

The US Environmental Protection Agency (US EPA) has issued its proposed rule for prioritizing chemical substances for purposes of risk evaluation, as required by the recently amended Toxic Substances Control Act (TSCA). The proposed rule was published in the Federal Register on January 17, 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 prioritization rule by June 22, 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.

US EPA has proposed a four-step process for prioritizing chemical substances on the TSCA Inventory: (1) pre-prioritization; (2) initiation; (3) proposed designation; and (4) final designation. Once formally initiated (Step 2), the prioritization process must last at least nine months, but cannot last longer than 12 months. Consequently, as noted below, US EPA expects to do much of its data collection on and analysis of chemicals substances in the pre-prioritization stage (Step 1), before the 9-12 month prioritization clock start ticking.

Pre-Prioritization: Identifying Candidate Chemical Substances

During the pre-prioritization step, US EPA proposes to identify a pool of substances by applying the criteria identified in TSCA section 6(b)(2), along with other criteria. Section 6(b)(2) requires US EPA to give preference to substances listed in the agency’s 2014 TSCA Work Plan that have a persistence and bioaccumulation score of 3, and those in the Work Plan that are known human carcinogens and have high acute and chronic toxicity.

As required by the amended TSCA, US EPA also will consider the hazard and exposure potential of the substance, its persistence and bioaccumulative properties, any potentially exposed or susceptible subpopulations and whether it is stored near significant sources of drinking water. US EPA also must consider the conditions of use (or significant changes in the conditions of use) and the volume or significant changes in the volume of the substance manufactured or processed. Although these factors are generally required by the amended TSCA to be considered during prioritization, US EPA is proposing to consider them during the pre-prioritization phase to inform the prioritization process early.

US EPA also is proposing to include the following additional exposure and hazard considerations to narrow the field of potential candidates for prioritization: (1) persistent, bioaccumulative and toxic; (2) used in children’s products; (3) used in consumer products; (4) detected in human and/or ecological biomonitoring programs; (5) potentially of concern for children’s health; (6) high acute and chronic toxicity; (7) probable or known carcinogen; (8) neurotoxicity; or (9) other emerging exposure and hazard concerns to human health or the environment. These considerations were used by US EPA to develop its list of Work Plan chemical substances. Chemical substances that meet one or more of these criteria may be identified as potential candidates for High-Priority Substance designation.

Additionally, because the amended TSCA requires that 50% of all ongoing risk evaluations be conducted on Work Plan substances, the agency intends to draw at least 50% of the high-priority substances from the Work Plan.

Because of the lack of data on many chemical substances on the TSCA Inventory, US EPA indicates that it “will need to do a substantial amount of upfront data gathering and review” on many substances before initiating the prioritization process for them. The agency expects to use its new authority to issue administrative orders (as well as rules and subpoenas) to collect this information during the pre-prioritization stage in order to screen chemical substances.

Formal 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 Section 4 test order. If, after the 90-day period (and any additional extended period), US EPA determines that the available information is insufficient to enable a substance to be designated as low-priority, the amended TSCA requires the agency to propose a high-priority designation for the substance. Consequently, US EPA is proposing a “default to high” priority approach in all cases in which there is insufficient information to designate a substance as low-priority.

US EPA is prohibited by the amended TSCA from considering costs or other non-risk factors in determining whether to designate a substance as high- or low-priority.

Proposed Designation as High-Priority or Low-Priority

At the proposed designation step, US EPA will propose that a chemical substance be designated as either high-priority or low-priority and will take public comment on the proposed designation for 90 days. US EPA points out that the comment period will be particularly important for proposed low-priority substances. Under the proposed rule, all comments raising issues concerning a proposed low-priority designation must be made during the 90-day period. Any issues not raised during the comment period will be considered to have been waived and may not form the basis for an objection or challenge to the low-priority designation in any subsequent administrative or judicial proceeding. Unlike a high-priority designation, a low-priority designation is a final agency action under the amended TSCA and is subject to appeal and judicial review.

Final Designation as High-Priority or Low-Priority

At the final designation step, US EPA will finalize the designation of a substance (via an announcement in the Federal Register). 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. US EPA notes in its proposal, however, that redesignation of a substance from low- to high-priority does not have to be based on new information but can be justified by reconsideration of information that was previously available to the agency.

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.

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. Although there is no requirement to continually designate low-priority substances, the proposed rule indicates that US EPA will do so, as “doing so ensures that that chemicals substances with clearly low hazard and exposure potential are taken are taken out of consideration for further assessment.”

Because of the requirement that a substance undergo risk evaluation when it has been designated as high-priority, the proposed rule states that US EPA must be “judicious in selecting the chemical substances that go into prioritization.” The proposed rule also states that US EPA “generally intends to ensure that it has a more complete set of data upfront” that would allow the agency “to evaluate a chemical substance under all conditions of use” within the statutory deadlines. As noted above, the proposed rule indicates that “[f]or substances with insufficient information to conduct a risk evaluation, EPA generally expects to pursue a significant amount of data gathering before initiating prioritization.”

Additionally, the proposed rule states that US EPA will designate the priority of a chemical substance “as a whole” and “will not limit its designation to a specific use or subset of uses.” US EPA’s position is that the phrase “conditions of use” was included in the amended TSCA “to move the Agency away from its past practice of assessing only narrow uses of a chemical substance, towards a comprehensive approach to chemical substance management.” US EPA further states that while it will broadly examine all conditions of use for a substance, it may designate a chemical substance as high-priority based on just a single condition of use. Conversely, US EPA believes that it cannot designate a substance as low-priority unless it determines “that under no conditions of use does the chemical meet the High-Priority Substance standard.” As a result, the proposed rule states that US EPA will base a low-priority designation on the hazard and exposure potential of the substance for all conditions of use.

The proposed rule also states that US EPA may prioritize and evaluate categories of chemical substances, in addition to individual substances.

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

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 prioritization rule by June 22, 2017. US EPA’s efforts to prioritize chemicals will have significant implications for manufacturers, importers and processors of chemical substances. The agency is indicating that it intends to use its new authority to issue administrative orders (as well as issue rules and subpoenas) to collect data and require testing of chemical substances up front in order to screen substances and identify candidates for prioritization. Moreover, once a chemical substance is designated as a High-Priority Substance, it must immediately undergo risk evaluation.

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

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