SQUIRE PATTON BOGGS

Environmental, Safety & Health
US EPA Issues TSCA Risk Evaluation Rule

Overview

On June 22, 2017, the US Environmental Protection Agency (US EPA) issued its rule outlining the process by which it will conduct risk evaluations on chemical substances under the amended Toxic Substances Control Act (TSCA), to determine whether the substances present an unreasonable risk of injury to health or the environment under the conditions of use. The rule was published in the Federal Register on July 20, 2017.

The rule identifies the steps in US EPA's risk evaluation process, including the scope of the risk evaluation, hazard assessment, exposure assessment, risk characterization and risk determination. US EPA will use this process for (1) the first 10 chemical substances that it selected for risk evaluation from its Work Plan chemicals list last November (as required by the amended TSCA); (2) substances designated as high-priority substances during the prioritization process; and (3) substances for which US EPA initiates a risk evaluation in response to manufacturer requests.

US EPA is required to complete a risk evaluation within three years, with the possibility of extending the timeline by six months for certain reasons. Rather than examining "all" conditions of use for a substance, US EPA intends to conduct the risk evaluation on the conditions of use "that raise the greatest potential for risk" as identified in the scoping document, which the agency will develop at the outset of the risk evaluation process. The rule states, however, that US EPA may conduct a risk evaluation in phases and make risk determinations on one or more conditions of use while other conditions of use remain under evaluation. If US EPA conducts a risk evaluation in phases, the agency will complete the full risk evaluation on all the conditions of use identified in the scope within the time frame provided in the amended TSCA.

Each risk evaluation must: (1) integrate and assess available information on hazards and exposure for the conditions of use of the chemical substance, including information on specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposure.

The rule incorporates TSCA's statutory science requirements, including best available science and weight of the scientific evidence.

Unreasonable Risk

TSCA does not define "unreasonable risk" and the rule does not either. The preamble to the rule notes, however, that US EPA may weigh a variety of factors in determining whether a substance presents an unreasonable risk, including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; and the population exposed (including any susceptible populations), the severity of hazard, the nature of the hazard, the irreversibility of hazard, and uncertainties.

Conditions of Use

US EPA will examine the conditions of use for a substance "that raise the greatest potential for risk," rather than assessing "all" conditions of use. The preamble to the rule states US EPA will use its discretion to identify the conditions of use and that the agency "may, on a case-by-case basis, exclude certain activities … in order to focus its analytical efforts on those exposures that are likely to present the greatest concern."

US EPA will identify any conditions of use excluded in the draft scoping document. The final scoping document will specify the conditions of use that US EPA expects to consider in the risk evaluation and will also identify whether particular conditions of use have been excluded. The preamble to the rule states that, as a general matter, US EPA will not evaluate intentional misuses of a substance, as well as "associated disposal" and "legacy disposal" that is not related to the ongoing or prospective manufacturing, processing or distribution of the substance.

As noted, because of the possible need to address a particular condition of use expeditiously (such as when a single use presents an unreasonable risk to the population as a whole or to a specific subpopulation), the rule states that US EPA may complete risk evaluations in phases and make risk determinations on individual conditions of use or categories of conditions of use at any time once the final scoping document is published.

The preamble to the rule also states that US EPA may consider potential risk from non-risk TSCA uses in evaluating whether a chemical substance presents an unreasonable risk, although the uses would not be within the scope of the risk evaluation. The preamble explains that the potential risks of non-TSCA uses "may help inform US EPA's risk determination for the exposures from uses that are covered under TSCA," for example, "as background exposures that would be accounted for" if US EPA decides to evaluate aggregate exposures for a substance.

Potentially Exposed or Susceptible Subpopulations

The amended TSCA requires US EPA to evaluate the risks that a chemical substance may present to a "potentially exposed or susceptible subpopulation." The statute defines this term as "a group of individuals within the general population identified by [US EPA] who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers or the elderly." The rule incorporates this statutory definition without change.

Aggregate and Sentinel Exposure

The amended TSCA requires US EPA to document whether it has considered aggregate or sentinel exposure in a risk evaluation but does not define those terms. The rule defines "aggregate exposure" as "the combined exposures to an individual across multiple routes and across multiple pathways." (The rule defines "pathways" as "the mode through which one is exposed to a chemical substance, including but not limited to: food, water, soil and air.") The rule also defines "sentinel" exposure as "the exposure to a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures."

Categories of Chemical Substances

The rule states that the agency has the authority to conduct risk evaluations on categories of chemical substances in addition to risk evaluations on individual substances.

Information Collection

The rule states that US EPA "generally expects" to initiate a risk evaluation when the agency believes that "all or most of the information necessary to perform the risk evaluation already exists and is reasonably available." US EPA expects to use its "authorities under TSCA and other information gathering authorities" to obtain the information needed to perform a risk evaluation before initiating the risk evaluation. The preamble to the rule adds that "there may be circumstances where additional information may need to be developed within the time frames of the risk evaluation process" and states that US EPA may use its authorities to obtain or require the generation of additional information even after the risk evaluation has been initiation. The preamble further states that US EPA also will require longer-term testing to address data gaps.

For identified data needs, US EPA "may" issue a voluntary call to the public for relevant information or otherwise engage directly with stakeholders, followed by using its TSCA information collection, testing and subpoena authorities to require submission or generation of new data "as appropriate."

The Risk Evaluation Process

US EPA is proposing a risk evaluation process that consists of seven aspects: (1) scope; (2) hazard assessment; (3) exposure assessment; (4) risk characterization; (5) peer review; (6) unreasonable risk determination; and (7) additional publicly available information.

1. Scope

The amended TSCA requires US EPA to define the scope of the risk evaluation no later than six months after initiating the risk evaluation. Although not required by the amended TSCA, the rule states that US EPA will provide a draft scope for a 45-day public comment period during this six-month time frame.

The scope will identify the conditions of use, hazards, exposures and any potentially exposed or susceptible subpopulations that the agency expects to consider in the risk evaluation. The scope will also include additional information, such as models, screening methods and any accepted science policies, expected to be used during the risk evaluation, along with a conceptual model that will describe the "actual or predicted relationships between the chemical substance and the receptors, either human or environmental." The scope will further include an "analysis plan" that will identify the approaches and methods the US EPA plans to use to assess exposure, effects and risk.

2. Hazard Assessment

The hazard assessment will identify the types of adverse health or environmental effects that can be caused by exposure to the chemical substance in question. For human health hazards, the assessment will consider all potentially exposed or susceptible subpopulation(s) identified in the scope. US EPA will use an "appropriate combination" of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing health effects to the population and "any other information or methodology consistent with scientific standards." An environmental hazard assessment will evaluate the relationship between the chemical substance and the occurrence of an ecological response and "may be conducted using reasonably available information from field or laboratory data, modeling strategies, and species extrapolations, if needed." The rule commits US EPA to using the best available science and a weight of the evidence approach.

3. Exposure Assessment

As required by the amended TSCA, the exposure assessment will take into account the likely duration, intensity, frequency and number of exposures under the conditions of use. For human health exposure, the assessment will consider all potentially exposed or susceptible subpopulation(s) identified in the scope and utilize any combination, as available, of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing exposures to the population, measurements in human tissues or relevant environmental or exposure media and any other relevant, scientifically valid information or methodology. An environmental health exposure assessment, will characterize and evaluate the interaction of the chemical substance with any ecological characteristics identified in the scope. Exposure information will be reviewed in a manner consistent with best available science and weight of the evidence.

4. Risk Characterization

The rule states that the risk characterization "will integrate the hazard and exposure assessments into quantitative and/or qualitative estimates of risk for the identified populations (including

any potentially exposed or susceptible subpopulation(s)) identified in the final scope and ecological characteristics for the conditions of use within the scope." It will also describe whether aggregate or sentinel exposures were considered; take into account the likely duration, intensity, frequency and number of exposures under the condition(s) of use; and describe the weight of the scientific evidence for the identified hazards and exposures. As required under the amended TSCA, the risk characterization cannot consider costs or other nonrisk factors.

5. Peer Review

US EPA will conduct peer reviews on each risk evaluation and will take public comment on the charge questions given to peer reviewers. However, US EPA will not seek peer review of the actual risk determination (i.e., US EPA's conclusion regarding whether a given risk is unreasonable). The plan for peer review will be set forth in the scoping document for the risk evaluation.

6. Unreasonable Risk Determination

In the final step of the risk evaluation, US EPA will determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment. US EPA will make individual risk determinations for all uses identified in the scope. As US EPA may make early determinations on one or more conditions of use, risk determinations may be published in multiple documents or in a single document containing all risk determinations for all identified uses. If the determinations are published in multiple documents, the final determination will be a composite document of all determinations made. US EPA will specify whether each condition of use identified for a chemical substance does or does not present an unreasonable risk of injury.

A determination that a condition of use does not present an unreasonable risk is a final agency action and is subject to judicial review. A determination that a condition of use presents an unreasonable risk is not a final action and is not subject to judicial review. This is because when it concludes that a risk is unreasonable, the agency must initiate a rulemaking under TSCA section 6 to address the risk. Because any rule would apply only to the condition(s) of use that present an unreasonable risk, any other identified conditions of use will not be subject to risk management. In the draft and final risk evaluation documents, US EPA will clarify specifically which condition(s) of use warrant risk management and which do not.

7. Additional Publically Available Information

US EPA will make publicly available (1) the draft scope; (2) all notices, determinations, findings, consent agreements and orders; (3) any information required to be provided by section 4 of TSCA; (4) a nontechnical summary of the risk evaluation; (5) a list of the studies considered in carrying out the risk evaluation; (6) each determination as to whether the chemical substance presents an unreasonable risk under one or more conditions of use, along with an identification of the information, analysis and basis used to make the determination; (7) the final peer review report, including the agency's response to peer review comments; and (8) the response to comments received on the draft scope and draft risk evaluation.

Manufacturer Requested Risk Evaluations

The amended TSCA allows a manufacturer or group of manufacturers to submit requests for US EPA to conduct risk evaluations on chemical substances that they manufacture (including import). Manufacturers may request that US EPA conduct a risk evaluation on only the conditions of use "that are of interest to the manufacturer." However, even if a manufacturer (or group of manufacturers) requests that the risk evaluation be based on a just a subset of the conditions of use, the rule states that US EPA may include additional conditions of use in the risk evaluation. US EPA will determine the additional conditions of use during the process of deciding whether to grant or deny the manufacturer request.

As part of the request, a manufacturer (or group of manufacturers) must submit "all of the information necessary to complete risk evaluation for the requested conditions of use." The information includes, at a minimum, all known names of the chemical substance, chemical identity, CAS number and molecular structure.

US EPA will give preference to manufacturer requests that demonstrate that restrictions imposed by one or more states have the potential to have a significant impact on interstate commerce, health or the environment, followed by a preference based on the order in which a request is received. These preferences, however, are versus other manufacturer requests. The amended TSCA prohibits US EPA from giving manufacturer-requested risk evaluations priority over other risk evaluations.

US EPA plans to take public comment on a manufacturer request for "at least 45 days." The agency anticipates that roughly 195 days will be needed from the time that it receives a manufacturer request to the time that it actually initiates the risk evaluation, if US EPA grants the request. This time period includes: (1) public notification of the request within 15 days of receipt; (2) publication of the request in the Federal Register within 60 days after receipt of the request ; (3) opening a docket to facilitate the public comment period of at least 45 days; (4) issuance of the decision to grant or deny the request within 60 days of the end of the comment period; and (5) a 30-day period after US EPA notifies the manufacturer of its decision within which the requester may withdraw the request. If the request is not withdrawn, US EPA will initiate the risk evaluation.

The rule provides that a requester may resubmit any denied request for a risk evaluation.

Next Steps

For more information on the proposed risk evaluation rule or any other aspect of TSCA, please contact one of the individuals listed in this publication.

Contacts

Stephen A. Owens
Partner
T +1 602 528 4170
T +1 202 626 6270
E steve.owens@squirepb.com

Allen A. Kacenjar Jr.
Partner
T +1 216 479 8296
E allen.kacenjar@squirepb.com

W. Caffey Norman
Partner
T +1 202 457 5270
E caffey.norman@squirepb.com

Karen A. Winters
Environmental, Safety & Health Practice Group Leader
T +1 614 365 2750
E karen.winters@squirepb.com