

EPA Proposes to Codify Changes to TSCA Risk Evaluations



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Summary

The U.S. Environmental Protection Agency (EPA) published proposed revisions of its procedural rule on risk evaluations under TSCA on October 30, 2023. The far-reaching changes are likely to affect all ongoing and future risk evaluations. Stakeholders likely to be affected

by future TSCA risk management rules should comment by December 14, 2023.

By the end of the Trump Administration, the Environmental Protection Agency (EPA) had completed the initial 10 risk evaluations under the Toxic Substances Control Act (TSCA) – or so it thought. In June 2021, the Biden EPA announced its plans to revise those risk evaluations using different policies. Since then, EPA has reworked risk determinations and, in one case, supplemented a risk evaluation. Now, EPA is proposing to codify its policy decisions announced in that policy statement and adopt new ones. These changes are likely to affect the 24 risk evaluations currently underway and new ones in the coming years.

This action came in the form of a [proposed rule](#) published on October 30, 2023, 88 Fed. Reg. 74292. It proposes amendments to the risk evaluation procedural framework rule adopted by the Trump EPA in 2017, 40 C.F.R. Part 702, Subpart B. Comments on this far-reaching proposal are due December 14, 2023.

Among the most important aspects of the proposal are these:

- ◆ **Whole Chemical Issue** – The Trump EPA risk evaluations made risk determinations for specific conditions of use of a chemical, finding that some present an unreasonable risk and others do not. The proposal would codify the Biden EPA policy that TSCA only allows EPA to make risk determinations for a chemical as a whole after considering all conditions of use. EPA would, however, identify the conditions of use that significantly contribute to that determination (with no statement that other conditions of use do not significantly contribute to the risk determination). See proposed § 702.39(f)(1). EPA has followed this approach in its revised risk determinations. This approach precludes any EPA determination that a particular condition of use does not present an unreasonable risk.
- ◆ **Use of Personal Protective Equipment** – The Trump EPA risk evaluations assumed, in the absence of evidence to the contrary, that employers are complying with applicable Occupational Safety and Health Administration (OSHA) standards requiring the use of personal protective equipment (PPE). The June 2021 policy statement found that assumption to be unrealistic. Instead, EPA has since then determined risk without that assumption. In some cases, it has calculated risk

with and without the use of PPE. In others, it has effectively assumed no use of PPE. Instead, it has regarded the use of PPE as an aspect of risk management, i.e., for consideration after making a determination of unreasonable risk. The proposed rule would require EPA to consider reasonably available information, including whether particular subpopulations of workers are exposed due to the absence or ineffective use of PPE. However, "EPA will not consider exposure reduction based on assumed use of [PPE] as part of the risk determination." See proposed § 702.39(f)(2). In other words, the burden would be on industry to establish that workers use PPE effectively, with that evidence being relevant to the risk management requirements to be imposed.

- ◆ **Scope of the Risk Evaluation** – The proposal would reject the Trump EPA's view that EPA can pick and choose among conditions of use to evaluate. Instead, EPA would have to evaluate all conditions of use, although some may receive more scrutiny than others in a "fit-for-purpose" risk evaluation. See proposed § 702.37(a)(4)-(5). This change could have the effect of increasing the application of preemption under § 18(a) of TSCA, where the extent of preemption of § 6 rules depends on the scope of the risk evaluation. It also could mean that all conditions of use other than those specifically listed for the WCPP would be banned – not just those listed in the scope document or the risk evaluation itself.
- ◆ **Timing for Draft Scope** – The 2017 rule provides that EPA will generally post a draft scope document within three months after initiating the risk evaluation process. The proposal would provide that EPA generally expects to publish the draft scope during the prioritization process concurrent with the publication of a proposed designation as a High-Priority Substance, but no later than three months after initiating the risk evaluation. See proposed § 702.37(a)(4). By starting earlier, EPA would be better able to make full use of its statutory period for conducting risk evaluations.
- ◆ **Exposures Through Air, Water, and Waste** – The Trump EPA risk evaluations generally left evaluation of exposure pathways in the air, water, and waste to other EPA offices. The Biden EPA has been adding evaluations of those pathways despite regulation by those offices. The proposal would require EPA to assess all exposure routes and pathways relevant to the chemical, "including those that are regulated under other federal statutes." See proposed § 702.39(d)(9). It would allow EPA to consider potential exposure-reducing regulations of other offices. EPA could also refer risk management to other offices – after making a risk determination under TSCA.
- ◆ **Aggregate and Cumulative** – The proposal would direct EPA to consider aggregate exposures, rather than just indicate whether aggregate exposure was considered, as provided in the 2017 rule. See proposed § 702.39(c)(8). The preamble indicates that EPA also plans to apply cumulative risk assessment techniques as appropriate.
- ◆ **Definitions** – The 2017 Trump EPA risk evaluation procedural rule included definitions of the statutory terms "best available science" and "weight of scientific evidence" in TSCA § 26(h) and (i). The proposal would delete those definitions out of concern that they could limit EPA as science changes in the future. Instead, EPA plans to rely on guidance, which is more easily updated. The 2017 definition of "potentially exposed or susceptible subpopulation" followed the statutory definition in TSCA § 3(12). The proposal would add to the list of examples of "overburdened communities," to take into account environmental justice considerations. It would also make minor changes to the definitions of "aggregate exposure" and "sentinel exposure." See proposed § 702.33.
- ◆ **Systematic Review** – The proposal would direct EPA to apply systematic review and/or systematic approaches in conducting risk evaluations. See proposed § 702.37(b)(2). The 2017 rule

referenced a systematic review in its definition of “weight of scientific evidence,” a definition that the proposal would delete.

- ◆ **Manufacturer-Requested Risk Evaluations** – Manufacturers requesting risk evaluations would have to identify all known conditions of use, not just those of interest to them. See proposed § 702.45(c)(4).

These proposed changes are not just for TSCA specialists – they could have real-world impacts on all affected industries. Comments are due December 14, 2023.

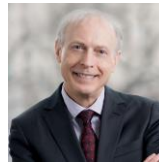
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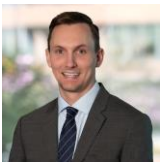
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