

EPA Marks First Anniversary of TSCA Reform With Three Implementing Rules

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On the first anniversary of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (also known as the TSCA Modernization Act of 2015), EPA promulgated three significant rules to implement the Act. The Act stands as the first significant amendment to the Toxic Substance Control Act (TSCA) since its inception in 1976 and significantly modifies EPA's responsibilities for several issues related to chemical safety. The three new rules establish: (i) the process for identifying high priority chemicals for risk evaluation and low priority chemicals for which no risk evaluation is needed, (ii) the process for evaluating high priority chemicals to determine if they present an unreasonable risk to health or the environment, and (iii) industry reporting requirements for chemicals manufactured or processed over the past ten years.

The risk evaluation rule establishes a framework under which EPA will first announce a chemical to be prioritized, giving the public 90 days to submit relevant information on the chemical. Next, EPA will screen the chemical using the following criteria: (1) hazard and exposure potential; (2) persistence and bioaccumulation; (3) potentially exposed and susceptible populations; (4) storage near drinking water sources; (5) conditions of use of the chemical; and (6) volume of the chemical manufactured or processed. Following screening, EPA will propose to designate a chemical as either high priority or low priority. High priority chemicals are ones that present an unreasonable risk to health or the environment. Low priority chemicals do not. This determination will be published for public comment for 90 days.

EPA's next rule establishes a process for evaluating high priority chemicals for determination of reasonable or unreasonable risk to health or the environment. A risk evaluation may be initiated by EPA or by the manufacturer of the chemical. The scope of a risk evaluation includes hazards, potential exposures, conditions of use, potentially exposed or susceptible populations, a conceptual model of the chemical's relationship with humans and the environment, and an analysis plan. EPA will also assess adverse health and environmental effects of the chemical and the duration and intensity of exposures to the chemical. It will then make a risk characterization and determination of whether the chemical presents an unreasonable risk to health or the environment. EPA's draft risk evaluation will be

published for public comment for 60 days, and a final risk evaluation must be published no later than three and a half years after identifying the high priority chemical.

The third rule requires manufacturers and importers to provide retrospective electronic notification to EPA of chemical substances manufactured or imported for commercial purposes during the past ten years. EPA will use these notifications to distinguish active substances from inactive substances and will include this distinction in the TSCA Inventory.

In addition to the three rules, EPA also released the list of the first ten chemicals to undergo risk evaluation. It also released guidance on how people interested in drafting and submitting risk evaluations to EPA should do so. All in all, EPA has taken significant steps in a relatively short period to implement the most significant amendment in TSCA's history.

Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act

Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act

TSCA Inventory Notification (Active-Inactive) Requirements

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