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EPA's Proposed Course Corrections to TSCA's Risk Evaluation Procedures

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The U.S. Environmental Protection Agency's (EPA) much-anticipated Toxic Substances Control Act (TSCA) proposed rule to amend the risk evaluation framework for existing chemicals was published in the Federal Register on September 23, 2025. This is the third attempt by the agency to "define" TSCA's risk evaluation procedures. The proposed rule seeks to align the risk evaluation process with other TSCA provisions – namely, Section 6 (risk determination orders), Section 9 (agency coordination), and Section 18 (preemption). Comments on the proposal are due **November 7**, **2025**. Wiley will host a webinar on October 14 to review the changes EPA is proposing. To register, click here.

Proposed Rule Seeks to Clarify EPA's Authority to Scope Its Risk Evaluations

EPA's current rule requires the agency to consider all conditions of use, and exposure pathways based on reasonably available information when conducting existing chemical risk evaluations. In the proposed rule, EPA acknowledges that TSCA "clearly envisions comprehensive risk evaluations." The agency goes on to explain why some discretion regarding the conditions of use and exposure pathways it will consider is necessary to carry out that mandate. EPA points to two parts of the statute that give it discretion in planning the scope of a risk evaluation with regard to the conditions of use: (1) the authority to determine what the conditions use are for a chemical substance under TSCA 6(b); and (2) it interprets TSCA Section 6(b)(4)(D) to allow EPA to exclude a condition of use from the scope of a risk evaluation. EPA proposes that the language in Section 6(b)(4)(D) is best read as permitting EPA some discretion to identity "the hazards, exposures, conditions of use, and the potentially exposed or

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susceptible subpopulations the Administrator expects to consider." The proposed rule explains why it needs to retain greater flexibility to scope out TSCA risk evaluations based on the learnings of the last nine years in areas such as *de minimis* levels, uses with minimal exposure potential, byproducts, and impurities.

The proposal also seeks to align the overall TSCA framework with other environmental statutes that manage risk. EPA explains that the requirement in 40 C.F.R. § 702.39(d)(9) – to assess exposure routes and pathways under conditions of use that are regulated under other federal statues and regulatory programs – affect the agency's ability to use Section 9(b)(1) of TSCA to allocate resources efficiently and avoid duplicating efforts. EPA is proposing that it should be able to rely on Section 9(b)(1) at the scoping stage, to avoid evaluating exposure routes and pathways under TSCA that have already been evaluated and are being managed by other EPA offices. However, when an exposure pathway of a chemical substance is not already evaluated and managed by another EPA program, EPA affirms its authority in the proposed rule to assess the particular exposure pathway under TSCA.

Proposal Returns to 2017 Final Risk Evaluation Rule Process of Making Risk Determinations for Each Condition of Use

EPA is proposing to modify 40 C.F.R. § 702.39(f)(1) to determine whether each condition of use of a chemical substance presents an unreasonable risk. Currently, EPA makes a single risk determination on the chemical substance as a whole. In the proposed rule, EPA asserts that if the agency finds that a chemical substance presents an unreasonable risk, every condition of use in the risk evaluation must proceed to risk management – including those conditions of use that EPA has previously found did not present an unreasonable risk or do not "significantly contribute" to the unreasonable risk. This interpretation may help to explain the breadth of the risk management rules that EPA has finalized.

In the proposed rule, EPA provides the following rationale to support its proposal to return to risk determinations on each use and outlines what was envisioned by Congress when it passed the Lautenberg Amendments:

- EPA points out that the authority to regulate chemicals under TSCA Section 6(a) is available only "to the extent necessary so that the chemical substance or mixture no longer presents [unreasonable] risk."
- EPA has independent authority under Section 6(b)(4)(F)(ii) to choose whether to conduct an aggregate or sentinel risk evaluation, which ensures that the agency remains capable of finding that a condition of use presents an unreasonable use in combination with other conditions of use.
- Risk determinations on each condition of use are required to ensure the public understands whether EPA has fully addressed unreasonable risk from a particular use.
- The risk management measures in Section 6(a) allow EPA discretion to regulate individual uses differently rather than in a singular way.
- A single risk determination does not provide EPA the ability to issue a final order under Section 6(i) for conditions of use that would not be regulated in a Section 6(a) rule.

- A single risk determination eliminates the possibility of preemption for conditions of use that do not contribute to the unreasonable risk under Section 18 of TSCA.
- A risk finding for each condition of use is consistent with using Section 9(a) of TSCA to coordinate with other federal agencies and avoid duplicative reviews and rules.

Using Reasonably Available Information to Guide Occupational Exposure Determinations

EPA is proposing to update 40 C.F.R. § 702.39(f)(2) to clarify that reasonably available information on engineering, administrative, and workplace controls is relevant when conducting exposure assessments in the risk evaluation process and that the presence or absence of such controls will be taken into consideration. EPA's proposed revision specifies that the agency will consider reasonably available information "that indicates the absence or ineffective use of worker exposure controls as well as information that indicates that these controls are in place and are being implemented properly."

Fine-Tuning Manufacturer-Requested Risk Evaluations

EPA is reexamining the changes made in 2024 for manufacturer-requested risk evaluations (MRREs) in this proposed rule. Those changes sought to address the challenges EPA encountered in its early experiences handling these requests. Early requests could be limited in scope, and EPA had only a short time to deny or grant the requests and complete the reviews. EPA's decision in 2024 to shift the burdens on industry to take on the same obligations as EPA to collect information and prepare comprehensive risk evaluations has proven equally burdensome to industry. The proposed rule adopts a shared approach whereby:

- Information collection by industry must be conducted according to the "known to or reasonably ascertainable" due diligence standard of other parts of TSCA;
- The scope of the MRRE can be limited to the conditions of use identified by the submitters;
- EPA will grant requests that are complete with respect to the uses identified;
- EPA will prepare a strategy to use its information collection authority to gather data on other uses required for a comprehensive risk evaluation. EPA would have up to a year to obtain information before initiating the risk evaluation; and
- MRREs that are withdrawn before they are granted do not incur fees.

Other Proposed Changes

The proposed rule appears to be primarily aimed at addressing the four areas that are having the greatest impact on how TSCA risk evaluations are conducted. However, there are a handful of additional provisions proposed for modification. EPA is proposing to:

- Update 40 C.F.R. § 702.43.(g)(3) to maintain the flexibility to revise final risk evaluations without having to go back through the prioritization process.

- Eliminate the requirement in the rule to explain why it did not conduct an aggregate risk evaluation where the agency chooses not to take an aggregate approach.
- Realign the susceptible subpopulations definition with the statutory definition and remove the term "overly burdened communities." The agency is asserting its authority to consider populations beyond the examples in the statutory definition.
- Include a new definition for "weight of the scientific evidence" that is consistent with Section 2(e) of Executive Order 14303.

The proposed rule includes 13 specific areas in which the agency is asking for comments, including the following provisions which are unchanged in the proposed rule:

- The current provisions on peer review do not reference specific guidance documents and indicate that EPA expects to – rather than will – conduct peer review on all risk evaluations. It allows the agency to use peer review for only portions of the risk evaluation.
- EPA is not proposing to reinstate a definition for the term best available science because the definition was incorporated elsewhere into the rule in the 2024 update.
- EPA acknowledges the confusion surrounding the derivation and use of Existing Chemical Exposure Limits (ECELs). EPA invites comments on whether the agency should establish occupational exposure values and the considerations that should be taken into account.

Summary

EPA's proposed risk evaluation framework rule is a pivotal opportunity for stakeholders to provide input, as it establishes the foundational process the agency will use for chemical risk evaluations. This process is essential not only for ensuring that federal preemption is properly addressed, but also for providing a process for EPA to revise scope or risk evaluation documents as new information and science is identified. Please join us for our October 14 webinar to learn more about how these changes affect your business.