

Practice Update

Toxic Substances Control Act: Landmark Federal Environmental Statute Reformed

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In June 2016, President Barack Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a bill reforming the Toxic Substances Control Act (TSCA) of 1976. After forty years the landmark environmental law was regarded by many as outdated and ineffective, resulting in a failure to provide uniform national regulation of chemical substances, causing both environmental advocates and industry groups alike to propose reform. It took several years and the support of legislators on both sides of the aisle, but TSCA legislation was passed in 2016 with broad bipartisan support and touted by most stakeholders as both comprehensive and innovative. The bill revises the U.S. Environmental Protection Agency (EPA) processes and requirements for evaluating and determining whether regulatory control of a chemical is warranted.

Major aspects of the TSCA legislation include the authority to regulate existing chemicals, strengthening transparency and quality of science required for EPA decision-making, evaluation of chemicals solely on the health risks posed, and increased regulatory options to address risk. The TSCA legislation outlines new and expanded EPA powers and detailed testing requirements, as well as

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rulemaking and administrative requirements. The TSCA bill preempts state law from establishing new restrictions on chemicals regulated by the EPA or assessing the hazards, exposures, risks, and uses of chemicals identified by EPA as subject to safety assessment and determination. The highlights of the bill are provided below.

New/expanded TSCA authorities:

- Provide EPA express authority to regulate existing chemicals as well as regulate new chemicals and new significant uses of existing chemicals
- Pre-manufacture notice requirements for the production of new chemicals
- Ability to request safety data from manufacturers and processors and to review both new and existing chemicals or significant uses of chemicals
- Development of information through consent agreement or order, in addition to rulemaking, and
- Authority to collect fees from manufacturers, importers, or processors, allowing for a consistent source of funding

Revisions to TSCA testing requirements:

- The EPA must conduct: (1) a safety assessment to determine the risk posed by a chemical under conditions of use and exposure information; and (2) a safety determination to determine whether the chemical meets the safety standard under the conditions of use
- Eliminated the requirement for a preliminary finding about risk before safety assessment testing can be required
- Prioritization of chemicals for assessment and determination, which must be based on persistence and bioaccumulation or human carcinogens that have high acute and chronic toxicity

- Chemical testing for safety assessment will be focused on risk-management alone; cost is no longer a factor
- Safety assessments must be conducted to provide protection from exposure to chemical substances for vulnerable groups, including children, pregnant women, elderly, and regarding worker's health, as well as consumers and the general public, and to ensure information is available to public health officials and first responders in case of emergency
- Testing procedures and deadlines for safety determinations must take relative cost, availability of facilities and personnel to perform testing, and applicable deadlines into consideration, and
- Manufacturers may request chemical assessment and determination upon payment of a fee

New rulemaking and administrative requirements for EPA:

- An initial list identifying high and low priority chemicals must be issued within one-hundred eighty (180) days
- A risk-based screening process and criteria for identifying existing chemicals that are high or low priority for assessment and determination must be issued within one (1) year
- Development of policies, procedures, and guidance to carry out the bill's requirements must be issued within two (2) years
- Prioritization of existing chemicals for risk evaluation, with clear and enforceable deadlines
- A chemical testing schedule and resources for completion of assessment and determination must be made public after designating a chemical high priority
- An annual plan must be published which identifies the assessments and determinations to be completed that year and details the current status of the initiated assessments and

determinations, with an opportunity for public comment, and

- An Independent Science Advisory Committee on Chemicals must be established by EPA to provide expert advice and consultations regarding the scientific and technical aspects of interpreting the TSCA legislation

The EPA is no longer required to restrict chemical substances in the least burdensome manner and is authorized to impose requirements necessary to eliminate risk to health or the environment, including banning substances.

Confidential Business Information. Chemical manufacturers, importers, and processors should be aware that testing information that is not confidential must be made publically available. Confidential business information (CBI) protection measures include the identification of categories of information presumed to be protected and those which are not protected, as well as provided an exception for public health or emergency information. The EPA must create a plan for reviewing all CBI claims. The TSCA legislation limits CBI protection to ten (10) years, with extensions of ten (10) years.

Companies that manufacture, import, or process chemicals in various industry segments may wish to evaluate whether to conduct an operations review to determine chemicals in use, those planned for future use, and to create a plan in preparation for the implementation of the TSCA legislation.

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