



Is the Chemistry Right for Chemical Safety Reform?

LATEST PROPOSAL PROVIDES FOR SYSTEMATIC EVALUATION OF SUBSTANCES

By EMILEE MOONEY SCOTT

Earlier this month, Sens. Tom Udall, D-N.M., and David Vitter, R-La., introduced the “Frank R. Lautenberg Chemical Safety for the 21st Century Act” (Lautenberg bill). Building from a bill introduced by Vitter and the late New Jersey Sen. Lautenberg in May 2013, the Lautenberg bill would make significant changes to the Toxic Substances Control Act (TSCA), the primary federal statute addressing the safety of chemicals in commerce.

The TSCA was first enacted in 1976, and its core chemical regulatory scheme has remained essentially unchanged since then (though provisions related to specific substances, such as lead-based paint, have been added). The TSCA regulates the introduction into commerce of new chemical substances, defined broadly to mean “any organic or inorganic substance of a particular molecular identity,” including those found in nature (but excluding such substances as drugs and pesticides regulated under other federal programs). The Environmental Protection Agency may also use TSCA to regulate substances already in commerce at the time of TSCA’s passage, but regulation of existing substances under TSCA has historically been less common.

Manufacturers and importers of new substances must make a filing called a pre-manufacture notice (PMN) before the substance may be manufactured/imported for commercial purposes. The PMN must include the substance’s identity, and must describe proposed uses and potential exposure pathways. If the EPA determines that the new substance may present unreasonable risks to human health, it may promulgate a Significant New Use Rule (SNUR)

describing permitted uses and delineating which potential future uses would require approval by the EPA. Often the SNUR simply limits allowed uses of the substance to those described in the PMN. If a manufacturer wishes to produce the substance for purposes beyond those allowed by the SNUR, it must submit a significant new use notice (providing information essentially equivalent to a PMN) and may not produce the substance for the proposed new use unless approved by the EPA.

The EPA may also promulgate SNURs relative to existing substances, and did so recently for ethylene glycol ethers (used as solvents and in other industrial applications). The EPA may regulate existing substances through a variety of tools, up to and including a ban, but only to the “extent necessary to protect adequately against such risk using the least burdensome requirements.” This standard has proved to be a high bar to EPA action, with a failed attempt at banning asbestos as the most famous example. In the 1991 case *Corrosion Proof Fittings v. EPA*, the U.S. Court of Appeals for the Fifth Circuit struck down the EPA’s asbestos ban because the agency had not adequately demonstrated that a full ban on asbestos was the least burdensome method of controlling risk.

While the EPA has tools to regulate existing substances, such substances were not subject to the same sort of organized evaluation that the EPA undertakes relative to new substances. In recent years, TSCA reform efforts have prioritized safety evaluation of existing substances, including both the Lautenberg bill and its 2013 precursor. The Lautenberg bill (like the 2013 bill) provides for a systematic evaluation of substances already in commerce. First, the EPA would be required to designate existing substances as “high” or

“low” priority for evaluation. Those substances identified as high priority by the EPA would be subject to a safety assessment. Following the safety assessment, the EPA would be required

to promulgate rules, as appropriate, to mitigate risks presented by the substance. These rules may vary in their impact from labeling requirements and production limits all the way to bans on production and use.

The Lautenberg bill would modify several other key TSCA sections, including the new substance review process and protections for confidential business information. The Lautenberg bill would also allow the EPA to collect “reasonable fees” from manufacturers submitting certain required filings, which will be used by the EPA to help defray the costs of its increased responsibilities.

Pre-emption Battles

The 2013 effort by Lautenberg and Vitter attracted dozens of co-sponsors evenly split between parties, and generated much positive attention, but it failed to progress past hearings in the Senate Environment and Public Works Committee. The most significant obstacle to the 2013 bill was a debate over the extent to which any TSCA reform bill would pre-empt state action, and the Lautenberg bill could face a similar fight. Sen. Barbara Boxer, D-Calif., then



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chairwoman (and now ranking member) of the Senate Environment and Public Works Committee, was a key voice arguing that state efforts should not be pre-empted. Conversely, several prominent industry groups have argued that it is burdensome and impractical to keep up with 50 evolving state programs.

It is no accident that Boxer is a leading voice against pre-emption. California has long been a leader in state-level chemical regulation, beginning with its Proposition 65 program. Under Proposition 65, warnings must be provided on products that contain certain toxic or carcinogenic substances. In October 2013, California's Safer Consumer Products Law went into effect, requiring several phases of analysis on specified substances present in consumer products and potentially culminating in restrictions on the use of such substances. Several other states, including Maine, Vermont and Washington, have enacted chemical regulatory programs in recent years, many of which focus on exposure pathways through consumer products.

The 2013 TSCA reform bill would have pre-empted much of this state-level activity. The 2015 Lautenberg bill, however, provides somewhat more room for states to continue

their own chemical regulatory programs. In a critical departure from the 2013 bill, the Lautenberg bill would not pre-empt state regulation of substances designated low priority. For high priority substances, however, state regulation would be pre-empted once the EPA's safety assessment is underway. The final regulatory action following a safety assessment may take up to seven years to be developed and enacted, so state regulation would be pre-empted for several years before the federal regulations are in place. While the Lautenberg bill provides that certain existing state laws are preserved, the relevant sections are in conflict and must be reconciled.

Boxer remains committed to preserving state programs, calling the Lautenberg bill "worse than current law." Just days after the introduction of the Lautenberg bill, Boxer and Sen. Edward Markey, D-Mass., introduced a rival TSCA reform bill. While the full text was not yet available at this writing, a one-page summary indicated several important differences from the Lautenberg bill, including more ambitious time lines for EPA action, a citizen's right to challenge low-priority designations in court, and a statement that state regulation would not be pre-empted.

Regulation of Existing Substances

Meanwhile, over the last several years, the EPA has taken a more aggressive approach to regulating existing substances under the TSCA authority it already has. In its TSCA Work Plan for Chemical Assessments, introduced in 2012 and updated in 2014, the EPA identified dozens of substances based on a combination of hazard presented, exposure pathways, persistence and bioaccumulation. The EPA is conducting hazard assessments on the substances identified in the work plan, with four already completed: methylene chloride in paint strippers; antimony trioxide in halogenated flame retardants; fragrance ingredient HHCB; and trichloroethylene/TCE as a degreaser, spot cleaner and protective coating. The EPA has indicated that further hazard assessments are forthcoming, and that it may use the results of these hazard assessments to pursue restrictions on the use of subject substances.

Political forecasters see a decent prospect of success for the Lautenberg bill. Whatever its fate, increased regulation on the use of existing substances should be expected. ■

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