wiley

ALERT

EPA Designates Low-Priority Chemical Substances

February 27, 2020

On February 26, the U.S. Environmental Protection Agency (EPA) finalized its first-ever "low-priority" designations for 20 chemical substances. 85 Fed. Reg. 11069 (Feb. 26, 2020). Designation as "low-priority" means that risk evaluations are not warranted at this time for these chemicals per Toxic Substances Control Act (TSCA) Section 6(b)(1)(A) and 40 C.F.R. § 702.15.

Under TSCA, a high-priority substance is defined as a chemical substance that EPA finds, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard or a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA. A low-priority substance is one that does not meet that definition based on sufficient information.

What Low-Priority Designation Means for Your Company

For companies that already manufacture, import, process, and use these chemicals, EPA's announcement should be welcome news. This designation status under TSCA means that these chemical substances are unlikely now or in the future to be subject to costly and complex risk evaluations by EPA. All 20 substances already benefit from being on EPA's Safer Chemical Ingredients List (SCIL). Companies who are seeking new ingredients with a low likelihood of TSCA regulation may want to consider these low priority chemicals when reformulating or designing new products. All companies who identify with these substances and want to promote EPA's recent announcement will need to make sure that their claims and assurances are truthful, not

Authors

Erik C. Baptist
Partner
202.719.7540
ebaptist@wiley.law

Martha E. Marrapese
Partner
202.719.7156
mmarrapese@wiley.law

Practice Areas

Environment & Product Regulation
Toxic Substances Control Act (TSCA)

misleading, and comply with EPA Safer Chemical and Federal Trade Commission guidelines.

Although EPA characterizes a low-priority designation as a "final, yet not permanent" finding that can be revisited, these substances have now undergone a rigorous screening for potential hazards and exposures. EPA is unlikely to turn back to these chemicals anytime soon. Nevertheless, interested stakeholders also should bear in mind that low-priority designations are final agency actions and judicially reviewable. Therefore, EPA could be challenged in court on these designations. EPA may face challenges on individual chemicals – or the entire group – by those who think that the designations are not based on sufficient evidence, fail to establish that the chemicals may not present unreasonable risks to health or the environment because of a potential hazard or a potential route of exposure, or ignore critical evidence. Groups representing potentially exposed and susceptible subpopulations may choose to disagree with the agency's designations.

In addition, low-priority designations do not benefit from federal preemption against state action. Despite the screening nature of these reviews, Congress was confident in 2016 that a strengthened federal chemical review program would inspire confidence among the states that regulatory attention was not needed for these chemicals. Therefore, the use of these low-priority chemical substances in current and new commercial applications should represent a great choice and should present a low risk of regulatory action at both the EPA and state levels.

Keep in Mind that Prioritization is not Risk Evaluation

A list of the TSCA 20 low-priority chemicals can be accessed here. In reaching these designations, EPA has relied on the screening approach it describes in the guidance document entitled Approach Document for Screening Hazard Information for Low-Priority Substances Under TSCA and the criteria and considerations in TSCA section 6(b)(1)(A) and 40 C.F.R. § 702.9. Each low-priority chemical has a separate public docket where the public can view the corresponding support document containing the agency's basis for the final designation. This process also has included 90-day comment periods following initiation of the prioritization process and proposal of the designations for low-priority substances. In response to public comments, EPA has made a limited number of changes. For example, each support document was updated to address comments that certain endpoints (immunotoxicity and respiratory sensitization) were not initially included.

In announcing the final designations, EPA takes care to explain that prioritization is not a risk evaluation, and that TSCA does not require risk evaluations at the prioritization stage. Factors the agency points to for support include the statutory window of no more than one year for the entire prioritization process, the statutory requirement for EPA to designate 20 low-priority substances by December 2019, and the plain statutory text explaining that EPA is to use a "screening process" to designate "low-priority" substances "for which risk evaluations are not warranted at the time." Nevertheless, the public comments on the rule signal that some groups expected EPA to perform a more exhaustive review and will judge the adequacy of EPA's designations on this basis.

Conclusion

Prudent companies who manufacture, import, process, or use any of these chemicals will want to monitor for developments associated with judicial review and state action in the coming months. If a court were to overturn EPA's low-priority designations for any or all of these chemicals, the agency may be forced to conduct full risk evaluations on these chemicals. The agency has taken the position that it is required to designate only 20 low-priority substances under the Lautenberg Amendments in Section 6(b)(2)(B) of TSCA. Having fulfilled this commitment, it remains to be seen if the agency takes on any future low-priority reviews. Should EPA have to legally defend these first twenty designations, after taking care to select chemicals that do not trigger any high-priority review criteria, it could tremendously disincentivize the agency from attempting to identify safer chemicals for the public in the future.