

## **TSCA Reform: The New State of Play**

**By Lynn L. Bergeson**

### **The Proposed Chemical Safety Improvement Act Would Streamline TSCA**

In a game-changing bipartisan show of support for reform of the Toxic Substances Control Act (TSCA) that few saw coming, United States (US) Senators David Vitter (R-LA) and the late Frank Lautenberg (D-NJ)—among bipartisan others—introduced on May 22, 2013, the *Chemical Safety Improvement Act* (CSIA), later designated Senate Bill 1009 (S.1009). CSIA provides a new and streamlined approach to reforming TSCA that stakeholders may view favorably when compared to legislative templates that have been considered previously by the Senate and the House of Representatives.

This draft legislation provides the US Environmental Protection Agency (EPA), industry, and other stakeholders a pragmatic and workable approach to chemical assessment, prioritization, and management in ways that address many of the key deficiencies long claimed by diverse stakeholders to plague TSCA and to prevent it from addressing effectively and credibly risk associated with chemical substances and mixtures.

The bill offers a new framework for TSCA reform, and it is inviting vigorous debate from all chemical stakeholders. This article summarizes key aspects of the bill and identifies issues and areas where further clarification is needed. This summary is not meant to be exhaustive, but it illustrates some of the challenges that lie ahead for the legislation notwithstanding its initial burst of public and bipartisan support.

## Section 2—Findings, Policy, and Intent

CSIA would replace this section in TSCA. A new Section 2(a), “Purposes,” provides two core purposes: “to improve the safety of consumers in the United States” and “to ensure that risks from chemical substances are adequately understood and managed by modernizing” TSCA Title I.

In Section 2(b) of the “Findings” section, the bill offers eight points, including:

- Chemicals “should be safe” for their “intended use” (a term of art defined in Section 3, discussed *infra*);
- “Unmanaged risks” of chemicals “may pose a danger;”
- “Public confidence in the Federal chemical regulatory program *has diminished over time;*”
- Scientific understanding “has evolved greatly” since TSCA’s enactment in 1976, “*requiring*” Congress to update the law to “*ensure*” that regulation of chemicals in the United States reflects “modern science, technology and knowledge;” and
- “Chemicals are used in diverse manufacturing industries and other valuable commercial, institutional, and consumer applications that have benefitted society.” (Emphasis added.)

### ***Additional Findings***

Importantly, there are also findings specifically relating to state preemption and the role of innovation, two much talked about elements of TSCA reform. Section 2(a)(7) offers a series of competing interests: “promoting uniform protections through regulation of chemical substances in commerce, to minimize undue burdens on commerce, and to minimize burdens on States, specified actions” by EPA “should preempt requirements by States and political subdivisions of States.”

Section 2(a)(8) points the legislation toward the future by recognizing that “innovation in the development of new chemical substances, especially safer chemical substances, *should be encouraged* to reduce risk, provide improved products, stimulate the economy, create jobs, and protect interstate commerce.” (Emphasis added.)

## **Policy**

In Section 2 CSIA also clarifies and substantially expands TSCA's "Policy" statement by stating that "this Act . . . should protect the health of people and the environment from unmanaged risks of chemical substances" and "should be modernized to build public confidence in the ability of the Federal regulatory system to protect health and the environment, promote innovation, and sustain a globally competitive chemical industry in the United States." These statements appear in Sections 2(b)(1)(A) and 2(b)(1)(B), respectively.

Further, in Sections 2(b)(2)(A) through 2 (b)(2)(F), the bill states that EPA should have the "appropriate . . . information necessary to make safety determinations," minimize the use of animal testing "where appropriate," encourage the use of "best laboratory practices," have authority to share confidential business information (CBI) with states and political subdivisions of states "subject to appropriate safeguards against inappropriate disclosure," have the "resources and tools" needed to implement the Act, and should implement the Act "in a manner that *promotes* transparency of information and decision making, *protects substantiated* [CBI], and *promotes* innovation," including in chemicals that have "reduced hazard, exposure, and risk patterns." (Emphasis added.)

Section 2 (b)(3) states that adequate data and information "should be available with respect to the effect of and exposure to chemical substances and mixtures on health and the environment, to the extent necessary for safety assessments and determinations," and that "where necessary, the development of such test data and information should be the primary responsibility of those who manufacture or process" such chemicals or mixtures. In Section 2(b)(4) the bill explicitly recognizes that "States have an important role in protecting health and the environment."

## **Section 3—Definitions**

CSIA retains all of TSCA's current definitions without change. New terms are added, however. These new terms and their definitions are:

- **Best available science**—means science that "maximizes the quality, objectivity, and integrity of information, including statistical information;" "uses peer-reviewed and publically available data;" and This is a reprint of an article published in *Environmental Quality Management*, Winter 2013. © 2013 Wiley Periodicals, Inc.

"clearly documents and communicates risks and uncertainties in the scientific basis for decisions."

- **Intended conditions of use**—is a critically important new term defined to mean "the circumstances under which a chemical substance is intended or reasonably anticipated to be manufactured, processed, distributed in commerce, used, and disposed of."
- **Safety assessment**—means a "risk-based assessment of the safety of a chemical substance that (A) integrates hazard; use; and exposure information about a chemical substance and (B) includes . . . an assessment of exposure under the intended conditions of use; and . . . reference parameters that may be appropriate with regard to a specific chemical substance (such as a margin of exposure)."
- **Safety determination**—means a determination by EPA "as to whether a chemical substance meets the safety standard under the intended conditions of use."
- **Safety standard**—means a standard that "ensures that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance."

The safety standard definition is particularly interesting and somewhat surprising in its continuation of the TSCA concept of "unreasonable risk." As structured in CSIA, this safety standard seems to represent a bit of a flip from the TSCA approach of "may" or "will" present an unreasonable risk to one that involves ensuring that "*no* unreasonable risk *will* result" from exposure to a chemical. Beyond a doubt, this new safety standard is one of the key issues that will be carefully considered, dissected, and debated as the bill progresses. (Emphasis added.)

#### **Section 4—Chemical Assessment Framework; Prioritization Screening; Testing**

CSIA introduces a new approach to TSCA chemical assessment and testing. Under CSIA, EPA is required to develop a "framework" for evaluating chemicals in accordance with a new Section 4(e), which outlines in considerable detail requirements for establishing a "Prioritization Screening Process."

## **Assessment Framework**

Under CSIA Section 4(a), "Chemical Assessment Framework," EPA "shall develop" a framework for evaluating chemicals that "shall employ the best available science and risk assessment principles in existence at the time." EPA alone is tasked with developing the framework, and EPA alone is tasked with developing the "policies and procedures" for implementing the framework to collect information, evaluate its quality, analyze the data, determine the need for additional data and information, and provide transparency (subject to Section 14), including both positive and negative findings. An early criticism that has been raised with CSIA is the limited number of firm deadlines embedded in the legislation. While this concern applies to the entire bill, the absence of deadlines is especially significant in the "assessment" component of the legislation.

Section 4(b)(5) requires EPA to develop and use a "structured evaluative framework" for making any decision under the Act and for determining the relevance, quality, and reliability of data and information. Among other provisions, this framework requires that EPA, "when consistent with the underlying data, consider, for both cancer and noncancer endpoints, whether available data support or do not support the identification of threshold doses of a chemical substance below which no adverse effects can be expected to occur."

Under this provision, EPA would appear to be required to determine whether a chemical acts through a threshold of toxicity such that adverse effects would not be associated with exposures below that threshold.

Section 4(c) requires that in making decisions under Sections 4(e)(5) and (6), that EPA "shall consider" data and information that are relevant and "reasonably available" to EPA "at that time," and that include information submitted to EPA by companies, the public, or by a state, or information submitted to a "governmental body in another jurisdiction under a governmental requirement relating to protection of human health and the environment, if the information is accessible to" EPA, derived through Structure Activity Relationships (SAR) analysis, inferred based on what is generally known as a "read-across" approach, or otherwise accessible to EPA.

Plainly the nod to “governmental body in another jurisdiction” would include data and information submitted in the European Union under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program.

Section 4(d) addresses “Transparency,” and requires that, subject to Section 14, EPA make available to the public information, guidance, procedures, and tools, including “the data underlying any study.” Section 4(d)(3) states that “[a]ny written guidance of general applicability prepared by [EPA] under this Act shall be subject to public notice and an opportunity for comment.”

### **Prioritization**

As noted previously, Section 4(e) concerns the “Prioritization Screening Process,” and Subsection (1)(A) states that EPA, not later than one year after enactment of the CSIA, shall establish a risk-based screening process for identifying existing chemical substances that are considered a “high priority” for a safety assessment and determination under Section 6 and a “low priority” for a safety assessment and determination. These are to be known, respectively, as “high-priority” and “low-priority” substances.

Section 4(e)(1)(B) is an important Subsection that discusses consideration of “active” substances in the screening process.

Section 4(e)(1)(C) requires that EPA “shall make every effort to complete the prioritization of all active substances in a timely manner.” Section 4(e)(2) requires that the proposed prioritization screening process be published for comment and that EPA shall establish criteria for determining a substance’s priority.

The criteria in Section 4(e)(2)(C) are required to consider state recommendations, the hazard and exposure potential of a chemical, intended conditions of use or significant changes in those conditions, evidence/indicators of exposure, volume and whether it is significantly increasing or decreasing, availability of hazard data—with an important proviso that limited availability of data can be a factor in designating a chemical as a high priority—and the extent of federal or state regulation or the impact of state regulation on the United States.

Section 4(e)(3) addresses EPA's prioritization screening decisions that are to apply the criteria specified under Subsection 4(e)(2)(A)(ii) and information reasonably available to EPA. Section 4(e)(3)(B) provides that if EPA determines that "additional test data and information are needed" to establish a chemical's priority, EPA "shall provide an opportunity for interested persons to submit" data and information that are "reasonably ascertainable." This provision allows for the voluntary submission of existing information, but seemingly does not allow for voluntary testing to be done.

Under Section 4(e)(3)(C), EPA may "defer" a prioritization screening decision "for a reasonable period of time to allow for the submission and evaluation of additional data and information." This Subsection appears to allow for the voluntary development of additional data, provided EPA can be persuaded to defer a prioritization decision.

### ***Identifying High-Priority Chemicals***

Section 4(e)(3)(E) discusses the identification of high-priority substances and states that a chemical, relative to other substances, that has the potential for high hazard *and* high exposure *shall* be identified by EPA as a high-priority. EPA "*may* identify" as a high-priority chemicals that, relative to other chemicals, have the potential for high hazard *or* high exposure. This provision might be relevant to the identification of chemicals with "limited availability of data" as a high-priority as discussed under Section 4(e)(2). EPA can also identify an inactive substance as a high-priority if it has not been subject to an EPA ban or phase-out regulatory action and demonstrates high hazard and high exposure. (Emphasis added.)

Section 4(e)(3)(F) also discusses the identification of low-priority substances. This provision states that EPA "shall" make this identification if it determines the chemical "is likely to meet the safety standard under the intended conditions of use."

Section 4(e)(5) states that any action under this Subsection shall *not* be considered a final agency action or subject to judicial review.

## **Testing**

Section 4(f) concerns development of new test data and information and states that EPA may require such development if it determines that data and information are needed to perform a safety assessment, to make a safety determination, or to meet testing needs under another federal statute. EPA is authorized to use rulemaking, a testing consent agreement, or order authority to require such testing. In taking such an action, EPA shall require the use of an evaluation framework that, prior to requiring additional testing of vertebrate animals, integrates relevant information and tiered testing in accordance with Subsection 4(h) to inform the decision as to whether higher tier tests are necessary.

In issuing a final action, EPA is required to issue a statement identifying the need intended to be met by the action, explaining why existing data are inadequate to fill that need, and encouraging the use of non-animal test methods. Additionally, in using an order, EPA also must explain why "good cause exists" for issuance of an order, including a discussion of efforts to obtain testing voluntarily, the ability to use available data on structurally related chemicals (SARs), and safety assessments on other chemicals to the extent relevant to the chemicals that would be the subject of the order (or rule, the inclusion of which seems to be in error in this Subsection).

Section 4 also discusses reduction of animal-based testing and includes several provisions whereby EPA "shall minimize the use of animals in testing." For stakeholders frustrated with the pace that alternative test methods are shown to be valid and subsequently applied in regulation, the promise of a strategic plan is encouraging. Section 4 also authorizes EPA to require manufacturers and processors of a chemical for which testing is needed per "Subsection 4(f)(4)(A)(i)" to conduct the needed testing, including those who begin to manufacture or process the chemical during the reimbursement period.



## Section 5—New Chemicals and Significant New Uses

CSIA retains in large part the current TSCA approach to new chemical notification and review with some important changes. TSCA Section 5(a) concerning Premanufacture Notifications (PMN) and Significant New Use Rules (SNUR) is retained other than requiring conforming changes. Section 5(b) is deleted in its entirety (including the “chemicals of concern list” provision at Section 5(b)(4)), as are Sections 5(c), 5(e), 5(f), and 5(g). TSCA Section 5(d) is redesignated as CSIA Section 5(b) and TSCA Section 5(h), which includes the various statutory and regulatory exemption provisions at Subsections (1) through (4), is retained and redesignated as Section 5(g).

Section 5(c), “Review of Notice,” requires that EPA conduct an initial review within 90 days of receipt of a notice, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment, and make any needed determinations under Section 5(c)(4).

This Subsection requires EPA to determine whether a new chemical or a significant new use of a chemical “is” or “is not” likely to meet the safety standard under the intended conditions of use, or if additional information is necessary to make a determination. EPA can extend the review period for a total of 90 days (or longer if the “additional information” determination is made). Under the “is likely to meet” determination, EPA is required to allow the review period to expire without additional restrictions, whereas under an “is not likely to meet” determination, EPA can, by consent agreement or order, prohibit or restrict manufacture, processing, or use.

If EPA determines additional data are needed, EPA “shall provide” an opportunity for the submitter to develop and submit the information and can, by agreement with the submitter, extend the review period. On receipt of the additional information, EPA “shall promptly make a determination.” In addition, EPA is authorized to restrict the chemical pending receipt of the information needed and can, as appropriate, allow the submitter to commence manufacture during this period. This provision seems to operate similarly to current TSCA Section 5(e), including EPA’s current approach of allowing commercialization and “triggered testing.”

Section 5(e) makes clear that EPA can review “former new chemicals” under Section 4(e) at any time following receipt of a Notice of

Commencement (NOC) or upon availability of “significant new information” regarding the chemical. Section 5(f), “Transparency,” requires EPA to make available all notices, rules, and orders, and all data and information submitted to EPA subject to Section 14.

Section 5(g) addresses exemptions. This section largely retains current exemptions with conforming changes.

## **Section 6—Safety Assessments and Determinations**

CSIA retains only TSCA Section 6(e) on polychlorinated biphenyls (PCB), redesignated as Section 6(d), and replaces the other sections in their entirety with a new approach to chemical substances safety assessments and determinations. Section 6(a) requires that EPA conduct a safety assessment on high-priority substances and make a safety determination for each such substance. Under this provision, and based on the results of the safety determination, EPA must, as appropriate, “establish requirements for risk management of a high-priority substance.”

Section 6(b) specifies the requirements pertinent to safety assessments. Subsection (1) provides that EPA “shall conduct a risk-based safety assessment of each high-priority substance, in accordance with such schedule as [EPA] establishes, to be based solely on considerations of risk to human health and the environment.”

### ***Procedural Rules for Safety Assessments and Determinations***

Section 6(b)(2) requires that EPA establish procedural rules for safety assessments and determinations, including schedules for submission of data and the initiation and completion of such assessments and determinations. These rules shall:

- Identify the basis on which EPA decides which high-priority substances take precedence;
- Require EPA to inform the public;
- Allow interested persons, “including States,” to submit information; and

- Subject to Section 14, require EPA to make available the information taken into consideration in preparing each safety assessment and determination, offer an opportunity to comment, and publish final safety assessments and determinations.

Further, the rules shall include “a schedule” by which each safety assessment and determination is expected to be conducted and “a deadline for the completion of each assessment and determination;” CSIA offers flexibility and “reasonable” time extensions “after an adequate public justification.”

CSIA Section 6(b)(3) specifies that in conducting a safety assessment, EPA “shall, at a minimum, take into consideration” the Section 4(c) data and information and any additional information submitted, and that each such safety assessment “shall include” a weight of the evidence summary and a nontechnical summary “explaining what the relevant information demonstrates in the context of the intended conditions of use and exposure patterns of the chemical substance.”

### ***Safety Assessment Methodologies***

Section 6(b)(4) requires that EPA develop “an appropriate science-based methodology for conducting safety assessments” and make the methodology available for public comment and peer review. In conducting a safety assessment, EPA is required to take into consideration exposures or significant subsets of exposures, exposure duration, intensity, frequency and number, and the vulnerability of exposed subpopulations. If EPA determines that additional test information is needed, EPA is required to provide an opportunity for interested persons to submit the additional information and may “promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information.” Finally, and importantly, Section 6(b)(6) states that a safety assessment “shall not” be considered a final agency action, and is not subject to judicial review.

### ***Safety Determinations***

Section 6(c) lays out the process for conducting safety determinations. As soon as possible after the date on which the safety assessment is completed, EPA “shall determine whether the chemical substance meets the safety standard under the intended conditions of use of the chemical substance.” Under Section 6(c)(2), EPA “shall determine, based solely on considerations of risk to human health and the environment,” that the substance meets the safety standard or does not meet the safety standard, “in which case [EPA] shall impose additional restrictions, as appropriate, under paragraph (9),” or that additional information is needed to make the safety determination.

In making the safety determination, EPA is required to take into consideration and publish a statement that includes a series of “considerations” under Section 6(c)(3), and to consider the safety assessment developed under Section 6(b) and the best available science. EPA is required to propose all safety determinations and provide notice and seek public comment.

### ***Restriction Actions, Bans, & Phase-Outs***

Section 6(c)(9)(B) outlines the wide variety of restriction actions that are available to EPA. These include labeling and warning requirements, recordkeeping requirements, data development obligations, production limits, and bans or phase outs of a chemical use, distribution method, or other aspect of a chemical determined not to meet the safety standard.

CSIA devotes an entire Subsection, specifically Section 6(c)(9)(D), to the “considerations” on which the decision to ban or phase out the “manufacture, processing, or use of a chemical substance” must be based. Section 6(c)(9)(D) then goes on to identify a host of economic and benefit factors that must be considered. These include the “availability of technically and economically feasible alternatives” for the chemical “under the intended conditions of use,” the risks posed by alternatives compared to those of the chemical at issue, the “economic and social costs and benefits of the proposed regulatory action and options considered, and of potential

alternatives,” and the “economic and social benefits and costs of . . . the chemical substance; . . . the alternatives to the chemical substance; and . . . any necessary restrictions on the chemical substance or alternatives.”

The actual wording of Sections 6(c)(9)(C) and (D) seems to limit the consideration of the cost-benefit considerations only in circumstances involving a “ban or phase out” of “the manufacture, processing, or use of a chemical substance.” It is unclear, however, if the drafters intended this narrow application of cost-benefit considerations.

Section 6(c)(10) identifies the circumstances under which EPA may consider an exemption from “any additional restriction established under paragraph (9).” EPA is authorized to make any of several determinations, including:

- National security;
- “Significant disruption in the national economy;”
- “Critical or essential use” for which no feasible alternative for the use would “materially reduce risk to health or the environment” or is “economically, technically, or efficiently available;” or that the use “as compared to reasonably available alternatives, provides a net benefit to human health, the environment, or public safety.”

Section 6(c)(11) states that a Section 6(c) safety determination, unlike safety assessments, “shall” be considered a final agency action and subject to judicial review.

## **Section 8—Information Collection and Reporting**

CSIA makes important changes to TSCA Sections 8(a), 8(b), and 8(e), and retains the other provisions [Sections 8(c) and 8(d)] without change.

In Section 8(a), CSIA adds new sections as follows. Section 8(a)(4) requires EPA to promulgate rules requiring reporting of information so that EPA “has the information necessary to carry out sections 4 and 6.” The reporting involves information “known by, or reasonably ascertainable by,” the person making the reporting, “including rules requiring processors to report information.” The “known by” language is different from the more customary “known to,” but the word change seems not substantively to

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change the interpretation, and the explicit recognition of reporting by processors may be intended to encourage EPA to require such reporting when needed.

Pursuant to Section 8(a)(4)(B), the rules may differ between manufacturers and processors, but the rules “shall be limited to active substances or mixtures containing active substances as designated under [Section 8(b)]; and . . . shall apply only to the extent” EPA determines the reporting is necessary for the effective enforcement of the Act. This seems to suggest that EPA has the discretion to designate all or some subset of mixtures containing the active substance. EPA is also required to develop guidance for these rules that includes the level of detail necessary to be reported and “the manner by which manufacturers and processors may report use and exposure information on a voluntary basis.”

### ***Nomenclature***

CSIA also adds a new Section 8(b)(3) that significantly changes the approach to the TSCA Chemicals Substance Inventory. Section 8(b)(3), “Nomenclature,” specifies that EPA *shall* maintain the use of “Class 2 nomenclature,” maintain the use of the Soap and Detergent Association Nomenclature System (used in the initial Inventory and further described in the 1985 edition of the Inventory), and “treat all components of categories that are considered to be statutory mixtures” as being on the Section 8(b)(1) Inventory. (Emphasis added.)

Section 8(b)(3)(B)(i) discusses situations where “existing guidance allows for multiple nomenclature conventions” and states that EPA “shall . . . maintain the nomenclature conventions . . . ; and . . . develop new guidance” that “establishes equivalency between the nomenclature conventions” and “permits persons to rely on that new guidance” for purposes of determining whether a chemical is on the Section 8(b)(1) Inventory. CSIA Section 8(b)(3)(B)(ii) requires EPA to develop guidance that recognizes Inventory chemicals having multiple Chemical Abstracts Service (CAS) number listings as a single chemical substance. This provision is presumably intended to address EPA’s current practice of treating chemicals with different CAS number listings as different chemical substances.

### ***Active and Inactive Designations in the TSCA Inventory***

Section 8(b)(4) through Section 8(b)(7) describe an approach and procedures for creating and updating a list of “active” versus “inactive” Inventory listed chemicals, while Section 8(b)(8) discusses public participation and confidentiality aspects. Section 8(b)(4)(A) requires EPA to make available a “candidate list of active substances in commerce.”

The candidate list includes any chemical: reported under the Inventory Update Rule (IUR)/Chemical Data Reporting (CDR) rule or as an export notice under TSCA Section 12(b) for the ten years prior to the date of enactment of CSIA; for which a NOC of manufacture or a Significant New Use Notification (SNUN) was submitted; or any other chemical identified by EPA as likely to qualify as “active.”

Subsection (B) requires EPA by rule to require manufacturers and processors to notify EPA of chemicals manufactured or processed for a nonexempt commercial purpose during the five-year period prior to enactment of CSIA. Further, under Subsection (C), prior to promulgating the rule, EPA is to develop guidance concerning accession numbers, PMN numbers, and generic names. For chemicals included on the confidential portion of the candidate list, the rule shall require reporting that indicates whether the manufacturer or processor claims the specific identity as CBI under Section 14.

Section 8(b)(5)(A) requires EPA, based on the reports received in response to the rule, to designate chemicals on the TSCA Inventory as “active” or “inactive,” and also to include as active chemicals those that have been the subject of an NOC or a CDR report received since the date of enactment, as well as any “inactive” chemicals that have been the subject of a notice under Section 8(b)(7)(C), as described below.

Further, Section 8(b)(5)(B) requires EPA to update the list of active and inactive chemicals following each CDR reporting cycle. Section 8(b)(7) discusses “Inactive Substances” and makes clear that such substances remain on the Inventory and can be changed to “active status” following notification to EPA under Section 8(b)(7)(C). The Subsection requires that such notification occur “before the date on which the substance is manufactured or processed,” after which EPA shall designate the chemical as “active” and, pursuant to Section 4(e), review the priority of the substance

as necessary. Section 8(b)(7)(D) specifies that the list of inactive chemicals shall not be considered a category under Section 26(c).

CSIA would amend TSCA Section 8(e) by adding a new section that allows “any person” to submit “information reasonably supporting the conclusion that a chemical substance or mixture does not present a substantial risk of injury.”

## **Section 14—Confidential Information**

This Section, with is Section 13 in the bill, addresses the much debated topic of CBI and amends TSCA Section 14 in a number of respects, but in essence retains the core concept of protecting from disclosure information claimed confidential provided certain requirements are met. Sections 14(b) and (c) refer to information generally protected from disclosure and information not protected from disclosure, respectively.

Information protected from disclosure includes specific information describing the manufacture, processing, or distribution of a chemical, marketing and sales information, customer information, and the other categories of information historically protected from disclosure, including the “specific identity of a chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance.” Information on a specific chemical identity is presumed confidential, but requires upfront substantiation.

Information not protected from disclosure includes:

- The identity of a chemical substance submitted after the enactment of CSIA not meeting the requirements of Subsection (d) (below);
- A safety assessment or safety determination developed under Section 6;
- Health and safety data for substances for which testing is required under Section 4;
- Health and safety data in notices of substantial risk submitted under Section 8(e) and in the underlying studies; and



- General information describing manufacturing volumes in ranges or general descriptions of industrial, commercial, or consumer functions and uses of chemical substances or mixtures.

Special provisions apply to confidentiality claims for chemical identities under Section 14(d), including upfront substantiation. A generic name for the chemical substance that can be disclosed must be provided that “discloses a maximum amount of information on the chemical . . . while protecting those features . . . that are considered confidential.”

Under Section 14(e), confidentiality will not apply under certain circumstances, including: law enforcement purposes; where disclosure to contractors is necessary to perform work under TSCA; importantly, where “the Administrator determines that disclosure is necessary to protect human health and the environment;” to a state or political subdivision thereof if protections are in place to maintain the confidentiality of the information and notice is provided to the submitter; or a health professional in emergency and non-emergency situations provided certain conditions, which are carefully spelled out in the bill, are met.

CSIA takes a more flexible approach to the duration of CBI claims. Under Section 14(f), protection from disclosure will continue for as long as the submitter requests or as EPA deems reasonable, unless prior to the end of that period, the submitter withdraws the claim or EPA becomes aware that the need for protection no longer exists.

EPA may request “redocumentation” of a claim of confidentiality at any time and of any person after a chemical substance is identified as a high-priority substance. As under current law, notice is required before EPA may release confidential information and judicial action may be brought in district court seeking a restraining order to prevent release of information the submitter wishes to retain as confidential.

## **Section 15—Preemption**

One of the most contentious issues to date in the TSCA reform debate is whether a modernized TSCA should expand the preemptive effect of EPA action under TSCA. Under TSCA Section 18(a), state regulation is generally

preempted with respect to chemical substance and mixture testing. Similarly, TSCA preempts state regulation to the extent EPA has issued a rule or order under TSCA Sections 5 or 6 unless such regulation is identical to the federal regulation, adopted pursuant to the Clean Air Act or other federal law, or “prohibits the use of such substance or mixture in such State or political subdivision (other than its use in the manufacture or processing of other substances or mixtures).”

Under TSCA Section 18(d), states and political subdivisions may petition EPA for an exemption from the preemptive effect of TSCA provided a state requirement is not “in violation of” the federal requirement, and the state restriction “does not unduly burden interstate and foreign commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance.”

CSIA significantly expands the preemptive effect of federal TSCA regulation. CSIA Section 15 would *prospectively and retrospectively* preempt state or local chemical regulatory restrictions falling into three categories: requirements for the development of test data on a chemical substance or category of substances that is reasonably likely to produce data and information required under TSCA Section 4, 5, or 6 by rule, order, or consent agreement; any prohibition or restriction on the manufacturing, processing, distribution, or use of a chemical after issuance of a safety determination; or any requirement for notification of a use of any chemical for which EPA has specified a significant new use and EPA has required notification under a Section 5 rule. CSIA would *prospectively* preempt state and local restrictions on the manufacture, processing, distribution, or use of a chemical EPA has identified as a high-priority or low-priority substance. (Emphasis added.)

CSIA would not preempt state or local requirements that: are adopted pursuant to other federal laws; implement “reporting or information collection requirement[s] not otherwise required” by EPA under TSCA; or are adopted by the state and are related to water or air quality or waste disposal and do not impose restrictions on the manufacture, processing, distribution, or use of a chemical substance and are not “otherwise required by or inconsistent with” an EPA action under Sections 5 or 6. In addition, states are authorized under CSIA to seek waivers from these limitations if the state determines “it cannot wait” and certifies to certain points.

EPA may provide a waiver if it determines that “compelling State or local conditions” warrant granting the waiver to protect health or the environment, the waiver would not “unduly burden interstate *and foreign* commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance,” the state requirement is not a violation of federal law, and the waiver is based on the “best available science and is supported by the weight of the evidence.” (Emphasis added.)

EPA determinations regarding waiver requests are subject to judicial review in the U.S. Court of Appeals for the D.C. Circuit, “which shall have exclusive jurisdiction over the determination.” Safety determinations “shall” be admissible as determinative evidence in court.

## **Section 16—Judicial Review**

This CSIA section consists primarily of conforming changes to TSCA Section 19. The specified changes include a provision that eliminates current TSCA Section 19(a)(3), which defines the contents of the rulemaking record. The eliminated section is mostly innocuous, but includes a curious provision that allows EPA to include in the record for review any “information that the Administrator considers to be relevant” if it is identified in a *Federal Register* notice published on or before the date of promulgation of the rule. This change will prevent EPA from attempting to use this provision to circumvent standard notice and comment requirements.

## **Current Status of CSIA**

On July 31, 2013, the Senate Committee on Environment and Public Works held a hearing on “Strengthening Public Health Protections by Addressing Toxic Chemical Threats.” Much of the testimony focused on whether CSIA would preempt existing state laws or prevent states from promulgating additional laws regulating toxic chemicals, a topic close to Senator Barbara Boxer (D-CA), given the pride her native California takes in its approach to chemical regulation.

In her opening statement, Senator Boxer listed various criticisms of CSIA, highlighting a July 31, 2013, letter from nine Attorneys General expressing their “deep concerns about the unduly broad preemption

language" in CSIA, which would amend TSCA and "could, in its current form, seriously jeopardize public health and safety by preventing states from acting to address potential risks of toxic substances and from exercising state enforcement powers." California was joined by Attorneys General from Connecticut, Delaware, Maryland, Massachusetts, New Mexico, Oregon, Vermont, and Washington.

Senator Vitter, Ranking Minority Member of the Committee, noted that CSIA is the first compromise bill to reform TSCA. According to Senator Vitter, bipartisan support for the bill continues to grow, and the bill is supported by the editorial boards of the *New York Times* and *Washington Post*. Senator Vitter stated that criticisms of the bill fall into two broad categories, misimpressions or actual distortions and legitimate suggestions. Senator Vitter emphasized that, when he and Senator Lautenberg drafted CSIA, they did not intend the bill to preempt private rights of action.

Other Committee members offered opening statements. According to Senator Jeff Merkley (D-OR), CSIA is a compromise bill and requires flexibility, and it could lose the bipartisan support that makes it passable. Senator Benjamin L. Cardin (D-MD) expressed his concern with the "unduly broad" preemption language. Senator Tom Udall (D-NM), Chair of the Environment and Public Works Subcommittee with jurisdiction over TSCA and an original co-sponsor of CSIA, stated that he believes CSIA takes successful elements of TSCA, while striking others, such as the least burdensome requirement that has prevented EPA from regulating asbestos. Senator Udall noted that CSIA could be improved by incorporating deadlines and timetables and better protecting vulnerable populations. Senator John Barrasso (R-WY) highlighted news reports favorably describing CSIA and urged the Committee not to let the opportunity to reform TSCA go by. Finally, Senator Kirsten Gillibrand (D-NY) stated that she co-sponsored both the Safer Chemicals Act (SCA), another version of TSCA reform legislation introduced by the late Senator Lautenberg, and CSIA. She described CSIA as a promising start, while acknowledging there are provisions to fix as the bill moves through Congress. Three separate sets of witnesses presented their views on various aspects of the bill. No further action on the bill has been taken as of this writing in late August.

## Conclusion

It remains to be seen how much fortitude or willingness the various constituencies will bring to the table in the coming months. The role of the House of Representatives in TSCA reform remains unclear. Even if compromise in the Senate is reached, it is not clear whether House members will be as willing to accept enhanced EPA authority of any kind. Nonetheless, given the introduction of a bipartisan Senate TSCA reform bill, the prospects for real TSCA reform remain better than they have been since any earlier time.

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