Long-Awaited TSCA Reform Finally Nears the Finish Line

By: Alison Lecker, *The Legal Intelligencer*

The Toxic Substances Control Act (TSCA), 15 U.S.C.A. Section 2601 et seq., was enacted in 1976 in response to concerns over hazardous chemicals that were not being regulated by other federal laws. TSCA is the only major federal environmental statute that has not yet been updated. After years of attempted reform, Congress reached a deal last month that reconciled conflicting House and Senate bills and allowed TSCA reform to move forward. Once enacted, the Frank R. Lautenberg Chemical Safety for the 21st Century Act will provide much needed strengthening of federal chemical regulation. TSCA regulates products, rather than waste, and was intended to protect human health and the environment from the risks posed by chemical substances. The TSCA authorizes the U.S. Environmental Protection Agency (EPA) to require the generation of data, review new chemical substances before they enter the marketplace and regulate existing chemical substances with identified risks. However, the TSCA has long been criticized as failing to provide the EPA with the necessary authority and resources to effectively regulate chemical substances.

Under the TSCA, chemical substances are divided into new and existing chemical substances. The EPA completed its inventory of existing chemicals in 1980, identifying approximately 64,000 substances. Any substance manufactured after 1980 is considered a "new" substance and is subject to stricter regulations. This division has garnered significant criticism as it has allowed thousands of grandfathered chemicals already in commerce to avoid a safety review, including BPA and PFOA (a component of teflon).

EPA regulates new chemical substances under Section 5 of the act. Since the 1980 inventory, approximately 22,000 new chemicals have been evaluated for safety. Chemical manufacturers are required to submit a pre-manufacture notice to the EPA at least 90 days prior to manufacturing. The EPA then conducts a review of available scientific data and determines whether to allow, restrict, or ban the entry of the substance into commerce. If the EPA fails to act after the 90-day period, the chemical substance is allowed to enter the market. The regulation of new chemical substances is thought to be one of the stronger programs in the otherwise weak statutory scheme.

Under the proposed legislation, the EPA's authority to regulate new chemical substances would be further strengthened and the EPA would also be mandated to evaluate the previously untested existing chemicals for safety. Under Section 6, existing chemicals are currently eligible for regulation by the EPA only if the agency determines that the substance will present an unreasonable risk to human health or the environment. The EPA can regulate these substances only through rulemaking and has a high burden of identifying alternatives and evaluating the compliance costs of regulating. After this evaluation, the EPA must select the "least burdensome" alternative. The policy behind the "least burdensome" requirement was to ensure that innovation in the chemical industry was not stifled by an overly burdensome regulatory scheme. The result, however, was that EPA was prevented from regulating existing chemicals in any meaningful way.

In the notorious 1991 asbestos litigation, the EPA's rule banning asbestos was overturned in federal court for failure to satisfy the agency's high burden of proving risk. See C*orrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). The EPA has not regulated any existing chemicals under the TSCA since the *Corrosion Proof Fittings* decision. The "least burdensome" requirement has garnered the loudest criticism and provided motivation for reform.

The proposed legislation revamps Section 6 of the act by requiring the EPA to prioritize chemicals for review and implement a risk-based screening process. Chemical substances will be classified as "high" or "low" priority based on health-based risk evaluations. Once a chemical substance is identified as posing a significant or "high" risk, the EPA must conduct a full risk evaluation.

Critically, the proposed legislation prohibits the EPA from considering cost when conducting this risk assessment. The EPA must determine whether a chemical substance may present an unreasonable risk because of a hazard or potential exposure pathway based only on health and safety impacts. The proposed reform also removes the "least burdensome" requirement.

Additionally, when conducting its risk evaluation, the EPA must consider vulnerable populations, potential exposure and conditions of use of the chemical. These are all important new concepts in the proposed legislation which significantly strengthen TSCA. The requirement that the EPA must consider the "conditions of use" or how the chemical is made, processed, used and disposed of, applies to determinations of new and existing chemicals. Vulnerable - populations include children, chemical workers, the elderly and pregnant women.

The EPA's authority to require testing of chemical substances under Section 4 of the TSCA has been criticized as putting the burden on the agency to conduct expensive testing before it is authorized to require the manufacturer to conduct additional testing. Additionally, the EPA must undergo rulemaking and make certain risk findings. The proposed legislation empowers the EPA with additional flexibility to issue orders and enter into consent agreements to require chemical testing. Limits on unnecessary animal testing have also been put into place.

Under the compromised bill, the EPA regulations would pre-empt most state regulations, with the exception of chemical monitoring and labeling. The current TSCA does not pre-empt states' abilities to regulate chemical substances. Indeed, states have been proactive in toxic chemical regulation in an attempt to fill the gap left by federal law.

The issue of pre-emption has been much debated by Congress. Environmental and health advocacy groups have argued strenuously against pre-emption and industry has argued that it needs the uniformity of a standard strengthened federal law. The compromised legislation does include pre-emption provisions and new state chemical restrictions are prohibited while the EPA is conducting risk evaluations of a high priority chemical, unless the state is granted a waiver from EPA. However, states are permitted to enforce the federal standards.

Section 14 of the TSCA allows manufacturers to identify scientific data or other information submitted to the EPA as confidential business information (CBI), thus preventing the information from being disclosed to the public. The EPA has issued guidance in recent years attempting to broaden disclosure of chemical safety data and limit industry's ability to claim CBI protections. The proposed legislation explicitly limits CBI protection by allowing health professionals and states to access underlying data, subject to confidentiality agreements and by providing expiration dates for CBI classifications. This could result in a large release of information for CBI claims that are now expired under the proposed revisions.

Once the proposed legislation becomes law, the next major hurdle will be implementation. One of the struggles under the current law was the lack of agency resources and funding. The EPA was also criticized for moving too slowly through its chemical reviews. The proposed legislation includes aggressive, judicially enforceable timelines for completing prioritizations and risk assessments. The bill also requires a new fee assessed on chemical companies to cover the cost of evaluating the chemicals, which should result in approximately $25 million each year. The EPA will be required under the new legislation to conduct extensive rulemaking and provide interpretive guidance over the next few years. While the EPA's implementation will be critical to the success of the reform effort, the proposed legislation provides much needed strengthening of the TSCA.

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