The Committee on Energy and Commerce

Memorandum

June 11, 2013

To: Members, Subcommittee on Environment and the Economy

From: Majority Committee Staff

Re: Hearing on Federal Environmental Law Governing Chemicals Manufacturing and Management

On Thursday, June 13, 2013, at 10:15 a.m., the Subcommittee on Environment and the Economy will be holding a hearing entitled "Title I of the Toxic Substances Control Act: Understanding Its History and Reviewing Its Impact." Witnesses are by invitation only.

I. WITNESSES

This is an oversight hearing to enhance the Subcommittee's understanding of current law and its operation. The following witnesses are expected to testify, and additional witnesses may be added.

Kathleen M. Roberts
Vice President
B&C Consortia Management, L.L.C.

Beth Bosley
President
Boron Specialties, L.L.C.

Charles M. Auer
Principal
Charles M. Auer & Associates, L.L.C.

Jeanne Rizzo
President and CEO
Breast Cancer Fund

Alfredo Gomez
Director
Natural Resources and Environment
Government Accountability Office

Daniel Rosenberg
Senior Attorney
Health and Environment Program
National Resources Defense Council

II. BACKGROUND SUMMARY

In 1971, the President's Council on Environmental Quality proposed comprehensive Federal legislation to identify and control potentially dangerous chemicals in U.S. commerce that were not adequately regulated under other Federal environmental statutes. President Ford signed the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*) into law on October 11, 1976.

Unlike other Federal environmental laws that control pollution outputs or govern its cleanup, TSCA regulates all phases of chemical manufacturing. Title I of TSCA authorizes the

Environmental Protection Agency (EPA) to gather information, require the testing of existing and new chemicals, identify potentially dangerous products or uses, and regulate the manufacture, processing, distribution in commerce, use, and disposal of chemical substance and mixtures. Title I also has sections that address protection of confidential business information and Federal pre-emption of State or local laws.

Core Sections of Title I of TSCA

Testing of Chemicals. Section 4 directs EPA to require the development of test data on existing chemicals and mixtures if EPA finds: (1) the manufacture, processing, distribution, use, or disposal of the chemical substance or mixture "may present an unreasonable risk of injury to health or the environment," or (2) the chemical substance or mixture is or will be produced in very large volume, and (a) a substantial quantity may be released into the environment or (b) there is or may be substantial or significant human exposure to it. Under either condition, EPA must issue a rule requiring tests if: (1) existing data are insufficient to resolve the question of safety, and (2) testing is necessary to develop the data. In the case of a chemical mixture, EPA is obligated to issue a test rule if health or environmental effects cannot be determined or predicted by looking at each component separately.

Section 4 established a special interagency committee to help EPA determine which chemicals should be considered, what their order of priority should be, and to coordinate testing needs and efforts among government agencies. Called the Interagency Testing Committee (ITC), it must consider candidate chemicals for inclusion on a list of substances recommended to EPA for the development and promulgation of test rules. Section 4 requires the ITC to consider the following factors when it makes listing decisions: (1) the quantity of the substance to be manufactured, (2) the quantity of the chemical in environmental releases, (3) the number of people who will be exposed occupationally and the duration of exposure, (4) the extent of non-occupational human exposure, (5) the similarity of the chemical to any other chemical known to present an unreasonable risk, (6) the existence of data concerning environmental or health effects of the chemical, (7) the quantity of information to be gained by testing, and (8) the availability of facilities and personnel for performing testing.

Chemicals known or suspected to cause or contribute to cancer, gene mutations, or birth defects are to be designated as higher priority. This list may contain no more than 50 "designated" chemicals at any time. When a chemical is designated, EPA has one year to respond by issuing a proposed test rule or a notice explaining why no testing is needed. In response to information that indicates "there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects," section 4 requires EPA action to prevent or reduce that risk or to publish a finding that the risk is not unreasonable.

***Pre-manufacture Notification for New Chemicals or Uses*.** Section 5 requires manufacturers, importers, and processors to notify EPA at least 90 days prior to producing or otherwise introducing a new chemical product into the United States. Section 5 also requires submission to EPA of any information or test data that might be useful in evaluating the chemical's potential adverse effects on human health or the environment. TSCA similarly

requires EPA to be notified about plans to produce, process, or use an existing chemical in a previously unpermitted fashion.

While the 90-day notice provides EPA with the opportunity to evaluate the chemical use and, if necessary, to prohibit or limit such activity before it occurs to prevent unreasonable risk of injury to human health or the environment, EPA also has 45 days after notification (or up to 90 days if it extends the period for good cause) to evaluate the potential risk posed by the chemical. If EPA determines that there is a reasonable basis to conclude that the substance presents or will present an unreasonable risk, the Administrator must promulgate requirements to protect adequately against such risk. Alternatively, EPA may determine that the proposed activity related to a chemical does not present an unreasonable risk. This decision may be based on the available data, or, when no data exist to document the effects of exposure, it may be based on what is known about the effects of chemicals in commerce with similar chemical structures and used in similar ways.

Section 5 aims to have EPA identify potential hazards, and control them before use of a chemical becomes widespread. If data are inadequate to make an informed judgment and (1) manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk, or (2) a chemical is to be produced in substantial quantities, and the potential for environmental release or human exposure is substantial or significant, EPA may issue an order to prohibit or limit such activities until sufficient data are submitted.

***Regulatory Controls for Hazardous Chemicals*.** If EPA "finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents, or will present an unreasonable risk of injury to health or the environment," section 6 requires it to issue a rule to "the extent necessary to protect adequately against such risk using the least burdensome" option. Specifically, section 6 authorizes EPA to apply any of the following requirements and tailor them to a specific region: (1) prohibit or limit the amount of production or distribution of a substance in commerce; (2) prohibit or limit the production or distribution of a substance for a particular use; (3) limit the volume or concentration of the chemical produced; (4) prohibit or regulate the manner or method of commercial use; (5) require warning labels and/or instructions on containers or products; (6) require notification of the risk of injury to distributors and, to the extent possible, consumers; (7) require record-keeping by producers; (8) specify disposal methods; and (9) require replacement or repurchase of products already distributed. Section 6 also precludes EPA from regulating if action under another Federal law administered by EPA could sufficiently eliminate or reduce the risks identified unless EPA determines "it is in the public interest to protect against such risk" under TSCA.

Information Gathering. Section 8 requires EPA to develop and maintain an inventory of all chemicals, or categories of chemicals, manufactured, or processed in the United States. All chemicals not on the inventory are, by definition, "new," subject to the notification provisions of section 5, and must be added to the inventory if they enter U.S. commerce. Chemicals need not be listed if they are only produced in very small quantities for purposes of experimentation or research.

Section 8 also gives EPA authority to require manufacturers or processors of a chemical substance to maintain certain records and submit reports to EPA on that chemical. EPA may require that such reports include (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) and manner or method of chemical disposal.

Finally, section 8 requires manufacturers, processors, and distributors of chemicals to maintain records of significant adverse reactions to health or the environment alleged to have been caused by a substance or mixture. Records of adverse effects on the health of employees must be retained for 30 years from the date of reporting. Industry also must submit lists and copies of health and safety studies. Studies showing previously unknown adverse effects must be submitted to EPA as soon as they are completed or discovered.

Judicial Review. Section 19 permits any person to petition for judicial review of a rule within 60 days of its issuance. To set aside a rule, a Court must find EPA's regulation is not supported by "substantial evidence" in the rulemaking record taken as a whole.

Confidential Business Information. Section 14 provides protection of proprietary confidential information about chemicals in commerce. 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.

Preemption. Section 18 preempts State or local laws requiring the testing of a chemical substance or mixture if EPA has required similar testing of that chemical or mixture. It also preempts State or local actions that establish or continue in effect requirements applicable to a new or existing chemical substance or mixture unless the requirement: (1) is identical to the Federal requirement, (2) implements another Federal law, or (3) is a complete ban of the substance or mixture. Section 18 permits a State or local government to petition EPA to allow its requirement to remain in effect if it provides a significantly higher degree of protection from risk than the Federal requirement.

For more information, please see:
http://www.crs.gov/pages/Reports.aspx?PRODCODE=RL31905&Source=search

III. STAFF CONTACT

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