The Committee on Energy and Commerce

Memorandum

January 31, 2014

To: Members, Subcommittee on Environment and the Economy

From: Majority Committee Staff

Re: Hearing on Sections 4 and 8 of Title I of the Toxic Substances Control Act (TSCA).

On Tuesday, February 4, 2014, at 10:00 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Environment and the Economy will hold a hearing entitled "Testing of Chemicals and Reporting and Retention of Information under TSCA Sections 4 and 8."

I. Witnesses

- Dr. Beth Bosley, President, Boron Specialties, LLC, On behalf of the Society of Chemical Manufacturers and Affiliates;
- Mr. Charles Drevna, President, American Fuel and Petrochemical Manufacturers;
- Dr. Brent Grazman, Vice President, Quality Assurance, Viasystems Group, Inc.;
- Mr. Robert Matthews, McKenna Long & Aldridge, LLP, On behalf of the Consumer Specialty Products Association;
- Dr. Catherine Willett, Director, Regulatory Toxicology, Risk Assessment, and Alternatives, The Humane Society of the United States;
- Dr. Jerry Paulson, Chairperson, Council on Environmental Health, Department of Federal Affairs, American Academy of Pediatrics; and
- Ms. Jennifer Sass, Senior Scientist, Natural Resources Defense Council.

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, assess, 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, September 18, 2013, and November 13, 2013, the Subcommittee held oversight hearings that reviewed several core sections of Title I of TSCA and Proposed Senate amendments to those sections. The February 4 hearing will provide the Subcommittee an opportunity to examine the way the Environmental Protection Agency (EPA) collects information on existing chemicals under TSCA.

Section 4, Testing of Chemical Substances and Mixtures.

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 (1) or (2), 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.[1]

In addition, section 4(b) mandates requirements contained in and considerations that must be included in a test rule. EPA has developed regulations, directing laboratory practices, test methodologies, and the sharing of costs among parties for tests performed pursuant to section 4.[2] In addition, section 4(g) provides an opportunity for a chemical manufacturer or processor to request the issuance of a test rule, under section 4, for a new chemical or new use of an existing chemical that is subject to the section 5 notification process.

Finally, section 4 establishes 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. This Interagency Testing Committee (ITC) 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.

Over the first 20 years under TSCA, EPA made significant progress in developing programs for testing existing chemicals, including rules governing testing regulations and negotiation of enforceable consent agreements.[3] Since then, though, EPA has promulgated few test rules under TSCA section 4, instead preferring to engage chemical manufacturers in voluntary testing programs that would produce screening level health effects data on chemicals produced at greater volumes.

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[1] §4(a).
[2] Carolyne Hathaway, et. al, "TSCA Deskbook, 2d Edition," Environmental Law Institute, 2012, p. 61.
[3] Id. p. 61.

EPA's reliance on voluntary initiatives, particularly for chemical substances that are not expected to enter the environment in substantial quantities or will not have high or meaningful exposure potential, can be traced to several factors. During an Environment and the Economy Subcommittee hearing on June 13, 2013, witnesses suggested that not only is the general rulemaking process under the Administrative Procedures Act time consuming and expensive, but so is the impact of judicial interpretations on EPA's ability to find the "unreasonable risk" needed in order to require testing. One such decision came in 1988 from the U.S. Court of Appeals for the District of Columbia, *Chemical Manufacturers of America v. the U.S. Environmental Protection Agency* (859 F.2d 977, 19 ELR 20001).[4]

Section 8, Reporting and Retention of Information:

The Statute: Section 8(b) 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 produced only in very small quantities for purposes of experimentation or research.

Section 8(a) 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(c) 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 and report these findings to EPA; section 8(d) requires EPA to have manufacturers, processors, commercial distributors of chemicals, or other interested persons to submit lists and copies of health and safety studies on a chemical; and section 8(e) requires manufacturers, processors, and distributors of chemicals or mixtures to report immediately to EPA any previously unknown information supporting a conclusion that a substantial risk of injury is presented by a chemical substance or mixture.

A processor or manufacturer (including an importer) of a chemical substance in quantities of 25,000 lbs. or greater is required to report to EPA the seven categories of information identified in the law. This reported information–which is made public–comprises what is known as the "TSCA Inventory," which contains every chemical that has entered U.S. commerce since 1975. EPA updates the list either when it receives a "Notice of Commencement" for commercial production of a new chemical or new use of an existing chemical, or when EPA regulations ask for information to update the Inventory – traditionally, every four years. All chemicals that are on the TSCA Inventory at the beginning of the update period are subject to reporting, except for those with a regulatory exemption.[5]

[4] Id. p. 64.
[5] 40 C.F.R. §710.45, .46.

While it is not authorized explicitly in statute, EPA maintains a confidential TSCA Inventory due to requirements in TSCA section 14, which prohibit EPA from disclosing confidential business or financial information submitted to EPA under the claim of confidentiality. When a confidentiality claim is asserted for a specific chemical's identity, EPA and the submitter develop a generic chemical name to protect the substance's confidentiality. The generic name is placed on the public TSCA Inventory, and the specific chemical description is placed on the internal, confidential TSCA Inventory.[6] Currently, EPA may only disclose that a particular chemical substance is on the confidential TSCA Inventory to persons demonstrating a bona fide intent to manufacture the substance.[7] Downstream users of chemical substances do not have access to the confidential TSCA Inventory listings.[8] In July 2009, EPA changed the identities of 530 chemicals listed on the TSCA Inventory from confidential to non-confidential.[9]

There is also a question about who EPA believes to be a "processor" for purposes of reporting under section 8. In 1992, EPA initiated a public process to solicit input on the appropriate definition of "processing" activities under TSCA, but never issued a clarification of the "processing" definition based on the input received.[10]

III. Possible Hearing Questions:

1. Should EPA prioritize chemicals for review, and does EPA need direct statutory authority to do it?
2. Does EPA have enough authority under section 8 to compel the data and information it needs to make the necessary findings under section 4?
3. Are there other sensible ways to allow EPA greater access to this information?
4. How should existing chemicals in U.S. commerce be scrutinized?
5. Who should be required to conduct testing?
6. Should minimum scientific standards apply, and what do those entail?
7. How can technology improve chemical assessment?
8. Does a screening-before-testing model make sense?
9. Can animal testing be avoided?
10. Does it make sense to have information quality standards for EPA to make decisions about chemicals? What should those standards look like?
11. How should EPA information on chemicals be organized? How should it be disseminated?
12. Who should report to EPA, and what should they report?
13. What types of information should EPA report to the public?
14. What is EPA's capacity to sort chemicals by priority?
15. Why is chemical testing important, and who benefits from testing?
16. How should new chemicals in U.S. commerce be scrutinized? Should EPA have authority to require the submission or generation of data sufficient to assess what risks new chemicals might pose?
17. What role should the scientific and medical communities play in assessing and improving new technologies for scientific testing and assessment? What mechanisms are in place to foster

[6] Id. p. 14, 42 Fed. Reg. 64573-74.
[7] Id. p. 14.
[8] Id. p. 14.
[9] 74 Fed. Reg. 37224 (July 29, 2009).
[10] Id. p. 9.

communication between the scientific and medical communities and EPA on new technologies for testing and assessment?

18. What role should the courts play in limiting or mandating new technologies for scientific testing and assessment in policymaking?
19. Are courts well-equipped to determine whether scientific studies provide a sound basis for regulation?
20. What information should public health officials have access to in the event of an accidental chemical release that endangers the drinking water for thousands of people?

IV. Staff Contact

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