Before the United States
Environmental Protection Agency
Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act
88 Fed. Reg. 74292 (Oct. 30, 2023); Docket EPA-HQ-OPPT-2023-0496

Comments of the Chemical Users Coalition

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 Rule").

CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances. Our members depend on the availability of certain existing substances for which there are not technically feasible substitutes as well as a reliable pipeline for innovative new chemistries to be able to thrive in a competitive, global economy. 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, but CUC is very concerned that the approach to risk evaluations EPA proposes to take under the Proposed Rule fails to provide an accurate picture of the risks presented by a chemical substance under the substance's actual conditions of use. CUC urges EPA to continue to make condition-of-use-specific risk determinations and to include reasonable assumptions regarding the use of PPE when making risk determinations. Such an approach is grounded in the statute and supported by sound science. CUC also recommends EPA retain portions of the current regulation, especially those terms related to the importance of conducting peer reviews of EPA risk evaluations, and the portion of the current rules which codify the important features of Section 26 of TSCA concerning the scientific standards the Agency should satisfy when conducting risk evaluations, as well as certain definitions associated with such scientific standards.

Although beyond the scope of the procedural rules for conducting risk evaluation, CUC recommends EPA consider undertaking a procedural rule that will clarify the Agency's procedures for considering and proposing risk mitigation measures for substances having completed risk evaluation. The considerable differences, inconsistencies, and unpredictability of the terms of

[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.

recently-proposed TSAC Section 6 risk mitigation rules demonstrate the need for such a procedural rule. Such a procedural rule could, among other things: (i) articulate a process for submitting 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. Finally, a procedural rule also could describe the methods EPA intends to use to evaluate the various statutory considerations the Agency must examine under Section 6(c) when proposing Section 6 rules, such as: (i) implementation deadlines, (ii) the availability of technically feasible alternatives for substances proposed for prohibitions, as well (iii) the unique considerations for addressing substances present in manufactured articles.

Scoping and the Whole Chemical Approach

In the Proposed Rule, EPA states that it now believes that TSCA's statutory text does not give EPA discretionary scoping authority (i.e., the ability to determine and provide public notice of what will be within the "scope" of the Agency's risk evaluation). Accordingly, applying EPA's new interpretation, all risk evaluations will need to be conducted on all "conditions of use" – the circumstances under which the chemical is known, intended, and reasonably foreseen to be manufactured, processed, distributed in commerce, used, and disposed. Furthermore, EPA now believes that TSCA requires a single unreasonable risk determination on the chemical substance in every instance, as opposed to determinations on a condition-of-use-by-condition-of-use-basis.

Both the position that a risk evaluation's scope needs to include all conditions of use and the non-discretionary use of the whole chemical approach are at odds with the structure Congress created in the 2016 TSCA amendments for prioritizing, evaluating, and managing the risks of existing chemical substances. Furthermore, mandating the use of these approaches actually runs counter to 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.

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).

The statute provides that EPA must publish a scope document, containing the conditions of use EPA expects to consider in the risk evaluation. The scope is the opportunity for the EPA to establish what requires evaluation, and to seek public comment on the scope determination. It is not simply a ministerial act of compiling use, exposure, and hazard data points. In granting this authority to EPA, Congress clearly intended for EPA to exercise discretion to select what was to be the focus of the risk evaluation process. If Congress had meant that EPA was to include all conditions of use, it could have made clear in the statute that EPA must evaluate all conditions of use and all exposure pathways. Rather, the statute states clearly that the scope must contain those elements that EPA "expects to consider," meaning EPA exercises its discretion. Furthermore, for all interested parties to know what EPA will be reviewing, EPA must publish a scope. If all uses must be evaluated for all substances, there was no need for the opportunity for public input to have been provided by Congress.

If the scope truly was intended to include all conditions of use in all risk evaluations, it would render TSCA preemption provision, which limits "pause preemption" to only those conditions of use in the scope, meaningless. There would be no limited preemptive effect of the Agency's action, as EPA would be considering all conditions of use. Congress's explicit statement that the preemptive effect only extends to "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope," provides clear textual evidence that there may be conditions of use not included in the scope of a risk evaluation.

As discussed above, EPA is also taking the position in the Risk Evaluation Rule Amendments that use of the "whole chemical" approach it has only recently adopted is mandatory and not discretionary. This interpretation would also render provisions in TSCA essentially meaningless. TSCA 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 under the conditions of use does not present an unreasonable risk. However, such determinations will never occur if the whole chemical approach is always 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. EPA would, under the whole chemical approach, be compelled to find that the substance, as a whole, presents an unreasonable risk. Consequently, EPA will never reach a conclusion that a substance does not pose an unreasonable risk, and therefore the provisions in TSCA about how such determinations are finalized, via an order, are rendered meaningless. Only if EPA is able to make determinations on a condition-of-use-by-condition-of-use basis could EPA make determinations that a substance, under a particular condition of use, does not present an unreasonable risk.

A single "unreasonable risk" determination for a chemical substance could be interpreted (mistakenly) by the public and the marketplace as a declaration that EPA has found the substance to present such risks under any and all circumstances, regardless of exposure, and use of protective equipment and other existing workplace controls and conditions of use. Expectations could be raised by EPA's actions that the substance will (and should) be banned from commerce. If EPA makes a whole chemical risk determination, but EPA's risk management rules provide "nuanced" risk management controls for such "whole chemicals," the public could be confused. The marketplace could react similarly to these whole chemical determinations. 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. When the European Union's REACH program's hazard-based framework labeled chemicals as "substances of very high concern" (SVHCs), European manufacturers noted that the European marketplace began de-selection of products containing these substances well before the EU regulated them. This could occur with whole chemical determinations of unreasonable risk, even if there are uses – including many environmentally beneficial uses – that EPA has determined present no unreasonable risk. EPA's current approach to risk evaluation and risk management, predicated on a single "unreasonable risk" determination for a chemical substance, places US industry at a clear disadvantage. Market expectations based on flawed science and/or over characterization of the real-world hazards and risk can lead to loss of domestic manufacturing and production as well as supply chain obsolescence, putting at risk our technology advantages and benefits to the US and global economies. No misguided interpretation(s) of the TSCA and/or implementation of flawed science should result in loss of market share to US businesses.

CUC is particularly concerned that EPA's implementation of these changes may have unwarranted impacts on the import of manufactured articles containing a chemical substance for which EPA conducts a risk evaluation. In many instances, the presence of a substance in an article does not present a risk. However, by taking a whole chemical approach, EPA likely creates a public perception that these conditions of use do present an unreasonable risk. This approach now unfairly implies, without any basis in the record, that articles containing a substance could present unreasonable risks. The whole chemical approach is certain to increase the likelihood that EPA will regulate the use of substances in articles despite that use not being deemed to present an unreasonable risk. EPA has stated that Section 6(a) permits EPA to regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities driving unreasonable risk (e.g., use) even if the upstream activities are not unreasonable risk drivers. To CUC, this raises the question of whether import or distribution of articles might be unfairly regulated to address downstream conditions of use, such as the continued use, recycling, or disposal of such articles. This is particularly concerning given Congress' explicit efforts in the 2016 amendments to ensure (by providing specific clauses in Section 5 and 6 of the amended Act) that EPA make the effort and apply sound science to assessing whether a risk is presented by a specific substance in particular articles. *See* Section 6(c)(2)(E) and Section 5(a)(5).

While CUC understands that EPA intends to include chemicals present in articles as a condition of use within the scope of risk evaluations, CUC would like to emphasize that risk is a function of both hazard and exposure. A substance's risk profile will differ significantly between a chemical

substance to which exposure occurs in its neat form or when the substance has been blended in a mixture versus when the same substance has been incorporated into a finished article. The whole chemical approach and EPA's reluctance to consider specific conditions of use separately, suggest the Agency is unwilling to conduct a risk evaluation that will critically evaluate and accurately reflect the likelihood of exposures that could result in harm from the substance's mere presence in articles. When it is clear such circumstances do not present an unreasonable risk, the Agency should exercise its discretion and exclude those uses from further risk evaluation. The whole chemical approach fundamentally wastes EPA resources and time unnecessarily, while creating confusion about what conditions of use will actually present unreasonable risks.

Exposure Pathways

EPA states in the Proposed Rule that although Section 9 of TSCA requires EPA to "coordinate actions" with other agencies, it cannot be read to displace the specific requirements under TSCA Section 6 to conduct a risk evaluation. Therefore, the existence of authority to assess or regulate a chemical, exposure pathway, or use under a statute other than TSCA does not equate to effective risk management of that chemical, exposure pathway, or use. EPA's position is that an assumption that risk will – or could be – managed in the future cannot be used to satisfy EPA's statutory obligations to evaluate existing chemical substances under TSCA and manage identified risks.

Accordingly, EPA is proposing to explicitly require that each risk evaluation assess all exposure routes and pathways relevant to the chemical substance under the conditions of use, including those that are regulated under other Federal statutes.

Should EPA finalize this approach, EPA must ensure that its actions are necessary and not duplicative. EPA has stated that the regulation of exposure pathways under a law other than TSCA does not necessarily equate to effective risk management under such authorities. If this is a "whole of government" conclusion, the EPA should take steps to coordinate work among different program offices or agencies to develop a harmonized approach to chemical risk mitigation. Doing so would save federal resources and duplicative efforts and help to ensure that there is shared risk management perspective across the board. Doing so also could avoid the creation of an inefficient patchwork of regulatory requirements.

Assumption of Use of Personal Protective Equipment (PPE)

EPA states that it intends to assess and include in the risk evaluation the use of PPE, any engineering controls, and other industrial hygiene practices at industrial, commercial, and Federal facilities. Where information is made available, the Agency will take into account known occupational control measures in the exposure assessments. However, the Agency has continued to make clear in the proposed amendments that it will not consider, as part of the overall unreasonable risk determination, that exposure reduction will necessarily occur based on assumed use of PPE by workers. EPA has made clear it thinks employers will not reliably provide PPE, and employees might not regularly use PPE, even when provided, in all instances.

EPA's proposal not to assume use of PPE is inconsistent with TSCA's Section 6(b)(4) 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." EPA is proposing to discount certain "known or reasonably foreseen" circumstances of manufacturing under Occupational Safety and Health Administration (OSHA) mandatory requirements and instead to rely upon only one presumed condition of use – one in which PPE is not required, used, or reliably complied with.

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. EPA's elimination of the PPE assumption also effectively eliminates "circumstances" from the definition of "conditions of use." 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 under 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. Therefore, under TSCA's requirements that risk determinations be made based upon reasonably available information about a chemical's "conditions of use," EPA should 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. EPA's proposal would disregard the integral role of PPE under these specific conditions of use.

Comments on Specific Regulatory Provisions

- Proposed Section 702.37 addresses how EPA will use applicable "EPA" guidance in the risk evaluation process, and that EPA will document that the risk evaluation is consistent with the "best available science." CUC believes that best available science can only be objectively measured, and not necessarily measured to EPA's subjective standards as reflected in EPA guidance documents. EPA should utilize the best available scientifically valid and relevant guidance for risk evaluation. EPA also should consider retaining the definition in Section 702.33 of the current rule defining the term best available science so there is a clear understanding of how the term will be interpreted and applied by EPA.
- Proposed Section 702.39(e)(2)(ii) mentions that EPA will include discussion on data quality "as necessary" in the risk evaluation. CUC believes that data quality is a critical aspect that should be considered a necessary component in a risk evaluation, to prevent the utilization of unreliable data. Moreover, the Information Quality Act and EPA's own implementing procedures for the IQA compel EPA to ensure data and information quality and integrity.
- Section 702.41 as proposed states that EPA expects that peer review will be consistent with applicable peer review policies, procedures and guidance. CUC finds it perplexing that the EPA is proposing to enshrine in its TSCA implementing regulation a peer review

requirement that is merely aspirational - "it expects." A scientifically valid and predictable peer review process is absolutely necessary and required. The provision should state that peer review activities **will be** consistent with applicable policies, procedures and guidance. Moreover, EPA should retain the requirement currently in Section 702.45, that "Peer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C 2605(b)(4)(A)." Anything short of regular, predictable and transparent peer review on the entirety of every risk evaluation fails to meet the standard of best available science.

- Section 702.43(c) states that at least a 60-day public comment period should be provided once the draft risk evaluation is published. If EPA wants substantive industry feedback on the findings of the draft evaluation, sufficient time would be needed for industry to gather data to provide such feedback. CUC suggests that at least a 90-day public comment period would be preferable and should be the standard.
- CUC believes that proposed Section 702.47 should be revised to explicitly state that EPA **shall** consult with other relevant Federal agencies.
- As discussed above, CUC requests EPA retain the current provision in Section 702.47 which states that "EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses within the scope of the risk evaluation, either in a single decision document or in multiple decision documents."

Conclusion

CUC supports EPA's efforts to appropriately evaluate risks presented by high priority substances. However, CUC believes that EPA must ensure that the risk evaluation procedures accurately reflect the legal requirements set forth in TSCA for risk evaluation. The real-world conditions of use must be evaluated. 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. EPA could have simply made small adjustments to the existing rule to clarify certain issues and address ministerial issues. Instead, EPA needlessly decided to propose drastic, wholesale revisions that would significantly change the way EPA conducts risk evaluations, and subsequent risk management rules, revisions that are inconsistent with the plain language of TSCA. Accordingly, CUC asks that EPA take a closer look at TSCA, the statutory requirements, the existing regulations, and objectively consider the many detrimental outcomes should EPA decide to finalize the Proposed Rule as currently drafted. CUC Members are especially concerned that the Agency's current approach to TSCA risk evaluations and the recently-proposed risk management rules, when predicated on a single "unreasonable risk" determination for a chemical substance, inevitably overstate risks, and result in requirements that ultimately place US businesses and operations occurring in the US at a clear competitive disadvantage. Regulatory proposals drafted on the basis of overly conservative characterizations of risk can negatively affect domestic manufacturing and production as place unnecessary constraints on the US economy and the global supply chain. CUC encourages EPA to strive for more practical approaches to TSCA Risk Evaluation procedures and Risk Management policies.

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.