitter’s customers (e.g., processors and users) who receive the PMN substance to ensure the Agency’s concerns are communicated and to enhance awareness in the processor and user communities that a SNUR will be issued.

Issuance of a SNUR imposes burdens beyond the reporting obligations of the SNUR. For example, following the issuance of a SNUR for a chemical substance, the Chemical Data Reporting (“CDR”) rule reporting threshold for that substance is reduced from 25,000 lb. to

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<sup>9</sup> When a SNUR is issued pursuant to a TSCA Section 5(e) order, the TSCA Section 5(e) Order ordinarily will contain requirements that the manufacturer of the chemical substance at issue only distribute the chemical substance to persons who agree to comply with the provisions of the consent order (*i.e.* to not engage in new uses of the chemical substance). This concern is therefore unique to SNURs for chemical substances for which a TSCA Section 5(e) order was not issued.

<sup>10</sup> See for example the proposed SNURs for substances identified in PMNs P-16-483 and 484 in the October 16, 2018 proposal in which the specific chemical identities and the specific conditions of use addressed in the PMN are claimed to be confidential and are not disclosed to third parties other than through the *bona fide* inquiry process. 83 Fed Reg. at 52,182.

2,500 lb.<sup>11</sup> Export notification obligations also arise. EPA issuance of a SNUR for a chemical substance that has been found not likely to present an unreasonable risk could impose CDR requirements and export notification responsibilities on entities that manufacture or use the chemical substance *even when* their use does not require the submission of a SNUN. Thus, when weighing the issuance of a SNUR for a chemical substance that has otherwise been found not likely to present an unreasonable risk, EPA should consider not only the regulatory obligations imposed directly by the SNUR, but also other regulatory obligations that are triggered by the issuance of a SNUR under TSCA and its implementing regulations.

### **EPA's TSCA Section 8(a) Authority**

The proposed SNURs contain several paragraphs outlining information that EPA has identified as being “potentially useful” in “characteriz[ing] the potential health and/or environmental effects” of the chemical substances covered by the SNURs.<sup>12</sup> CUC notes that, to the extent that EPA is simply interested in seeking information about alternative uses of a chemical substance, TSCA Section 8(a) may be a more appropriate tool for the collection of this information.<sup>13</sup> By utilizing TSCA Section 8(a), CUC believes that EPA could collect the same information about ongoing uses as it is requesting in the SNURs without creating an unnecessary obstacle to market entry for new uses that do not present an unreasonable risk.

### **Conclusion**

CUC appreciates the Agency's interest in soliciting public input on the recently proposed SNURs and would be pleased to meet with EPA personnel to discuss these comments and related issues if doing so would assist in the development of the final SNURs.

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<sup>11</sup> 40 C.F.R. § 711.8(b).

<sup>12</sup> 83 Fed. Reg. 52,181.

<sup>13</sup> 15 U.S.C. § 2607(a)(2).