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ALERT

Risk Evaluation of Existing Chemicals Under the Toxic Substances Control Act

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On July 20, 2017, the U.S. Environmental Protection Agency (EPA) published the final rule establishing the process for conducting risk evaluations under the Toxic Substances Control Act (TSCA).

EPA also released the following actions (click for summaries):

· Prioritization of Existing Chemicals Under the Toxic Substances Control Act

· Inventory Reset Under the Toxic Substances Control Act

· Scoping Released for First 10 Chemicals to Undergo New Risk Evaluation Process

EPA will immediately take up the first ten "high-priority" chemical substances selected in December 2016 for risk evaluation. Chemical substances for which EPA initiates a risk evaluation in response to manufacturer requests also will proceed directly to risk evaluation. EPA also must identify at least an additional 10 chemicals as "high-priority" by the close of 2019. Any other chemicals EPA selects from the 2014 Work Plan or for other reasons designated as High Priority based on the criteria and procedures explained in the prioritization rule will subsequently move into the risk evaluation program.

The overarching objective of this new process is for EPA to determine whether a condition of use of a chemical substance presents an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation. Given the very strong program emphasis on how these chemicals are currently being used in products, we expect processors and downstream users of these chemicals to be more

Authors

Martha E. Marrapese
Partner
202.719.7156
mmarrapese@wiley.law

Practice Areas

Environment & Product Regulation
Toxic Substances Control Act (TSCA)

affected by TSCA than ever before.

Highlights of the final rule include new definitions for key science terms, a more robust program for accepting manufacturer nominations, and greater flexibility to consider and reach early decisions on conditions of use. The following summary discusses this and other changes in the final rule.

Overview

TSCA Section 6(b)(4)(D) identifies the minimum components that EPA must include in all chemical substance risk evaluations. A final high priority designation moves the chemical substance immediately into the risk evaluation process, which must be completed in 3.5 years.

The first thing EPA will do is publish is a draft scoping document for public comment that will include the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. The scope document must be published within 6 months of the initiation of the risk evaluation. For more information on the draft scope documents EPA has published for the first 10 chemicals identified for risk evaluation, click here. EPA has, by rule, adopted a requirement that the draft scope documents will be subject to a 45-day public comment period prior to the publication of the final document. Next, EPA will proceed to conduct a hazard assessment, exposure assessment, and a risk characterization, and ultimately make a risk determination.

Risk evaluation is guaranteed to be a complex undertaking, and EPA has issued guidance to help manufacturers develop and submit their own draft risk evaluations. Click here for a copy of this guidance. TSCA Section 6(b)(4)(F) requires each risk evaluation to be developed in such as way so as to integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance, and describe the weight of the scientific evidence for the identified hazard and exposure. Non-risk factors will not be considered until the risk management phase of EPA's process. EPA must describe the weight of scientific evidence for the identified hazards and exposure. Peer review will be part of each risk evaluation at the end of the process. EPA will provide a 30-day public comment period for each draft risk evaluation prior to publishing a final risk evaluation.

Chemicals that manufacturers ask EPA to review may form 25-50 percent of the agency's high priority substance evaluation workload. Requests to review 2014 Work Plan chemicals are not counted toward this minimum workload level.

EPA intends to initiate risk evaluation on a chemical substance only when EPA determines that sufficient reasonably available information exists to complete the evaluation, and when it has already identified all of the conditions of use. Manufacturers will need to include a list of the reasonably available information on hazard and exposure for all the conditions of use in their submissions, and all data must be in the possession of the requestor. Up front substantiation of CBI claims will be required. The agency will automatically grant

any manufacturer's request that complies with its criteria until the statutory minimum of 25% is met. EPA retains discretion after that to decide whether to grant requests for adding non-Work Plan chemicals to its workload. When a manufacturer request is received, it will be published for a 30-day public comment period. EPA will grant or deny the request with nine months afterward and industry will have 60 days to supplement requests that are initially denied for reconsideration. EPA must give preference to requests where restrictions have been imposed by one or more states that have the potential to significantly impact interstate commerce. EPA also will give preference to requests with relatively high exposures and hazards under the conditions of use.

The definitions in the rule did not change for science-based terms such as 'potentially exposed or susceptible subpopulation', 'aggregate exposure', and 'sentinel exposure'. EPA's description of how it will conduct a weight of the evidence analysis also is largely unchanged from what was proposed. EPA states that all data considered will need to be documented and scientifically acceptable. The process will be for EPA to assemble the data, evaluate those data against current acceptance and quality criteria, and present the conclusions regarding the results for each study. In general, EPA will examine multiple lines of evidence considering a number of factors, including for example the nature of the effects within and across studies, including number, type, and severity/magnitude of effects and strengths and limitations of the information.

EPA believes it is required to ensure that risk evaluations encompass all known, intended, and reasonably foreseen activities associated with the chemical substance. EPA states that it interprets this requirement to be threshold-based and future looking. This means that, on a case-by-case basis, some activities may not constitute a "condition of use" appropriate for further evaluation such as intentional misuse, discontinued legacy uses, legacy disposal, *de minimis* exposures, and uses already adequately regulated by EPA or another agency. Although the agency acknowledged that different readings of the law may be possible at the proposal stage, the final rule indicates that EPA will "lock down" the conditions of use in the scoping phase to focus the agency's efforts on the conditions of use that raise the greatest potential for risk in the future. That narrowing will carry through to completion of the risk evaluation except in exceptional cases where the agency might act sooner on specific conditions of use.

Key Takeaways

Any company who manufactures, processes or uses a 2014 EPA Work Plan listed chemical is affected, since at least 50 percent of the high priority chemicals EPA selects for risk evaluation at any one time have to be drawn from the Work Plan until the list is exhausted. It is not yet clear to what extent these chemicals remain in commercial use or the degree to which they are used in consumer products. Certainly EPA had reason to think their use was sufficiently prevalent in commerce at the time they were originally selected. In other words, this process has the potential for very significant commercial disruption. Presumably, the process will provide companies with an early indication of the agency's concerns, together with some lead time in which to respond before risk management rules would go into effect. Affected companies should engage in strategic planning now that these rules are out to manage the potential for future commercial impacts.

EPA's comprehensive review of conditions of use is a fundamental shift away from the manner in which chemicals have been reviewed in the past. Congress rewrote section 6 of the new TSCA so as to consistently ground the EPA's review of existing chemicals based on their use. TSCA defines the term "conditions of use" to mean 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 agency is interpreting the amended law to require a a comprehensive rather than selective approach to chemical substance management. Arguably, EPA clearly retains some discretion in determining those conditions of use; nevertheless, EPA considers that it would be an abuse of that discretion to disregard known, intended, or reasonably foreseen uses in its analyses.

In many cases, the way in which an existing chemical is made, processed, distributed and used is well-established. Existing chemicals are less likely to be able to compete with newer, improved chemistries when substitutes are needed. Existing work practices also will be well defined, and will include a hierarchy of engineering controls, work practices, and the use of personal protective equipment. Given the well-established uses and handling practices associated with existing chemicals, the basis on which EPA will find an intended or reasonably foreseen use, one that is not a current use of a chemical with an established market, is uncertain. EPA has said that it does not intend to review legacy uses that are no longer allowed for a chemical, such as the demolition of existing structures containing asbestos. In addition, the disposal and reclaiming of chemicals is regulated separately by EPA under the Resource Conservation and Recovery Act (RCRA). Some uses of a chemical may not be regulated by TSCA, such as use in pesticides, drugs, cosmetics, food, or food packaging. However, EPA could argue that it needs to identify all uses of a chemical, including non-TSCA uses, during the prioritization stage for planning purposes, particularly if an aggregate risk evaluation approach is selected. EPA currently has no aggregate risk assessment methodology in place. Based on our experience with this kind of assessment under the pesticide laws, EPA will need to seek scientific input to develop such a process.

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