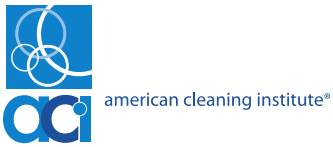

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Submitted via www.regulations.gov

RE: Procedures for Chemical Risk Evaluation under TSCA
EPA-HQ-OPPT-2025-0260

The American Cleaning Institute (ACI) appreciates the opportunity to provide these comments regarding the U.S. Environmental Protection Agency's ("EPA" or "the Agency") proposed rule, "Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act ("TSCA")" (the "Proposed Rule")[1].

ACI is the home of the U.S. Cleaning Products Industry® and represents the $60 billion U.S. cleaning product supply chain. ACI members include the manufacturers and formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and chemical distributors. ACI serves the growth and innovation of the U.S. cleaning products industry by advancing the health and quality of life of people and protecting our planet. ACI achieves this through a continuous commitment to sound science and being a credible voice for the cleaning products industry.[2]

ACI supports science-based, efficient, and transparent chemical management that promotes both health protection and innovation.

Introduction

ACI supported the passage of the Lautenberg Act amendments to TSCA in 2016[3] and has since been engaged with numerous EPA activities undertaken either to implement the amendments or pursuant to these new provisions. ACI has had the opportunity to see firsthand the consequences of the differing approaches to risk evaluation taken by EPA at different points in time. After reviewing the Proposed Rule, ACI commends EPA for proposing amendments that promote flexibility, scientific rigor, and efficiency to the TSCA risk evaluation framework. The revisions reflect many of the suggestions made by ACI in response to EPA's 2017 proposal for Procedures for Chemical Risk Evaluation under TCSA (EPA-HQ-OPPT-2016-0654-0073), which are attached and incorporated by reference. ACI believes that the Proposed Rule represents a significant step towards the return to a more balanced and durable risk evaluation program.

[1] 90 Fed. Reg. 45690 Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability. Published September 23, 2025
[2] For more information: www.cleaninginstitute.org
[3] *See:* EPA-HQ-OPPT-2023-0601-0330

Summary of Comments

ACI supports adoption of the Proposed Rule, which promotes scientific rigor, flexibility, and transparency. The proposal reestablishes EPA's discretion to focus risk evaluations on significant and higher-risk conditions of use rather than every conceivable use and exposure pathway, reinstates condition-of-use–specific determinations to ensure clarity and statutory fidelity, and directs EPA to consider real-world occupational controls and personal protective equipment ("PPE") as part of a substance's "conditions of use." ACI also commends EPA's reinforcement of scientific standards, including adoption of a definition for "weight of scientific evidence" that promotes transparent, high-quality evaluations, and its commitment to robust, transparent peer review that enhances the scientific integrity of risk determinations. Finally, ACI supports restoring EPA's authority to revise final risk evaluations to correct scientific errors or incorporate new information, ensuring that TSCA decisions remain credible, data-driven, and consistent with best available science.

Comments on Specific Proposals

1. Scoping Flexibility and Focus on High-Risk Uses

The Proposed Rule would eliminate prior provisions that require EPA to consider all conditions of use and each and all exposure pathways based on reasonably available information. Instead, EPA would be able to exercise discretion when establishing the scope of risk evaluations, including the specific conditions of use and exposure scenarios to be reviewed. The requirement that EPA must include every possible condition of use in risk evaluation runs counter to the objective of meeting TSCA's ambitious statutory deadlines while conducting risk evaluations that address (to the extent possible) actual conditions of use. EPA's clarification of its discretion to exclude certain conditions of use and exposure pathways based on real-world applicability, aligns with ACI's recommendation that EPA focus evaluations on significant and meaningful risks. The Proposed Rule establishes a fit-for-purpose approach that improves EPA staff efficiency by allowing prioritization of higher-risk uses while efficiently addressing lower-risk scenarios.

To further increase efficiencies in the risk evaluation process, ACI believes that if there are other regulatory frameworks under which a particular exposure pathway is addressed, EPA should carefully determine as to whether such exposure pathway be included in the scope of the risk evaluation. The TSCA risk evaluation process should not duplicate work that has already been done, nor should it lead to potential conflicts between different regulatory programs. If EPA determines that the risk from a certain exposure pathway for a substance is addressed under other legal requirements, EPA could decide to include such pathway in the scope of the risk evaluation. However, in such a situation, ACI believes that EPA may rely on the existing regulatory structure for that pathway when evaluating actual risk in the TSCA risk evaluation process. Incorporating the real-world impact of implemented regulations that control a certain exposure pathway will aid in maintaining consistency through different regulatory programs and increase efficiencies when EPA is conducting TSCA risk evaluations.

While ACI supports EPA being able to exercise discretion in the scoping process, ACI suggests that when EPA establishes the scope of the risk evaluation, EPA must provide details justifying its decisions. For example, for a condition of use or exposure pathway that EPA believes is low risk, EPA could either choose not include such use or it could issue a succinct condition-of-use-specific risk determination. EPA should explain the rationale for what is included and excluded in the scope of work to provide transparency and to allow stakeholders to understand and respond to the approach.

EPA noted that a de minimis exposure could potentially be one that would be excluded from the scope of a risk evaluation as it is highly likely that it will not pose any risk. Noting the significance of a de minimis level, ACI believes EPA should define "de minimis." Without a clear and predictable definition, the term could be used inconsistently, leading to different risk assessments treating similar exposure levels differently. Lack of a definition also creates uncertainty for manufacturers and importers who look to the de minimis threshold to benchmark for what exposures and uses might be viewed as "safe" and therefore excluded from risk evaluation and potential regulation.

2. Condition-of-Use–Specific Risk Determinations

TSCA provides that EPA is to make determinations as to whether a substance presents an unreasonable risk **under the conditions of use**. The "Whole Chemical" approach embodied in the 2024 Rule resulted in a de facto determination of "presents risk" for every substance, as by definition, the substances EPA was evaluating were "high-priority." "Whole Chemical" determinations are opaque and because the criteria for which conditions of use drive a determination, the approach is not always clear and transparent. This procedure has led to confusion and misunderstanding about the true nature of EPA's findings on a substance. ACI strongly supports EPA's revision to reinstate separate risk determinations for each condition of use. ACI supports case-by-case risk determinations as the clearest way to communicate which uses present unreasonable risk and where to direct risk management strategies. This approach would fulfill the statutory requirement to evaluate risk 'under the conditions of use' and provide clarity, to both the evaluators and stakeholders regarding which specific uses present unreasonable risk and ultimately whether and how risk mitigation is best accomplished.

3. Consideration of Real-World Occupational Controls

The Proposed Rule provides that EPA's consideration of occupational exposure scenarios would 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 ("PPE"). This change stands in stark contrast to the 2024 Rule, which adopts the policy that EPA will not consider that exposure reduction will necessarily occur based on use of PPE by workers. This existing provision is inconsistent with the requirement under TSCA for EPA to evaluate a substance under its "conditions of use," which includes use of PPE. ACI supports the change in the Proposed Rule that, when making risk determinations based upon reasonably available information about a chemical's "conditions of use," EPA should consider PPE and other applicable industrial hygiene regulations, standards and practices as part of the

conditions of use in TSCA risk evaluations This provides a more robust and realistic approach to the risk evaluation, while also providing transparency to the public with insights into how occupational handlers are mitigating any existing risks of concern while ensuring that no employee will suffer impairment of health or functional capacity even if such employee has regular exposure to the hazard.

4. Occupational Exposure Values

The EPA requested comments on whether the Agency should establish occupational exposure values (OEVs) and if OEVs should be set during Risk Evaluation, Risk Management or both. ACI recommends setting one OEV as part of the risk evaluation process. This would provide industry with the opportunity to "pressure check" the proposed value by verifying whether testing protocols and existing industrial hygiene sampling methods are capable of detecting below the OEV. It would also allow potentially affected facilities to gather new data before the risk management rules that may incorporate an OEV, are proposed. Prior to proposing an OEV, ACI recommends EPA first review existing exposure limits, whether they be set by the US Department of Labor's Occupational Safety and Health Administration (OSHA") or generally accepted industry standards, and understand the basis for the specific exposure limit. ACI also recommends that EPA continue to collaborate with OSHA to best leverage OSHA's experience with industrial hygiene and understanding of existing exposure limits that reflect the latest scientific standards.[4]

5. Improvements to Peer Review and Public Engagement

ACI welcomes EPA's recognition of the importance of robust peer review. Transparent review at key stages will enhance scientific integrity and confidence in TSCA risk evaluations. ACI is in favor of EPA conducting peer review that requests the Science Advisory Committee on Chemicals (SACC) review the entire risk assessment. The current process, under which EPA can tailor the scope of peer review, restricts the SACC review, limits the independence of the SACC and the utility of the review. Comments and suggestions that result from peer review can be valuable and the response to such, when incorporated into risk determinations, serve to strengthen the scientific underpinnings of EPA's decisions. Additionally, EPA should make clear how it will conduct peer review by referencing specific guidance, policies, procedures and methods. The final rule should allow EPA to update these references, keeping stakeholders fully aware of how decisions are made, and the peer review panel remains balanced and independent. Additionally, ACI has observed that in the case of certain risk evaluations, EPA failed to address comments that resulted from peer review in the risk determination. ACI also suggests that EPA explain how the risk determination responds to findings and suggestions that resulted from the peer review process.

6. Reinforcement of Scientific Standards and Transparency

ACI supports EPA's addition of a definition for 'weight of scientific evidence' derived from Executive Order 14303. This definition ensures that risk evaluations apply quality, relevance, and transparency criteria. ACI reiterates its belief that EPA should evaluate the

[4] For more information: 25-MOU-018 OSHA and Environmental Protection Agency (EPA) - MOU (004) (004).pdf

weight of evidence at the hazard evaluation phase, the exposure assessment phase and when both the draft and final risk evaluations are being completed. ACI suggests adding a specific definition for weight of scientific evidence to be, "a transparent approach to evaluating scientific information by integrating multiple lines of evidence based on their quality, relevance, and reliability, to draw conclusions about risk under TSCA. Quality and relevance determinations, at a minimum, should include consideration of study design, fitness for purpose, replicability, peer review, uncertainty, and consistency across data sources."

ACI recommends EPA update its systematic review methodology to eliminate the use of pre-existing documents that were conducted according to a different systematic review process that may not be consistent with TSCA scientific standards. The EPA IRIS values can be based on limited or older data that does not always reflect the latest available data. Often, the EPA IRIS values choose overly conservative assumptions that lead to unrealistically low safe-dose levels that can drastically impact a risk evaluation and thus risk management strategies.

ACI encourages EPA to provide guidelines on how it treats information and data that typically do not undergo peer review. This can support industries and data submitters improve their study protocols when preparing data submissions and risk assessment inquiries from the EPA. The supporting decision documents should include a discussion on the strengths and limitations of the data and information available to EPA and how those were considered in the determination process.

7. Authority to Revise Final Risk Evaluations

ACI believes that when it becomes apparent that a risk evaluation does not meet the statutory science standards under TSCA, EPA must be able to fix it. Furthermore, ACI believes that any risk evaluation procedural rule should contain provisions that set forth EPA's ability to make these revisions and how such revisions will be made. Accordingly, ACI supports deletion of the existing §702.43(g)(3), restoring EPA's authority to revise final risk evaluations without reinitiating prioritization. This flexibility allows scientific corrections or updates in response to new data, consistent with TSCA's best available science requirements. For example, in the context of 1,4 dioxane, EPA issued its first final risk evaluation in 2020. However, after that time, a New York State law took effect that restricted 1,4 dioxane concentrations in certain products. This led to product reformulations, and consequently, the data that EPA used on emissions of 1,4 dioxane from a certain condition of use was outdated and the EPA determination was no longer based on the best available science. It is precisely because of situations such as this that EPA should be able to revise determinations efficiently and expediently, without the need to restart the evaluation process from scratch.

8. **Defining Specific Terms**

The EPA requested comments on whether the Proposed Rule should include a definition of the term, "unreasonable risk." ACI advocates for codification of unreasonable risk criteria that affirms unreasonable risk is not no, low or unlikely risk and is only based on

a consistent, reproducible and transparent risk determination framework.

The EPA also asked the public to comment on whether a definition of "reasonably foreseen" would enhance the transparency and predictability of EPA's decisions on the circumstances of manufacture, processing, distribution in commerce, use, or disposal that constitute conditions of use. ACI advocates that EPA define "reasonably foreseen" and recommend alignment to the extent possible with the definition used for EPA's TSCA Section 5 New Chemicals program. ACI proposes defining "reasonably foreseen" as a "condition of use of a chemical substance that is not currently intended or known, but which a reasonable person would expect to occur in the future based on facts, patterns of use, market trends, or analogous chemical behavior. This does not include speculative, hypothetical, or intentionally abusive uses.

Conclusion

ACI thanks EPA for promoting flexibility and transparency and strengthening EPA's commitment to using the best available science. Collectively, ACI believes that the Proposed Rule realigns the TSCA risk evaluation process with statutory intent, scientific best practices, and practical implementation. EPA's proposal reflects ACI's longstanding advocacy for a flexible, transparent, and efficient program that promotes safety and innovation.

We appreciate the opportunity to comment and look forward to continued collaboration as EPA finalizes this important rulemaking.

Respectfully submitted,

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