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ALERT

Prioritization 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 prioritizing existing chemicals in commerce for risk evaluation under the Toxic Substances Control Act (TSCA).

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

· Risk Evaluation 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

The process is entirely new and mandated by the 2016 amendments to TSCA. The rule carries out EPA's objective to be transparent without unduly restricting the flexibility of the agency to adapt with changes in science when conducting these evaluations. But, while EPA's rules recognize that Congress required the agency to follow numerous specific procedural steps and to meet judicially enforceable deadlines, beyond those minimum elements, the agency has reserved significant discretion designed to maintain agency control over the substance, pace, progress, and outcomes of the reviews.

A key highlight of the final rule is that EPA withdrew the concept of a formalized "pre-prioritization" phase of screening chemicals for prioritization, although the agency suggests that such a process necessarily already exists and that more formal rules or guidance might be developed by EPA in the future. The following summary discusses this and other changes in the final rule.

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Practice Areas

Environment & Product Regulation
Toxic Substances Control Act (TSCA)

Overview of the Process

EPA will conduct risk-based screening to identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at the time. Once the agency formally initiates its prioritization evaluation of a specific chemical substance, the high- or low-priority designation must be made within nine to 12 months, a time frame that also includes two periods reserved to receive and respond to public comments. The statute does not give EPA the ability to pause or delay prioritization once it is initiated. EPA will consider the quality, objectivity, utility, and integrity of the available information as part of the screening process. Sufficiency of information remains a crucial factor in the selection of the chemicals EPA chooses to put into prioritization, making data-rich chemicals more likely to be selected.

As noted above, EPA declined to formalize the process by which EPA will select chemicals to enter the prioritization process, which had been referred to as "pre-prioritization." In the final rule, instead of the formalized pre-prioritization process, EPA indicates it will apply the two statutory preferences in Section 6(b)(2) to select candidates with persistence and bioaccumulation scores of three under the EPA Work Plan, and known human carcinogens with high acute and chronic toxicity.

The proposal also had included a list of specific "exposure and hazard considerations" borrowed from the former EPA Work Plan that had appeared in the proposed rule, including elements such as the use of the product in children's and consumer products. Those considerations would have informed EPA's pre-prioritization process, and while EPA's preamble to the final rule does not provide an explanation for this change apart from the wholesale removal of the pre-prioritization process, it seems likely that these criteria will continue to be used to inform EPA's pre-screening process on an informal basis.

Formal initiation of the prioritization process triggers a 90-day public comment period (which can be extended by an additional three months), followed by a decision announcing the proposed high- or low- priority designation along with another 90-day period for public comment, and then a final designation decision.

A high-priority substance is one that EPA finds, without consideration of non-risk factors such as cost, may present an unreasonable risk of injury to health or the environment because of the potential hazard and routes of exposure under the conditions of use, taking into account potentially exposed subpopulations. As EPA explains, it is a chemical where "available information suggests that it may present a hazard and that exposure is present under one or more conditions of use, but where an unreasonable risk determination cannot be made without a more extensive and complete assessment through risk evaluation." EPA states that it expects a large number of chemicals to meet this definition. A low-priority substance is one that does not meet the high-priority substance definition. In the case of a low-priority designation, no further action is needed. The low-priority designation is a final agency action subject to judicial review.

After announcing the initiation of prioritization, EPA will screen chemicals for the statutory criteria in Section 6 (b)(1)(A) of TSCA:

1. The chemical substance's hazard and exposure potential;
2. The chemical substance's persistence and bioaccumulation;
3. Potentially exposed or susceptible subpopulations;
4. Storage of the chemical substance near significant sources of drinking water;
5. The chemical substance's conditions of use or significant changes in conditions of use;
6. The chemical substance's production volume or significant changes in production volume; and
7. Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance.

Chemicals that pose a potential risk based on these factors for one or more conditions of use will be designated as "high-priority." Chemicals that do not raise any of these considerations are likely good candidates for low-priority designation, though that result is not mandated. Of interest to numerous stakeholders is EPA's statement that it will not consider substitutes in the prioritization process as a "non-risk" consideration that cannot be part of this stage in EPA's process.

Other Related Issues

The final rule acknowledges EPA's obligation to comply with Section 26 of TSCA, which requires EPA to use certain scientific standards and base those decisions on the weight of the scientific evidence. The inclusion of this definition responds to numerous comments requesting definitions of these terms, and while not all stakeholders will agree with the content of the definition, having a definition should provide more predictability to the process.

TSCA directs EPA to identify at least 20 chemicals as low-priority in the next three and a half years. In the proposed rule, EPA took the position that it is not required by statute to designate more than 20 low-priority substances. However, Section 6(b)(2)(B) requires EPA to "continue to designate priority substances" and conduct risk evaluations. The sentence does not modify the word "priority" with the words "low" or "high" so that EPA could continue to designate both low and high-priority substances, and conduct risk evaluations on those deemed as high-priority. In the final rule, EPA states that it will continue to review low-priority candidates even after it reaches the statutory minimum number of 20.

Key Takeaways

These rules will govern how the regulated community must interact with EPA in the context of chemical reviews for many years to come. The way that EPA conducts these procedures will be extremely important to the ultimate determination and communication of the risks associated with a particular chemical.

The low-priority threshold remains more rigorous to meet, because the safety of all conditions of use will need to be established to support the designation. There must be "information sufficient to establish" that a substance is low-priority. For a high-priority designation, in contrast, EPA need only find that one condition of use meets the need for high-priority designation to go forward with the chemical for risk evaluation. In that

case, all conditions of use will continue to go forward into the risk evaluation phase. Because EPA intends to move all identified conditions of use into risk evaluation for high-priority designations, as a result, companies with uses that are not of concern should still expect to plan for and engage in this process for the long haul. While manufacturers are most directly impacted, processors and downstream users will need to consider whether to participate and support these risk evaluations with exposure and use information.

It will be critical to thoroughly comment at each stage of the process, because if an issue related to the prioritization is not raised during the comment periods, it cannot be a basis for objecting or challenging the risk evaluation in a future proceeding.

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