The Committee on Energy and Commerce

Memorandum

November 8, 2013

To: Members, Subcommittee on Environment and the Economy

From: Majority Committee Staff

Re: Hearing on Senate-Introduced Legislation Reforming the Toxic Substances Control Act (TSCA), S. 1009

On Wednesday, November 13, 2013, at 10:15 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Environment and the Economy will hold a hearing on S. 1009, Chemical Safety Improvement Act.

I. Witnesses

Panel I:

The Honorable Jim Jones
Assistant Administrator, Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.

Panel II:

Calvin M. Dooley
President and CEO
American Chemistry Council

Richard E. Goss
Vice President, Environment and Sustainability
Information Technology Industry Council

Richard Denison, Ph.D.
Senior Scientist
Environmental Defense Fund

Andy Igrejas
National Campaign Director
Safer Chemicals, Healthy Families

Ernie Rosenberg
President and CEO
American Cleaning Institute

Wendy Wagner
Professor
University of Texas School of Law

II. Background Summary

On October 11, 1976, the Toxic Substances Control Act (TSCA, 15 U.S.C. 2601 *et seq.*) became law. Designed to identify and control potentially dangerous chemicals in U.S. commerce that were not adequately regulated under other Federal environmental statutes, TSCA regulates all phases of chemical

manufacturing. As several new titles have been added to TSCA since 1976, the original law is redesignated as Title I.

On June 13, 2013, July 11, 2013, and September 18, 2013, the Subcommittee held oversight hearings that reviewed Title I of TSCA, including several of TSCA's core sections dealing with the regulation of new and existing chemicals, protection of confidential business information, and Federal preemption. The November 13 hearing will provide the Subcommittee an opportunity to examine legislation introduced in the U.S. Senate to reform TSCA Title I.

S. 1009, the Chemical Safety Improvement Act (CSIA): On May 22, 2013, Senator David Vitter and the late Senator Frank Lautenberg introduced CSIA to reform and modernize TSCA Title I. S. 1009 has 25 bipartisan cosponsors.

CSIA would amend 23 of 31 sections in TSCA. Below is a summary of the changes proposed to the core sections of TSCA Title I and how they compare to existing law.

Definitions: CSIA would define the following new terms: "best available science," "intended conditions of use," "safety assessment," "safety determination," and "safety standard." These terms (except "best available science") help form the basis for a new regulatory standard for Title I that S. 1009 would create.

Data Development Requirements: Current TSCA section 4 authorizes EPA to establish priorities to review chemical substances and create an Interagency Testing Committee to inform this work. New section 4 directs the U.S. Environmental Protection Agency (EPA) to develop a framework, policies, and procedures for collecting, evaluating, and developing data (including maintenance of the ITC and opportunities for public and private sector interests to participate in informing and educating EPA on various chemical substances).

New section 4 does not mandate the development of a minimum set of data about a chemical substance, but does allow EPA to gather information for determining the risk posed by a chemical substance's intended conditions of use under sections 5 and 6, as well as use by any other Federal agency. New section 4 directs EPA to establish a risk-based screening process and criteria for identifying whether a chemical substance in commerce is a high or a low priority for a safety assessment and determination. Priorities would be determined based on (1) the ability of EPA to schedule and complete safety assessments and determinations in a timely manner and (2) reasonably available data and information concerning the hazard, exposure, and use characteristics at the time the decision is made. EPA would be required "in a timely manner" to evaluate all existing chemical substances or categories of substances active in commerce. Substances would be removed from the list of high-priority substances when a safety determination is published.

New section 4 also decreases the administrative burden on EPA's ability to gather test information under TSCA. Specifically, the Administrator would be authorized to issue a rule or order for development of new test data or to enter into a testing consent agreement if the Administrator identifies and publicly explains the need for those data.

In addition, new section 4 requires the integration of information from multiple sources into a tiered testing framework and places an emphasis on EPA using such data and information that meet the criteria of "best available science."[1] Section 4 also encourages EPA to promote the use of non-animal testing data and information.

Notice Requirements for New Chemicals and Uses: Existing TSCA section 5 requires manufacturers and importers of new chemicals, and manufacturers, importers, and processors of a chemical substance that EPA has determined by rule is a significant new use to notify EPA at least 90 days prior to commencing its manufacture, import, or processing for commercial purposes. Based on information submitted with that notice (including, to the extent known or ascertainable, the chemical identity and structure of the substance, the categories of use, estimates of the amount manufactured or processed for each category of use, anticipated byproducts, estimated employee exposure, and expected method of disposal[2]), EPA has up to 90 days to determine whether a new chemical may present an unreasonable risk of injury to health or the environment.[3]

New section 5 would continue the new chemical pre-manufacture notification requirement and the notice needed prior to a significant new use of a chemical. In response to a pre-manufacture notice from a manufacturer to EPA, new section 5 would require EPA to categorize new chemicals and new uses of existing chemicals based on available information within 90 days of receiving a notice (but the period may be extended). Section 5 establishes three categories for new substances and uses (1) not likely to meet the safety standard, (2) additional information is needed, or (3) the substance is likely to meet the safety standard under intended conditions of use. A chemical substance that is not likely to meet the safety standard under the intended conditions of use would be subject to various restrictions, ranging from labeling requirements to outright prohibitions on manufacture and usage.[4]

Safety Assessments, Determinations, and Regulatory Restrictions: TSCA section 6 allows chemicals to remain in U.S. commerce until EPA promulgates a rule restricting production or use of a chemical based upon a finding that the manufacture, processing, distribution in commerce, use, or disposal of a chemical presents or will present an "unreasonable risk" to human health or the environment. If EPA demonstrates that a risk associated with a chemical is unreasonable (relative to the benefits provided by the chemical and the estimated risks and benefits of any alternatives), the required rulemaking must (1) be "to the extent necessary protect adequately against such risk" and (2) use "the least burdensome" requirements.[5]

S. 1009 changes the existing legal structure for requiring control measures to be attached to a chemical substance. Under new section 6, the Administrator would make a "safety determination" based upon a risk-based assessment of use, hazard, and exposure ("safety assessment") information provided to EPA about a chemical, including under section 4, that "no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance" based upon the intended or reasonably anticipated circumstances presented by the chemical's manufacture, processing, distribution in

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[1] http://www.crs.gov/pages/Reports.aspx?PRODCODE=R43136&Source=search#_Toc370476618

[2] *See* Carolyne Hathaway, et. al, "TSCA Deskbook, 2d Edition," Environmental Law Institute, 2012, p. 21.
[3] http://www.crs.gov/pages/Reports.aspx?PRODCODE=R43136&Source=search#_Toc370476618
[4] Id.
[5] Id, TSCA §6(a).

commerce, use or disposal. A chemical substance that EPA determines does not meet this safety standard under the intended conditions of use is subject to various restrictions, ranging from labeling requirements to outright prohibitions on manufacture and usage.

S. 1009 would direct EPA to develop and use a framework for decision making that incorporates most of the analytic, data quality control, publication, and notice and comment requirements of rulemaking and the Information Quality Act (Section 515 of P.L. 106-554). In order to regulate, EPA would only need to find that "harm" rather than "injury" will result. EPA would not need to show that regulation is least burdensome, and EPA would no longer need to regulate to solely mitigate the risk posed.

Information Gathering and the TSCA Inventory: TSCA currently requires EPA to develop and maintain an inventory of all chemicals, or categories of chemicals manufactured or processed in the United States. Chemicals need not be listed if they are only produced in very small quantities for purposes of experimentation or research. EPA has authority to require maintenance of certain records and submittal of reports to EPA on each such chemical, including: (1) chemical identities, names, and molecular structures; (2) categories of use; (3) amounts manufactured and processed for each category of use; (4) description of byproducts resulting from manufacture, processing, use, and disposal; (5) environmental and health effects; (6) number of employees exposed and the duration of exposure; (7) manner or method of chemical disposal; and (8) significant adverse reactions to health or the environment alleged to have been caused by a substance or mixture.

New section 8 directs EPA to disclose its generic identifying information about a qualifying chemical on the non-confidential part of the TSCA Inventory of chemicals. It also adds reporting requirements for information known by, or reasonably ascertainable by, the manufacturer. These rules may impose different requirements; be limited to substances or mixtures actively being made and traded in commerce; and apply only to the extent the Administrator determines submission is necessary.

New section 8 also provides that EPA create a list of candidate "active" chemical substances. A chemical substance is "active" if it is or has been in commerce in the last five years or has been produced in small quantities for research in the last five years (if not, it is considered "inactive"). This list must be updated each time EPA updates the TSCA Inventory.

Imports: Current law directs the Secretary of the Treasury to refuse entry into the United States of chemicals that are in violation of TSCA or a rule promulgated under TSCA.

New section 12 is similar to the current statute, but authorizes the Secretary of Homeland Security to refuse entry into the United States chemicals that do not meet the safety standard under the intended conditions of use or that are in violation of a rule or order in effect under proposed TSCA. In addition, proposed section 13(c) requires a person offering a chemical substance or mixture for entry into the United States to certify that the chemical is in compliance with any applicable rule, consent agreement, or order under proposed TSCA sections 5 or 6 and is included on the list under proposed section 8(b) or exempt from the inventory requirements. Such person also is required to notify the Secretary of Homeland Security if the chemical is a high-priority substance, a chemical for which the United States is obligated to provide export notification by treaty, or has been found not to meet the safety standard and is identified in a rule promulgated as meriting notification due to the potential impact of the chemical substance or mixture or article on human health or the environment.

Confidential Business Information: TSCA section 14 protects as proprietary, information about chemicals in commerce that is designated confidential by manufacturers, processors, or distributors in commerce. In a case where EPA is authorized to propose releasing such data to the public, then the EPA Administrator must notify the manufacturer, processor, or distributor who designated the information confidential. Disclosure by EPA employees of such information is not permitted, except to other Federal employees, or when necessary to protect health or the environment. Disclosure is not permitted to other State regulators or other countries. Data from health and safety studies of chemicals is not protected unless its disclosure would reveal a chemical process or chemical proportion in a mixture. Wrongful disclosure of confidential data by Federal employees is prohibited, and may result in fines, imprisonment, or both.[6]

New section 14 is similar to the current statute in that it prohibits EPA from disclosing trade secrets and other information defined as presumed to be protected. S. 1009, however, would require substantiation of any claim for disclosure protection and explicitly does not protect disclosure of (1) the identity of a chemical if it does not meet substantiation requirements; (2) specified health and safety information and determinations; and (3) generic or otherwise general information. Substantiation of a confidentiality claim under new section 14 includes justification as to why information qualifies for confidentiality protection and certification that the information submitted is true and correct.

In addition to dictating a process for receiving and acting on claims for information protection, and for providing recourse in the event the Administrator decides to release such data, S. 1009 would require the Administrator to protect CBI from disclosure for the period of time requested by the person submitting and justifying the claim, or for such period of time as the Administrator determines to be reasonable. The Administrator would be authorized to request subsequent "redocumentation" of a claim. Finally, S. 1009 would permit protected information to be disclosed to a State or political subdivision of a State, a health professional under specified circumstances, or when necessary in a proceeding under TSCA.

Pre-emption: If the Administrator has already pursued regulatory action to require testing of a chemical substance or to restrict its manufacture, processing, distribution in commerce, or use, TSCA section 18, generally preempts State and local authorities from establishing or continuing in effect regulations on that chemical substance. A State or local government may maintain a similar requirement for management of a chemical substance, notwithstanding EPA's restrictions on it, if it is identical to the Federal requirement, is adopted under authority of another Federal law, or generally prohibits the use of the substance in the state or political subdivision. If a State does not meet one of those criteria, TSCA authorizes States and political subdivisions to petition EPA, and allows EPA to grant petitions by rule to exempt a law in a State or political subdivision under certain circumstances.

S. 1009 would preempt *new and existing* State laws that (1) require testing or information "reasonably likely to produce the same data and information required" by rule, consent agreement, or order under proposed TSCA sections 4, 5, or 6; (2) prohibit or restrict the manufacturing, processing, distribution in commerce, or use of a chemical after issuance of a completed safety determination under proposed TSCA section 6; or (3) require notification for a significant new use of a chemical if EPA requires

[6] Ibid.

notification under proposed TSCA section 5. S. 1009 also would preempt *new* State prohibitions or restrictions for any high-priority and low-priority substance.[7]

Exceptions to the general preemption provision would include laws adopted under the authority of any other Federal law; implementing a reporting or information collection requirement not redundant of Federal law; or adopted pursuant to State authority related to water quality, air quality, or waste treatment or disposal, as long as it does not impose a restriction on the manufacture, processing, distribution in commerce, or use of a chemical and is not redundant or inconsistent with an EPA action under new sections 5 or 6.

III. Staff Contact

Please contact Jerry Couri or David McCarthy with the Committee Staff at (202) 225-2927 with any questions.

[7] Ibid.