



The Committee on Energy and Commerce

Memorandum

July 8, 2013

To: Members, Subcommittee on Environment and the Economy

From: Majority Committee Staff

Re: Hearing on Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation

On Thursday, July 11, 2013, at 9:30 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Environment and the Economy will hold a hearing entitled “Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation.”

I. Witnesses

Mr. Craig Morrison
CEO of Momentive Performance Materials
Holding, LLC and
Chairman of the Executive Committee
American Chemistry Council

Mr. Len Sauers
Vice President, Global Sustainability
Procter and Gamble

Mr. David Isaacs
Vice President, Government Affairs
Semiconductor Industry Association

Dr. Rainer Lohmann
Professor of Oceanography
University of Rhode Island

Ms. Heather White
Executive Director
Environmental Working Group

II. Background Summary

On October 11, 1976, President Ford signed the original Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*) into law. The law was designed to identify and control potentially dangerous chemicals in U.S. commerce that were not adequately regulated under other Federal environmental statutes. Unlike other Federal environmental laws that control pollution or govern its cleanup, 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, the Subcommittee held an oversight hearing that generally reviewed Title I of TSCA. The July 11 hearing will provide the Subcommittee a more in-depth opportunity to examine the

regulatory implementation and “real world” implications of TSCA section 5, requirements concerning the manufacture and processing of new chemicals, and TSCA section 14, limiting public disclosure of data submitted to EPA on existing and new chemical substances and mixtures.

Section 5 of TSCA, Pre-manufacture Notification for New Chemicals or Uses.

TSCA section 5 sets out the notification requirements on manufacturers (including importers) of new chemical substances and manufacturers and processors of existing chemical substances who contemplate a significant new use. The requirements are intended to provide EPA “with an opportunity to review and evaluate information with respect to the substances to determine if manufacture, processing, distribution in commerce, use, or disposal should be limited, delayed or prohibited because data is insufficient to evaluate the health or environmental effects or because the substance or the new use presents or will present an unreasonable risk of injury to health or the environment.”¹

Section 5 applies to both new chemicals, and new uses for “existing” chemicals previously listed by EPA. Specifically, manufacturers (including importers) of new chemicals, and manufacturers, importers, and processors of a chemical substance that EPA has determined by rule is a significant new use (or Significant New Use Rule (SNUR)), must notify EPA at least 90 days prior to commencing its manufacture, import, or processing for commercial purposes.² Depending on whether it is a new chemical or significant use, notices made to EPA take the form of a pre-manufacture notice (PMN) or a significant new use notice (SNUN). Both PMNs and SNUNs submitted to EPA are required to include, 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.³

Section 5 also requires PMNs or SNUNs submitted to EPA to include all relevant test data in the petitioner’s possession and to describe any other information that might be useful in evaluating the chemical’s potential adverse effects on human health or the environment.⁴ In two situations, EPA may require additional testing of the chemical: (1) if the substance is subject to a test rule under TSCA section 4, *Testing of Chemical Substances and Mixtures*, or (2) EPA decides the substance could present an unreasonable risk of injury to health or the environment.⁵

At its enactment, Congress was concerned about minimizing job loss and harm to capital investment in new technologies due to regulatory action.⁶ It recognized that “the most desirable time” to determine the health and environmental effects of a substance and take any needed action against adverse effects would be prior to commercial production.⁷ Unless EPA takes some regulatory action about a specific PMN or SNUR within a finite review period, the review period expires and the submitter may manufacture or import the chemical substance. According to 40 CFR 720.75(d), “EPA

¹ Statement of the Managers to Accompany the Conference Report on S. 3149, the Toxic Substances Control Act, Report No. 94-1679, September 23, 1976, p. 65.

² TSCA §5(a) and (b)

³ See Carolynne Hathaway, et. al, “TSCA Deskbook, 2d Edition,” Environmental Law Institute, 2012, p. 21.

⁴ Ibid. p. 22

⁵ Ibid. p. 22.

⁶ Op. Cit. Rept. No. 94-1679, p. 65

⁷ Ibid.

will notify the submitter when the notice review period has expired or that EPA has completed its review of the notice. Expiration of the review period does not constitute EPA approval or certification of the new chemical substance, and does not mean that EPA may not take regulatory action against the substance in the future.”⁸ A PMN manufacturer (or importer) is required to submit a Notice of Commencement to EPA within 30 days of beginning manufacture or import.

If, however, the original 90-day notice requirement prior to commercial action is not enough time for EPA to evaluate the substance, EPA is permitted, for “good cause,” to extend the notification period up to, but not longer than another 90 days.⁹ If EPA determines within 45 days of its 90 day review that there is not enough information available to make “a reasoned evaluation,” it also may issue a proposed order placing restrictions on the manufacture, processing, distribution in commerce, use, or disposal of the substance.¹⁰ Finally, if EPA determines that there is a reasonable basis to conclude that the substance or new use presents or will present an unreasonable risk of injury, and if regulatory action under TSCA section 6 will not be completed soon enough to address the risk, EPA may, before expiration of the 90 day review period, either issue a restricting regulation or an order prohibiting the manufacture, processing, distribution in commerce, use, or disposal of the new chemical or significant use.¹¹

Section 5 provides some exemptions from PMN requirements for new chemicals. These include: test marketing, submission of data already in the possession of EPA, small quantities of chemicals for research and development, chemicals produced in a closed-loop system, or chemicals EPA has already determined would not present an unreasonable risk.¹²

Section 14 - Confidential Business Information (CBI).

In order to fulfill its responsibilities under TSCA, EPA requires access to substantial information, including technical material, to make scientific and regulatory determinations. Since these data could include manufacturing process details or precise percentages of components in a mixture, regulated entities are permitted to designate certain submitted information for confidential treatment.¹³

Public disclosure of CBI could eliminate a competitive business advantage, discouraging innovation and investment.¹⁴ Section 14 provides the same information protection afforded under the Freedom of Information Act (FOIA),¹⁵ to information submitted to EPA about chemicals in commerce that are “trade secrets and commercial or financial information obtained from a person which is privileged or confidential.”¹⁶

⁸ TSCA §5(g)

⁹ TSCA §5(c)

¹⁰ TSCA §5(e)

¹¹ TSCA §5(f)

¹² TSCA §5(h)

¹³ Op. Cit. Hathaway, p. 137.

¹⁴ Op. Cit. Hathaway, p. 137.

¹⁵ 5 U.S.C. §552(b)(4)

¹⁶ Op. Cit. Hathaway, p. 138.

Under TSCA section 14, disclosure by EPA employees of such information is not permitted, except to other Federal employees, or when necessary to protect health or the environment.¹⁷ Section 14 requires advance notice to the submitter if EPA intends to publicly release confidential business information. This gives the manufacturer an opportunity to challenge EPA's decision.¹⁸ 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.¹⁹ Wrongful disclosure of confidential data by Federal employees is prohibited, and may result in fines, imprisonment, or both.²⁰

III. Issues For Consideration

- a. TSCA section 5, Pre-manufacture and Significant New Use Notices, and TSCA section 14, Protection of Confidential Information, affect innovation.
- b. Strengths and weaknesses with the Pre-Manufacture Notice Program, Significant New Use Regulations, and Significant New Use Notices under section 5.
- c. Adequacy of EPA's tools to make informed decisions under section 5.
- d. The protection provided to confidential business information under section 14 appropriate.
- e. Other countries treatment of new chemical production and information protection.

IV. Staff Contact

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

¹⁷ TSCA §14(a)(1)

¹⁸ TSCA §14(c)

¹⁹ TSCA §14(b)

²⁰ TSCA §14(d)