

ALERT

EPA Overhauls Rules for Evaluating Existing Chemical Risks: Three Key Takeaways for Downstream Users

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Only six months after proposing to amend the procedures for risk evaluations under the Toxic Substances Control Act (TSCA), the final rule was published in the Federal Register on May 3, 2024. A flurry of activity will soon follow on many reviews that were put on hold while the U.S. Environmental Protection Agency (EPA or Agency) made fundamental shifts in direction on how these evaluations will be conducted in the years to come.

There is plenty to digest in this rule, and Wiley will host a webinar on May 16 to discuss the changes in a comprehensive and thorough way. In the meantime, below are three key takeaways for companies to be thinking about if you process or use one or more existing chemicals for which TSCA risk evaluations are planned or are underway. For a full list of the chemicals under scrutiny, [click here](#).

Takeaway #1. Too many companies remain unaware of how comprehensive these reviews are and do not appreciate the power EPA has to regulate, including prohibiting, most uses of the chemical or banning the chemical altogether. This makes it vitally important to provide EPA with information on how the chemicals are used. The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or non-risk factors, including unreasonable risk to potentially exposed or susceptible subpopulations, identified as relevant to the risk evaluation by EPA, under the conditions of use. Many companies may not be aware of how important it is to provide EPA with information on how the chemicals are used. EPA is codifying in the regulations that these risk

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evaluations must include all conditions of use. This requirement leaves no room for discretion. EPA also can apply this approach to categories of chemical substances. While the Agency is finalizing the questionable assumption that no workplace exposure protections will be assumed, the final rule now signals that this door has opened just a crack – the Agency states that it is “committed” to considering exposure information supplied by industry during the risk evaluation. Therefore, it is incumbent on downstream users to avail themselves of that opportunity, which may be the primary and only means of avoiding an unreasonable risk determination for your use of the chemical under review.

Takeaway #2. Risk communication breakdowns for chemicals under review can close markets short of a ban, or at least result in mounting pressure to deselect these ingredients in products. EPA is proposing that risk evaluations will always culminate in a single risk determination on the “chemical substance” instead of individual risk determinations on individual conditions of use. The burden is now almost entirely on industry to provide EPA with the information necessary to distinguish which conditions of use contribute to an unreasonable risk determination and those that do not. EPA is committing to improving communications on conditions of use, but the Agency’s ability to do so is largely dependent on having accurate information on which to base their public communications.

Takeaway #3. EPA decided, as noted in the proposed rule, to remove key definitions that serve as guardrails for objective reviews, those for best available science and weight of the evidence. The silver lining here is that both of these science-based concepts nevertheless remain firmly embedded in the statute itself. The final rule works in the requirement for EPA to follow the statutory elements of best available science for each risk evaluation, as well as explain how the Agency has used a weight of the evidence approach. EPA intends to ensure that its risk evaluations are consistent with EPA’s guidance and methodologies in applying these terms.

These and other changes will be applied to all risk evaluations initiated on or after the date of the final rule. For risk evaluations in process as of the date of the final rule, EPA would expect to apply the proposed changes to those risk evaluations only to the extent practicable, taking into consideration the statutory requirements and deadlines. The avant-garde artist Andy Warhol remarked, “They always say time changes things, but you actually have to change them yourself.” If no other lesson emerges for industry from this rulemaking, let this be it.