

**Before the United States
Environmental Protection Agency
Problem Formulations for the First Ten Chemicals for Risk Evaluation Under TSCA
83 Fed. Reg. 26,998 (June 11, 2018); Dockets EPA-HQ-OPPT-2016-0736, et al.¹**

Comments of the Chemical Users Coalition

The Chemical Users Coalition (“CUC”) appreciates the opportunity to provide these comments regarding the U.S. Environmental Protection Agency’s (“EPA”) Problem Formulations for the first ten chemical substances for Risk Evaluation under Section 6 of the Toxic Substances Control Act (“TSCA”).²

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.³ 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.

CUC supports the successful implementation of the 2016 amendments to TSCA in a manner that assures the various TSCA programs are both effective and efficient. Our members appreciate the Agency’s efforts to solicit input on the initial Scoping Documents for the first ten substances to undergo Risk Evaluation pursuant to the amended statute and to later expand and refine the Scoping Documents in the form of the Problem Formulations. CUC’s comments regarding the Problem Formulation Statements generally support the Agency’s determination as stated in the Problem Formulations to focus EPA resources during the first ten Risk Evaluations on “evaluat[ing] the conditions of use that raise the greatest potential for risk.”⁴ CUC encourages EPA to be mindful that the Agency’s approach to the first ten risk evaluations undertaken pursuant to the amended Section 6 of TSCA will set a precedent for how the Agency

¹ The relevant docket numbers for the problem formulations are: EPA-HQ-OPPT-2016-0736 (Asbestos); EPA-HQ-OPPT-2016-0741 (1-Bromopropane); EPA-HQ-OPPT-2016-0723 (1,4 Dioxane); EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride); EPA-HQ-OPPT-2016-0735 (Cyclic Aliphatic Bromide Cluster (HBCD)); EPA-HQ-OPPT-2016-0742 (Methylene Chloride); EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone (NMP)); EPA-HQ-OPPT-2016-0725 (Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d’e’f] diisoquinoline-1,3,8,10(2H, 9H)-tetrone)); EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene); EPA-HQ-OPPT-2016-0737 (Trichloroethylene (TCE)).

² CUC is aware that individuals, various businesses, and other organizations are submitting comments on specific Problem Formulation statements. CUC defers to the expertise of those entities and groups with respect to specific chemical substances and does not intend to submit comments that are specific to a particular substance or related document.

³ 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.

⁴ See, e.g., U.S. Env’tl Protection Agency, Problem Formulation for the Risk Evaluation for Asbestos, EPA-740-R1-7018 (May 2018).

conducts future Risk Evaluations. Consequently, EPA should carefully establish the foundation for its decision to exclude a category or conditions of use from a Risk Evaluation's scope, including the first ten Risk Evaluations under TSCA Section 6.

I. EPA Correctly Determined that It Is Not Required to Evaluate All Conditions of Use

CUC supports EPA's efforts to articulate in the Problem Formulations the basis for narrowing the scopes of the first ten Risk Evaluations to cover only those uses that are "intended, known to be occurring, or reasonably foreseen."⁵ As CUC expressed in our comments to EPA's "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act," CUC believes it is important that EPA maintain flexibility in determining the appropriate scope of a Risk Evaluation.⁶ EPA has the authority under TSCA to define the "conditions of use" for a substance for the purpose of a Risk Evaluation.⁷ EPA has indicated in the Problem Formulations that, pursuant to this authority, it intends to exclude "legacy uses, associated disposals, and legacy disposals," from the scope of the first ten Risk Evaluations.⁸ EPA has also indicated that it intends to exclude from the scope of the first ten Risk Evaluations exposure pathways that are adequately addressed by other federal environmental statutes,⁹ and uses that present only *de minimis* exposure risk.¹⁰ CUC appreciates the steps that EPA has taken to focus the scope of the Risk Evaluations of the first ten chemical substances. However, CUC provides several suggestions for ensuring that EPA's approach to defining the scope for the first ten chemical substances sets a positive and credible precedent for future Risk Evaluations.

II. EPA Should Clearly Define Criteria for Excluding Uses from Risk Evaluations

CUC recommends that exclusion of certain conditions of use from consideration should be primarily a risk-based determination. CUC encourages EPA to exercise its authority to define the final scopes of the first ten Risk Evaluations by taking into consideration factors that affect not only hazard but also those reasonably foreseen conditions of use that determine the likelihood of human exposure and environmental release and consequently potential risks. Bearing in mind that EPA's inclusion or exclusion of certain conditions of use from these first ten Risk Evaluations will be viewed as setting a precedent for how EPA defines the scope of future Risk Evaluations, CUC suggests that EPA develop and articulate well-defined criteria for the exclusion of conditions of use from the scope of a Risk Evaluation which reflect reasonable and repeatable "rules of thumb" that will enable manufacturers, importers, processors and users of substances that are prioritized for Risk Evaluation to credibly predict whether their practices are likely to remain within "scope" and if so, to understand more fully the additional data which might be needed and assess information they can collect or generate and provide to the Agency

⁵ *Id.* at 8.

⁶ Chemical Users Coalition, Comments on Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (March 2017), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0654-0043&attachmentNumber=1&contentType=pdf>.

⁷ 82 Fed. Reg. 33,726, 33,728 (July 20, 2017).

⁸ *See, e.g.*, U.S. Env't'l Protection Agency, Problem Formulation for the Risk Evaluation for Asbestos, EPA-740-R1-7018 8 (May 2018).

⁹ *See, e.g.*, U.S. Env't'l Protection Agency, Problem Formulation for the Risk Evaluation for 1-Bromopropane, EPA-740-R1-7019 13 (May 2018).

¹⁰ 82 Fed. Reg. at 33,729.

to establish that those conditions of use will not present unreasonable risks. When exercising its discretion to determine whether a condition of use will be included within the scope of a Risk Evaluation, the Agency should simultaneously provide guidance for the makers and users of substances of interest and the public generally about the kinds of exposures and releases that should be scrutinized as well as those measures which are being implemented currently to appropriately mitigate risks.

The inclusion or exclusion of a condition of use from the scope of a Risk Evaluation can have a significant impact on not only the producers but also the processors and users of chemical substances like CUC's members. The development of well-defined criteria for the exclusion of specific uses from the scope of a Risk Evaluation will allow users of chemical substances, as early as the initiation of the prioritization process for that chemical substance, to ensure they are critically considering the materials they purchase and use, and the conditions of use at their facilities, to ensure all potential risks are being identified, addressed and mitigated. CUC therefore encourages EPA to offer additional guidance on its approach for pre-prioritization, and for scoping future Risk Evaluations after public comments on the current round of Problem Formulation Statements is completed and prior to the end of the first five-year review period for EPA's "Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act."¹¹

When excluding from consideration certain uses on the basis of resource constraints, or policy or legal reasons, EPA should be clear and consistent in its approach. CUC considers it to be within the Agency's discretion to exclude from consideration uses that are better evaluated and addressed under other authorities administered by EPA, or other federal agencies. Section 9 of TSCA provides this authority and Congress did nothing in the course of enacting the 2016 amendments to discourage consideration and use of that provision. When making scope-limiting determinations, CUC encourages EPA to do so with consistency and to provide clarity in articulating such decisions. Moreover, CUC encourages EPA to state the effect of such determinations on the potential "risk equation," particularly such a decision's potential to affect susceptible subpopulations. Thus, for example, as part of a decision by EPA to exclude from the scope of a Risk Evaluation consideration of disposal practices for substances that have been phased out (and manufactured products that have been discontinued), the Agency also should address why this determination is reasonable and appropriate as a matter of environmental policy. This can be accomplished for example, by explaining in future Scope (and/or Problem Formulation) documents whether and how disposal practices already are adequately being addressed under other authorities and why it is appropriate to conclude current practices are not presenting unreasonable risks (including to susceptible subpopulations). It is important that the Agency instill confidence in the general public and the regulated community, as well as state and local governments, that EPA is making Risk Evaluation scoping decisions rationally, with an awareness of TSCA's capacity to function as a "gap-filling" statute, as well as with deference to EPA's responsibilities under Section 9 of the Act.

¹¹ *Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under TSCA*, U.S. Env't'l Protection Agency, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/guidance-assist-interested-persons-developing-and> (last updated June 22, 2017); 82 Fed. Reg. at 33,731.

III. EPA Should Clarify the Status of Excluded Uses

When establishing the final scope for a Risk Evaluation, EPA should provide clarification on the status of uses excluded from the scope of such an evaluation. The exclusion of a condition of use from the scope of a Risk Evaluation signals that exposures resulting from a particular use either do not present an unreasonable risk, or that any risk that may be posed by that condition of use already is being adequately mitigated under another federal environmental statute. It should be clear and reasonable on the basis of EPA's final Scoping Document (or Problem Formulation Statement) that an entity engaged in a use that EPA has excluded from the final scope of the Risk Evaluation for that chemical substance can reasonably expect the Agency will not be likely to impose new restrictions on that use under TSCA.¹² CUC suggests that, if EPA excludes a use of a chemical substance from the scope of a Risk Evaluation, the excluded use should be given a designation of "low-priority," as described in EPA's "Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act."¹³ CUC further suggests that, if EPA determines that it wishes to revise the designation of a low-priority use of a chemical substance, the Agency should do so by restarting the prioritization process for that use of the chemical substance.¹⁴ This will allow users of chemical substances like CUC's members to adjust for the potential prohibition or restriction on the use of the chemical substance, or provide information to EPA which could lead to a different conclusion.

IV. Other Areas of Interest to CUC Members

The Problem Formulation Statements clarify that several of the first ten Risk Evaluations will examine the potential risks presented by a chemical substance when it is incorporated into an article.¹⁵ In situations where EPA has determined that it is appropriate to evaluate risks posed by exposure to an article containing a chemical substance, CUC reminds the Agency that the evaluation must consider the requirements of the amendments to TSCA Section 6. Specifically, Section 6(c)(2)(E) provides that EPA shall only issue a TSCA Section 6 rule to restrict or prohibit the manufacture, processing, distribution, use, or disposal of an article or a category of articles to the extent that such restriction is "necessary to address the identified risks from exposure" to the article or category of articles.¹⁶ EPA should also consider carefully whether there may be differences in the chemical content of specific articles, or the manner in which particular articles might be used or disposed, that can affect the likelihood of exposures to, or

¹² Cf. Chemical Users Coalition, Comments on Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act 4 (March 2017), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0654-0043&attachmentNumber=1&contentType=pdf> (noting that the inclusion of a use within the scope of a Risk Evaluation would suggest to the public that EPA was concerned about the risks posed by that risk).

¹³ 82 Fed. Reg. 33,753 (July 20, 2017).

¹⁴ See *Prioritizing Existing Chemicals for Risk Evaluations*, U.S. Env'tl Protection Agency, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation> (last updated Jan. 9, 2018).

¹⁵ Pursuant to TSCA Premanufacture Notification regulations, an article is defined as "[A] manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 720.36(g)(5), except that fluids and particles are not considered articles regardless of shape or design." 40 C.F.R. § 730.30.

¹⁶ 15 U.S.C. § 2605(c)(2)(E).

releases of, the substance of concern within the article such that a restriction on the chemical content or manner of use of an article might be more appropriate than a complete prohibition on the manufacture, processing, distribution, use or disposal of the chemical substance itself.

CUC supports EPA's efforts to enhance and expand the Scoping Documents by issuing the Problem Formulation Statements for the first ten chemical substances. The Problem Formulation Statements contain much of the information that CUC would expect to be included in Scoping Documents for future Risk Evaluations. CUC encourages EPA to adopt a format similar to that of the Problem Formulation Statements for Scoping Documents for future Risk Evaluations. CUC also encourages EPA to ensure that it adopts a consistent format for such documents when generated for future Risk Evaluations, much as has been done with the Problem Formulation Statements. Additionally, CUC recommends that, in Scoping Documents for future Risk Evaluations, EPA present more clearly the uses that the Agency has determined will be included in the scope of the Risk Evaluation, and those uses that are excluded from the scope of the Risk Evaluation, and specify with greater clarity the reasons why the Agency has determined which uses are or are not being included in the scope of the Risk Evaluation. Greater clarity might be achieved by more carefully employing and distinguishing the terms "use" and "conditions of use" in the Problem Formulation Statements (and future Scoping Documents). This is especially important when identifying a particular *exposure* pathway that presents a concern for a substance (e.g., releases to water) when compared to those pathways which are not of concern. EPA should articulate clearly which condition of use is of interest to EPA when the condition might occur only under a particular use scenario. For example, a Problem Formulation Statement (or Scoping Document) might distinguish concerns for releases to water of substance X that occur during use of substance X as a solvent when the facility has no systems in place for containment or pretreatment of the substance prior to release from those use scenarios where substance X is used as a solvent but the facility captures, contains and reuses substance X, rather than releasing it to water. This is of critical importance in those passages in Problem Formulation Statements (and Scoping Documents) in which the Agency is explaining that it intends to exclude a particular use or condition of use from further review.

Finally, CUC recommends that EPA discuss potential alternatives in future Scoping Documents. The Scoping Document for a Risk Evaluation provides an excellent opportunity for EPA to formally seek input from stakeholders on the various chemical substances that might be considered to be potential alternatives for a chemical substance that is undergoing review, and whether alternatives are available (and suitable) for particular uses of a chemical substance.¹⁷ Stakeholders are likely to have information about the availability and technical feasibility of such alternatives that will be helpful to EPA as the Agency is developing the scope of a Risk Evaluation for a chemical substance. Providing information to stakeholders on the specific chemical alternatives that EPA is likely to consider for a chemical substance at the Scoping Document stage will provide stakeholders with additional time to consider, critically evaluate, and provide information to EPA on available alternatives for a particular chemical substance under a specific condition of use. Doing so in this manner will better enable and support EPA's ability to fulfill its obligations under the amendments to Section 6 of TSCA to carefully consider

¹⁷ The alternatives should be identified using specific CAS Registry numbers and CAS – preferred names for the sake of clarity and ease of reference.

the availability of technically feasible alternatives *before* adopting a particular approach to risk management in the rulemaking context.

Conclusion

CUC appreciates the Agency's interest in soliciting public input on the Problem Formulations and the additional time to do, and would be pleased to meet with EPA personnel to discuss these comments and related issues if doing so would assist the Agency in finalizing the scope of the Risk Evaluations for the first ten chemical substances.