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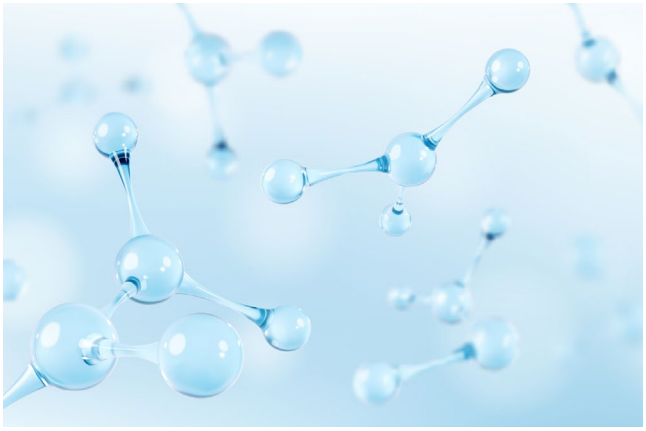
News Alert

EPA Proposes Changes to TSCA Risk Evaluation Framework Rule – Again



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Summary

The U.S. Environmental Protection Agency (EPA) published proposed revisions to the procedural framework rule for conducting risk evaluations under the Toxic Substances Control Act (TSCA) on September 23, 2025, 90 Fed. Reg. 45690. The proposed rule seeks to overhaul significant portions of the 2024 Biden-era rule, 89 Fed. Reg. 37028 (May 3, 2024), 40 C.F.R. Part 702, Subpart B, citing the need for a more efficient evaluation process that can be completed within the statutory timeframes. That 2024 rule had revised the first Trump EPA's version of the Risk Evaluation Framework Rule, 82 Fed. Reg. 33726 (July 20, 2017). The Office of Information and Regulatory Affairs (OIRA) website indicates that EPA expects to issue a final rule in April 2026.

The preamble to the proposed rule states that the proposed revisions specifically target changes made in the 2024 final rule that may not be consistent with the best reading of TSCA and that may impede the timely completion of risk evaluations, unnecessarily impairing the effective and efficient protection of health and the environment. The preamble also frequently references issues raised during the public comment period for the Biden-era rule as support for seeking to ease the regulatory burden associated with risk evaluations.

The proposed rule includes the following proposed revisions:

1. A requirement for EPA to make a determination of unreasonable risk for each of the conditions of use within the scope of the chemical's risk evaluation, instead of a single risk determination on the chemical substance as a whole.
2. Changes as to how EPA will consider occupational exposure controls such as personal protective equipment (PPE) and industrial controls when conducting risk evaluations and making risk determinations.
3. Changes regarding EPA's discretionary authority to determine which conditions of use, exposure routes, and exposure pathways it will consider in a risk evaluation.
4. Revisions to certain regulatory definitions.
5. Revisions to the procedures and requirements EPA would follow when revising or supplementing risk evaluation documents.

6. Amendments to the process and requirements that manufacturers (including importers) are required to follow when they request an Agency-conducted TSCA risk evaluation.

Comments on the proposed changes are due by November 7, 2025.

Proposed Revisions

Risk Determinations by Condition of Use

Chief among the proposed changes is the elimination of the "whole chemical" approach to risk evaluations. The Risk Evaluation Framework Rule adopted by the first Trump administration in 2017 provided that EPA "will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of use." In practice, this amounted to individual risk determinations for each condition of use. In 2021, the Biden EPA announced a different approach, stating, "The agency plans to make the determination of unreasonable risk just once for the whole chemical when it is clear the majority of the conditions of use warrant one determination." The 2024 revision of the Risk Evaluation Framework Rule provided that "EPA will make a single determination as to whether the chemical substance presents an unreasonable risk … under the conditions of use." The 2025 proposed rule would reverse course again, saying, "EPA will determine whether the chemical substance presents an unreasonable risk … by making separate risk determinations for each condition of use."

Both approaches rely on interpretations of TSCA section 6(b)(4)(A). It provides that EPA is to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk … under the conditions of use." Multiple courts of appeals are considering this very issue in judicial review of the risk management rules issued by the Biden EPA and their respective risk evaluations. Under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), a court is to determine the "best" interpretation of a statute, not an agency, meaning that the courts will not defer to either of EPA's conflicting interpretations of this TSCA provision.

Occupational Exposure Controls

Another proposed change relates to the consideration of whether exposure controls, including PPE, are used to protect employees from exposure to a chemical substance. The proposed rule would add:

> In determining whether unreasonable risk is presented, EPA's 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 language would replace the 2024 rule's provision, taking the opposite approach, under which a risk evaluation would consider:

> known and reasonably foreseen circumstances where subpopulations of workers are exposed due to the absence or ineffective use of personal protective equipment. EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination.

This issue also involves statutory interpretation, specifically the meaning of the definition of "conditions of use" in TSCA section 3(4), which includes both "reasonably foreseen" conditions and those that are intended or known. Non-use of exposure controls may be reasonably foreseen, but use of exposure

controls may be generally known to prevail. This is another issue ongoing in the judicial challenges to risk management rules and their risk evaluations.

In the preamble to the proposed rule, EPA requests comment on whether a definition of "reasonably foreseen" would be helpful. If so, the preamble indicated that EPA would likely rely on language used in determinations under TSCA section 5 that a chemical substance is not likely to present an unreasonable risk:

> Reasonably foreseen conditions of use are future circumstances, distinct from known or intended conditions of use, under which the chemical substance may be manufactured, processed, distributed, used, or disposed of. EPA expects that the identification of "reasonably foreseen" conditions of use will be made on a fact-specific, case-by-case basis.

EPA's Discretionary Authority Over Scope of Risk Evaluations

TSCA section 6(b)(4)(D) directs EPA to identify in the scope for the risk evaluation the conditions of use that "the Administrator expects to consider." The 2017 Risk Evaluation Framework Rule's preamble found that the quoted language:

> suggest[s] that EPA is not required to consider all conditions of use. Consequently, EPA may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination.

The 2024 revision disagreed with that approach and instead declared that "EPA will not exclude conditions of use from the scope of the risk evaluation." It added that "a fit-for-purpose approach may result in varying types and levels of analysis and supporting information for certain conditions of use."

Now, the 2025 proposal would restore the 2017 position by deleting the 2024 statement because "EPA believes that TSCA is best read as permitting the Agency to exercise discretion … under TSCA section 6(b)(4)(D) in determining what conditions of use EPA expects to consider in a risk evaluation, recognizing that the statute clearly envisions comprehensive risk evaluations." The preamble identified uses of a chemical substance as an impurity or byproduct as conditions of use that might be excluded from the scope of a risk evaluation for that substance, although "generally the better approach for most chemical substances" is to consider those uses together with other uses of that substance, citing the example of 1,4-dioxane. Another example mentioned as an excludable condition of use is use in a product at *de minimis* levels.

This issue has not arisen in cases contesting risk management rules and their conditions of use.

Regulatory Definitions

EPA proposes removing the phrase "overburdened communities" from the definition of "potentially exposed or susceptible subpopulation." The statutory definition in section 3(12) does not mention that phrase. The Biden EPA added the phrase to the definition's list of examples of groups of individuals that may be at greater risk. The proposed definition would become essentially identical to the statutory definition:

> "Potentially exposed or susceptible subpopulation" means "a group of individuals within the general population identified by EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly."

EPA proposes to take this action in response to concerns from commenters that the phrase and its explanations in the 2024 rule preamble were overly broad and vague. EPA requests comments on whether its regulatory definitions should depart from the statutory definitions.

EPA proposes to add a definition for "weight of scientific evidence." The 2017 final rule added a definition, but the 2024 rule deleted it, on the basis that it was "both unnecessary and could inhibit the Agency's flexibility to quickly adapt to and implement advancing scientific practices and approaches." The proposed 2025 definition would differ from the one in the 2017 rule. It would state:

> "Weight of scientific evidence" means "an approach to scientific evaluation in which each piece of relevant information is considered based on its quality and relevance, and then transparently integrated with other relevant information to inform the scientific evaluation prior to making a judgment about the scientific evaluation. Quality and relevance determinations, at a minimum, should include consideration of study design, fitness for purpose, replicability, peer review, and transparency and reliability of data."

The 2024 rule also deleted the 2017 definition of "best available science," but the current proposal does not include a definition for that term. Both terms are used in section 26, but TSCA does not define either term. Whether EPA relied on the best available science is an issue in the pending litigation on the asbestos risk management rule.

Revisions to Existing Risk Evaluations

The 2024 version of the rule added a provision on revising final risk evaluations, whereby EPA generally must undergo the prioritization process again before making revisions. The 2025 proposal would eliminate that restriction, asserting that EPA must be able to efficiently fix risk evaluations that do not meet the statutory science standards under TSCA sections 26(h) and (i). This regulatory change would allow EPA to revise a risk evaluation without re-prioritization in other circumstances as well. For example, EPA would be able to revise a risk evaluation when a scientific error results in a determination that a condition of use presents an unreasonable risk, when, in fact, it does not. Under the proposed change, EPA would have to publish a new draft and final risk evaluation and solicit public comments and peer review, as appropriate.

Simplifying Requirements for Manufacturer-Requested Risk Evaluations

EPA is proposing to scale back information collection obligations that the 2024 rule imposed on manufacturers requesting risk evaluations. Specifically, EPA proposes to delete language requiring manufacturers to provide EPA with the information necessary to carry out the risk evaluation, shorten the meaning of "known to or reasonably ascertainable by" in this context, and only require manufacturers to submit information on the conditions of use that are identified in the risk evaluation request.

Commentary

This ping-pong approach to the Risk Evaluation Framework Rule reflects the conflicting statutory interpretations and policy views of the different Administrations. Another example of multiple revisions of regulatory requirements is EPA's Risk Management Program, 40 C.F.R. Part 68. See our alert here.

At some point, the courts may resolve certain of these statutory interpretation disputes by providing what they consider to be the "best" reading of TSCA. A judicial challenge to the 2024 rule was argued before the D.C. Circuit on March 21, 2025; however, that case is currently held in abeyance pending further court

order. While publication of the 2025 proposed rule might result in resolution of that case, it is likely that the first case to go to decision is the one involving the methylene chloride rule and its risk evaluation, as the case was argued before a panel of the Fifth Circuit on June 3, 2025, four months ago.

The Risk Evaluation Framework Rule is the basis for all chemical substance evaluations conducted according to its procedures. The proposed rule is deregulatory in nature, with significant scale-backs from the 2024 final rule and the proposed reimplementation of some 2017 provisions. It raises important issues for many stakeholders. Beveridge & Diamond encourages affected companies and their trade associations to submit comments by November 7, 2025. Please contact the authors for assistance.

Beveridge & Diamond's Chemicals Regulation practice group and Chemicals industry group provide strategic, business-focused advice to the global chemicals industry. We work with large and small chemical and products companies whose products and activities are subject to EPA's broad chemical regulatory authority under TSCA and state chemical restrictions.

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