

Client Alert

Environmental, Health & Safety Practice

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EPA Issues Proposed Rule for Prioritizing Existing Chemicals for Risk Review

Proposed Four-Step Process Aims to Incentivize Early Information Submission

The United States Environmental Protection Agency (EPA) has published its proposed rule for the prioritization of existing chemicals for the risk evaluation mandated under the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA).¹ The LCSA granted EPA new authority to assess and manage the risk of existing chemicals, and it gave EPA one year to create regulations to fulfill this new authority, including a rule defining a risk-based screening process to designate existing chemicals as either high or low priority.² In the proposed rule, EPA outlines four phases it intends to use to accomplish its prioritization task:³

(1) Pre-Prioritization – The LCSA directs EPA to consider hazard, exposure, proximity to drinking water sources, potentially exposed or susceptible subpopulations, production volume, and conditions of use when it makes its designation.⁴ In order to ensure that EPA makes an appropriate designation, the proposed rule uses these factors in the pre-prioritization phase to narrow the pool of candidate chemicals. EPA will also consider whether the chemical:

- is persistent, bioaccumulative, and toxic;
- is used in children's products or consumer products;
- has been detected in human and/or ecological biomonitoring programs;
- presents potential concerns for children's health;
- exhibits high acute and chronic toxicity; is a probable or known carcinogen; or is neurotoxic; or
- presents "other emerging exposure and hazard concerns to human health or the environment, as determined by the Agency."

At this stage, EPA may also invoke its new information-gathering authority under the LCSA to fill any gaps in the information it needs for prioritization and evaluation.⁵

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- 1) Initiation⁶ – EPA will announce that it is assessing a chemical and give stakeholders 90 days to provide information on that chemical to EPA. “Of particular interest to EPA will be information related to ‘conditions of use’ that are missing from the screening results.”⁷ As incentive for providing such information, the proposed rule alerts stakeholders that “EPA is proposing to require a default-to-high in all cases in which insufficient information exists to designate the chemical as a Low-Priority Substance at both the proposed and final designation.”⁸
- 2) Proposed Designation⁹ – EPA will propose either a “high priority” or “low priority” designation and give stakeholders another 90 days to comment on the proposed designation. The proposed rule clarifies that EPA will consider all uses of a chemical substance in making its designation. EPA further notes that it considers the “high priority” threshold to be a “low bar” that many chemicals will exceed, and a “low priority” designation cannot be made unless all uses fall below this bar.¹⁰
- 3) Final Designation¹¹ – EPA will issue the final designation. A “high priority” chemical moves on to the risk evaluation process. A “low priority” designation terminates the risk evaluation process for that chemical.¹²

EPA also seeks input on other important issues, including its proposal to leave important terms – including “best available science,” “weight-of-the-evidence,” “sufficiency of information,” “unreasonable risk,” and “reasonably available information” – undefined;¹³ how and whether to obtain public input at the pre-prioritization phase; and how to account for the availability of substitute chemicals in its review.¹⁴

Comments on the prioritization rule are due no later than March 20, 2017. EPA must issue a final rule no later than June 22, 2017.

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¹ 82 Fed. Reg. 4825 (Jan. 17, 2017).

² High priority chemicals are those that “may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation.” Low priority chemicals are those that do not meet the standard for a high priority designation.

³ 82 Fed. Reg. at 4826.

⁴ *Id.*

⁵ See proposed 40 C.F.R. §§ 702.5, 702.6.

⁶ See proposed 40 C.F.R. § 702.9.

⁷ 82 Fed. Reg. at 4832.

⁸ 82 Fed. Reg. at 4827.

⁹ See proposed 40 C.F.R. § 702.11.

¹⁰ 82 Fed. Reg. at 4830.

¹¹ See proposed 40 C.F.R. § 702.13.

¹² Low priority designations are subject to judicial review, and EPA may revisit such a designation if new information indicates a redesignation may be warranted. Significant changes in the volume of a chemical in commerce represent one such type of new information.

¹³ 82 Fed. Reg. at 4828.

¹⁴ 82 Fed. Reg. at 4831.