

Manufacturers Outside The Chemical Industry Will Be Impacted by the New TSCA Amendments

September 2016

On June 22, 2016, President Obama signed into law the “Frank R. Lautenberg Chemical Safety for the 21st Century Act.” The new act amends the Toxic Substance Control Act (TSCA), significantly overhauling the way that the EPA regulates the tens of thousands of chemicals made and used in American industry. The chemical industry took notice, but many other manufacturers have not realized they will be impacted too.

While the Lautenberg Act’s most immediate impacts likely will be felt by companies bringing new chemicals to market, the most dramatic impacts may actually fall on companies that use chemicals in manufacturing processes or as constituents in their products. These companies are called “processors” in TSCA parlance. This is because Congress mandated that EPA go back and review all of the chemicals which are already in commerce. Existing processes, formulas, and product compositions may be placed in jeopardy if one or more chemicals used in the production of an end-product is placed under review. “Processors” not paying attention may be caught unaware by significant changes in their supply chain or manufacturing processes.

And the impact is coming fast. A week after the President signed the new law, EPA released its “First Year Implementation Plan.” It lists the various actions EPA is required to take and a number of other changes EPA intends to implement within the first year. Meeting all of these deadlines and goals will require a significant effort from the agency, with several opportunities for potentially-affected companies to speak up.

Authors

Tracy Heinzman
Partner
202.719.7106
theinzman@wiley.law

Practice Areas

Environment & Product Regulation
Occupational Health and Safety
Toxic Substances Control Act (TSCA)

EPA also immediately must begin the process of reviewing (or re-reviewing) all of the 80,000+ chemicals on the current TSCA Inventory employing the procedures it will just have established and documented in regulations. Recognizing that asking EPA to review all 80,000+ chemicals at the same time would have been an impossible request, Congress authorized the agency to first cull the current TSCA Inventory to a more manageable size, and then prioritize which chemicals to review first.

The first step in the culling process is referred to as the “inventory reset.” Under the inventory reset, EPA will require reporting of chemicals which have been manufactured or used within the previous 10 years. The burden likely will fall on both chemical manufacturers and users (processors). Upon receipt of a report, EPA will designate those chemicals as “active.” Chemicals with no reports will be designated “inactive.” EPA can then set the inactive chemicals aside from further consideration. The hope is that the inventory reset process will significantly reduce the number of chemicals that EPA could be required to evaluate. (But the inactive chemicals will not be removed from the inventory, so that manufacturers and processors can readily provide EPA with notification if use of the chemical starts again.)

EPA is required to initiate the inventory reset process within one year—with industry reports due six months after that. EPA’s Implementation Plan states that EPA intends to meet that deadline. Chemical processors will need to ensure that the chemicals they use are properly reported to EPA to be considered active. Processors that import a chemical from a foreign supplier may need to assume the reporting burden if their foreign supplier does not actively participate in EPA’s reporting process. Failing to do so could cause the chemical to be listed as “inactive” and trigger more paperwork—and possible enforcement action—later.

The second step in EPA’s culling process is to designate among the active list “high priority” and “low priority” chemicals. Once EPA designates a chemical as a high priority, that chemical must undergo a complete risk evaluation that is intended to determine whether the chemical poses an “unreasonable risk of injury to health or the environment.” To inform that evaluation, EPA has the authority to mandate industry—including users as well as manufacturers—to fund, develop and submit new technical and scientific data. The development of that new information could be very expensive. EPA also will assess fees on both manufacturers and users (processors) to fund the agency’s evaluation of existing chemicals.

The challenge to chemical users is clear: a company’s existing supply chain costs, including commodity chemicals, may increase dramatically if EPA imposes significant new data development requirements and evaluation fees on industry. Chemical processors could see their existing pricing and cost structures significantly altered as previously predictably priced chemicals see cost increases. Cost increases alone could drive the switch to alternative chemicals, even if EPA ultimately does not impose additional restrictions on the chemical.

EPA is required to identify ten high priority chemicals within the first six months—even before it has promulgated the regulations that will govern how it chooses high priority chemicals in future years, and before the inventory reset is finished. Those first ten chemicals will be drawn from EPA’s existing TSCA Work Plan. That plan lists 89 chemicals that EPA has been considering for some time. EPA is then required to designate high priority chemicals over the next several years, and is required to maintain a minimum of 20 high priority

chemicals under review.

At the end of EPA's evaluation, if EPA determines that a chemical poses an unreasonable risk, EPA is required to adopt restrictions on usage to address the identified hazards. EPA has the authority to impose a wide range of restrictions on the use of new and existing chemicals, not just on their manufacture. In the worst case, EPA could order the complete ban of a chemical from the market, eliminating the availability of that chemical to manufacturers and processors. But, even if EPA does not take such a dramatic step, other restrictions could directly impact downstream processors. For example:

1. EPA could impose nationwide volume restrictions on the amount of the chemical which can be manufactured or imported. If the chemical is today used in greater volumes, this could lead to escalating prices and supply shortages for downstream processors.
2. EPA could impose emissions limits, or work with OSHA to set workplace exposure limits. This could mean that processing facilities will be required to install new, costly, pollution control devices and/or require employees to don additional personal protective equipment such as respirators.

Product manufacturers also will need to pay attention to TSCA's unique method of dealing with preemption of state laws based chemical regulation. Over the past several decades, a number of states—most notably California—have created their own chemical regulation regimes, with varying degrees of success. The new law has the potential to replace those regimes. But there will not be the immediate and wholesale replacement that some originally sought: state laws are only impacted on a chemical-by-chemical basis, if and when EPA takes a chemical-specific action.

Notably, certain existing laws and regulations will remain untouched even if EPA takes action. By design, California's Proposition 65 will continue in force, and the state may even be able to add additional chemicals to that program. However, other existing laws, such as California's Green Chemistry law, will be subject to some preemption.

In short, this means that unless EPA has taken action on a chemical the states remain free to do so instead. This has been described by state action advocates as allowing states to "step in" and fill a gap if EPA is too slow or unwilling to act on a specific chemical. However, it also means that states could put chemical and product manufacturers through a state-based process imposing new restrictions—all at great expense to industry—only to have that effort duplicated at a federal level and the restrictions replaced by something different.

Chemical users ("processors") must be paying attention to EPA's implementation of the panoply of new requirements, both the implementing regulations and the individual chemicals named for evaluation. Processors should not assume that their suppliers are taking care of everything: suppliers may have different economic interests; have other chemicals which are of greater concern to them; or may simply be unaware of the importance of a particular chemical. Chemical users should already be communicating with their suppliers to share their concerns and keep up to date, and should begin evaluating their chemical supply chains for potential concerns.