



US Environmental Regulations

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The Toxic Substances Control Act (TSCA), the primary federal regulatory framework for industrial chemicals in the U.S. TSCA, was amended significantly in 2016 with the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. While many sections of TSCA were altered under the Lautenberg Act, the key changes impacting the regulated community involve:

- Assessments for new chemicals and significant new uses under Section 5;
- Expanded authorities for U.S. Environmental Protection Agency (EPA) to require chemical testing under Section 4;
- Imposition of industry fees under Section 26; and
- Risk management for existing chemicals under Section 6.

Below are more details related to Section 6 risk management.

Inventory Notification:

While not a Section 6 action, the Inventory notification reporting plays a role in EPA risk evaluations. IAEG members were required to report by February 7, 2018, chemicals that they manufactured or imported during the ten-year lookback period. IAEG members that process chemicals in the U.S. have the opportunity to report voluntarily those chemicals not already notified by manufacturers or importers. The processor reporting ends on **October 5, 2018**. At the end of the Inventory notification process, EPA will publish an updated TSCA Inventory, in which chemicals will be designated as “active” or “inactive” chemicals. This list is expected in **December 2018**. Once the active and inactive lists are

final, inactive chemicals may not be manufactured, imported, or processed without first notifying EPA, which will then designate the notified chemical as “active.”

Prioritization:

The first step under the Section 6 risk management approach is prioritization during which EPA will screen chemicals to determine if they are high or low priority for risk evaluation purposes. EPA states it will focus prioritization efforts on chemicals designated as active. Amended TSCA mandates that EPA consider hazard and exposure potential, persistence, bioaccumulation, susceptible subpopulations, storage near drinking water, conditions of use, and production/import volumes in the prioritization process. EPA is also mandated to give high priority designation to those chemicals on the 2014 Work Plan that have a persistence and bioaccumulation score of 3, are known human carcinogens, and have high acute and chronic toxicity.

Chemicals that may present an unreasonable risk because of potential hazard and exposure will be designated as high priority. Chemicals that do not meet the high priority standard will be considered low priority. If there is insufficient information to support a low priority designation, the chemical will be considered high priority by default.

If a chemical is high priority, EPA is required under the law to conduct a risk evaluation.

Risk Evaluation:

The centralizing concept for TSCA is “unreasonable risk.” A TSCA risk evaluation will not include consideration of cost/benefit factors, will focus on conditions of use as determined by EPA, and will consider potentially exposed or susceptible subpopulations. Based on recent experiences, it seems evident that EPA is particularly interested in workers within a chemical’s value chain as susceptible subpopulations.

Industry stakeholders will need to engage with EPA to present relevant information on their specific conditions of use for a subject chemical. Information elements that may be helpful include industry description, concentrations used, type of processing, physical form, storage on site, concentration in final product, waste treatment, environmental controls, permits, and established worker exposure controls.

If a chemical is found to present unreasonable risk, EPA is required under the law to proceed to risk management.

Risk Management:

EPA is required to establish risk management measures that manage the identified risk “to the extent necessary.” There are some exemptions in amended TSCA for risk management activities, including criticality of use, no available safer alternatives, and adverse impact on national economy, national security, or critical infrastructure.

Section 6 Timelines:

Once the risk prioritization process starts, EPA must make a prioritization designation within 12 months. If the chemical is high priority, EPA will immediately initiate a risk evaluation and complete it within three years, with a possible six-month extension. If EPA finds the chemical presents a risk, EPA must issue the risk management actions within two years, with a two-year extension possible. These

timeframes, mandated in the TSCA legislation, provide minimal time for industry sectors to evaluate and implement commercial changes for impacted chemicals.

What's Coming Next:

EPA will soon finalize the industry fee assessments for actions under Sections 4, 5, and 6. Section 6 risk assessment fees are proposed to be \$1,300,000 to \$2,600,000 per chemical. Industry stakeholders are expected to share the assessment fees.

EPA will be identifying additional chemicals that will be subject for review under Section 6. Given TSCA directs EPA to use the 2014 Work Plan list as a primary basis for choosing such chemicals, IAEG members should carefully review that list and identify those listed chemicals that may be critical for their businesses. Decisions need to be made as to whether and how to ensure whether uses can continue or whether new formulations need to be developed.

