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Historic Amendments to Toxic Chemicals Law Enacted

By

On June 22, 2016, President Obama signed into law a bill to amend and modernize the 40-year old Toxic Substances Control Act (TSCA). The “Frank R. Lautenberg Chemical Safety for the 21st Century Act” is the culmination of many years of effort to revamp the outdated chemical safety law. The legislation represents a remarkable bipartisan achievement by Congress, particularly in an election year.

Congress enacted TSCA in 1976 to fill a regulatory gap by authorizing the EPA to regulate the import, manufacture, and processing of chemicals used in industrial and consumer products that are not regulated under other laws, such as foods, drugs, cosmetics, pesticides and tobacco. In practice, however, TSCA proved unwieldy and difficult to implement. The shortcomings of TSCA included the absence of a clear mandate for EPA to evaluate and regulate the more than 62,000 existing chemical substances grandfathered under the statute, as well as the inclusion of onerous statutory standards that EPA must meet before taking regulatory action. As a result, EPA promulgated TSCA regulatory controls over only a small number of existing chemicals, including polychlorinated biphenyls (PCBs), asbestos, lead and mercury.

The new legislation makes several significant changes in the law. Perhaps most important, it adopts a new safety standard, which explicitly precludes EPA from considering costs and other non-risk factors in making safety determinations for chemicals. It also requires EPA to identify populations that are disproportionately at risk either due to greater exposure to the chemical or greater susceptibility to injury to the chemical, and specifies that such populations must include infants, children, pregnant women, workers and the elderly. EPA’s decision whether or not to impose regulatory controls over the chemical must be based on risks to these vulnerable populations, and any restrictions must protect these groups.

The new TSCA amendments also remove the requirement that EPA choose the “least burdensome” way to address risks posed by a chemical. This requirement proved to be a major impediment to regulatory action under the original version of TSCA. The new law makes clear that cost considerations cannot override the requirement for restrictions to ensure chemical safety, and that the balancing of costs and benefits is *not* required; rather it may be considered only “to the extent practicable based on reasonably available information.” If a chemical does not meet the safety standard, EPA is required to act to prohibit or restrict the manufacture, processing, use, distribution or disposal of the chemical as necessary to ensure safety.

The law imposes a series of deadlines by which EPA must designate existing chemicals as high- or low-priority, conduct safety assessments for high-priority chemicals, and promulgate regulatory controls. By three years after the enactment, EPA must have at least 20 “high-priority” chemicals under review at all times. The law expedites action on “persistent, bioaccumulative and toxic” chemicals (PBTs), 30 of which EPA has already identified. In addition, companies can request EPA to conduct a safety assessment for a chemical. EPA may grant such requests, provided that company-requested assessments do not exceed 30% of all assessments, and that EPA does not give them preference over high-priority chemicals.

The new law retains the requirement that a company wishing to manufacture or import a new chemical substance (not on the EPA TSCA “inventory”) must submit a “pre-manufacturing notice” (PMN) to EPA at least 90 days in advance. The law strengthens this pre-marketing review provision, however, by requiring EPA to make an affirmative finding that the chemical is likely not to present an unreasonable risk before the company may commence manufacture or importation.

The legislation authorizes EPA to collect “user” fees from industry for both new and existing chemicals, as well as those designated as high-priority, to support the EPA’s massive task of assessing the safety of all TSCA chemicals. The level of fees is to be set to cover approximately 25% of the relevant EPA program costs up to $18 million/year. Companies must pay 100% of the costs of assessments they request. EPA may also require industry to conduct testing of new and existing chemicals under certain conditions.

The TSCA amendments also significantly cut back the ability of chemical manufacturers and processors to protect as private and confidential information regarding the specific chemicals contained in their products.

Finally, the legislation contains a complex set of provisions regarding preemption of state law chemical regulatory requirements. These provisions reflect of a political compromise among different interested parties, some of whom (e.g., environmental groups) sought to preserve the states’ ability to take action against dangerous chemicals, and others (e.g., industry groups), who favored a single federal regulatory standard. Most notably, the law preserves, and does not preempt, California’s “Proposition 65,” which requires disclosure of the presence of substances in products identified as either carcinogens or neurotoxins.

The new TSCA amendments will have profound impacts on the businesses of chemical manufacturers, processors, and users. Interested parties should pay close attention as EPA proceeds to implement them.

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