FEBRUARY 2017

COMMENTARY

EPA Proposes Rules to Implement TSCA Reform

The Frank R. Lautenberg Chemical Safety for the 21st Century Act was signed into law on June 22, 2016. We previously summarized that bill's key changes to the Toxic Substances Control Act ("TSCA"). This *Commentary* highlights several rules that the United States Environmental Protection Agency ("EPA") recently proposed to implement the new law. Comments on each of these rules are due in March, with final rules to be issued by summer 2017.

Inventory Reset Rule

On January 13, 2017, EPA proposed the TSCA Inventory Notification (Active-Inactive) Requirements rule ("Inventory Reset Rule"). The Inventory Reset Rule stems from the mandate in the amended TSCA for EPA to designate chemical substances on the TSCA Inventory as either "active" or "inactive" in United States commerce. Under the proposed rule, manufacturers will be required, and processors have the option, to report each chemical substance on the TSCA Inventory that they manufactured or processed for nonexempt commercial purposes during the 10 years between June 21, 2006, and June 21, 2016. Chemicals not reported will be designated as "inactive." Going forward, a person who wants to manufacture or process a chemical designated as inactive would be required to notify EPA in advance. All reporting under this rule must be submitted electronically through EPA's Central Data Exchange portal, and there is a five-year recordkeeping requirement for those that submit any notices under the rule. For active chemicals on the confidential portion of the TSCA Inventory, if those submitting notices want to keep information about the chemical confidential, they must substantiate the need for continued treatment as confidential. Comments on the Inventory Reset Rule are due by March 14, 2017. The Inventory Reset Rule is expected to be finalized by summer 2017, with manufacturer notices due within 180 days and processor notices due within 360 days of publication of the final rule in the Federal Register. If a chemical substance is designated as "active" it is eligible for consideration under the Prioritization Rule.

Prioritization Rule

EPA proposed a rule entitled Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act ("Prioritization Rule") on January 17, 2017. Comments on the Prioritization Rule are due by March 20, 2017. The Prioritization Rule will establish the process and criteria that EPA will use to identify chemical substances as either "high priority" or "low priority." High priority chemicals will then be subject to risk evaluation. EPA proposes that

the prioritization process would include the following steps: pre-prioritization; initiation; proposed designation; and final designation.

In the pre-prioritization stage, EPA would consider whether the chemical substance meets one or more of the following criteria: persistent, bioaccumulative, and toxic; used in children's products; used in consumer products; detected in human and/or ecological biomonitoring programs; potentially of concern for children's health; high acute and chronic toxicity; probable or known carcinogen; neurotoxicity; and other emerging exposure and hazard concerns to human health or the environment. EPA would then perform a screening review using the following considerations: hazard exposure potential; persistence and bioaccumulation; potentially exposed or susceptible subpopulations; storage near significant sources of drinking water; conditions of use; production volume; and any other relevant risk-based criteria. Pursuant to the amendments to TSCA, EPA may not consider costs or other non-risk factors at any point in this process.

The initiation phase would involve publication of the results of EPA's screening review in the Federal Register to allow for a 90-day public comment period. EPA would then publish a proposed designation in the Federal Register and commence another 90-day comment period. Any comments on proposed designations of chemicals as low priority must be submitted during this window or will be considered waived. Lastly, EPA would issue a final designation between 9 and 12 months following publication of the screening review in the Federal Register.

EPA has noted that the bar for prioritizing a chemical as low priority is relatively high, and that if EPA has insufficient information to designate a chemical as low priority, it will be designated as high priority. The proposed rule also states that EPA may revise a final designation of low priority to high priority at any time if it receives information suggesting the need for such a change. Under the Prioritization Rule, a low priority designation would be considered final agency action subject to judicial review. A high priority designation would not be subject to judicial review, but would trigger the obligation for EPA to commence an assessment under the Risk Evaluation Rule.

Risk Evaluation Rule

Under the revised TSCA, EPA must perform risk evaluations for certain chemicals, including chemicals designated as high priority,[1] to determine whether they present an unreasonable risk of injury to health or the environment. On January 19, 2017, EPA proposed a rule outlining how it will conduct such risk evaluations: Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act ("Risk Evaluation Rule").[2] EPA proposes that risk evaluations would include the following components: scope, including a conceptual model and analysis plan; hazard assessment; exposure assessment; risk characterization; and risk determination.

The scope would be based on various factors, including conditions of use (actual and reasonably foreseeable), potentially exposed populations, and life cycle of the chemical. EPA plans to publish proposed scopes in the Federal Register for public review and comment no later than three months after initiating a risk evaluation. Comments on scope not made during the 30-day comment period will be considered waived. After the final scope is published in the Federal Register, EPA would conduct a hazard assessment by evaluating potential human and environmental hazard endpoints. EPA would then conduct an exposure assessment and develop a risk characterization, which would be peer reviewed. (EPA has, however, requested comments on whether there are circumstances where peer review is not warranted.) EPA would then publish a draft risk assessment in the Federal Register and provide the opportunity for public review and comment. All comments that could be raised regarding the draft risk assessment must be made during this comment period or will be considered waived.

As a final step, EPA would publish a final risk evaluation, determining whether the chemical poses an unreasonable risk of injury to health or the environment. EPA's finding would be

1 Other chemicals subject to risk evaluation are the first 10 chemicals selected by EPA from the update to the TSCA Work Plan and chemicals requested for risk evaluation by manufacturers.
2 This proposed rule also lays out the steps for manufacturers that want to request a risk evaluation.

published in the Federal Register no later than three years after the date on which the risk evaluation is initiated, with the potential for an extension of up to six months. If EPA concludes that the chemical does pose an unreasonable risk, the revised TSCA obligates the agency to draft rules designed to prevent such risk. A determination that a chemical does not pose an unreasonable risk, however, is considered a final agency action. Comments on the Risk Evaluation Rule are due by March 20, 2017.

Lawyer Contacts

For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com/contactus/.

Jane B. Story
Pittsburgh
+1.412.394.7294
jbstory@jonesday.com

Alina Fortson
Chicago
+1.312.269.1542
afortson@jonesday.com

Mary Beth Deemer
Pittsburgh
+1.412.394.7920
mbdeemer@jonesday.com

Kevin P. Holewinski
Washington
+1.202.879.3797
kpholewinski@jonesday.com