

**Before the United States
Environmental Protection Agency
Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act
90 Fed. Reg. 45690 (Sept. 23, 2025); Docket EPA-HQ-OPPT-2025-0260**

Comments of the Chemical Users Coalition

The Chemical Users Coalition (“CUC”)¹ appreciates the opportunity to provide these comments regarding the U.S. Environmental Protection Agency’s (“EPA’s” and “the Agency’s”) Proposed Rule for Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (“TSCA”) (the “Proposed Amendments”).

CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances. To thrive in a competitive, global economy our members depend on (1) the availability of certain existing substances for which there are not technically feasible substitutes; and (2) a reliable pipeline for innovative new chemistries. Consequently, our members encourage EPA to develop regulatory approaches that encourage innovation and permit sustainability. Thus, CUC supports measures that protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with economic development in the United States. This is critical in the area of chemical regulatory policy, which necessarily addresses emerging information about health and environmental risk.

CUC supported passage of the 2016 amendments to TSCA and has been actively engaged with EPA on issues pertaining to the approaches taken to risk evaluation. This is particularly true for the approach that was initially adopted as policy by EPA in 2021 and then formalized in the rules for Procedures for Chemical Risk Evaluation in 2024. CUC submitted comments on both the original proposal in 2017 (the “2017 Rule”) and the revisions proposed in 2023 (the “2024 Rule”). Additionally, CUC commented on procedural issues in the context of evaluation of specific substances, such as methylene chloride. CUC members have experienced firsthand the impact of the adoption of the 2024 Rule and appreciate that EPA has revisited and carefully reviewed the risk evaluation procedures rule.

Summary of CUC’s Comments

CUC believes that the approach to risk evaluations EPA proposes to take under the Proposed Amendments will enable EPA to provide a more accurate picture of the risks presented by a chemical substance under the substance’s actual conditions of use. For this and for other reasons detailed below, CUC is in favor of the Proposal. Our members support EPA’s proposal to make

¹ The members of CUC are Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, National Electrical Manufacturers Association, RTX Corporation, Sony Electronics Inc., and TDK U.S.A. Corporation.

condition-of-use-specific risk determinations in EPA’s risk evaluations and to rely on reasonable assumptions regarding the use of Personal Protective Equipment (PPE) when making risk determinations. This approach is grounded in the statute and supported by sound science. CUC also recommends that EPA include provisions in the final amendments related to the importance of conducting peer reviews of EPA risk evaluations, the scientific standards the Agency must meet when conducting risk evaluations, as well as certain definitions associated with such scientific standards.

Although not specifically addressed in this proposal, CUC recommends EPA consider formalizing in the Rule the circumstances under which EPA will address the presence of the chemical being evaluated in manufactured products (articles) as a condition of use. Additionally, EPA should also consider undertaking a procedural rule that will articulate a process for submitting requests to EPA for exemptions from Section 6 rules pursuant to Section 6(g) of the statute and explain the Agency’s criteria for considering and reaching determinations on such exemptions.

EPA Discretion in Scoping and Determinations Made on a Condition of Use Basis Are Supported by Law and Good Policy

In the Proposed Rule, EPA is proposing to remove the provisions in the 2024 Rule that require EPA, when conducting a risk evaluation , to consider each and every condition of use and each and every exposure route and pathway based on reasonably available information. Additionally, EPA is proposing to return to the risk determination approach incorporated in the 2017 Rule, which provided that EPA could make risk determinations for a substance either in a single decision document or in multiple decision documents for different conditions of use. CUC supports these changes and encourages them to be promulgated without delay.

These approaches were indeed an integral part of the structure Congress created in the 2016 TSCA amendments for prioritizing, evaluating, and managing the risks of existing chemical substances. They support EPA’s objective of conducting risk evaluations that address (to the extent possible) actual conditions of use – the uses and risks to which humans and/or the environment are exposed. CUC believes that the plain reading of TSCA supports these approaches.

TSCA states:

(4) Risk evaluation process and deadlines

(A) In general

The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

....

D) Scope

The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider . . .

15 U.S.C. § 2605(b)(4)(A), (D) (emphasis added).

Thus, the statute clearly provides that, as its first step in the risk evaluation process, EPA must publish a scope document enumerating the conditions of use EPA expects to consider in the risk evaluation. CUC considers the scope to be the opportunity for the EPA to establish which conditions of use require evaluation, and to seek public comment on the scope determination. It is not simply a ministerial act of compiling all known uses, routes of exposure, and potential hazards. In granting this authority to EPA, Congress clearly intended for the Agency to be able to exercise discretion to select which conditions of use would be the focus of the risk evaluation. If Congress had meant EPA to include **all** conditions of use in the risk evaluation's scope (which is the approach adopted in the 2024 Rules), the statute could have explicitly stated that EPA must evaluate all conditions of use and all exposure pathways. What TSCA does say is that the scope must contain those elements that EPA "expects to consider," meaning EPA must exercise discretion when formulating the scope. Furthermore, if all uses and exposures must be evaluated for all substances, formal issuance of a scope is not needed. CUC believes that this understanding of TSCA clearly supports EPA's approach in the Proposed Amendments.

As mentioned above, the Proposed Rule would make clear that EPA can make determinations on a condition-of-use-by-condition-of-use basis. CUC considers this approach to be supported by TSCA and to more accurately reflect that potential risks can be most accurately assessed on a specific condition of use basis. TSCA specifically provides that EPA is to make determinations as to whether a substance presents an unreasonable risk under the conditions of use. The statute presumes that EPA can make findings that a substance **either does or does not** present an unreasonable risk under its actual conditions of use. However, such determinations will never occur – and they did not occur – when the "whole chemical approach" adopted in the 2024 Rule is utilized.

By definition, risk evaluations are only performed on "high priority" substances. These are substances that have been determined by EPA, after undergoing a screening exercise, to potentially (i.e., "may") present an unreasonable risk. It is therefore inevitable that some conditions of use of a high priority substance will be determined to present an unreasonable risk. Under the "whole chemical" approach adopted by the 2024 Rules, EPA is compelled to find that the substance, as a whole, presents an unreasonable risk. Consequently, EPA will never reach the conclusion that a substance does not pose an unreasonable risk. The provisions in TSCA about how such determinations are finalized, via an order, were rendered meaningless. Only if EPA is able to make determinations on a condition-of-use-by-condition-of-use basis, as EPA proposes, can EPA make a determination that a substance, under a particular condition of use, does not present an

unreasonable risk. Again, CUC believes that this interpretation of TSCA supports EPA's approach in the Proposed Amendments.

CUC believes that policy considerations support this approach as well. A single "unreasonable risk" determination for a chemical substance could be interpreted (mistakenly) by the public, workers and the marketplace as a declaration that EPA has found the substance to present such risks **under any and all circumstances**, regardless of exposure, use of protective equipment, other existing workplace controls or conditions of use. The marketplace could react to these "whole chemical" determinations, and instead of waiting for EPA's risk management rule, the marketplace would begin the process of "product deselection" of a chemical as soon as EPA makes a whole chemical determination of unreasonable risk for a chemical.

This could occur even if there are uses – including many environmentally beneficial uses – that EPA has determined present no unreasonable risk. The provisions in the 2024 Rule, predicated on a single "unreasonable risk" determination for a chemical substance, place U.S. industry at a clear disadvantage. Market expectations based on flawed science and/or over-characterization of potential real-world hazards and risk can lead to loss of domestic manufacturing and production as well as supply chain obsolescence, putting at risk our technological advantages and benefits to the U.S. and global economies. CUC believes the Proposed Amendments' approach allows for a more precise and accurate representation of the risks, if any, associated with specific conditions of use, and therefore a better understanding by all stakeholders of such. CUC therefore supports these proposed changes.

CUC Supports EPA Discretion in Scoping for both Conditions of Use and Exposure Pathways

CUC agrees with EPA's proposal to remove provisions in the 2024 Rule that require EPA to consider each and every condition of use and exposure route and pathway. It has become evident that the risk evaluation process is more protracted and resource intensive than envisioned by Congress. When Congress established statutory deadlines in the 2016 amendments to TSCA, it implicitly recognized that risk evaluations had to be conducted by EPA in a fashion that was as thorough as needed to address actual risks but within the allotted time. To ensure this could be accomplished, Congress granted EPA some discretion as to the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations to be considered in the risk evaluation. This approach, which allows EPA to select conditions of use and exposure pathways to include in the "scope," permits EPA to meet its statutory obligations by focusing risk evaluations on the areas of greatest concern without conducting evaluations on uses that are speculative in nature, or do not present risks likely to be of concern, or are redundant of evaluations conducted by other EPA program offices.

The preamble to the Proposal clarifies that EPA will consider excluding from a risk evaluation's scope, certain *de minimis* uses and those uses with minimal exposure potential. These are just two examples of how the amended procedures will enable EPA to very appropriately and responsibly choose to better focus its future risk evaluations. CUC agrees that it is consistent with the statute and with good public policy to focus risk evaluations on the conditions of use likely to present the

greatest risks. CUC suggests that, in addition to the cited examples, EPA consider polymers and the presence of substances in manufactured (including imported) articles as additional categories of uses that, absent specific findings otherwise, could be presumed to be “minimal risk” and thus considered for exclusion from the scope of a risk evaluation.

However, CUC believes that EPA need not necessarily exclude exposure pathways that are addressed by other federal statutes and regulations in their entirety. EPA could take the approach of including such pathways in the scope of the evaluation while incorporating in EPA’s review the risk mitigation measures already being implemented due to existing regulations. This would help to more accurately represent the true conditions of use for a substance, and to ensure the risk evaluation more accurately reflects exposures and risks.

While CUC supports the provisions that allow EPA to exercise discretion when setting the scope of the risk evaluation, CUC recommends that EPA provide explanations in its proposed scoping document as to why certain conditions of use and exposure pathways were included or excluded. In that way, stakeholders can understand the rationale for the proposed scope and can provide EPA with feedback on the selected and excluded conditions of use.

CUC Supports Consideration of Use of PPE and Other Occupational Controls

EPA is proposing that consideration of occupational exposure scenarios will take into account reasonably available information on the implementation and use of occupational exposure control measures, such as engineering and administrative controls and personal protective equipment. This is in contrast to the approach adopted in the 2024 Rule, whereby EPA does not consider, as part of the overall unreasonable risk determination, that exposure reduction will necessarily occur based on assumed use of PPE by workers. CUC members strongly encourage EPA to adopt the approach in the Proposed Amendments, by focusing its risk evaluation on how the given substance is actually used. Doing so will allow EPA’s exposure assessment to more accurately reflect the real world (especially workplace) exposures and to appropriately permit EPA to issue a more accurate overall risk evaluation.

CUC endorses this approach because it is consistent with the terms of the amended statute. Specifically, TSCA’s Section 6(b)(4) contains risk evaluation requirements relating to “conditions of use.” Section 6(b)(4)(A) requires that EPA conduct risk evaluations “to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment ... under the conditions of use.” TSCA Section 3(4) defines “conditions of use” as “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” Compliance with Occupational Safety and Health Administration (OSHA) mandatory requirements and other generally accepted industry practices (including certain consensus standards adopted by industrial hygiene (IH) professionals) are indeed known circumstances under which a chemical is manufactured.

The structure of the definition of “conditions of use” makes clear that “circumstances” includes more than the fact that a substance is manufactured, imported, processed, etc. Therefore, “circumstances” logically includes aspects of the context in which a chemical substance is

manufactured, imported, processed, etc., including whether workers wear PPE. Use of PPE is a circumstance that “is intended, known, or reasonably foreseen.” PPE use therefore belongs as a component of the conditions of use that the TSCA Section 6 risk evaluations must consider.

When PPE is specifically required by OSHA, it is an integral part of the condition of use of manufacturing and processing. PPE is required and utilized as an additional layer of protection. As TSCA requires that risk determinations be made based upon reasonably available information about a chemical’s “conditions of use,” CUC supports EPA’s proposal to consider PPE and other applicable OSHA standards and practices as part of the conditions of use in TSCA risk evaluations, including in the risk determinations of those conditions of use. Should EPA identify situations where there are gaps in PPE use, potential risks posed by those scenarios can be addressed, if needed, in risk management rules. CUC considers this approach to be consistent with the Section 6 requirements and Section 26 amended scientific standards which require the Agency to consider all information available, to use a weight of the evidence approach, and to ensure its risk evaluations reflect the best available science.

Other Comments

- **Peer Review** - CUC believes that a scientifically valid and predictable peer review process is essential and required. Anything short of regular, predictable and transparent peer review on the entirety of every risk evaluation fails to meet the legal standard of best available science. CUC therefore believes that the 2017 language describing peer review provisions should be restored. CUC suggests that a provision can be added in the final amendments that would allow EPA to develop new and updated peer review guidance once public notification of future reliance on such documents has been given. CUC also suggests that EPA include provisions in the final amendments that require EPA to explain how suggestions or comments that came from the peer review panel were addressed in the Agency’s risk determination.
- **Opportunity to Comment** - Section 702.43(c) states that at least a 60-day public comment period should be provided once the draft risk evaluation is published. CUC recommends that, to encourage thoughtful and substantive feedback on the findings of a draft evaluation, more time would be needed for interested and affected parties to gather data and information to provide such feedback. CUC suggests that the final rule provides for at least a 90-day public comment period, which would be preferable and should be the standard.
- **Cumulative Assessment** - TSCA does not explicitly require cumulative risk or combined exposure assessments. While TSCA authorizes EPA’s use of these evaluative methods, TSCA does not mandate use of these approaches. CUC members do not think EPA should be required to explain if it opts not to utilize these approaches in every risk evaluation, although there may be benefits to doing so in specific instances in the interest of transparency.
- **Best Available Science and Weight of the Scientific Evidence** – CUC supports restoration of the 2017 Rule’s definition for “best available science.” CUC also supports EPA’s proposed definition of “weight of the scientific evidence.” Including definitions of

critical terms helps to promote clear understanding of EPA's implementation of the statutory provisions, and promotes transparency, accountability and predictability.

- **Potentially Exposed or Susceptible Subpopulation** - CUC supports EPA in conforming the definition of "potentially exposed or susceptible subpopulation" to that which appears in TSCA. Adding categories only serves to invite confusion and lack of clarity as to how EPA interprets the term.
- **Existing Chemical Exposure Limits (ECELs)** – CUC believes that there can be utility in including ECELs in a risk evaluation. However, when doing so, the technical basis for an ECEL that is under consideration should be explained clearly in the draft risk evaluation so public comment can be invited. Moreover, when an ECEL is being considered, CUC recommends the Agency consider carefully whether already adopted consensus standards exist, the sectors in which they are being implemented, and whether substantial exposure reduction benefits could be practically achieved by adopting a comparatively lower EPA developed ECEL than that of regulatory imposed limits.²
- **TSCA 6(g)** – When EPA establishes the scope for a risk evaluation, certain sectors for which use of the substance is critical, such as in defense applications, may be identified. Being that these critical sectors are often identified early within the risk evaluation process, EPA should consider undertaking a procedural rulemaking now that will articulate a consistent process for affected entities to be able to submit to EPA requests for exemptions from Section 6 rules pursuant to Section 6(g) of the statute, and explain the Agency's criteria for considering and reaching determinations on such exemptions. If such procedures are known from the outset, those entities with critical uses can be better prepared to engage throughout the risk evaluation process and it can create efficiencies for EPA in the long run.

Conclusion

CUC supports EPA's efforts to appropriately evaluate risks presented by high priority substances. CUC appreciates that EPA is adopting an approach that ensures that the risk evaluation procedures accurately reflect the legal requirements set forth in TSCA for risk evaluation. The Agency must evaluate real-world conditions of use. The risks, if any, of such real-world uses must be properly characterized. Any risk management rule that is then proposed to address such risks must be based on data and information and the best available science, not conjecture or assumptions. The Proposed Amendments realign EPA's practice with TSCA's mandates and goals, and CUC supports this approach.

² Recognizing that this issue is more specific to the risk management rule development phase, CUC members reiterate their strong recommendation that, when EPA is developing ECELs, and implicitly considering the need for a Workplace Chemical Protection Program for a substance being evaluated, EPA consult with IH professionals and OSHA personnel on the use of regulatory terms to ensure certain concepts and terms are harmonized across regulatory agencies (especially when referring to workplace exposure requirements and controls). Prior TSCA Section 6 regulations have created complexity for multi-employer work sites by EPA's use of terms such as "owner/operator", rather than the term "employer" (as is used by OSHA). Additionally, EPA must ensure that ECELs are practical and attainable.

CUC members would be pleased to meet with EPA personnel to discuss these comments and related issues as the Agency continues its efforts to identify and address risks associated with the use of high priority substances.