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House Releases Discussion Draft of TSCA Reform Legislation

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Reform of the Toxic Substances Control Act (TSCA) may be a little closer to reality since Rep. John Shimkus (R-IL), Chair of the House Energy and Commerce Subcommittee on Environment and the Economy, released on February 27, 2014, a much anticipated discussion draft that would update TSCA. The Chemicals in Commerce Act (CICA) keys off of Senate Bill (S.) 1009, the Chemical Safety Improvement Act (CSIA), which was introduced on May 22, 2013, by late Sen. Frank R. Lautenberg (D-NJ) and Sen. David Vitter (R-LA). Under Shimkus's leadership, the Subcommittee has held five hearings that reviewed core sections of Title I of TSCA and the proposed Senate amendments to those sections. This column provides an overview of the discussion draft of the new, not-yet-numbered House bill, the CICA, and compares its key provisions with the Senate's approach to TSCA reform under S. 1009.

The discussion draft of the CICA, which is discussed below, is available at: http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/analysis/CICADD.pdf. Direct quotes from the discussion draft included in this column are followed by the page numbers at which they can be found in the document. Highlights of the bill are available at http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/analysis/20140227-CICA-DiscussionDraft-Highlights.pdf. Memoranda regarding S. 1009 and on the Congressional hearings held to date are available at http://www.lawbc.com/regulatory-developments/tsca.

Section 2: Findings

The findings in the CICA generally align with those in the CSIA. The CICA limits provisions in this section to "findings" and "purpose." It does not offer statements of "intent" or "policy" as was done in TSCA and the CSIA.

The purpose of the Act is to "promote uniform" protection of human health and the environment through regulation while minimizing undue burdens on commerce.

Section 3: Definitions

The CICA retains all of TSCA's definitions and proposes definitions for "(2) best available science," "(8) intended conditions of use," "(12) potentially exposed subpopulation," "(15) publicly available information," and "(16) safety determination." Definitions (2), (8), and (16) are somewhat revised from those in CSIA, while the others are new. A change to "intended conditions of use," which drops a reference to "disposal" among the commercial activities, may be significant and has been carried through other parts of the discussion draft.

Section 4: Testing

The CICA revises TSCA Section 4 in several regards, including by giving the United States (US) Environmental Protection Agency (EPA) rule, consent agreement, and order authority to require testing (as did the CSIA) and by deleting Section 4(e) on the Interagency Testing Committee (ITC). It differs from CSIA Section 4 by not including that bill's detailed discussion of a Chemical Assessment Framework and Prioritization Screening elements, but otherwise generally mirrors the CSIA approach to testing.

Under the CICA discussion draft, EPA would have the authority to require testing in four instances:

- To perform a determination about the safety of an existing chemical, (interestingly, the openness of this provision appears to allow chemical testing for purposes of prioritization, or at least does not preclude this as does the CSIA);
- To ensure compliance with restrictions on new or existing chemicals or significant new uses of a chemical;
- To review chemicals intended only for export; or
- To help another federal agency with implementing its own statute if the testing is needed to meet a "regulatory testing need" determined by that agency.

This last provision may be intended to provide a more focused alternative to the ITC approach in TSCA. In developing hazard or exposure testing information, EPA is to start with screening-level information and must require additional information if EPA determines "that additional information development is necessary" (Discussion Draft, 2014. p. 9).

The CICA, unlike the CSIA, would require EPA to undertake expedited consideration of any significant new information concerning "a significant risk of serious or widespread harm to human health" (Discussion Draft, 2014. P. 16). Under TSCA, the provision was limited to new information on cancer, mutagenicity, and birth defects.

The data compensation provisions in Section 4(d) are slightly different. Under the CICA, entities "seeking to use" new hazard and exposure information must provide fair and equitable reimbursement for such information, and absent agreement, the dispute will be resolved by arbitration according to the terms of the contract between or among the parties or by regulations developed by EPA. Under the CSIA, EPA action under Section 4 is not conditioned upon resolution of data compensation claims.

Section 5: New Chemicals and Significant New Uses

The CICA takes a generally similar approach to new chemicals and significant new uses as is the case with The CSIA with some important differences. As in the CSIA, EPA is required to review the Section 5 notice and make a determination, although the nature of the determination has been changed. In the CSIA, the notice relates to whether the chemical is "not likely to meet the safety standard," whereas in the CICA, EPA action is dependent on a determination that the chemical "is likely to result in an unreasonable risk of harm" (Discussion Draft, 2014. p. 23).

The CICA gives EPA authorities similar to those in the CSIA to regulate new chemicals and significant new uses, although in the CICA, EPA must implement any testing requirements "subject to Section 4," which would appear to require use of processes and procedures found in that section. CICA Section 5(a)(3) would also clarify EPA's significant new use authority

related to articles in which a chemical substance it included. EPA must "identify" specific types of articles and, in taking an action, must determine that an unreasonable risk "may result from exposure to a chemical substance in the article," (Discussion Draft, 2014. p.19) and that "such risk cannot be addressed adequately through requirements placed on the chemical substance" (Discussion Draft, 2014. p. 19). Similar to the CSIA, the CICA retains the TSCA Section 5(h) exemptions for chemicals made in small quantities for experimentation, research, analysis, or test marketing and where there is not human or environmental exposure.

The CICA also includes a new exemption provision at Section 5(f)(5) that has no counterpart in TSCA or the CSIA. This provision concerns new obligations for byproduct chemical substances and requires EPA to develop a rule that codifies, with changes, the current exemption provision at 40 Code of Federal Regulations Section 710.4(d). The change involves replacing the "extract[ing] component chemical substances" language with "extracting, by reaction or otherwise, a chemical substance to recycle or reclaim" (Discussion Draft, 2014. p. 31).

Section 6: Existing Chemicals

The CICA discussion draft "provides a structure to evaluate, prioritize, review, and, if necessary, regulate a chemical that poses an unreasonable risk of harm to human health or the environment under its intended conditions of use" (Discussion Draft Highlights, 2014. p. 2). The discussion draft would require EPA to establish a system to designate and list all "active" chemicals (as identified pursuant to Section 8(b), below) as high or low priority.

Consistent with the CSIA, the CICA does not impose a deadline for completing the prioritization process. Unlike the CSIA, the CICA does not include an element allowing for an "inactive" chemical to receive a high-priority designation, and, concerning the factors to be considered in assigning priorities, it does not include the CSIA factor concerning state government recommendations. Otherwise, the approach to determining priorities is similar to that in the CSIA.

Chemicals with potential for high hazard and high exposure are high priority. Those chemicals with high hazard or high exposure may be

assigned as a high priority. Chemicals not likely to result in unreasonable risk of harm to health or the environment under the intended conditions of use are low priority. Low-priority chemicals are not subject to further safety review and determination unless redesignated as a high priority. EPA may revise priority assignments based on new information. Priority designations are subject to notice and comment. In a key change from the CSIA, the CICA would make low-priority designation subject to judicial review as final agency action.

The CICA discussion draft would require EPA to determine whether a high-priority substance will result in an unreasonable risk of harm to human health or the environment under its intended conditions of use. EPA would have the authority to require the development of information on hazard, exposures, and uses by promulgating a rule, issuing an order, or entering into a consent agreement. EPA would be required to use "best available science," analyze the types of exposures, incorporate reference parameters, and consider threshold doses.

If EPA determines that a chemical poses an unreasonable risk of harm to health or the environment under its intended conditions of use, EPA would be required to issue a rule on the chemical substance. The regulation "may" apply to mixtures or to articles. In the latter instance, certain requirements must be satisfied in taking the action. EPA must identify specific types of articles, show that adequate mitigation cannot be obtained through restrictions on the chemical or mixture, and "shall exempt" previously manufactured replacement parts. Restrictions can include requirements such as warning labels, use, exposure monitoring, restrictions, phaseouts, or volume limitations on the use of a chemical substance.

Importantly—and the cause of some controversy—the CICA Section 6(f)(4) states that the restrictions must be proportional to the risks avoided, result in net benefits, be cost-effective, be imposed only when alternatives that materially reduce risk to health or the environment are unavailable, and provide for a reasonable implementation period. Some believe this is every bit as high a bar as existing in Section 6. The CICA has dropped the CSIA provision at Section 6(c)(10) concerning exemptions from regulation, although some of the terms have seemingly been retained in CICA Section 6(f)(4).

An EPA determination that a chemical *does not* present an unreasonable risk is a final agency action subject to judicial review. Interestingly, a decision that a chemical *does* present an unreasonable risk is subject to judicial review as a final agency action when the control rule is promulgated.

Section 8: Information Collection and Reporting

The CICA discussion draft would require EPA to develop guidance concerning the types and detail of information required and to promulgate a rule under Section 8(a) within two years requiring reporting by manufacturers and processors concerning use and exposure information on chemicals that are active in commerce. This deadline did not appear in the CSIA. Using the information available to it, EPA would, under the CICA Section 8(b), delineate between "active" chemicals in commerce and those that are no longer in commerce—or "inactive"—on the TSCA Inventory, using an approach similar to that in the CSIA although the "candidate list" step has been removed. The process for changing from "inactive" to "active" is unchanged from that in the CSIA.

The CICA picks up the nomenclature provisions in the CSIA concerning Class 2, statutory mixtures, and related nomenclature systems. The CICA would also make Section 8(a) inapplicable to chemical substances "extracted, by reaction or otherwise . . . for the purpose of recycling or reclaiming such extracted chemical substance" (Discussion Draft, 2014. Pp. 47-48). The CICA slightly rewords the Section 8(e) language while also dropping the provision that appeared in the CSIA allowing for reporting on "non-8(e)" information.

Sections 12 and 13: Exports and Imports

The CICA discussion draft somewhat simplifies TSCA's export provisions. EPA would have the authority to require an exporter to notify EPA annually when it is intending to export a new or existing chemical substance or mixture that is subject to a rule under Sections 5 or 6. Exporters would be required to notify EPA if they are exporting a substance or mixture subject to treaty export notification requirements.

The CICA discussion draft would require anyone importing a chemical substance or mixture into the United States that EPA has designated as a high-priority chemical or that is regulated under Sections 5 or 6 to certify to the Department of Homeland Security (DHS) that it is included on the Section 8 list or is exempt from inclusion on that list. DHS must refuse entry to a chemical if its importation would violate a restriction in Sections 5 or 6.

Section 14: Confidential Information

The CICA discussion draft, in an approach generally similar to that in the CSIA, provides several new categories of persons who may obtain confidential business information (CBI) and the reasons that EPA may disclose protected information to them. The CICA's Section 14(d) would provide exceptions to EPA's requirement to protect the information from public disclosure, including sharing protected information with:

- A US government employee or contractor carrying out official duties;
- A state that agrees to protect the information in the same manner as EPA;
- A health professional who needs the information for diagnostic and treatment purposes and who, in non-emergency cases, agrees beforehand to protect the information. In emergency cases, no advance notice is required, and the written agreement to protect the information may follow receipt of the information.

The CICA also takes a generally consistent approach to the CSIA concerning information that, except as allowed per CICA Section 14(d), shall not be disclosed. This includes:

- Information exempt as a trade secret under the Freedom of Information Act (FOIA; 5 United States Code Section 552(b)(4)); specific information describing manufacturing, processing, or distribution; marketing and sales information; constituents of a mixture; specific information on use, function, or application of a

chemical substance or mixture in a process, mixture, or product; or specific production or import volumes.

- The specific identity of a chemical substance if the person seeking protection from disclosure submits written documentation establishing that he or she will take measures to protect the confidentiality of the chemical's identity; disclosure is not required under another federal law; disclosure of the chemical's identity harms a competitive position; and the information is not "reasonably believed to be readily discoverable" through reverse engineering (Discussion Draft, 2014. p. 67).

- The applicant seeking information protection must establish the time period for which the applicant claims protection and provide a generic name that may be disclosed.

The CICA discussion draft would prohibit EPA from protecting from disclosure:

- Health and safety information on a substance offered for commercial distribution, including a notice of substantial risk posed by a chemical;

- Information required by EPA to be developed pursuant to Sections 4, 5, or 6, unless specific elements of it are protected; and

- General information describing ranges of volumes in which the chemical is manufactured or other types of information customarily shared with the general public or within the industry.

The CICA would allow EPA to disclose confidential information to protect health or the environment or to the extent necessary to avoid

impairing a proceeding under TSCA. The use of the information for an unauthorized purpose or the forwarding to an unauthorized person would be punishable as a prohibited act under TSCA. EPA would be required to protect the information until it has been publicly disclosed through another means or until it no longer meets the criteria in Section 14. An EPA decision to deny or limit a confidentiality claim would be reviewable in federal district court.

Section 16: Penalties

The CICA discussion draft would increase the penalties for violations of TSCA. Civil penalties for violation of TSCA would be increased from $25,000 to $37,500 per day for each violation. Criminal penalties would be increased from $25,000 to $50,000 per day for each violation. The discussion draft would create a new penalty for persons who knowingly violate TSCA and know in doing so that they are placing another person in imminent danger. This penalty would be a fine of $250,000, imprisonment for five years, or both.

Section 17: Preemption

The issue of state preemption has been one of the most contentious when considering how to amend TSCA. The CICA discussion draft would preserve the authority of states to ban chemicals until EPA determines that the chemical is not likely to cause an unreasonable risk or promulgates a rule restricting the chemical. The discussion draft would preempt state or local law or regulation:

- That requires development or submission of information on a chemical substance, mixture, or article, or its intended conditions of use that EPA has required under Sections 4, 5, or 6;

- That prohibits or restricts a chemical once EPA has determined that a new or existing chemical, under its intended conditions of use, is not likely to result in an unreasonable risk of harm, has designated the

chemical as a low priority under Section 6, or the review period under Section 5 has expired;

- From requiring use notification for a chemical if EPA has required notification under Section 5; and

- That includes any requirements imposed on chemicals by EPA under Sections 5 or 6 prior to the enactment of the CICA.

The discussion draft would preserve:

- State or local laws or regulations adopted or authorized pursuant to any other federal law; and

- Judicial causes of action under state law for personal injury, death, or property damage.

The CICA would address the provision in the CSIA that invited criticism from the trial attorneys and plaintiffs' bar by explicitly stating that the preemption provisions of the law do not "preempt any cause of action under State law for damages or equitable relief alleging personal injury, death, or property damages arising from exposure to a chemical substance or mixture" (Discussion Draft, 2014. p. 80).

Section 18: Judicial Review

To the apparent dismay of TSCA detractors and consistent with the approach in the CSIA, under the House discussion draft, the judicial standard of review remains the more stringent, "not supported by substantial evidence in the rulemaking record," (Discussion Draft, 2014. p. 83) as opposed to the more forgiving and customary standard found in other federal environmental statutes, the arbitrary, capricious, abuse of discretion,

or otherwise not in accordance with law standard urged by detractors of TSCA, which defers to EPA's expertise in rulemaking matters.

Next Steps

Rep. Shimkus stated that the House Energy and Commerce Subcommittee on Environment and the Economy will hold a hearing on the discussion draft; a hearing has been scheduled for March 12, 2014. A second hearing has been scheduled for March 26, 2014. Shimkus intends to introduce a bill for markup in April 2014, and he hopes to take it to the floor of the House in May.

Rep. Henry Waxman (D-CA), Ranking Member of the House Energy and Commerce Committee, released a statement on February 27, 2014, that criticizes the discussion draft. According to Waxman, while he "could not support the Republican draft in its current form," "bipartisan discussions have started, and I'm hopeful that the draft can be significantly modified to provide the kind of reform that American families want" (Waxman, 2014). Similarly, the Environmental Defense Fund (EDF) issued a release on February 28, 2014, stating that its "preliminary review of the posted draft has identified very serious concerns that, if not addressed, would fail to fix key flaws in TSCA and would weaken current law" (EDF, 2014).

Discussion

While the House discussion draft fixes some of the CSIA's excesses and unusually detailed and sometimes inconsistent "frameworks" and "methodologies," document does little to reconcile the widely divergent TSCA stakeholder views on such core issues as the safety standard, preemption, standard for judicial review, and the need for deadlines to ensure timely EPA action. In reviewing high-priority existing chemicals, the burden of proof, an issue of intense debate, falls squarely on EPA to prove that a chemical substance "will result in unreasonable risk of harm to human health or the environment under intended conditions of use" (Discussion Draft, 2014. p. 37). In imposing limitations on chemicals, EPA must show the restrictions will result in "net benefits," and that the restrictions are "cost-effective" compared to "alternative requirements or restrictions" that EPA may adopt.

Requirements of cost effectiveness when compared to alternatives will alarm some as a new iteration of the dreaded "least burdensome" requirement of current law cited by many as the most glaring failure of the statute.

There are a variety of new terms, which, at best, will need thorough legislative vetting before easing concerns of critical stakeholders (for example, the definition of "proportional to the risks" when authorizing EPA to take control actions). In imposing limitations on specific uses of a chemical substance, EPA may only do so when "technologically and economically feasible alternatives that materially reduce risk to human health or the environment compared to the use proposed to be prohibited or substantially prevented are available and likely to be used as a substitute for the use proposed to be prohibited or substantially prevented" (Discussion Draft, 2014. p. 44). This is a high burden, and likely to invite strenuous opposition.

The good news is the House is plainly engaged. The bad news is that key provisions in the CICA are already drawing fierce criticism from stakeholders. In a quote included in a report from the Safer Chemicals, Health Families published on February 28, the organization's director, Andy Igrejas, stated that the "bill would do nothing whatsoever to protect the public from the health impacts of toxic chemicals and would instead roll back the very limited oversight that we currently have" (Safer Chemicals, Healthy Families, 2014). While the absence of even a glimmer of receptivity is not necessarily fatal, it does not move the needle appreciably and will make the task of compromise all the more difficult.

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