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Rewriting Risk: EPA's Evolving Chemical Review Actions Under TSCA

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Special to the Legal

In the decade since Congress amended the Toxic Substances Control Act (TSCA), the EPA's approach to evaluating chemical risks has evolved through cycles of regulatory expansion, contraction and judicial review. As successive administrations reinterpret the statute's "unreasonable risk" mandate and courts reconsider the scope of agency deference following the U.S. Supreme Court's opinion in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), the EPA's exercise of its authority to regulate chemical exposures stands at a point of transition. The agency's recent proposed revisions to its risk evaluation procedures and the pending litigation over its chemical-specific rules highlight the current administration's emphasis on deregulation and a more streamlined approach to TSCA chemical risk regulation.

BACKGROUND ON THE EPA'S RISK EVALUATION RULES AND JUDICIAL DEVELOPMENTS

Since Congress amended TSCA through the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act, the EPA's process for assessing risks from existing chemicals has been a topic of great scrutiny and interest from a variety of stakeholders that include the public, advocacy organizations, manufacturers and users of these chemicals. The agency's first Risk Evaluation Rule, Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33726 (July 20, 2017) (2017 Risk



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Evaluation Rule), established the basic framework for determining whether a substance presents an "unreasonable risk" to health or the environment. It required the EPA to define the scope of each evaluation, assess hazards and exposures, and issue final risk determinations for every "condition of use." Notably, the 2017 Risk Evaluation Rule excluded "legacy uses" and associated disposals, such as asbestos in older building materials, focusing only on current or reasonably foreseeable uses.

Environmental groups challenged the 2017 Risk Evaluation Rule, and in *Safer Chemicals, Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019), the U.S. Court of Appeals for the Ninth Circuit held that TSCA required inclusion of legacy uses and associated disposals, compelling the EPA to revisit how it scoped and structured chemical evaluations. The Biden administration's 2024 Procedures for Chemical Risk Evaluation Under the Toxic Substances

Control Act, 89 Fed. Reg. 37,028 (May 3, 2024) (2024 Risk Evaluation Rule), expanded the program's scientific scope and public health protections. It required the EPA to evaluate all known and reasonably foreseeable conditions of use and exposure pathways, including those covered under other environmental statutes, and to issue a single, "whole-chemical" risk determination rather than separate findings for each use. The rule also prohibited assuming that conditions of use included the consistent use of personal protective equipment (PPE), broadened the definition of "potentially exposed or susceptible subpopulations" (PESS) to include overburdened communities, and imposed more rigorous data-submission duties on manufacturers seeking evaluations. Critics of the rule claimed that it was an impracticable expansion of the scope of the EPA's TSCA review process that would raise costs, slow the process of risk evaluations, and result in overly broad restrictions on chemicals that are necessary to industrial operations. Several industry and environmental petitioners challenged the 2024 Risk Evaluation Rule in the D.C. Circuit, where the case remains in abeyance pending the current EPA's reconsideration.

The EPA finalized five Biden-era chemical-specific risk management rules under the 2024 framework between March and December 2024 for asbestos, methylene chloride, carbon tetrachloride, perchloroethylene and trichloroethylene. These final rules effectively eliminated the manufacture and use of these chemicals except for certain "critical uses" identified by the EPA, which are permitted only under workplace chemical protection programs that are much more stringent than OSHA's analogous

requirements. After the 2025 change in administration, the EPA launched a review of this framework under Executive Order 14219, Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative. The agency concluded that key aspects of the 2024 Risk Evaluation Rule, particularly the whole-chemical approach and the requirement to evaluate all conditions of use, exceeded TSCA's authority and imposed unnecessary burdens on industry. Citing *Loper Bright*, which overturned *Chevron* deference, the longstanding doctrine requiring courts to defer to an agency's reasonable interpretation of statutes it administers when the statute is ambiguous, the EPA announced plans to revise the 2024 Risk Evaluation Framework rule to restore what it described as a more streamlined and flexible process for risk evaluation and management.

2025 PROPOSED RISK EVALUATION RULE AMENDMENTS

On Sept. 23, 2025, the EPA proposed significant revisions to the 2024 Risk Evaluation Rule, restoring the agency's discretion to define the scope of evaluations under TSCA. See Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 90 Fed. Reg. 45690 (Sept. 23, 2025). The proposed rule removes the requirement to include every condition of use and all exposure pathways, allowing "fit-for-purpose" review under TSCA Section 6(b). It would allow the EPA to exclude de minimis or low exposure uses, defer to other programs for regulation of certain exposure pathways, and issue narrower evaluations. It would delete the 2024 Risk Evaluation Rule language prohibiting such exclusions, reaffirming EPA's authority to determine which conditions of use it "expects to consider."

The EPA would also abandon the 2024 Risk Evaluation Rule's "whole-chemical" model and return to condition-of-use specific risk determinations, while retaining discretion to aggregate related uses when appropriate. The rule clarifies the basis for the EPA's risk findings, directing the agency to evaluate each use according to hazard severity, exposure magnitude, affected populations, and data reliability. This replaces the 2024 "significantly contributes" standard, which critics viewed as too imprecise

to explain how or why certain uses were deemed to present unreasonable risk.

For occupational exposures, the EPA proposes to consider all reasonably available information on exposure controls, reversing the 2024 prohibition on assuming PPE effectiveness. It also removes the requirement to justify the absence of aggregate exposure analyses and deletes "overburdened communities" from the PESS definition to align with TSCA, while allowing case-by-case inclusion of at-risk groups.

The EPA's 2025 proposed amendments to its procedural framework for risk evaluations would return TSCA practice to more a targeted scope, use-specific determinations, and streamlined review. The EPA is accepting public comments on the proposal until Nov. 7, 2025.

LITIGATION OVER THE BIDEN-ERA CHEMICAL RULES

While the EPA has reversed its approach to the framework rule, each of the EPA's five Biden-era chemical risk management rules has faced industry-led challenges in federal court. Cases are pending across multiple circuits, including *Texas Chemistry Council v. EPA*, No. 24-60193 (5th Cir. 2024) (asbestos); *Olin v. EPA*, No. 25-1014 (8th Cir. 2025) (carbon tetrachloride); *United Steelworkers International Union v. EPA*, No. 25-1055 (3d Cir. 2025) (trichloroethylene); *FabriClean Supply v. EPA*, No. 25-60006 (5th Cir. 2025) (perchloroethylene); and *East Fork Enterprises v. EPA*, No. 24-60227 (5th Cir. 2024) (methylene chloride). Four of these cases are currently held in abeyance while the EPA reconsiders each rule under its broader deregulatory review.

The exception, *East Fork Enterprises*, No. 24-60227 (2024), marks the first appellate test of the EPA's chemical regulation approach under TSCA Section 6(a) since the 2016 Lautenberg Amendments. Despite the EPA's request for an abeyance of the litigation, the Fifth Circuit ordered the parties to proceed with oral argument in June 2025, after industry petitioners argued that an abeyance would cause harm because compliance obligations are already in effect and associated costs are mounting. During argument, the three-judge panel questioned the EPA's authority to set workplace exposure limits traditionally overseen by OSHA and pressed the agency on its "unreasonable risk" finding for methylene chloride, ask-

ing how many workers have, in practice, been adversely affected by the chemical. The EPA defended its methodology, which had its basis in the 2024 Risk Evaluation Rule, citing both human and animal data and the endorsement of its Science Advisory Committee on Chemicals. By contrast, industry counsel stressed concern that the EPA was regulating "any risk," rather than "unreasonable risk"—a distinction that may take on heightened importance after *Loper Bright*, 603 U.S. 369 (2024), which held that courts, not agencies, must determine the best interpretation of their authorizing statutes.

While the Fifth Circuit has yet to issue its decision, *East Fork Enterprises* is likely to be a defining case. It is the only TSCA chemical-specific rule since the 2016 amendments to reach oral argument and could reshape the limits of the EPA's authority over occupational risk, evidentiary standards, and the balance between TSCA and OSHA regulation in a post-*Chevron* era, even as the EPA has seemed to pull back its exercise of that authority in its 2025 proposal.

THE FUTURE OF TSCA REGULATION

The EPA's ongoing review of both its risk evaluation framework and its chemical-specific rules underscores that TSCA implementation remains in flux. The Fifth Circuit's forthcoming decision in *East Fork Enterprises* may clarify how courts interpret the EPA's "unreasonable risk" standard, shaping chemical regulation for years to come. As the EPA works to reconcile its statutory boundaries with a renewed policy focus on deregulation, the next three years will reveal how this administration defines the next phase of chemical risk regulation under TSCA.

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