

The US Environmental Protection Agency (US EPA) has issued its proposed rule outlining the process by which it will conduct risk evaluations on chemical substances under the recently 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 proposed rule was published in the Federal Register on January 19, 2017. Comments on the proposed rule must be submitted to US EPA by March 20, 2017. The amended TSCA requires US EPA to promulgate the final risk evaluation rule by June 22, 2017.

The proposed 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 is proposing to use this process for 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), substances designated as high-priority substances during the prioritization process and 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. US EPA intends to conduct the risk evaluation on all conditions of use of a substance identified in the scoping document within this time, but US EPA's proposal states that the agency may conduct a risk evaluation in phases "to allow the Agency to proceed with risk management" 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.

## Unreasonable Risk

TSCA does not define "unreasonable risk," and the proposed rule notes that US EPA may weigh a variety of factors in determining whether a substance presents an unreasonable risk, including (but not limited to) characterization of cancer and non-cancer risks, the population exposed (including any susceptible subpopulations), the severity of hazard, the irreversibility of hazard, uncertainties and estimates of cumulative exposures. The proposed rule states that US EPA has not proposed a definition of unreasonable risk because of the case-by-case nature of these factors, but the agency is requesting comments on whether it should define unreasonable risk in the final rule.

## Scope and Conditions of Use

The proposed rule states that US EPA intends to interpret the conditions of use for a chemical substance for purposes of risk evaluation as meaning all conditions of use, rather than a subset of uses or a single use. US EPA intends to "lock down" the conditions of use included in a risk evaluation at the time of scoping and will provide an opportunity for public comment on the scoping document to ensure that all uses are addressed. The proposal emphasizes, however, that any objections to the draft scope document will be waived if they are not raised during this comment period and stakeholders will be precluded from identifying additional uses later in the process (such as when commenting on the proposed risk determination).

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 proposed rule "explicitly recognizes" US EPA's authority to complete risk evaluations in phases and manage unreasonable risks as they are identified in those phases.

## 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 [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."

US EPA is proposing to incorporate the phrase "including but not limited to" before the specific subpopulations identified in the statute to make clear that the agency may identify additional subpopulations where warranted. US EPA is also proposing to include "specific authorization" in the rule for the agency "to consider both intrinsic (e.g., life stage, reproductive status, age, gender, genetic traits) and acquired (e.g., pre-existing disease, geography, socioeconomic, cultural, workplace) factors" when identifying a subpopulation.

## 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 agency is proposing to define “aggregate exposure” as “the combined exposures to an individual across multiple routes and across multiple pathways.” (US EPA is proposing to define “pathways” as “the mode through which one is exposed to a chemical substance, including but not limited to: food, water, soil and air.”) US EPA is also proposing to define “sentinel” exposure as “the exposure(s) of greatest significance, which may be the maximum exposure to an individual, population (or subpopulation) or the environment to the chemical substance of interest (or any combination thereof).”

## Categories of Chemical Substances

US EPA's proposal states that the agency has authority to conduct risk evaluations on categories of chemical substances in addition to risk evaluations on individual substances.

## Information Collection

US EPA's proposal states that the agency generally expects to initiate a risk evaluation only 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 will exercise its TSCA information collection, testing and subpoena authorities “when necessary to generate the information needed to perform a risk evaluation for a chemical substance before initiating the risk evaluation.” The proposal notes that US EPA will also look to collect information pursuant to TSCA section 8(e), which requires any person who manufactures (including import), processes or distributes a chemical substance to immediately provide to US EPA any information it obtains that supports the conclusion that the substance presents a substantial risk of injury to health or the environment.

## The Risk Evaluation Process

US EPA is proposing a risk evaluation process that consists of eight aspects: (1) scope; (2) hazard assessment; (3) exposure assessment; (4) risk characterization; (5) peer review; (6) unreasonable risk determination; (7) additional publicly available information; and (8) reassessment of unreasonable risk determination.

### 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, US EPA is proposing to provide a draft scope for a 45-day public comment period during this six month time frame. US EPA's proposal states that all comments that could be raised on information and approaches presented in the scope must be presented during this comment period. As noted, the proposal emphasizes that any issues related to scope not raised in comments at this time cannot form the basis for an objection or challenge in a future administrative or judicial proceeding.

According to US EPA's proposal, 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. US EPA is also proposing to 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 exposures to “some agent in question.” US EPA's proposal states that the assessment may include, but may not be limited to, evaluation of the potential toxicity of the chemical substance with respect to cancer, mutation, reproductive, developmental, respiratory, immune, metabolic and cardiovascular impacts and neurological impairments. For human health hazards, the assessment will consider all potentially exposed or susceptible subpopulations identified in the scope and will use, if available, “population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing health effects to the population and any other relevant, scientifically valid information or methodology.” For environmental hazards, the assessment will evaluate the relationship between the chemical substance and the occurrence of an ecological response using field or laboratory data, modeling strategies and species extrapolations.

### 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. US EPA's proposal states that for human health exposure, the assessment will consider all potentially exposed or susceptible subpopulations identified in the scope and utilize, as available, “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.” For an environmental health exposure assessment, US EPA will characterize and evaluate “the interaction of the chemical substance with any ecological characteristics in the scope.”

### 4. Risk Characterization

US EPA's proposal states that the risk characterization of a chemical substance will consist of the “individual components” of the hazard and exposure assessments, “plus an integrative analysis.” The proposal states that the risk characterization will also “determine whether aggregate or sentinel exposures were considered and provide the evidence and information to support the consideration.”

## 5. Peer Review

US EPA's proposal states that US EPA will conduct peer reviews on each risk evaluation using the guidance provided in executive branch peer review directives that are included in the OMB Bulletin for Peer Review and US EPA's Peer Review Handbook. US EPA will identify "aspects of the analysis" on which peer review will be conducted, as well as any "novel" models or analyses "that warrant an in-depth peer review." The proposal also states that "the entire risk assessment" will undergo peer review. The proposal emphasizes, however, that US EPA will not seek review of any determination as to whether the risk are unreasonable, which the proposal calls "an agency policy judgment."

Additionally, the proposal states that US EPA will ensure that all supporting analyses and components of the risk evaluation are "fit for purpose" and "well-tailored to the problems and decisions at hand."

## 6. Unreasonable Risk Determination

The proposal states that US EPA will announce the availability of the draft risk assessment in the Federal Register and will seek public comment on the draft, although the proposal does not say how long the comment period will be. The draft will indicate US EPA's initial determination whether the chemical substance does or does not present an unreasonable risk of injury to health or the environment under the conditions of use. The proposal states that all comments that could be raised on components of the draft risk evaluation must be presented during the comment period. Any issues not raised during this time will be considered to have been waived and may not form the basis or an objection or challenge in any subsequent administrative or judicial proceeding. The proposal notes that an eventual final determination by US EPA that a chemical substance does not present an unreasonable risk will be issued by order. This determination is considered a final agency action subject to judicial review, as provided by the amended TSCA.

## 7. Additional Publicly Available Information

The proposal states that, as required by the amended TSCA, US EPA will make available (1) all notices, determinations, findings, consent agreements and orders; (2) any information required to be provided by Section 4 of TSCA; (3) a nontechnical summary of the risk evaluation; (4) a list of the studies, considered in carrying out the risk evaluation; and (5) the final peer review report, including the agency's response to peer review comments.

## 8. Reassessment of Unreasonable Risk

US EPA's proposal states that the agency may reassess a final unreasonable risk determination "at any time" based on information "available" to it.

## Manufacturer Requested Risk Evaluations

The amended TSCA allows a manufacturer or group of manufacturers to submit requests or US EPA to conduct risk evaluations on chemical substances that they manufacture (including import). As part of the request, US EPA is proposing to require that a manufacturer (or group of manufacturers) must submit "full information" on the chemical identity of the chemical substance that is the subject of the request.

The proposal states that the information includes, at a minimum, "all known names of the chemical substance, including common or trade names, chemical identity, CAS number and molecular structure."

US EPA is proposing to require that such manufacturers demonstrate in their request "that there is sufficient, reasonably available information for the agency to conduct a risk evaluation on the chemical substance under the conditions of use." Manufacturers would have to submit a list of the reasonably available information on hazard and exposure for all the conditions of use and explain "why such information is adequate" to enable US EPA to conduct the risk evaluation. Manufacturers would also have to include a commitment to provide US EPA any referenced data if the data is not publicly available and certify that the information submitted is accurate and complete. US EPA will not accept a manufacturer request if any of the relevant data is not in the possession of the requestor.

US EPA's proposal underscores that "the burden is on the requester to include all information that is necessary" for the agency to conduct a risk evaluation. The proposal further states that US EPA "intends to deny requests for risk evaluation if the requester does not have access to the information necessary for risk evaluation."

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, as well as requests where US EPA has determined that there are relatively high estimates of hazard and/or exposure for the substance. This preference, however, is versus other manufacturer requests. The amended TSCA prohibits US EPA from giving manufacturer-requested risk evaluations priority over other risk evaluations.

US EPA is proposing to take comments for at least 30 days on a manufacturer request for a risk evaluation to allow the public to identify and/or submit any reasonably available information regarding hazard, exposure, potentially exposed populations and subpopulations and conditions of use that may help inform a risk evaluation, including information gaps. The requesting manufacturer could also submit any additional information during the comment period.

US EPA's proposal states that within nine months after the end of the comment period, US EPA will review the request along with any additional information received during the comment period to determine whether the request meets the regulatory criteria and will notify the requesting manufacturer of the agency's determination. The proposal states that this time will allow US EPA to develop the "equivalent of a conceptual model to describe actual or predicted relationships between the chemical substance and the receptors, either human or environmental, with consideration of potential hazards throughout the life cycle of the chemical substance." If US EPA determines that the request is "insufficient," the agency will notify the manufacturer about identifying the information that would be necessary to conduct the risk evaluation, and the manufacturer will have 60 calendar days to submit the required information.

## Next Steps

As noted, comments on the proposed rule must be submitted to US EPA by March 20, 2017, and US EPA must promulgate the final risk evaluation rule by June 22, 2017. The process by which US EPA will conduct risk evaluations on chemical substances will have significant implications for manufacturers, importers and processors of chemical substances. The risk evaluation process is particularly important because, under the amended TSCA, if US EPA concludes that a substance presents an unreasonable risk of injury to health or the environment, the agency must impose requirements on the substance under TSCA section 6 to ensure that the substance no longer presents such risk. Additionally, US EPA is proposing to consider a wide range of information and concerns in scoping and conducting risk evaluations and will seek substantial data from companies where needed, using its new authority under the amended TSCA. Further, US EPA intends to place the burden on manufacturers to provide the information necessary for a requested risk evaluation and will deny such a request if the manufacturer is unable to provide the information.

Our lawyers are closely monitoring US EPA's development of the risk evaluation rule and its other actions under the amended TSCA. For more information on the proposed risk evaluation rule or any other aspect of TSCA, please contact one of the individuals listed below.

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