

Grounds for optimism?

The latest US Congressional bill on TSCA reform stands a better chance of adoption than its predecessors



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In a rare showing of bipartisan support for reform of the Toxic Substances Control Act (TSCA), senators David Vitter (Republican-Louisiana) and the late Frank Lautenberg (Democrat-New Jersey) recently introduced the Chemical Safety Improvement Act (CSIA). The bill offers a new and potentially politically viable framework for TSCA reform and renewed hope that needed modernisation of this important chemical management law may happen.

TSCA consists of five main sections, or "Titles". The bill (S1009) would amend Title I, the section that manages risks from industrial chemicals, and a topic that has invited strenuous and divisive debate for years. A range of topics – states' rights, federalism, the public's "right to know", chemical risk, health effects, confidentiality, to name a few – are central to this national discussion, and are what make this legislative drama so compelling. Enacted in 1976, Title I has never been substantively amended. Given advances in technology, the evolution of our understanding of chemicals, and the sophistication of political activism in all things chemical, this is a surprising fact.

There has been growing recognition by all stakeholders that TSCA needs modernising. Prior legislative efforts, primarily championed by Mr Lautenberg, have inspired industry opposition based on concerns that the framework he envisioned was too costly, too restrictive, and job and innovation "killing." As recently as 10 April, Mr Lautenberg reintroduced the newest version of the Safe Chemicals Act (S696), which was similar to legislation introduced in past Congresses, such as S847, and reported favourably out of the Senate Environment and Public Works Committee (EPW) on a party-line vote. S847 and S696



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Capitol Hill sees few examples of successful bipartisanship: will TSCA be one?

are perceived by many industry groups as political non-starters. Few were aware, however, that while introducing yet another Safe Chemicals Act a few short months ago, senator Lautenberg was working behind the scenes with senator Vitter, ranking minority member of the EPW, on a new, bipartisan bill. Senator Vitter's home state of Louisiana hosts many petroleum refiners and chemical manufacturers, and his interest in joining the TSCA reform effort last year infused new life into legislative efforts to reform the act, thought dead without bipartisan interest.

CSIA in brief

If adopted, the CSIA would establish a new safety standard that "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", and 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 with the new draft "findings, policy, and intent" statements in Section 2(c) of S1009 (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 US Environmental Protection Agency (EPA) would be required under S1009 to use a structured evaluation framework for decision making that employs the "best available science" and "science-based criteria". The bill specifies data and information quality requirements, and would ensure the agency considers 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 is presumably intended to ensure the data and information now being generated in the EU under its TSCA analogue, the REACH Regulation, is also used for domestic chemical regulatory assessment and regulation purposes, long a goal of business groups in modernising TSCA and animal rights supporters in minimising animal testing.

Chemical prioritisation and screening

The EPA would have to propose a screening process and selection criteria to identify substances as either “high” or “low” priority for safety assessment and determination. The agency would be required to prioritise chemicals in active commerce; and it would have the power to also prioritise unregulated, inactive chemicals of high hazard and high exposure. This prioritisation approach would “reset” the TSCA Inventory, another goal industry tends to support as the total number of chemicals in the inventory (over 84,000) grossly overstates the actual number of chemicals believed to be in commerce.

Safety assessments

The EPA would have to conduct a “safety assessment” for each high priority substance. Safety assessments would need to evaluate hazard, use and exposure information, including vulnerability of exposed subpopulations, and would have to include a weight-of-the-evidence summary. They would also need to be “based solely on considerations of risk”. For the most part, industry seems aligned in supporting the approach. Some stakeholders have expressed concern with the absence of mandatory deadlines requiring EPA action, but generally the assessment framework is thought acceptable.

Safety determination

The agency would have to determine whether or not a chemical meets the safety standard under intended conditions of use. The safety standard under the bill is based on TSCA’s current “unreasonable risk” standard, and embeds the balancing of risks and benefits which industry groups seek. The EPA would have to impose additional restrictions to abate the risks, if the standard is not met. Safety determinations would be subject to notice and comment, final agency action, and be subject to judicial review.

Risk Management

If the EPA decided additional restrictions were required, it would have to 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 would

include national security interests.

Confidential business information

The need to keep certain information from public disclosure is regarded by industry as essential if it is to remain competitive and if innovation is to be protected, while respecting the public’s right to know information that is not considered proprietary. Many industry groups have insisted that specific “chemical identity” is not an essential element of health and safety studies, and this information should be protected from disclosure. Specific chemical identity is presumptively protected under S1009 if claimed confidential and not waived, even if the information is embedded in a health or safety study. This is an important point, as “chemical identity” is often the magic pixie dust that differentiates one product from another, and thus is fiercely protected by the manufacturer.

Confidentiality would last as long as requested by the submitter or as the EPA deems reasonable.

Pre-emption

TSCA’s pre-emptive effect on state and local chemical regulation is a critically important issue with which industry has long been concerned. Under the bill, certain EPA regulatory actions would retrospectively and prospectively “pre-empt”, or take precedence over, state and local chemical regulatory requirements. Agency decisions to designate a substance as high or low priority would pre-empt state regulations. Existing requirements, however, would continue in effect until a safety determination was made. As under current law, states would be able to seek a waiver from the pre-emptive effect of an EPA action, but would need to meet certain eligibility criteria. The waiver decision would be subject to comment and would be reviewable. EPA safety determinations would be admissible in state tort actions as determinative evidence of whether a chemical meets the safety standard.

Senator Barbara Boxer (Democrat-California), EPW chairman, has expressed concern with the pre-emptive effect of S1009 ([CW 12 June 2013](#)). California has long been a trendsetter in chemical legislative and regulatory initiatives, and senator 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 it reflects “some positive reforms” to TSCA, “the areas of concern overshadow these improvements”. Both senator Boxer and the DTSC have expressed concern about the bill’s impact on the California Safer Consumer Products Regulations. The DTSC is tasked with implementing the Safer Consumer Products Regulations once they are adopted, probably this autumn ([CW 10 June 2013](#)).

S1009 has sparked controversy because of issues including pre-emption, the regulatory safety standard, and the lack of deadlines for EPA actions. As Congress begins the deliberative process of hearings and eventual legislative mark-up, these and other issues will be discussed in granular detail. Many factors apart from 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 that would reform TSCA. Industry groups and some prominent NGOs, such as the Environmental Defense Fund, have expressed support for the bill. This fact alone will go a long way in sustaining the momentum that the introduction of CSIA has created, and in encouraging Congress to get to the hard work of modernising TSCA. The House of Representatives has yet to introduce TSCA reform legislation this session, but convened an oversight hearing on TSCA on 13 June ([CW 13 June 2013](#)). While the hearing was not on any legislative vehicle in particular, that it focuses on TSCA generally was a step in the right direction. A second hearing is being planned.

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

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