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EPA Releases TSCA Final Rule on Prioritization of High-Priority and Low-Priority Chemical Substances

Under the amended TSCA, prioritization – EPA’s process for selecting which chemical substances to evaluate for possible regulation – is the gatekeeper. EPA has just adopted a final rule describing its process for selecting chemicals for designation as a high or a low priority for a risk evaluation. Only those designated as High-Priority will receive detailed scrutiny; a decision on whether or not they present an unreasonable risk to health or the environment under the conditions of use; and risk management requirements (where a finding of unreasonable risk is made).

On July 20, 2017, EPA issued its final rule, effective September 18, 2017, for prioritizing High- and Low-Priority chemical substances.¹ The rule sets forth a risk-based screening process and criteria for identifying and designating High-Priority Substances, which must undergo risk evaluations, and Low-Priority Substances, which do not meet the High-Priority screening criteria and will not receive a risk evaluation. EPA was required to adopt the rule by section 6(b)(1)(A) of the Toxic Substances Control Act (TSCA), as amended by the Frank Lautenberg Chemical Safety for the 21st Century Act (LCSA).

This alert explains the criteria EPA will consider in prioritizing chemical substances. It also highlights differences between EPA’s proposed rule and final rule, provides a timeline for prioritization, and suggests next steps for companies that might be affected by the rule.

The Final Rule: Overview

EPA’s prioritization rule sets forth the process by which EPA will designate chemical substances as either High- or Low-Priority for risk evaluation. The final rule follows and incorporates much, but not all of, of the provisions in [EPA’s proposed prioritization rule](#).²

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¹ *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act*, Final Rule, 82 Fed. Reg. 33753 (July 20, 2017) (codified as 40 C.F.R. Part 702, Subpart B), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14325.pdf>.

² 82 Fed. Reg. 4825 (Jan. 17, 2017).

Prioritization Process

1. Initiation

EPA will initiate the prioritization process for a chemical substance of interest once it is confident that all information required to prioritize the chemical substance has been made “reasonably available.”³ (The preamble indicates that a chemical may be of interest even if it is a recent PMN chemical or classified as inactive through the Inventory Reset process, although EPA does not expect this to be the case often.) EPA will then publish a notice of initiation in the Federal Register identifying the chemical substance and a general explanation for why it chose to initiate prioritization on that substance.⁴ This publication will trigger a 90-day public comment period for interested persons to submit relevant information, which may include information that assists EPA with its screening review of the chemical substance.⁵

EPA noted in the preamble that it expects to select for High-Priority Substances that present the “greatest hazard and exposure potential first.” The rule provides that EPA will aim to select as candidates for High-Priority prioritization those chemical substances listed in the [2014 Update of the TSCA Work Plan for Chemical Assessments](#) that:

- Have persistence and bioaccumulation scores of 3; and
- Are known human carcinogens and have high acute and chronic toxicity.⁶

EPA aims to ensure that, “at any given time” at least 50% of all high-priority risk evaluations are drawn from the 2014 Update.⁷

2. Screening

The plan sets forth seven screening criteria that EPA will consider to determine whether the chemical substance is High- or Low-Priority. The information that EPA will use to assess these criteria may include hazard and exposure data listed in [Appendices A and B of the TSCA Work Plan Chemicals: Methods Document](#) (February 2012), as well as information received from the public during the initial 90-day public comment period. The rule further requires EPA to consider the chemical substance as a whole, and not to consider a chemical’s specific uses or “conditions of use,” as defined by section 3 of TSCA. The criteria are:

- Hazard and exposure potential of chemical;
- Persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations;
- Storage near significant sources of drinking water;
- Conditions of use or significant changes in the conditions of use of the chemical substance;
- Volume or significant changes in the volume of the chemical substances manufactured or processed; and
- Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance’s priority.

The first six criteria are drawn directly from section 6(b)(1)(A), and the final is a general catch-all for EPA to consider other, potentially unknown risks. EPA must prioritize a chemical substance without considering costs or other non-risk factors.⁸

³ 40 C.F.R. § 702.7(a).

⁴ 40 C.F.R. § 702.7(b).

⁵ 40 C.F.R. § 702.7(d).

⁶ These substances are identified 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>, Attachment 1.

⁷ 40 C.F.R. § 702.5.

⁸ 40 C.F.R. § 702.9(d).

EPA's designation of High or Low-Priority turns on whether the substance "may present an unreasonable risk of injury to health or the environment" based on hazard and exposure risks.⁹

As discussed below, the final rule does not include any provision addressing what the proposal had described as pre-prioritization activities. Instead, EPA will generally expect to obtain sufficient information before beginning the prioritization process by using voluntary methods and its authority under section 4 (requiring testing on environmental and health effects); section 8 (requiring submission of health and safety studies); and section 11 (subpoenas), for which there is no time deadline.¹⁰ This provision suggests that EPA hopes to avoid the situation where at the end of the 12-month period for prioritization it still has insufficient information, because section 6(b)(1)(C)(iii) requires EPA in that situation to designate the chemical being prioritized as a High-Priority substance.

3. *Proposed designation*

Upon determination that a chemical substance meets one or more criteria, EPA will propose to designate the chemical substance either High- or Low-Priority. It will publish the proposed designation in the Federal Register.¹¹ A proposed designation triggers a second 90-day public review period.¹²

4. *Final designation*

Following the 90-day review period, EPA will make a final designation of a chemical as either a High-Priority or Low-Priority chemical substance. This designation will be published in the Federal Register.¹³ A High-Priority designation requires EPA to immediately begin a risk evaluation on the chemical substance. Thus, a High-Priority designation is not a final agency action and is not subject to judicial review.

The final rule states that "designation as a High-Priority Substance is not a finding that the chemical substance presents an unreasonable risk."¹⁴ Commenters on the proposed rule expressed concerns that a High-Priority designation could stigmatize chemicals before they undergo risk evaluation. EPA responded by amending the proposed rule to provide that it will generally aim to publish information and grounds on which the final designation is supported. For High-Priority substances, EPA will further identify which specific conditions of use were the basis for the designation.¹⁵ Under section 6(b)(2)(B), EPA must designate 20 chemical substances as High-Priority by December 22, 2019.

Conversely, EPA will designate a chemical substance as Low-Priority where none of the chemical's conditions of use meets the criteria or health or environmental risks of a High-Priority Substance.¹⁶ Section 6(b)(2)(B) requires that EPA designate 20 chemical substances as Low-Priority by December 22, 2019. The preamble explains that determination that a chemical is Low-Priority is considered a final agency action, and as such it is subject to judicial review. That said, EPA may revisit a Low-Priority designation should information become available that demonstrates that the chemical could meet the High-Priority criteria.¹⁷

5. *Repopulation of High-Priority Substances*

As required under section 6(b)(3)(C), the rule provides that EPA must designate at least one High-Priority chemical substance for every substance for which it completes a risk evaluation. This one-for-one substitution does not apply to risk evaluations that were requested by a chemical manufacturer pursuant to 40 C.F.R. § 702.37.¹⁸ The preamble noted

⁹ 40 C.F.R. § 702.3.

¹⁰ 40 C.F.R. § 702.5(e).

¹¹ 40 C.F.R. § 702.9(g).

¹² 40 C.F.R. § 702.9(g).

¹³ 40 C.F.R. § 702.11.

¹⁴ 40 C.F.R. § 702.17.

¹⁵ 40 C.F.R. § 702.11(c).

¹⁶ 40 C.F.R. § 702.15.

¹⁷ 40 C.F.R. § 702.15.

¹⁸ 40 C.F.R. § 702.11(d).

that EPA aims to facilitate the one-for-one substitution by identifying the “complete or near-complete risk evaluation that the new High-Priority Substance will replace” in a notice published in Federal Register designating the new High-Priority Substance. EPA aims to designate a new High-Priority Substance no later than 45 days following completion of a risk evaluation.

TSCA does not expressly mandate one-for-one substitution for the 20 Low-Priority Substances due by December 22, 2019. In the final rule EPA has made no commitment to designate any Low-Priority Substances after the initial 20.

EPA provided a [timeline](#) for the prioritization process.

Major changes from proposed rule

Pre-prioritization

The most striking change from the proposed rule is omission of the pre-prioritization step. The proposed rule suggested that EPA would be constrained by the 9 to 12 month timeframe for prioritization, and so included a preliminary pre-prioritization process prior to initiation. EPA suggested that it would use the pre-prioritization step to consider the screening criteria at an early stage, prior to initiation and any public comment period. However, EPA ultimately struck this step from the final rule, noting that the proposal was subject to “widely differing, and often irreconcilable views by commenters.” EPA thus deferred a final decision on pre-prioritization until it engages in further discussions with stakeholders, after which time it may consider adding a pre-prioritization provision to the rule.

Default to High-Priority

EPA also struck the default characterization of a chemical substance to High-Priority where, after initiation, EPA determined that data and available information was inadequate. EPA’s proposed rule suggested that such a default characterization would encourage public comment and submission of information during the comment periods. This default characterization was ultimately deleted from the final rule.

Ranking or hierarchy

The proposed rule stated that EPA would not select candidates or initiate prioritization in any ranked or hierarchical order. EPA struck this statement from the final rule. It reasoned that such language was unnecessary because TSCA does not require EPA to implement an ordering or ranking system in the first place.

General Objectives for both High- and Low-Priority chemical substances

The proposed rule included a general objective only for identifying High-Priority Substances. However, commenters suggested that the final rule include general objectives for identifying Low-Priority Substances as well. EPA amended the rule to provide general objectives for both High- and Low-Priority Substances.¹⁹

Substitute chemical substances

EPA deleted the statement in the proposed rule that it may “consider the relative hazard and exposure of potential candidate’s substitutes” in selecting a chemical for prioritization. EPA will instead consider chemical alternatives as part of risk management rules.

¹⁹ 40 C.F.R. § 702.5(a).

Next steps

Companies may want to contact EPA early and often, and offer to serve as a resource if they believe that chemicals they manufacture or process may be candidates for prioritization. As a proactive step, they may want to review the chemicals that are listed the 2014 TSCA Work Plan Update list and provide information to EPA or conduct new studies of hazard or exposure to fill data gaps or to counter problematic existing studies.

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