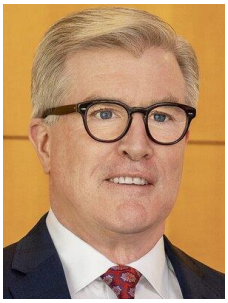
LAW360

Portfolio Media. Inc. | 230 Park Avenue, 7th Floor | New York, NY 10169 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

New TSCA Risk Rule Gives EPA Broad Discretion On Science

By **John McGahren and Debra Carfora** (May 30, 2024, 3:54 PM EDT)


John McGahren


Debra Carfora

On May 3, the U.S. Environmental Protection Agency released its final amendments to the procedural framework it uses to evaluate the health and environmental risks of chemical substances under the Toxic Substances Control Act, or TSCA.

The newly amended risk evaluation rule codifies certain policy considerations expanding the scope of risk evaluations, while leaving the EPA broad discretion in how it interprets and implements the science.

As required under Section 6(b)(4) of the 2016 TSCA amendments, the EPA promulgated a 2017 version of the risk evaluation rule that established the procedures the agency uses for collecting, assessing and integrating available scientific information on the hazards and exposures of active chemicals in commerce.

At the end of 2020 and the beginning of 2021, the EPA finalized the first 10 risk evaluations under the 2016 TSCA amendments and the 2017 implementing regulations.

But in June 2021, shortly after President Joe Biden took office, the agency withdrew the risk evaluations completed by the previous administration and announced a new path forward based on important policy changes. The May 3 version of the risk evaluation rule codifies these new policy initiatives.

The language used in the 2017 version of the rule left the EPA broad discretion in conducting risk evaluations, while including certain scientific definitions meant to clarify how the agency would implement the scientific criteria of the statute. The 2024 version of rule does the opposite: It codifies certain policy considerations for how the EPA conducts risk evaluations, while leaving the agency broad discretion in how it interprets and implements the science.

These changes are legally significant for two reasons: (1) They open the door for a single judicial decision that resolves the broader implementation policy debate in a vacuum — i.e., on the regulation's face instead of as applied in context; and (2) they endow the EPA with vast discretion regarding the consideration of important scientific and technical information without objective criteria to guide that discretion and ensure that the agency's decisions are not arbitrary.

For context, the 2016 TSCA amendments established a three-step process for the EPA to systematically review the safety of all chemicals in active commerce — a gargantuan task, considering that there are

more than 40,000 chemicals in this category.

First, the agency must prioritize individual chemicals as either low- or high-priority. A low-priority designation ends the process for a chemical, and is considered final agency action, subject to potential judicial challenges.

Second, high-priority chemicals move on to the risk evaluation phase, where the EPA has up to three and a half years to determine whether the chemical poses an unreasonable risk to human health or the environment. A finding that a chemical poses no unreasonable risk ends the process, and is considered final agency action, subject to potential judicial challenges.

Upon determination that a chemical poses unreasonable risks under any of its conditions of use, the EPA has up to an additional four years to complete the third and final step in the process: a risk management regulation to remove the identified risk. The risk management decision, including the risk evaluation and unreasonable risk determination supporting it, are considered final agency action, subject to potential judicial challenges.

Finding the right policy and regulatory balance for continuing to advance chemical innovation while protecting public health has fueled controversy over the EPA's existing chemicals TSCA program from the start. The problem is that an understanding of health outcomes from individual chemical exposures may not always match real-world exposures to multiple pollutants at different concentrations among susceptible populations.

Likely in anticipation of this controversy, there were two key bipartisan compromises built into the 2016 TSCA amendments. The first was use of the term "conditions of use," and the second was establishing mandatory scientific standards for making science-based decisions under the statute.

The May 3 amendments to the risk evaluation rule implicate both congressional compromises. Congress understood that because chemicals in commerce have multiple uses — manufacturing, industrial, commercial and consumer — there are some categories of use that pose greater potential for exposure than others, and the risks from certain categories of use could be negligible or already well controlled by other federal statutes.

Therefore, Congress included the statutory phrase "conditions of use" to assure that the EPA had the ability to focus on the circumstances of exposure to a chemical substance that raise the greatest potential for risk.[1] The phrase "conditions of use" is statutorily defined as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

The 2017 risk evaluation rule codified a procedure that allowed the EPA to exercise discretion in making sound scoping decisions as to which conditions of use it will address in the risk evaluation, and to issue individual risk determinations based on any one condition of use or under any combination of uses. In 2017, the agency believed that the reasonable exercise of this discretion would allow it to focus its analytical efforts on conditions of use that raise the greatest potential for risk within the TSCA's strict deadlines.

The 2024 risk evaluation rule explicitly requires that the EPA assess all conditions of use together in a single risk determination for the chemical substance being evaluated. This amendment sets the stage for potential challenges to the agency's controversial interpretation of Congress' instruction to determine

whether a chemical substance presents an unreasonable risk under its conditions of use.

In 2016, Congress was also concerned with eliminating the possibility of predetermined political outcomes through the manipulation of scientific information and underlying data. To promote fair and objective decision making based on open and transparent science, Congress added certain scientific standard provisions to the TSCA.[2]

The 2017 risk evaluation rule codified definitions for key scientific terms, including "best available science" and "weight of the scientific evidence," among others, to instill confidence, increase transparency and provide the public with assurance that the EPA would meet those congressional objectives.

But the 2024 risk evaluation rule eliminates the scientific definitions, and codifies other changes that appear to weaken the scientific protections build into the 2016 TSCA amendments, by expanding its flexibility in science-based analytical approaches.

For example, the 2024 risk evaluation rule:

- Requires that risk evaluations do not exclude any conditions of use or exposure pathways, including those that are regulated under other federal statutes;
- Requires that risk evaluations consider cumulative risk, including an explicit requirement to consider overburdened communities;
- Requires that risk evaluations will always culminate in a single risk determination; and
- Includes new regulatory text that the EPA will not consider exposure reduction based on assumed use of personal protective equipment.

Simultaneously, the 2024 risk evaluation rule eliminates the codified definitions of "best available science" and "weight of scientific evidence" — instead relying on outdated agency guidance documents to guide its scientific evidence analyses — and allows the EPA to consider the costs and time considerations that would result from submitting risk evaluations for peer review.

While there is no doubt that the 2024 risk evaluation rule will face judicial review, it should not be overlooked as perhaps the most significant regulatory action since the 2016 statutory amendments. This is because the new rule will finally and definitively resolve the implementation policy debates raised by the 2017 version of the rule — which would not have otherwise been resolved until those policies were applied in context of a "no unreasonable risk" finding or an ultimate risk management rule (see step 3 discussed above).

Indeed, the timing of the amended risk evaluation rule is likely not a coincidence. In March, the EPA released the first risk management rule since the 2016 TSCA amendments, banning ongoing uses of chrysotile asbestos. In April, the agency finalized prohibitions and workplace protections for methylene chloride.

Additionally, final risk management rules for perchloroethylene, trichloroethylene, carbon tetrachloride and N-methylpyrrolidone are all expected to be released this year. While industry is focused on technical review of the science underlying these rules, it must not lose sight of the statutory interpretation questions at the heart of the underlying policy approaches to the underlying risk

evaluations that support these risk management rules.

The timing of a challenge to the amended risk evaluation rule will also likely align with the U.S. Supreme Court's reconsideration of a key administrative law doctrine from its 1984 decision in Chevron v. National Resources Defense Council.[3] Chevron has required courts to defer to agencies' interpretations of statutes that confer them authority, if that statute leaves a gap between its goals and the specifics necessary for implementation.

The current challenges to Chevron in Loper Bright Enterprises v. Raimondo[4] and Relentless v. U.S. Department of Commerce[5] come on the heels of recent Supreme Court decisions recognizing the major questions doctrine. Should the court limit the scope of Chevron deference, these decisions together would send a strong signal that the courts are required to serve as a check on expansive interpretations of agency authority.

While Chevron and the major questions doctrine focus on the limits to the EPA's interpretations of statutes, they do not directly address the deference owed to an agency's interpretation of its own regulations. Furthermore, highly technical and complex scientific assessments — like the TSCA risk evaluations that underlie the ultimate risk management rules — are the types of decisions courts have historically hesitated to interfere with.

Thus, there is significant strategic value in attacking the EPA's procedural and policy interpretations of the TSCA through a challenge to the amended risk evaluation rule on the heels of the Supreme Court's decision shifting power away from the EPA.

Any person or corporation may file a petition for review of the amended risk evaluation rule within 60 days of the date on which a rule is promulgated — which would be July 2, in this case. Under the TSCA, the petition must be filed directly in a federal court of appeals — either the U.S. Court of Appeals for the D.C. Circuit, or the court of appeals for the federal circuit in which the petitioner resides or has its principal place of business.

John McGahren is a partner, the Princeton litigation practice leader and the deputy chair of the global environmental practice at Morgan Lewis & Bockius LLP.

Debra Carfora is an associate at the firm.

[1] See 162 Cong. Rec. S3511-01 (daily ed. June 7, 2016) at S3519.

[2] See 162 Cong. Rec. S3511-01 (daily ed. June 7, 2016) at S3522.

[3] Chevron U.S.A. Inc. v. Natural Resources Defense Council Inc., 467 U.S. 837 (1984).

[4] Loper Bright Enterprises Inc. v. Raimondo, 143 S.Ct. 2635 (2023).

[5] Relentless Inc. v. Dep't of Com., 144 S. Ct. 325, 217 L. Ed. 2d 154 (2023).