TSCA amendments: Highlights and implications for downstream users of chemicals

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On June 22, 2016, President Obama signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Act), a bipartisan bill passed by large margins in both houses, which amended the Toxic Substances Control Act of 1976 (TSCA). Effective as of that date, the Act made substantial revisions in the regulation of chemicals in the United States, which by its terms must now be implemented by the U.S. Environmental Protection Agency (EPA), subject to the challenges which EPA outlined in its First Year Implementation Plan for the Act. The Act received broad stakeholder support and reflected compromises acceptable to business and public interest groups. The following highlights the most significant structural changes to TSCA and identifies implications for downstream users of chemicals.

Risk-based safety standard

Central to the Act is a new, risk-based safety standard, based on whether a chemical presents an unreasonable risk of injury to potentially exposed or susceptible subpopulations under the conditions of use. This amendment eliminates TSCA's prior risk/benefit analysis. EPA may not consider costs or other nonrisk factors in its evaluation; if EPA finds that a chemical presents "an unreasonable risk," it must take regulatory action to eliminate that risk. In this phase, while EPA is no longer required to select the "least burdensome" requirements available, EPA may consider cost and other nonrisk factors in selecting among risk management options as long as such risk is eliminated; the Act also provides for an exemption process by rule for critical uses.

New chemical review

EPA is required to make affirmative findings respecting all new chemicals or significant new uses (SNUs) of existing chemicals subject to Significant New Use Rules (SNURs). EPA must find whether the chemical or SNU presents an "unreasonable risk." If so, EPA must take regulatory action to eliminate such risk prior to market entry. If EPA finds that the chemical or SNU is not likely to present an unreasonable risk and publishes such a finding, manufacturing/processing/import can immediately take place. If EPA finds that it has insufficient information to make such a determination, or finds that the chemical may present an unreasonable risk of injury or that such chemical will be made in substantial quantities, EPA shall take regulatory action. In any case, EPA must take affirmative action for a chemical's manufacture, import, or use to commence. This requirement contrasts with prior TSCA provisions, which provided that the

manufacture, importation, or significant new use of a chemical could commence if EPA failed to act within a 90-day window after notification.

Existing chemical review

By June 2017, EPA must establish by rule a risk-based process for prioritizing chemicals, considering various hazard and exposure factors. EPA must designate a chemical as high priority if it finds that the chemical may present an unreasonable risk of injury. EPA must conduct a risk evaluation on any chemical designated as high priority.

Within 180 days, EPA must begin risk evaluations on at least 10 priority chemicals from EPA's TSCA Work Plan; high-priority designation triggers mandatory completion within 3 years, with a possible 6-month extension. Within 3½ years of enactment, EPA must have 20 risk evaluations ongoing (50 percent of all ongoing risk evaluations must be drawn from the TSCA Work Plan) and designate at least 20 chemicals as low priority. EPA must also give preference to chemicals on the TSCA Work Plan with a Persistent, Bioaccumulative and Toxic (PBT) score of 3, as well as known human carcinogens or chemicals with high acute and chronic toxicity.

Testing authority

The Act provides EPA with expanded authority to test chemicals for prioritization or conducting risk evaluations. EPA will no longer have to show potential risk to require testing.

CBI

The Act makes it more difficult for the regulated community to protect its Confidential Business Information (CBI) from disclosure. Greater substantiation of a CBI claim will be required, and CBI protection will expire after 10 years, unless renewed.

Preemption

The Act preempts state laws that: (1) restrict chemicals that EPA has restricted, (2) require notification of SNUs specified by EPA, (3) require testing already required by EPA, or (4) otherwise conflict with EPA actions under TSCA. States also may not restrict chemicals determined by EPA to not present an unreasonable risk and may not impose new restrictions on high-priority chemicals during EPA risk evaluations. However, where EPA has determined that a chemical presents an unreasonable risk, but has not yet completed its risk management rulemaking, states may "fill the gap" by imposing restrictions on such chemicals. Once EPA restricts such chemicals, any state law would again be preempted. Preemption will not apply to state laws or regulations enacted before April 22, 2016, nor to future actions taken under state laws passed before August 31, 2003, such as California's Proposition 65. The Act does not restrict states from requiring additional reporting and monitoring respecting regulated

chemicals.

Downstream impacts

The Act in section 3 introduces a new concept in the term "Conditions of Use," which is defined as the "circumstances, as determined by the Administrator, under which a chemical is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." Not only will EPA's determination be important to manufacturers and importers, it will also be significant to their downstream users as well, since it is the basis for risk evaluations and resultant regulatory actions restricting that chemical. Given EPA's authority under TSCA to restrict chemicals that contravene the safety standard, a downstream user (as well as those parties up the supply chain) will need to participate in rulemakings.

Articles

The Act does limit EPA's authority to require Significant New Use Notifications for import or processing of a chemical as part of an article or category of articles if EPA makes an affirmative finding by rule that the reasonable potential for exposure to the chemical through the article or category of articles justifies notification. The Act also limits EPA's authority to restrict chemicals contained in an article or category of articles "only to the extent necessary to address the identified risks from exposure" to such chemical and exempts replacement parts for "complex durable goods and complex consumer goods" as specified in the Act unless EPA finds that they contribute significantly to the risk in question.

Relationship to other federal laws

The Act requires EPA, when it learns of chemical releases or exposures that may be prevented or reduced under other federal laws, to notify the relevant agency and, if such agency does not act in the time period prescribed by EPA, EPA is required to take regulatory action. While the Act specifically requires EPA to consult with the U.S. Occupational Safety and Health Administration (OSHA) prior to EPA's imposing restrictions addressing workplace exposures, this is no guarantee that EPA and OSHA will agree and, if not, what the impact on the regulated community will be.

Implications for downstream users

Given that there has been very little regulatory action restricting the use of chemicals under TSCA to date, the TSCA compliance obligations of downstream users have been, by and large, limited to ensuring that chemicals they buy are on the TSCA Inventory. This will need to change, given the likely increase in EPA regulatory action restricting the use of chemicals.