



# **EPA Proposes Major Revisions to TSCA Chemical Risk Evaluation Framework Rule**

**SEPTEMBER 25, 2025** 

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**Subject:** EPA Proposes to Rescind and Revise Key Provisions of the 2024 TSCA Risk Evaluation Framework Rule, impacting scope, risk determinations, and manufacturer obligations.

# **Background**

The U.S. Environmental Protection Agency ("EPA" or "the Agency") is proposing significant amendments to the rule governing existing chemical risk evaluations (the "Framework Rule") under the Toxic Substances Control Act (TSCA). 89 Fed. Reg. 45690 (Sept. 23, 2025). EPA's proposed rule revises or rescinds several key provisions of the 2024 amendments to the Framework Rule, aiming to prevent procedural requirements from delaying timely risk evaluations or hindering effective protection of health and the environment. EPA states that the proposed changes to the Framework Rule ensure chemicals already in the marketplace are reviewed in a way that adheres to Congress's intent for TSCA, uses the best available science, and provides certainty for the regulated community. The proposed changes would affect manufacturers and importers of TSCA-regulated chemical substances, including those in Chemical Manufacturing (NAICS code 325) and various plastics, rubber, and petroleum refining sectors.

The rulemaking follows a review of the <u>2024 Framework Rule</u>, which was issued during the Biden Administration to amend the 2017 Framework Rule. The current review and proposed revisions were initiated consistent with President Trump's Executive Order 14219 ("Ensuring Lawful Governance") and Executive Order 14303 ("Restoring Gold Standard Science").

### **Rationale for Proposed Changes**

EPA is seeking to revise or eliminate provisions of the 2024 Framework Rule that it considers overly burdensome or unnecessary, or likely to impede the timely completion of chemical risk evaluations. EPA Administrator Lee Zeldin stated that this action would "protect human health and the environment while allowing manufacturing and industrial sectors to thrive," aligning with the EPA's "Powering the Great American Comeback" initiative. EPA believes certain provisions of the 2024 Framework Rule are not based on the best reading of the statute, especially following the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), which requires agencies to apply the single best interpretation of the statute. We are highlighting several key aspects of the proposed revisions.

# **Proposed Changes**

### 1. Reverting to Condition-of-Use Specific Risk Determinations

EPA proposes to repeal the 2024 Framework Rule's requirement that the Agency make a single determination of unreasonable risk for the entire chemical



substance. Instead, EPA proposes to return to the approach of the 2017 Framework Rule, which requires separate risk determinations for each condition of use within the scope of the risk evaluation.

The proposed revision to 40 C.F.R. § 702.39(f)(1) requires EPA to "determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use by making separate risk determinations for each condition of use." EPA argues this is the "best reading of TSCA section 6" and gives independent meaning to the phrase "under the conditions of use," which Congress added in the 2016 TSCA amendments.

## 2. Restoring EPA Discretion in Scope of Evaluation

To restore EPA's discretionary authority, the proposed rule eliminates provisions in the 2024 Framework Rule that required EPA to assess "each and every condition of use and each and every exposure route and pathway." The proposed approach allows EPA to determine which conditions of use, exposure routes, and exposure pathways it "expects to consider."

EPA emphasizes that risk evaluations must be "fit-for-purpose" and that attempting to evaluate all conditions of use without exception makes meeting the statutory deadlines of 3 to 3.5 years a significant challenge. By restoring its scoping discretion, EPA argues it will be better positioned to focus its evaluations on conditions of use that raise the "greatest potential for risk."

Furthermore, EPA proposes to delete 40 C.F.R. § 702.39(d)(9), which requires the assessment of all exposure routes and pathways, including those regulated under other federal statutes (such as the Clean Air Act or Clean Water Act). EPA maintains that duplicative assessments are not an efficient use of resources and are contrary to the purpose of TSCA section 9(b), which directs coordination with other EPA programs.

# 3. Adjusting Occupational Exposure Assumptions

EPA is proposing to revise 40 C.F.R. § 702.39(f)(2) to clarify that EPA's review of occupational exposure scenarios will consider reasonably available information on the implementation and use of occupational exposure control measures such as engineering and administrative controls and Personal Protective Equipment (PPE). The 2024 Framework Rule constrained and prohibited EPA from considering exposure reduction based on the assumed use of PPE. EPA states that the 2024 provision was overly confusing and appeared to discount information showing that exposure controls are properly implemented.

### 4. Reducing Burden for Manufacturer-Requested Risk Evaluations (MRREs)

EPA proposes to scale back the extensive information collection obligations that the 2024 Framework Rule imposed on manufacturers requesting a risk evaluation. The proposed revision to 40 C.F.R. § 702.45(a)(8) redefines "known to or reasonably ascertainable by" to include only information in the manufacturer's possession or control, plus information that "a reasonable person similarly situated might be



expected to possess, control, or know." This change is expected to reduce the regulatory burden associated with these voluntary submissions.

## **Next Steps**

The proposed rule is open for public comment. All interested entities, particularly manufacturers and importers of TSCA-regulated chemical substances, should review the proposed changes, as they significantly alter the framework for how chemical risk is assessed and regulated in the United States.

Comments must be received on or before **November 7, 2025**. Any available hearing information was not available at the time of publication.

# **For More Information**

For further technical information or assistance, contact <u>Britt Speyer Fleming</u>, <u>Dana Stotsky</u>, or any member of Van Ness Feldman's Environmental practice.

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