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# Recent reform of the Toxic Substances Control Act – What you need to know and steps you can take

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Act) was signed into law by President Obama. The Act was the first significant reform of the Toxic Substances Control Act (TSCA) since enacted in 1976. The Act primarily affects chemical manufacturers and processors, but it will also impact downstream businesses - companies that use, import or export, or sell products containing chemicals.

The Act lowers the burden for the U.S. Environmental Protection Agency (EPA) to regulate chemicals that it finds pose a risk to health, requires the EPA to approve new chemicals before they hit the marketplace, and puts limits on new chemical legislation by states. While the full consequences of the Act will take time to discern as it is implemented and interpreted, there are some immediate steps all affected companies should take:

- Consider seeking preemptive EPA safety review of chemicals you manufacture
- Review your processes for protecting confidential business information (CBI), and review your prior submissions of CBI to the EPA
- Take stock of all chemicals manufactured or processed in last the 10 years in preparation for new reporting requirement
- Take a more proactive role in determining the chemicals you use and make contingency plans for possible restrictions

Companies should also prepare for slower speed to market of new chemicals and prepare to provide safety information to the EPA for all new chemicals before they go on the market.

## Overview of the Act

Since its enactment in 1976, the TSCA has been widely criticized as impotent because of the standard the EPA was required to meet before it could regulate chemicals. Industry had also become increasingly concerned about a patchwork of state laws enacted to fill the regulatory void created by the EPA's inaction. The Act was the result of a bipartisan effort and a coalition featuring both industry and environmental/ public health groups.

Here are five top highlights of the Act:

**1. Mandatory EPA safety review of all chemicals**

The Act creates enforceable deadlines for the EPA to prioritize and review all chemicals, including new chemicals and those already on the market. The EPA must finalize an initial list of high priority chemicals within 12 months, then conduct safety review of high priority chemicals within 3 years of being added to the list. If a chemical fails to pass the safety review, the EPA must finalize regulation of the chemical within two years.

The Act requires expedited action on certain persistent, bioaccumulative and toxic chemicals (PBTs), chemicals widely considered to pose environmental and health risks. The EPA has already identified 30 PBTs.

Manufacturers can preemptively request EPA review of a chemical at the manufacturer's cost. By requesting EPA review of a PBT, a manufacturer can delay the EPA's action to regulate that PBT.

**2. Mandatory review of new chemicals before use**

The EPA must now make an affirmative finding that a chemical is not likely to present an unreasonable risk before a manufacturer can commence production. Manufacturers are required to submit premanufacture notices to the EPA 90 days before beginning to manufacture or process a new substance. The EPA must then review all new chemicals and significant new uses before manufacturing or processing can commence.

**3. Lowered burden for EPA to regulate chemicals**

The Act lowers the safety standard that the EPA must show to regulate a chemical. The EPA was previously required to take the cost of regulation on industry into account when deciding whether to regulate a chemical, but now may consider only health and environmental factors.

The EPA also now has broader authority to act once it has decided to regulate a chemical. The EPA was previously required to use the least restrictive possible means to regulate a chemical. Now, the EPA must decide how to regulate chemicals based on an array of factors, including cost benefit analysis with a focus on health risks and special emphasis on vulnerable populations like pregnant women, infants and the elderly. EPA's regulatory options include labeling requirements, use restrictions, phase-outs or bans.

The Act now mandates that the EPA regulate chemicals found unsafe. If the EPA fails to regulate a chemical it found unsafe, it can be compelled to do so through private litigation.

**4. Preemption of state laws**

The Act provides a framework for preemption of state laws. In general, any state laws passed after the Act will be preempted with respect to a chemical once the EPA makes a final determination about that chemical. All state restrictions currently in place, however, will remain in place.

States may continue to initiate new restrictions unless the EPA adds a chemical to the high priority list; states are then prohibited from establishing new restrictions that address the same scope the EPA plans to review. If the EPA declares a chemical safe, states are preempted from regulating that chemical. If the EPA declares a chemical unsafe, states may impose restrictions while the EPA decides how to regulate the chemical, but once the EPA finalizes its regulations, states may not regulate the chemical unless they obtain a waiver from the EPA.

**5. Less protection for confidential business information**

Companies are now required to substantiate claims of CBI at the time of submission of materials to the EPA. The claims must be re-substantiated no less than every 10 years. This affects CBI claims made, for example, when companies submit toxicity information on chemicals (which the EPA may now require with greater frequency) or comply with reporting requirements. Moreover, the EPA now has broader authority to share certain information with state and local governments and health providers.

## What happens next and steps you can take

The EPA has already begun assigning chemicals to the high priority list and will soon begin chemical reviews. The EPA will also commence formulating regulations on topics such as the prioritization process, risk evaluation process, and guidance for industry-requested evaluations and confidential business information handling. Industry will have opportunities to weigh in on proposed rules and regulations.

Manufacturers and processors of chemicals will see the greatest impacts from the Act, including the following:

- Higher likelihood the EPA will determine chemicals pose a risk and then take action to regulate such chemicals
- Slower speed to market time for new chemicals or uses as EPA must conduct risk evaluation before market entry
- Greater burden on companies to protect their confidential business information

In light of these impacts, manufacturers and processors should discuss with their advisors where and how to take the following steps:

- **Consider initiating a manufacturer-requested review of chemicals.** This may provide greater certainty to your company, reduce delay in waiting for regulatory approval, and preempt future state regulation. In addition, manufacturer requests can potentially force EPA to conduct risk evaluation of PBTs before it can take expedited action as otherwise required by the Act.
- **Manufacturers will be required to report on chemicals manufactured or processed in the last 10 years.** Manufacturers therefore should consider how to begin gathering the data needed to comply with this requirement.
- **Review your company's prior CBI claims and consider confidentiality claims you may make in the future**. Consider taking reasonable measures to protect CBI prior to making a CBI claim, as companies will be required to demonstrate such measures.

Downstream producers and retailers should consider possible impacts on their businesses as well, including addressing with their suppliers the potential impact of new chemical restrictions on their products.

## Conclusion

The Act contains both positives and negatives for businesses. The Act will result in increased regulation of certain chemicals and potentially slower speed to market for new chemicals, but will reduce regulatory uncertainty and unpredictability. Companies that take appropriate action now to prepare for the Act's implementation will be in a better position to profit from the new regulatory environment and mitigate the risk of heightened regulation.