

REVISED TSCA REGULATIONS READY FOR PRESIDENT OBAMA'S SIGNATURE

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After months of negotiations, an overwhelming majority of the U.S. House of Representatives (403 to 12) and a unanimous Senate approved a historic reform of the Toxic Substances Control Act (TSCA). The legislation, titled the *Frank R. Lautenberg Chemical Safety for the 21st Century Act* (H.R. 2576, the "Lautenberg Act"), revises the framework for regulating chemicals and provides EPA stronger authority to test and regulate chemicals. President Obama, who issued a statement in support of the reform legislation on May 23, was presented with the bill on June 14 and is expected to sign the Lautenberg Act into law soon.

TSCA was enacted in October 1976 to regulate certain chemical substances present in commercial goods in the United States to protect human health and the environment by requiring testing and use restrictions. In the 40 years since its enactment, TSCA has been largely regarded as one of the least effective federal environmental laws, in part because EPA was granted very little authority to actually enforce TSCA. For example, at the time of TSCA's enactment, almost 65,000 chemicals were grandfathered in and did not require EPA to review them for safety, resulting in an enormous of chemicals still currently approved for use that the federal government and consumers know very little about. Much of the criticism stems from Section 6 of TSCA, which provides a loophole that allows harmful products to remain in circulation if banning the product would have a significant impact on industry profits. For example, in 1989, EPA issued a final rule under Section 7 of TSCA banning most asbestos-containing products. In 1991, however, this rule was vacated by a landmark decision in the Fifth Circuit, *Corrosion Proof Fittings v. Environmental Protection Agency*, which overturned the ban on the grounds that EPA failed to demonstrate that a ban was the least burdensome alternative to regulating asbestos.

Unlike other environmental statutes, TSCA has not been significantly amended since its enactment – that is, until now. Once enacted, the Lautenberg Act will: (1) bolster EPA's ability to get information about and regulate chemicals, (2) require companies to pay fees for agency risk reviews, and (3) require them to justify the confidential business information claims they make. The Lautenberg Act will also require EPA to reduce animal testing where scientifically reliable alternatives exist that would generate equivalent or better information. Some of the key changes that might affect manufacturers, industries, and other interested entities (collectively, "interested entities") include:

- **New testing protocols:** Previously, EPA struggled to impose testing requirements because notice-and-comment rulemaking requirements delayed rule enactments. The new legislation permits EPA to bypass the Administrative Procedure Act rulemaking process altogether and instead issue orders requiring manufacturers and processors to conduct testing.
- **Confidentiality designations:** TSCA allows companies to claim the exact identity and formula of a chemical as confidential business information to prevent competitors from making the same substance, without requiring substantiation of such claim. New mandates under the Lautenberg Act, however, would require companies to substantiate the reason they claim confidentiality, and require EPA to periodically review the substantiation. Substantiation requires a statement that the company has (1) taken reasonable measures to protect the confidentiality of the information, (2) determined that the information is not required to be disclosed or otherwise made available to the public under any other federal law, (3) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the company's

competitive position, and (4) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

- **Opportunities to influence EPA decisions about prioritization of risk evaluations:**

- Before initiating the chemical prioritization process or proposing a priority designation for a chemical substance, EPA must allow interested persons to submit relevant information on the chemical substance at issue.
- After proposing to designate a chemical as either high- or low-priority, EPA must publish information regarding the information, analysis, and basis used to make the proposed designation and provide interested entities 90 days to submit public comments on the proposed designation;
- Interested entities can comment on draft risk evaluations and proposed risk management rules; and
- A chemical manufacturer can request that EPA conduct risk evaluations on chemical substances, subject to a fee.
- Note: If a chemical is designated as a low-priority substance, any person may commence a civil action to challenge the designation no later than 60 days after the publication of that designation.

- **Use of science:** The Lautenberg Act directs EPA to make decisions based on the weight of scientific evidence, and to ensure that its decisions are consistent with the best available science. EPA will consider, as applicable, five different factors, including the relevancy of the scientific evidence and the extent of independent verification or peer review of the scientific evidence, such as the procedures, measures, methods, protocols, methodologies, and models used.
- **Preemption:** The Lautenberg Act ensures that individual states maintain a significant role in assuring chemical safety by grandfathering in past state actions, preserving states' ability to take many types of actions, and providing for states to get waivers to act both before and after the EPA takes final action on a chemical. For example, all state restrictions on chemicals that were taken as of April 22 of 2016 will remain in place regardless of what EPA decides about that same chemical in the future. States are free to initiate new restrictions on a chemical until and unless EPA classifies the chemical as High Priority and publishes a document outlining the scope of the risk evaluation it plans to undertake. Companies should continue to monitor and track regulations in different states and, in addition to TSCA regulations, follow all state regulations.
- **Safety standards:** EPA must determine whether a chemical is likely to meet the safety standard before it enters the market. EPA will consider sensitive subpopulations, such as pregnant women and children, in this determination.

Once signed by President Obama, EPA must immediately begin implementing the amended TSCA, which identifies short- and long-term deadlines, such as:

- Within 90 days, EPA will publish a list of mercury compounds prohibited from export beginning January 1, 2020.
- Within 180 days of enactment, EPA must ensure that risk evaluations are being conducted, report to Congress regarding its capacity to carry out risk evaluations, and decide whether to revise its standards for what qualifies for a small business.
- One year after enactment, EPA must establish a risk-based screening process and criteria for designating chemical substances as high- or low-priority substances, publish a final Inventory reset rule requiring manufacturers and processors to submit information about chemicals in commerce, and establish a Science Advisory Committee on Chemicals.

Due to these fast-approaching deadlines, it is recommended that interested entities thoroughly read and understand the new law and consider what kinds of potential impacts it will have on their businesses. Some suggestions for interested entities are to identify what chemicals they use, make, import, or ship; identify the healthy, safety, and exposure data they have for those chemicals; be prepared to participate with and communicate to EPA regarding the risk designation procedures; and prepare possible substantiations for confidentiality claims regarding chemicals.

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