

A Bi-Partisan Agreement to Expand EPA Authority to Regulate Toxic Substances

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Rarely do both sides of the legislative aisle in Washington join in overwhelming approval to expand the authority of the Environmental Protection Agency ("EPA"). Recently, the House of Representatives and Senate did just that, and President Obama joined them on June 22, 2016, by signing into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("TSCA Reform Act") to update the Toxic Substances Control Act ("TSCA").

In 1976, Congress enacted the TSCA to regulate toxic and chemical substances to prevent "unreasonable risk of injury to health or the environment." Unlike other environmental laws, the TSCA focused on pollution prevention through regulation of products rather than by regulation of the disposal of wastes. The idea behind the TSCA was to reduce and prevent unreasonable risks to human health by making industry develop data on the environmental effects of chemicals produced, but without stymieing technological innovation or business growth. Under the TSCA, the EPA could require manufacturers to test substances prior to introducing a new chemical substance into the market for a "significant new use." However, the TSCA's balance between environmental protection and economics meant that the EPA was limited to applying the "least burdensome requirement" when restricting the use of harmful chemicals, and this manner of regulating the manufacture, import, processing, distribution, and use of chemicals under the TSCA remained unchanged for 40 years.

The TSCA Reform Act removes the "least burdensome requirement" from the regulation of toxic chemicals to allow the EPA to restrict or ban the use of those substances posing unreasonable risks. Other significant changes to the TSCA that will affect manufacturers, processors, suppliers, and importers of chemicals include:

- Risk Assessment and Prioritization: The EPA will evaluate new and existing chemicals to determine whether they present an "unreasonable risk of injury to health or the environment," and will designate them as high or low priority. These affirmative determinations are to be made without consideration of cost or other non-risk factors when evaluating harm. The EPA can issue unilateral orders (in addition to the more common consent agreements already available under the TSCA) to elicit testing from manufacturers on existing chemicals to make its determinations.
- Reduction of Animal Testing: The EPA must promote the development and implementation of alternative methods and strategies to reduce the use of vertebrate animals in chemical testing.
- Pre-Manufacture Notification ("PMN"): The TSCA mandates that manufacturers submit a PMN to the EPA 90 days prior to commencement of the manufacture or import of a new chemical substance demonstrating that there is no unreasonable risk of injury to health or the environment. Prior to the TSCA Reform Act, the EPA did not have to make a safety determination, so the manufacture or import of a chemical substance could proceed if there was no response to the PMN from the EPA. The TSCA

Reform Act, however, requires the EPA to review each PMN and make an affirmative determination on the risk of injury from the chemical substance.

- Preemption: The TSCA Reform Act is intended to provide a uniform federal scheme preempting and invalidating inconsistent state laws. The TSCA Reform Act partially precludes states from passing or enforcing laws or regulations that are inconsistent with the TSCA. The prohibitions differ depending on the chemical subject to restriction, type of state requirements, when the state statute or regulation was put into place, and whether the EPA is undertaking a risk evaluation. State laws enacted prior to April 2016 are grandfathered.
- Confidential Business Information ("CBI"): Claims to protect CBI from disclosure to the public will be significantly curtailed under the TSCA amendments. CBI claims will be limited to 10 years. Companies must request a renewal for CBI protection and substantiate the need for the continued treatment.
- Increased Costs, Penalties, and Prison Terms: The EPA is now authorized to charge higher fees for its chemical review process. In addition, the caps on civil and criminal penalties have been increased. The risk of imprisonment for certain willful and knowing violations brings the TSCA in line with other environmental statutes.
- Rules Implementation: The TSCA Reform Act requires the EPA to develop rules to implement its processes and requirements such as those mentioned above with various policies, procedures, and guidance documents over the next one to two years. The EPA has published a FAQ's sheet to address initially how it plans for this to occur.

The implications of TSCA reform and the EPA's expanded regulation of the manufacture and sale of chemicals will be felt by a community used to more benign oversight. There will be an increased burden on manufacturers and processors to gather information and conduct analyses to prepare for the EPA's restrictions on chemical and toxic substances based on the risk designations. It will now take longer for companies to introduce new chemicals into commerce because of the EPA's required affirmative determination on PMNs. Protection of CBI, limitation of public accessibility to such information, and renewal of protective claims may oblige companies to develop stronger management of data and information produced when developing new chemicals. In this new age of the reformed TSCA, staying abreast of the EPA's implementation of its new authority will be critical to understanding and compliance.

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