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News Alert
July 20, 2017

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EPA's Risk Evaluation Framework Rule Incorporates Key Industry Suggestions

Under the 2016 TSCA amendments, risk evaluation is the critical step toward EPA banning or restricting chemicals, or else determining that they will not be regulated. As required by those amendments, EPA has promulgated a final rule governing the risk evaluation process for the foreseeable future. This important development means that stakeholders have a better idea of how they can impact EPA's review of chemicals important to them.

June 22, 2017 marked the one-year anniversary of President Obama signing into law the Frank R. Lautenberg Chemical Safety Act (LCSA), which made sweeping revisions to the Toxic Substances Control Act (TSCA). That day also marked EPA's deadlines to finalize rules establishing procedures for conducting risk evaluations of chemicals already in commerce, to release guidance for third parties submitting draft risk evaluations to EPA, as well as a number of other deadlines discussed in separate alerts.

On July 20, 2017, EPA issued its final rule, effective September 18, 2017, for chemical risk evaluation under the amended TSCA.[1] EPA said it will use the process described in the rule for the first ten substances currently undergoing risk evaluation "to the maximum extent practicable," and it will follow the rule fully for all subsequent risk evaluations. The same rule also fulfills EPA's statutory requirement to establish procedures for evaluating manufacturer requests for risk evaluations. The final rule differs from the January 19, 2017 proposed rule in that it incorporates changes suggested by some stakeholders.[2] Notably, the final rule does not require EPA, when conducting a risk evaluation, to consider all current and foreseeable uses of a chemical. Instead, it provides EPA with discretion to focus on only the uses most likely to present an unreasonable risk.

EPA also published related guidance for third parties to submit a draft risk evaluation to the agency.[3] In that document, EPA recommends that third

[1] *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act,* Final Rule, 82 Fed. Reg. 33726 (July 20, 2017) (codified as 40 C.F.R. Part 702, Subpart B), https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf.
[2] *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, Proposed Rule, 82 Fed. Reg. 7562 (Jan. 19, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01224.pdf.
[3] EPA, *Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act* (June 2017), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/guidance-assist-interested-persons-developing-and-1.

parties adhere to the same scientific principles and procedures the agency will follow in developing risk evaluations. EPA noted that only high-quality third-party draft risk evaluations would be helpful to EPA in developing its own risk evaluations.

Role of Risk Evaluations in the Regulatory Process

Under TSCA section 6(b), EPA must perform risk evaluations for the first ten chemicals identified for risk evaluations; for those designated as high priority for a risk evaluation through the prioritization process (the subject of another final rule issued on June 22); and for chemicals for which manufacturers requested EPA to conduct risk evaluations where EPA granted those requests. The final result of a risk evaluation is an EPA determination either that a chemical presents an unreasonable risk to health or the environment under the conditions of use, or that it does not. If EPA makes an unreasonable risk determination, it must adopt a rule banning or restricting the chemical. If it determines that the chemical does not present an unreasonable risk, the regulatory process ends. Thus, the risk evaluation is a critical piece of the amended TSCA approach to addressing chemicals in commerce.

The risk evaluation process also impacts the potential for federal preemption of state restrictions on chemicals. Preemption of new state restrictions may occur upon issuance of the scope document for a risk evaluation, discussed below. A determination that a chemical does not present an unreasonable risk may preempt both new and certain existing state requirements. However, a determination that a chemical presents an unreasonable risk will not preempt existing state requirements at least until EPA adopts a rule under section 6(c) banning or restricting the chemical.[4]

Scope of Risk Evaluations

One of the most controversial aspects of January's proposed rule was language that would have required EPA to consider all known, intended, and reasonably foreseen activities associated with a chemical. Consistent with some industry comments, the final rule allows EPA to use its discretion to focus only on uses likely to present the greatest concern. However, it may consider all conditions of use if it chooses to do so.

Of particular note is what the scope of a risk evaluation will not include. EPA decided that the term "under the conditions of use" does not extend to intentional misuse of a chemical (e.g., inhalant abuse), even if reasonably foreseeable, in light of legislative history to that effect. Further, EPA concluded that the term does not extend to "the circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution." It made the same decision with respect to disposal from such uses (such as the future disposal of insulation that contains a chemical that is no longer manufactured, processed, or distributed for use in insulation), and with respect to past disposal (such as insulation already in landfills).

Instead, EPA concluded that, as amended, TSCA directs it "to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or ongoing), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal .... In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle." EPA did caution that in a particular risk evaluation it may consider legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure.

EPA will exercise its discretion on whether or not to evaluate impurities unintentionally present with the chemical that is the subject of the risk evaluation. In some cases, it may decide to conduct a separate risk evaluation on the impurity

[4] TSCA § 18. The preemption provision and other aspects of the LCSA are discussed in Beveridge & Diamond, P.C., "What's New About the Revised TSCA" (June 2, 2016), http://www.bdlaw.com/assets/htmldocuments/2016-06-02%20What%E2%80%99s%20New%20About%20the%20Revised%20TSCA.pdf.

itself.[5] Finally, EPA noted that TSCA does not authorize it to regulate non-commercial use, such as use by consumers where there is no ongoing manufacture, processing, or distribution in commerce.

On June 22, EPA issued scope documents for the first ten chemicals to be evaluated.[6]

Procedures for Risk Evaluations

The final rule closely follows the statutory mandates in section 6(b). It provides that risk evaluations will consist of the following steps:[7]

1. Scoping. As part of this step, EPA will determine which uses of a chemical will be considered as part of the risk evaluation. EPA will also identify potentially exposed or susceptible subpopulations, ecological receptors, and hazards to human health and the environment that the agency anticipates considering. EPA will also describe the reasonably available information and science approaches it plans to use, as well as a plan for peer review. The final risk evaluation framework rule requires EPA to publish a draft scope for a risk evaluation and allow at least 45 days for public comment. The final scoping document must be published in the Federal Register within six months of initiation of the risk evaluation. EPA indicated that it expects most decision-making about proposed scope to be made during the prioritization process.
2. Hazard assessment. Following the scoping phase, EPA will conduct a hazard assessment that identifies the types of adverse health or environmental effects or hazards that can be caused by exposure to the substance. This will include a dose-response assessment. It may also include evaluation of the potential activity of the substance with respect to cancer, mutation, reproductive, developmental, respiratory, immune, cardiovascular, and neurological impacts.
3. Exposure assessment. EPA must also conduct an exposure assessment, which will include information on physical-chemical properties, and environmental fate and transport parameters. It will also include a discussion of the individuals or populations expected to be exposed. In the preamble to the final rule, EPA stated that exposure assessments will typically be quantitative and will be estimated for each identified condition of use.
4. Risk characterization. EPA must also conduct a risk characterization, which will convey its judgment as to the nature and presence or absence of risks. This will include an explanation of how the risk was assessed, what assumptions were used, what uncertainties remain, and what policy choices will need to be made in the risk determination.
5. Peer review. Each risk assessment will undergo independent peer review. This review will include the hazard assessment, exposure assessment, and risk characterization. EPA will seek public comment on the questions that will be posed to peer reviewers. The peer review will not include any determination on whether the identified risks are unreasonable, which EPA views as an agency policy determination.

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[5] One of the first ten chemicals to receive a risk evaluation is 1,4-dioxane, which is a common impurity or byproduct as well as a commercial chemical. The scope of that risk evaluation will not include its presence as an impurity or a byproduct in other chemicals. EPA concluded, "In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane." EPA, Scope of the Risk Evaluation for 1,4-Dioxane (June 2017) at 8, https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf.

[6] Beveridge & Diamond, P.C., EPA Unveils Scoping Analysis for Risk Evaluations under Amended TSCA, Requests Comments on the First Ten Chemicals (July 5, 2017), http://www.bdlaw.com/assets/htmldocuments/2016-07-05%20Alert%20-%20EPA%20Unveils%20Scoping%20Analysis%20for%20Risk%20Evaluations%20under%20Amended%20TSCA%20Requesting%20Comments%20on%20the%20First%20Ten%20Chemicals.pdf.

[7] 40 C.F.R. § 702.41.

6. Unreasonable risk determination. The final step of a risk evaluation will be EPA's determination whether the substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment. A separate determination will be made for each condition of use in scope of the inquiry. If EPA determines, for any relevant conditions of use, that the substance presents an unreasonable risk, EPA must initiate a separate rulemaking that will impose requirements to manage that risk. Any risk management rule would only apply to the conditions of use EPA identified as presenting unreasonable risk. EPA noted in the preamble that it will have the discretion to revisit any unreasonable risk determinations, although it did not include language in this rule about how and when this might happen.

The final rule states that EPA may make and announce the results of a risk evaluation in stages.[8] EPA may make early risk determinations that a substance does or does not present an unreasonable risk under certain conditions of use. Such expedited determinations may be made at any point after the final scope is published and would become part of the final, complete risk evaluation.

Under TSCA section 6(b)(4)(G), EPA must complete risk evaluations within three years, with the possibility of a six-month extension. The three-year window begins when a chemical is designated as a high-priority substance or upon completion of the manufacturer request process (see below). The window closes when the final risk evaluation is published.

Science Requirements

The preamble to the proposed rule discussed the application of the "good science" requirements of section 26(h) and (i) to the risk evaluation process, but some commenters asked for additional explanation and regulatory provisions. The final rule adds definitions for the terms "best available science" and "weight of scientific evidence."[9] It also provides that in conducting a risk evaluation, EPA will use its existing guidance, as applicable, where it represents the best available science for the particular risk evaluation.[10] EPA must document that it has used the best available science and the weight of the scientific evidence approaches in the risk evaluation process.[11] Hazard information must be reviewed in a manner consistent with the best available science and the weight of scientific evidence.[12]

Manufacturer-Requested Risk Evaluations

Section 6(b)(4)(C)(ii) of TSCA allows a manufacturer, or a group of manufacturers, to request risk evaluations for substances they manufacture. The risk evaluation framework rule fulfills EPA's mandate to establish, by rule, the "form and manner" and "criteria" that govern such requests. Section 6(b)(4)(E) requires EPA to grant any such requests that meet the criteria, until the statutory minimum of 25% of the total EPA-initiated risk evaluations is met. Once this minimum threshold has been met, EPA has discretion to grant or deny further requests, up to the statutory maximum of 50%. In this circumstance, TSCA requires EPA to give preference to chemicals regulated by states in a manner that may significantly impact interstate commerce. When promulgating the final rule, EPA announced that it plans to give further preference to requests in the order they are received. It expects to receive about five requests per year.

The final rule gives a manufacturer the option of requesting risk evaluations only for uses relevant to that manufacturer.[13] If the risk evaluation goes forward, however, EPA will determine the scope in the same manner as any other risk evaluation. A manufacturer request must include information on the substance's hazard and exposure potential; the substance's persistence and bioaccumulation; any relevant or potentially exposed or susceptible subpopulations; whether

[8] 40 C.F.R. § 702.47.
[9] 40 C.F.R. § 702.33.
[10] 40 C.F.R. § 702.41(a)(2).
[11] 40 C.F.R. § 702.41(a)(4).
[12] 40 C.F.R. § 702.41(d)(2).
[13] 40 C.F.R. § 702.37.

there is any storage of the substance near significant sources of drinking water; the substance's production volume or significant changes in production volume; and any other information relevant to the risks potentially presented by the substance.

Within 15 days of receiving a valid request, EPA will give public notice of its receipt, either on its website or by email announcement. Within 60 days from receipt, EPA will publically announce the request in the Federal Register, and will open a docket for public comment. The comment period will last at least 45 days. The Federal Register notice will also announce EPA's determination about whether the uses identified by the manufacturer warrant risk evaluation, and whether EPA has identified other uses that warrant review. Within 60 days of closure of the comment period, EPA will notify the manufacturer whether it will grant or deny the request. If EPA indicates the request will be granted, the manufacturer will have 30 days to withdraw the request for a risk evaluation, if it chooses to do so in light of EPA's action.

Under section 6(b)(4)(E)(ii), manufacturers whose requests are granted must pay a fee. Under section 26(b)(4)(D), the fee will be 50% of EPA's cost of conducting the risk evaluation for chemicals listed in the 2014 update to the TSCA Work Plan and 100% of the cost for other chemicals. The risk evaluation rulemaking did not identify what that cost would be, since it will be the subject of a separate rulemaking. However, EPA has previously reported that it estimates the full cost of a risk evaluation to be $3.7 million.[14]

EPA Guidance for Developing and Submitting Draft Risk Evaluations

Section 26(l)(5) of TSCA requires EPA to issue guidance for assisting third parties in submitting draft risk evaluations for consideration by EPA. The guidance is required to include, at a minimum, the quality of information and process to be followed for third-party draft risk evaluations. The guidance released on June 22 discusses the science standards third-party draft risk evaluations should follow, as well as the sections they should contain. These track generally with the standards EPA set for itself in the final risk evaluation framework rule.

Science Standards

EPA recommends that persons preparing third-party draft risk assessments use the best available science, as that concept is described in section 26(h) and defined in the risk evaluation rule. The rule defines "best available science" as "science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)."

EPA also recommends use of weight-of-evidence approaches in third-party draft risk assessments. The rule defines "weight of evidence" as "a systematic review method, applied in a fit-for-purpose manner, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance." EPA cautions that a weight-of-evidence approach is an interpretive process, and is more than simply tallying the number of positive and negative studies.

Finally, EPA recommends implementation of a system that ensures the use of quality data. EPA recommends that third parties considering a draft risk evaluation review EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.*[15]

[14] EPA, Initial Report to Congress on the EPA's Capacity to Implement Certain Provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Jan. 2017) at 4, https://www.epa.gov/sites/production/files/2017-01/documents/tsca_report_to_congress.pdf.

[15] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (October 2002), https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf.

Sections of Third-Party Draft Risk Evaluations

EPA recommends that third-party draft risk evaluations be organized similarly to the risk evaluations it will develop. The agency recommends that third parties engage in a scoping exercise following the principles described in the risk evaluation rule. Once the exercise is scoped appropriately, EPA recommends that the third party prepare sections on exposure assessment, hazard assessment, and risk characterization.

- Exposure assessment. EPA recommends that exposure assessments include, among other things: relevant physical-chemical properties of the substance; environmental fate and transport parameters; characterization of relevant exposure information; disclosure of all data used for the calculations (both modeled and measured); exposure of relevant exposed or susceptible subpopulations; the basis for selecting studies; and integrative discussion based on the best available science and the weight of evidence.
- Hazard assessment. EPA recommends that hazard assessments include, among other things: characterization of the nature and severity of relevant human health and ecological effects; dose or concentration response information; disclosure of all data used (both modeled and measured); hazards to relevant exposed or susceptible subpopulations; models used to develop dose-response curves and the basis for selecting them; basis for selecting studies; and integrative discussion based on the best available science and the weight of evidence.
- Risk characterization. EPA recommends that risk characterizations include, among other things: discussion of the risk estimation approach, including equations and pertinent assumptions; summary of the magnitude of the human health and environmental risk estimates; discussion of the major issues associated with determining the nature and extent of the risk; discussion of the overall characterization and/or analysis of the impact of the uncertainty and variability on estimates risks; and, if appropriate, discussion of plausible alternative interpretations of the data and analysis.

Implications for Stakeholders

With the publication of this final rule, stakeholders now have a better insight into how EPA plans to conduct its risk evaluations under the amended TSCA. Manufacturers must recognize the substantial burdens they face, both informational and financial, in choosing to submit requests that EPA conduct risk evaluations. Persons concerned about legacy uses of chemicals no longer in active commerce have assurance that EPA will not take up those uses in its risk evaluation of current uses. Advocates for an EPA determination that a chemical does not present an unreasonable risk under particular conditions of use may focus their arguments on those conditions of use. All stakeholders may want to take advantage of the opportunities for comment available under the risk evaluation process rule.

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