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Hope Is Restored In Finally Modernizing TSCA

Law360, New York (June 19, 2013, 12:23 PM ET) -- In a rare bipartisan expression of support for reform of the Toxic Substances Control Act (TSCA), Sen. David Vitter, R-La., and the late Frank Lautenberg, D-N.J., introduced on May 22, 2013, the Chemical Safety Improvement Act (CSIA), S. 1009. The bill offers a new and potentially politically viable framework for TSCA reform and renewed hope that badly needed modernization of this ancient law may occur.

Before reviewing the key elements of the bill, a word about the significance of this legislation is important. The chemical industry's role in the U.S. economy cannot be overestimated. According to the American Chemistry Council, over 96 percent of all manufactured goods are dependent in some way on the chemical industry. The domestic chemical industry produces 19 percent of the world's chemical output, amounting to $689 billion.

Lawyers and others in this space need to be keenly aware of these legislative efforts as TSCA modernization will directly and significantly impact for many years to come domestic chemical manufacture, processing and use and will greatly influence the business operations of hundreds of thousands of downstream product manufacturers in the electronics, personal care products, consumer products and dozens of other business sectors dependent upon chemical suppliers for components essential to their manufacturing operations.

S. 1009 amends TSCA Title I. This is the title that manages risks from industrial chemicals, a topic that invites strenuous political, scientific, and often emotional, debate. A broad range of topics — states' rights, federalism, right-to-know, chemical risk, health effects, confidentiality, to name a few — are front and center in this national discussion, which is what makes this legislative drama so compelling.

Enacted in 1976, Title I has never been substantively amended. That's right — the United States' chemical management law has not been amended in almost 40 years. Given advances in technology, the evolution of our understanding of chemicals and the potential risks they pose and the sophistication of political activism in all things chemical, this is an astonishing fact.

For years, there has been growing recognition by all stakeholders that the TSCA needs modernizing. Prior legislative efforts, primarily championed by the late Sen. Lautenberg, have inspired fierce industry opposition based in large part on concerns that the framework he envisioned was too costly, restrictive and job- and innovation-killing.

As recently as April 10 of this year, Lautenberg reintroduced the newest version of the Safer Chemicals Act (S. 696), similar to legislation introduced in past Congresses (S. 847) and reported favorably out of the Senate Environment and Public Works Committee (EPW) on a party-line vote in the 112th Congress.

S. 847 and S. 696 are perceived by industry groups as political nonstarters. The framework is premised on a safety standard of "reasonable certainty that no harm" will result from aggregate exposure to chemicals, a safety standard believed by many to be unacceptable and unworkable.

The preemption provisions are also believed to be weak and would fail to stem the growing tide of state and local chemical regulations believed by business groups to be disruptive and costly to industry. They would also inappropriately grant sweeping new authorities to the U.S. Environmental Protection Agency (EPA) that would unilaterally empower the government to act to abate risks identified by the EPA, while limiting opportunities for judicial appeal.

Few were aware, however, that while introducing yet another Safe Chemicals Act a few short months ago, Lautenberg was quietly working behind the scenes with Sen. Vitter, ranking minority member of the EPW, on a new, bipartisan bill. Vitter's home state of Louisiana hosts many petroleum refiners and chemical manufacturers, and his expressed interest in joining the TSCA reform effort last year infused new life into legislative efforts to reform TSCA, which was thought dead absent bipartisan interest.

CSIA in Brief

The CSIA establishes a new safety standard of "no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance" under "intended conditions of use." The standard is consistent with the current TSCA standard, which is also based on the concept of "unreasonable risk."

This standard firmly embeds the balancing of risks and benefits, a goal strenuously pursued by industry groups as essentially non-negotiable in the TSCA reform debate. This interpretation aligns well the new draft "findings, policy, and intent" statements in Section 2(c) of S. 1009 (the administrator shall "rely on robust scientific evidence … in a way that balances the mutual goals of promoting the safety of American consumers and preventing harm to American innovation, manufacturing, and the economy").

Chemical Assessment Framework

The EPA is required under S. 1009 to use a structured evaluative framework for decision-making that employs the "best available science" and "science-based criteria." The bill specifies data and information quality requirements and ensures that the EPA consider data and information submitted "to a governmental body in another jurisdiction under a governmental requirement relating to the protection of human health and the environment," among other sources.

This reference to other governmental requirements presumably is intended to ensure the data, and information now being generated in the European Union under its TSCA analog, the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program, is utilized for domestic chemical regulatory assessment and regulation purposes, long a goal of business groups in modernizing TSCA.

Chemical Prioritization Screening Process

The EPA must propose under the CSIA a screening process and criteria to identify substances as either high or low priority for safety assessment and determination. The EPA must prioritize chemicals in active commerce; it may prioritize unregulated, inactive chemicals of high hazard and high exposure.

This prioritization approach essentially "resets" the TSCA chemical inventory, another goal industry groups support as the total number of chemicals listed on the TSCA inventory (well over 80,000) grossly exceeds the actual number of chemicals in commerce and thus distorts the reality of chemicals actually in commerce.

Safety Assessments

The EPA is required to conduct a "safety assessment" for each high-priority substance. Safety assessments must evaluate hazard, use and exposure information, including vulnerability of exposed subpopulations, and must include a weight of the evidence summary.

Safety assessments are "to be based solely on considerations of risk." While this section of the bill in particular will be examined and dissected, for the most part, the industry seems aligned in supporting the approach. Some stakeholders have expressed concern with the noticeable absence of mandatory deadlines embedded in the bill requiring EPA actions by dates certain, but on the whole, the assessment framework is thought acceptable.

Safety Determination

The EPA must determine whether or not the chemical meets the safety standard under intended conditions of use. As noted, the safety standard under the bill is based on the TSCA's current unreasonable-risk standard and embeds the balancing of risks and benefits, which industry groups seek.

Some have speculated that one interpretation of the new standard suggests that it is more protective of human health and the environment than under current law, but it is unclear if the drafters intended this result or if this is an artifact of hasty drafting.

In cases where the safety standard is not met, the EPA must impose additional restrictions to abate the risks. Safety determinations are subject to notice and comment, considered final agency action and subject to judicial review. The insistence upon notice and comment rulemaking is another must-have for industry groups, and the draft bill ensures this result.

Risk Management

If the EPA determines additional restrictions are required, it must establish these and the magnitude of risk. These restrictions include a range of options such as requirements for warnings, record keeping, testing, quantity limitations, notices to value chain, bans and phase-outs. Exemptions from restrictions include, among others, national security interests.

Confidential Business Information (CBI)

CBI has been another hot button issue for industry. The need to keep from public disclosure certain formation is regarded as essential to industry to remain competitive and protect innovation, while respecting the public's right to know information that is not proprietary. Many industry groups have been insistent that specific "chemical identity" is not an essential element of health and safety studies, and this information should be protected from disclosure.

Under the bill, specific chemical identity is presumptively protected if claimed as confidential and not subsequently waived even if the information is embedded in a health or safety study. This is an important point as chemical identity often is the magic pixie dust that differentiates one product from another and thus is fiercely protected by the manufacturer.

Importantly, confidentiality lasts as long as requested by the submitter or as the EPA deems reasonable and is renewable. The EPA is authorized to seek resubstantiation.

Preemption

The TSCA's preemptive effect on state and local chemical regulation is a critically important issue with which industry has long been concerned as the relentlessly growing number of state and local chemical restrictions are claimed to impede commerce and unnecessarily burden chemical and product manufacturers with inconsistent and often conflicting requirements.

Under the CSIA, certain EPA regulatory actions retrospectively and prospectively preempt state and local chemical regulatory requirements. Decisions by the EPA to designate a substance as high or low priority preempt state and local regulations. Existing requirements, however, would continue in effect until a safety determination is made.

As under current law, states may seek a waiver from the preemptive effect of an EPA action but must meet certain eligibility criteria. The waiver decision is subject to notice and comment and is judicially reviewable. EPA safety determinations are admissible in state tort actions as determinative evidence of whether the chemical meets the safety standard.

Sen. Barbara Boxer, D-Calif., EPW chairwoman, has already expressed concern with the broad preemptive effect of the bill. California has long been a trendsetter in chemical legislative and regulatory initiatives — Prop 65 and the state's innovative volatile organic compound (VOC) emissions control program come to mind — and Boxer has withheld her support for the bill pending clarification on this and other issues.

The California Department of Toxic Substances Control (DTSC) has also weighed in, stating it is "extremely concerned" with the bill and noting that while the bill reflects "some positive reforms" to TSCA, "the areas of concern overshadow these improvements."

Both Boxer and the DTSC have specifically expressed concern with the bill's impact on the soon-to-be-implemented California Safer Consumer Products regulations, the state's innovative and precedent-setting program requiring chemical alternative assessments for chemicals of concern found in "priority products" sold to consumers and believed potentially to cause harm. The DTSC is tasked with implementing the Safer Consumer Products regulations when issued in final, perhaps as soon as next month but more likely this fall.

Discussion

That there is controversy over a handful of provisions in S. 1009 — preemption, the regulatory safety standard applicable in the EPA's determinations of an "unreasonable risk" of a chemical under "intended conditions of use" and the lack of clear deadlines for EPA actions — is hardly surprising.

As Congress begins the deliberative process of hearings and eventual legislative mark-up through subcommittee and committee, these and other issues will be discussed in granular detail. Many factors outside of the specifics of the legislation, even if language is agreed upon, could derail the bill.

What is important and not to be missed is the fact that this is the first bipartisan bill reforming the TSCA. This is good news. Industry groups and prominent nongovernment organizations, including the Environmental Defense Fund, among others, have expressed support for the bill.

This fact alone will go a long way in sustaining the momentum that the introduction of the CSIA has created and for encouraging Congress to double-down and get to the hard work of modernizing the TSCA. As of this writing, the House held a hearing on the TSCA for June 13, 2013, another promising sign. While the hearing was not on any legislative vehicle in particular, that it focused on the TSCA generally is a step in the right direction.

The stakes are high, the advocacy strenuous and the outcome uncertain in this area. What is certain is that legislation is badly needed to restore public confidence in the federal chemical regulatory program, to address more effectively chemical risks and to ensure that our domestic chemical management framework is as robust as those that have emerged in the European Union, Canada and in developed economies elsewhere.

Lautenberg did not live long enough to see TSCA reform become a reality. Enactment of sensible legislation modernizing our chemical management law would be a fitting tribute to his legacy and tireless efforts to ensure that the TSCA is an effective law for assessing and managing chemical risks.

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