

Overview

On June 22, 2017, the US Environmental Protection Agency (US EPA) issued its rule for prioritizing chemical substances for purposes of risk evaluation, as required by the amended Toxic Substances Control Act (TSCA). The rule was published in the Federal Register on July 20, 2017.

Under the amended TSCA, US EPA is required to prioritize chemical substances on the TSCA Inventory as “high priority” or “low priority.” US EPA then must conduct risk evaluations on the high-priority substances.

The rule sets forth a three-step process that US EPA will follow for prioritizing chemical substances on the TSCA Inventory: (1) initiation; (2) proposed designation; and (3) final designation. Once formally initiated (Step 1), the prioritization process must last at least nine months, but cannot last longer than 12 months.

US EPA had proposed a “pre-prioritization” step to precede the proposed designation, during which time the agency would identify a pool of substances based on certain criteria identified in TSCA and gather information on these substances before formally initiating the prioritization process. In response to stakeholder comments, US EPA deleted the pre-prioritization step from the final rule and will be taking further public comment on how the agency will identify candidate substances for prioritization.

The preamble to the rule states that US EPA’s “primary objective” will be to identify high-priority substances that have the “greatest hazard and exposure potential” first. The preamble further states that US EPA will designate the priority of a chemical substance as a whole under its conditions of use and will not limit its designation to a specific use or subset of uses of the substance. The preamble adds, however, that US EPA will not necessarily consider every activity involving a substance to be a condition of use and that the agency has determined that certain activities should not be considered conditions of use. To that end, US EPA will identify the “circumstances” that constitute the “conditions of use” for each chemical substance it is prioritizing and consider those conditions of use when prioritizing the substance.

Even though the rule does not include a formal pre-prioritization step, US EPA “expects to consider the existence and availability of risk-based information on a candidate substance before initiating the prioritization process” and “resolve any concerns” about the sufficiency of information on a substance “before subjecting that chemical substance to the prioritization process.” US EPA “generally expects” to use a “tiered” approach to information gathering, but will exercise its authorities under the amended TSCA to require submission or generation of new data as necessary.

The amended TSCA requires US EPA to give preference to substances listed in the agency’s 2014 TSCA Work Plan that are persistent and bioaccumulative, that are known human carcinogens and/or have high acute and chronic toxicity. Additionally, because the amended TSCA requires that 50% of all ongoing risk evaluations be conducted on substances listed on the Work Plan, the agency intends to draw at least 50% of the high-priority substances from the Work Plan.

Although substances newly added to the TSCA Inventory are candidates for prioritization, the preamble to the rule states that such substances are not likely to be high-priority candidates given that they recently have undergone premanufacture notice (PMN) review.

Initiation of the Prioritization Process

During the initiation step, US EPA will formally announce (via a notice in the Federal Register) that a substance is a “candidate” for prioritization and give the public 90 days to submit relevant information about it. US EPA can extend the comment period for up to an additional three months in order to receive or evaluate information from a TSCA test order.

After the close of the 90-day public comment period, US EPA will “screen” the candidate substance against several “criteria and considerations” outlined in the amended TSCA: (1) the substance’s hazard and exposure potential; (2) the substance’s persistence and bioaccumulation; (3) potentially exposed or susceptible subpopulations; (4) storage of the substance near significant sources of drinking water; (5) the substance’s conditions of use or significant changes in conditions of use; (6) the substance’s production volume or significant changes in production volume; and (7) other risk-based criteria that US EPA determines to be relevant to the priority designation of the substance.

Proposed Designation as High-Priority or Low-Priority

Based on the results of the screening review, US EPA will propose that a chemical substance be designated as either high-priority or low-priority. The proposed designation also will include an identification of the information, analysis and bases to support the proposed designation. US EPA will take public comment on the proposed designation for 90 days.

As noted, US EPA expects to select as high-priority substances chemicals with the greatest hazard and exposure potential first. The rule states that the agency may propose a high-priority designation based on one or more conditions of use of the substance. The rule further states that US EPA will propose to designate a substance as a high-priority substance if there is insufficient information to enable the substance to be designated as a low-priority substance (after any extension of the comment period during initiation of the prioritization process for information gathering purposes).

Relatedly, US EPA will propose a substance for low-priority designation where the information on hazard and exposure under the conditions of use for the substance "is sufficient to establish that a risk evaluation is not warranted." The preamble to the rule notes that, before a substance can be designated as low-priority, TSCA requires US EPA to determine that the substance does not meet the definition of a high-priority substance under any of the conditions of use.

TSCA prohibits US EPA from considering costs or other non-risks factors in making a proposed priority designation.

Final Designation as High-Priority or Low-Priority

US EPA will finalize the designation of a substance via an announcement in the Federal Register. When the final designation is issued, US EPA also will publish an identification of the information, analysis and basis used to support the designation. US EPA also will identify which conditions of use were the primary bases for the priority designation.

If the substance is designated as high-priority, US EPA must initiate a risk evaluation of the substance. If the substance is designated as low-priority, US EPA will not conduct a risk evaluation of it – unless and until the agency has information that causes it to reconsider the designation.

A low-priority designation is a final agency action under the amended TSCA and is subject to judicial review. A high-priority designation, however, is not a final agency action.

As noted, the amended TSCA prohibits US EPA from considering costs or other non-risk factors in the designation of a chemical substance as high- or low-priority.

Scientific Standards

The rule incorporates certain standards from the amended TSCA statute regarding how US EPA will utilize scientific information when making priority determinations. The rule states that US EPA's proposed priority designations and final priority designations will be consistent with the standards, including those relating to best available science and weight of the scientific evidence.

Repopulation of High-Priority Substances

The amended TSCA requires US EPA to designate at least 20 chemical substances as high-priority within three and a half years after enactment (i.e., by December 2019). At least 20 other substances also must be designated as low-priority within that same time frame. Further, once US EPA completes a risk evaluation on a chemical substance, it must begin a risk evaluation on another high-priority substance to ensure that at least 20 substances are undergoing risk evaluation at any time. Consequently, US EPA must continually designate high-priority substances. In that regard, US EPA generally expects to identify the particular risk evaluation that the new high-priority substance will replace.

Next Steps

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

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