# Issues the Chemical Safety Improvement Act does not address

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On May 22, 2013, David Vitter (R-LA), Ranking Member of the U.S. Senate's Environment and Public Works Committee, and the late U.S. Senator Frank Lautenberg (D-NJ) introduced Senate Bill 1009, the Chemical Safety Improvement Act ("CSIA"). At present, the CSIA is cosponsored by 12 Democrats and 13 Republicans and, as such, is the first and only TSCA modernization bill to enjoy bipartisan support. If enacted into law, the CSIA would modernize TSCA, give EPA enhanced authority to collect data and regulate potentially problematic chemical substances, clarify EPA's obligation to protect confidential business information, and address the difficult issue of conflicting and duplicative actions by U.S. states to regulate commercial chemical substances.

Since the passage of TSCA in 1976, the Dentons/TSG TSCA Practice Group has been advising clients on TSCA regulatory, enforcement and compliance matters; we literally wrote the book on the subject as the authors of the "The TSCA Handbook," currently in its fourth edition. The TSCA Practice Group also has been presenting the "Toxic Substances Control Act: Fundamentals and More" seminar for more than 25 years. Through this new series of advisories, we now offer our analyses of the CSIA.

In this first advisory in a series dedicated to the CSIA, we discuss two current TSCA issues left unresolved by the CSIA.

The CSIA presents a nearly comprehensive modernization of TSCA, with a focus on a new safety standard for commercial chemicals, enhanced EPA ability to require data submission, and a mandate to review the risks posed by existing chemical substances. Some have characterized the CSIA as "industry friendly." In fact, the bill focuses primarily on a handful of core issues but does not address several of industry's longstanding problems with TSCA. These unresolved problems are worth considering as the legislative process moves forward. For example, the CSIA does not address the unclear reporting standards for substantial risk information under TSCA § 8(e) or the difficulties faced by premanufacture notice ("PMN") submitters when EPA imposes consent orders under TSCA § 5(e). We explain each issue below.

## Section 8(e) Reporting Standards

The CSIA does not address the lack of clear reporting standards under existing section 8(e) of TSCA, which perpetuates substantial compliance difficulties and uncertainties for regulated entities. In the absence of clarity under the CSIA, EPA's continuing (and perhaps even increased) discretion to interpret section 8(e) as it likes remains an unresolved problem for industry.

When TSCA was enacted in the 1970s, the nation had recently been hit with revelations that widely used chemicals, including asbestos, polychlorinated biphenyls ("PCBs"), and the vinyl chloride monomer, had more serious effects than previously understood by regulators. Accordingly, Congress drafted TSCA § 8(e) in broad terms to place a

general obligation on chemical manufacturers, processors, and distributors to immediately report to EPA any information obtained that "reasonably supports the conclusion" that a chemical substance or mixture "presents a substantial risk to human health or the environment."

Congress did not, however, grant EPA rulemaking authority to interpret and refine section 8(e)'s broad and general terms, much less require the Agency to undertake such rulemaking. The result has been problematic, to say the least. EPA's initial 1978 enforcement policy for TSCA § 8(e) and informal guidance issued shortly thereafter turned section 8(e) from a requirement to report information regarding *substantial risks* into a requirement to report information on *hazardous properties*, which substantially broadened the original statutory obligation. In other words, although "risk" arises from a combination of a chemical's hazardous properties *and* the potential for exposure to the chemical, EPA disregards the exposure element and asserts that TSCA § 8(e) applies even to research-and-development chemicals that never leave the laboratory, never become commercial products, and, therefore, present no credible risk of exposure.

EPA also asserts that the five-year general federal statute of limitations does not apply to TSCA § 8(e) violations. Therefore, per-day penalty provisions of TSCA raise the specter of astronomical fines for a single failure to report a study or other reportable information under section 8(e), if the report owed to EPA goes unfiled for years. Under these circumstances, the reporting standards for TSCA § 8(e) should be as well defined as possible.

In the early 1990s, it became clear that industry and EPA had different interpretations regarding TSCA § 8(e)'s reporting standards, which prompted the Agency and the American Chemistry Council ("ACC") to develop the Compliance Audit Program ("CAP"). Under the CAP, 123 companies, including many major chemical manufacturers, signed consent agreements and agreed to audit their compliance with TSCA § 8(e) and to submit any unreported studies that met the reporting standards. For its part, EPA issued more detailed guidance on the Agency's interpretation of various reporting issues under section 8(e), including responses to several hypothetical scenarios presented by ACC.

In the 17 years prior to the CAP, EPA received approximately 1,100 reports under TSCA § 8(e). Under the first phase of the CAP, which covered toxicity studies, EPA received 11,264 reports. Under the second phase of the CAP, participants were supposed to audit possible under-reporting of discoveries of environmental contamination, but EPA could not produce guidance that would clearly identify when such information was not reportable. Industry indicated that absent such "safe harbor" guidance, EPA would be inundated with reports that would outnumber the submissions made under the CAP's first phase. In response, EPA unilaterally modified the consent agreements to eliminate the CAP's second phase. In the revised consent agreements, EPA pledged not to enforce against companies for failing to report information about environmental contamination until after the Agency had issued new guidance and, even then, only when the reportable information was obtained after the publication of EPA's guidance.

Any notion that the CAP's participants, which included many of the most TSCA-sophisticated companies, previously had misread a "clear" reporting standard over 11,000 times obviously is unwarranted. The volume of reports reflects unclear standards, which remained unclear even after EPA issued the additional CAP-related guidance, and the CAP participants simply erred greatly on the side of submitting previously unreported studies.

The lack of fair notice of reporting obligations remains problematic; EPA updated its TSCA § (e) enforcement policy in 2003 and has issued additional informal reporting guidance, but companies can still be blindsided by new Agency interpretations of section 8(e) developed in enforcement actions, as distinct from public rulemaking. Challenging such a new EPA interpretation means litigating a TSCA § 8(e) enforcement action to its conclusion -- a daunting prospect, even when EPA's new interpretation is fundamentally flawed. The company charged faces not only the possibility of civil penalties but also the stigma of months, or even years, of unresolved accusations that the company "withheld substantial risk information" about one of its chemicals or products. The CSIA does nothing to address this serious and ongoing problem.

# TSCA Section 5 Consent Order Negotiations

The CSIA makes it easier for EPA to extend the 90-day premanufacture notification ("PMN") review period but does not acknowledge the realities of the section 5(e) consent order negotiation process or address the problems that PMN submitters face when EPA decides that a chemical should be subject to regulation under TSCA § 5(e). In reality, EPA generally determines within the first 30 days of a PMN's review – and notifies the PMN submitter – that EPA will require the PMN submitter to enter into a section 5(e) consent order before commercial manufacture may commence. EPA then asks the submitter to withdraw the PMN or agree to "voluntarily" suspend the PMN review period while a section 5(e) consent order is negotiated.

The PMN submitter then faces a Hobson's choice: either agree to a "voluntary" suspension or irritate EPA by refusing to do so, thereby forcing the Agency to expend resources to issue either a unilateral section 5(e) order banning manufacture or a unilateral section 5(c) extension of the PMN review period. Faced with this choice, PMN submitters ordinarily withdraw the PMN or agree to a suspension of the review period.

Once the PMN review period is suspended, however, EPA has little incentive to provide detailed information regarding the underlying assumptions and modeling processes that went into the Agency's decision that the PMN substance must be regulated. In the initial written notice to the PMN submitter, EPA provides only a summary of the Agency's concerns and conclusions. Trying to obtain the details of EPA's reasoning can be an interminable process, when the Agency wants to limit discussion to the wording of the proposed section 5(e) consent order.

The CSIA does not require EPA to provide PMN submitters with a detailed explanation of the Agency's decision that a PMN substance is not likely to meet the safety standard and must be restricted. Given concerns in Congress and the regulated community regarding transparency, EPA should provide detailed information regarding its decision to restrict any PMN substance. Instead, the CSIA removes the current TSCA § 5(c) requirement for EPA to publish its reasons for any unilateral extension of the review period, which provides EPA with even more latitude to withhold its reasoning from the PMN submitter. Likewise, the CSIA's provisions on "transparency" also do not address this issue and, instead, provide only that certain information be made available to the public. In short, under the CSIA, PMN submitters may continue to be kept in the dark when EPA decides that a PMN substance is not likely to meet the safety standard and must be restricted.

In sum, the CSIA addresses core issues of concern to EPA, non-governmental organizations, and the chemical industry and establishes a framework that may ultimately provide a basis for modernizing TSCA. The CSIA does not, however, address certain longstanding problems that continue to trouble industry. Thus, characterizing the CSIA as an "industry-friendly" bill is unwarranted. The CSIA represents a compromise approach and should be recognized as such.

# Your Key Contacts


**Stanley W. Landfair**
Senior Counsel,
San Francisco/Oakland
D +1 415 267 4170
stan.landfair@dentons.com

**Andrew Shaw**
Partner, Washington, DC
D +1 202 496 7116
andrew.shaw@dentons.com