The Committee on Energy and Commerce

Memorandum

March 10, 2014

To: Members, Subcommittee on Environment and the Economy

From: Majority Committee Staff

Re: Hearing on the Discussion Draft entitled "The Chemicals in Commerce Act."

On Wednesday, March 12, 2014, at 10:00 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Environment and the Economy will hold a hearing on the Discussion Draft entitled "The Chemicals in Commerce Act."

I. Witnesses

- Dr. Beth Bosley, President, Boron Specialties, LLC, On behalf of the Society of Chemical Manufacturers and Affiliates;
- Dr. Carolyn Duran, Director of Chemical Risk and Compliance, Global Sourcing and Procurement, Intel Corporation;
- Ms. Connie DeFord, Director of Product Sustainability & Compliance, the Dow Chemical Company;
- Mr. Roger Harris, President, Producers Chemical On behalf of the National Chemical Distributors Association;
- Mr. James Stem, National Legislative Director-Transportation Division, Sheet Metal, Air, Rail, and Transportation Union;
- Ms. Jennifer Thomas, Director, Federal Government Affairs, Alliance of Automobile Manufacturers;
- Mr. Mark Duvall, Principal, Beveridge & Diamond, PC;
- Mr. Michael Belliveau, Executive Director, Environmental Health Strategy Center;
- Mr. Barry Cik, Founder, Naturepedic, *On behalf of Companies for Safer Chemicals;*
- Ms. Anna Fendley, MPH, United Steelworkers; and

- Dr. Phillip J. Landrigan, Dean for Global Health. Ethel H. Wise Professor and Chairman, Professor of Pediatrics and Director, Children's Environmental Health Care Center, Ichann School of Medicine at Mount Sinai.

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, November 13, 2013, and February 4, 2014, the Subcommittee held oversight hearings to review several core sections of Title I and proposed Senate amendments to those sections.

On February 27, 2014, Chairman Shimkus released a Discussion Draft to amend Title I of TSCA entitled "The Chemicals in Commerce Act." The March 12 hearing will provide the Subcommittee an opportunity to review the provisions of the Discussion Draft.

III. Summary of the Major Provisions in the Discussion Draft

A. Section 3: Definitions

The Discussion Draft adds five (5) new definitions to TSCA, including: (1) "best available science," (2) "intended conditions of use," (3) "potentially exposed subpopulations," (4) "publicly available information," and (5) "safety determination."

B. Section 4: Testing

The Discussion Draft creates a tiered information development system, allowing the Environmental Protection Agency (EPA) to obtain the hazard and exposure information it needs to carry out the law.

EPA is authorized to mandate information development in four (4) instances: (1) to perform a determination about the safety of an existing chemical, (2) to ensure compliance with restrictions on new chemicals or new uses of an existing chemical, (3) to review chemicals meant only for export, or (4) to help another Federal agency with implementing its own regulations. In carrying out these activities, EPA must first consider all the available information about a chemical substance or mixture. If that available information is insufficient either to rule out or demand testing, EPA is authorized, by rule, order, or consent agreement, to require manufacturers and processors to screen or test, as appropriate, that chemical or mixture.

Groups of manufacturers or processors jointly may develop the information to share in the cost and EPA is expected to use high quality data, minimize the use of animal testing, and publish the non-confidential information it gathers.

C. Section 5: New Chemicals and Significant New Uses

The Discussion Draft maintains most of the elements of existing requirements on new chemicals and new uses of existing chemicals, including the current notice exemptions for chemicals made in small quantities for experimentation, research, analysis, or test marketing; where the substance will exist temporarily and there will be no human exposure; or where (with notice and comment) EPA determines it likely will not result in risk of harm.

Section 5 of the Discussion Draft continues the TSCA practice of requiring a 90-day advance notice to EPA if a person intends to manufacture a new chemical for commercial production or commercially manufacture or process a chemical for a new use, which EPA considers significant. While the Discussion Draft continues to require that EPA determine, by rule, whether the new use of an existing chemical is significant, it now explicitly permits EPA to determine that use of a substance as part of an article is a significant new use, but only where the risk cannot be addressed through requirements placed on the chemical substance.

Section 5 of the Discussion Draft maintains the requirement that EPA, within 90 days of receiving the notice of intent to manufacture, review the chemical substance described in the notice and, if necessary, request additional information to determine whether exposure to the chemical substance under intended conditions of use is likely to result in an unreasonable risk of harm to human health or the environment. This review period can be extended for up to another 90 days or, if mutually agreed to by the manufacturer or processor, as long as needed in order to allow for the development and submittal of additional information about the chemical. Before EPA's review period ends, the Discussion Draft requires EPA to determine whether the new chemical or the significant new use of an existing chemical is likely to pose an unreasonable risk of harm under its intended conditions of use. Within 30 days of commencement of manufacture and prior to commercial sale, the Discussion Draft requires notice to EPA for a new chemical substance that is not likely to pose an unreasonable risk of harm under its intended conditions of use; otherwise, the new chemical substance is subject to a rule restricting its use.

Finally, the Discussion Draft allows EPA to reconsider a decision made under sections 5 or 6 about a chemical or its use if EPA receives new information about the substance or use of the substance.

D. Section 6: Existing Chemical Regulation

The 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.

For prioritizing existing chemicals for review by EPA, the Discussion Draft requires EPA, based upon public input, to establish a system to designate and list chemicals that have been actively in commerce the previous 5 years as either a high priority or low priority chemical. Inactive chemicals are evaluated when they are again in commerce. Chemicals with the potential for high hazard and high exposure are high priority. Those chemicals with the potential for 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 they are redesignated as a high priority based on new information. Priority designations are subject to notice and comment, and low priority designations are subject to judicial review as final agency action.

Once established as a high priority chemical, EPA must determine whether the substance will result in an unreasonable risk of harm to human health or the environment under its intended conditions of use. Using its section 4 authority, EPA may require the development of information on hazard, exposures, and uses. Section 6 of the Discussion Draft requires EPA's safety determination to use best available science, analyze types of exposures (including for potentially exposed subpopulations), incorporate reference parameters, and consider threshold doses. Upon making a safety determination, EPA must publish its findings and rationale.

Section 6 of the Discussion Draft requires EPA to regulate a chemical substance if EPA determines that it poses an unreasonable risk of harm to health or the environment under its intended conditions of use. This rule, which may apply to mixtures or, if necessary, articles, may contain requirements such as warning labels, use and exposure monitoring, restrictions, phase-outs, or volume limitations on the use of the chemical. In addition, these regulations 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 available; and provide for a reasonable implementation period.

E. Section 8: Information Collection and Reporting

The Discussion Draft's section 8 requires EPA to delineate its public reporting of all chemicals – active and inactive – that have ever been in U.S. commerce and those that are currently active. It also compels EPA to obtain more information about chemicals to help the Agency make decisions and requires EPA to develop guidance concerning the types and detail of information required, as well as the manner by which manufacturers and processors can report use and exposure information.

Section 8 of the Discussion Draft formalizes EPA's confidential list of information that it keeps internally, in addition to its public list of information on chemicals that is not protected from disclosure under TSCA.

F. Sections 12 and 13: Exports and Imports

Under section 12 of the Discussion Draft, EPA may require an exporter to notify EPA annually when intending to export a new or existing chemical substance or mixture that is subject to a restrictive rule under section 5 or 6. The Discussion Draft also requires exporters to notify EPA if exporting a substance or mixture subject to treaty export notification requirements.

Section 13 of the Discussion Draft requires anyone importing a chemical substance or mixture into the United States, which EPA has designated as a high priority chemical or regulated under section 5, to certify to the U.S. Customs and Border Protection whether it is included on the section 8 list or is exempt from inclusion. The Discussion Draft also requires the U.S. Department of Homeland Security to refuse entry to a chemical if its importation would violate a restriction on section 5 or 6.

G. Section 14: Confidential Business Information

The Discussion Draft's Section 14 clarifies the protection of chemical identity under TSCA. It also provides several new categories of persons who may obtain confidential business information and the reasons that EPA may disclose protected information to them.

Section 14 prevents EPA from disclosing information exempted as a trade secret under the Freedom of Information Act, as well as information describing manufacturing, processing, or distribution; marketing and sales information; constituents of a mixture; information on use, function, or application of a chemical substance or mixture in a process, mixture, or product; or specific production or import volumes.

Section 14 requires EPA to protect from disclosure the specific identity of a chemical substance (name, formula, CAS number) if: (1) the person seeking protection from disclosure submits written documentation establishing that they take measures to protect its confidentiality, (2) disclosure is not required under another Federal law, (3) public disclosure harms their competitive position, and (4) the information cannot be discovered though reverse engineering. Such an application for protection under section 14 must establish the time period requested for protection and provide a generic name that may be disclosed. EPA would be required to protect this information until it has been publicly disclosed or it no longer meets the protection criteria of TSCA.

Section 14 of the Discussion Draft continues TSCA's current policy that does not permit EPA to protect from disclosure 1) health and safety information about a chemical if the information is needed to protect health or the environment, and 2) information needed to avoid impairing a proceeding under TSCA. Section 14 of the Discussion Draft also permits sharing of information required for chemical review under section 5 or 6 – so long as elements that should be protected within that grouping are as well as general information describing ranges of volumes in which the chemical is manufactured or other types of information customarily shared with the public.

In addition, the Discussion Draft provides new classes of persons that may have access to confidential business information if it is used for those purposes and is not further shared,

including: (1) a State that agrees to protect the information in the same manner as EPA and (2) a health professional that needs the information for diagnostic and treatment purposes.

Use of protected information for an unauthorized purpose or forwarding it to an unauthorized person would be punishable as a prohibited act under TSCA.

When it is not feasible for EPA to review each confidentiality claim for compliance with section 14, the Discussion Draft permits EPA to use sampling. Further, an EPA decision to deny or limit a confidentiality claim would be reviewable in Federal district court and information in dispute may not be disclosed pending court proceeding.

H. Section 16: Penalties

Civil penalties for TSCA violations are increased from $25,000 to $37,500 per day for each violation. Criminal penalties are increased from $25,000 to $50,000 per day for each violation. A new penalty is added for persons who knowingly violate TSCA and knowingly place another person in imminent danger. This penalty is a fine of $250,000, imprisonment for 5 years, or both.

I. Section 17: Preemption

Section 17 of the Discussion Draft preserves authority of States to restrict or ban chemicals until the point when EPA determines that the chemical is not likely to cause an unreasonable risk or promulgates a rule restricting the chemical. The Discussion Draft also would preempt a State or local law that: (1) 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; (2) regulates a new chemical once the review period for it under section 5 has expired; (3) requires use notification for a chemical if EPA has required notification under section 5; or (4) mandates requirements that currently are preempted because EPA regulated them under section 5 or 6 prior to enactment of the Chemicals in Commerce Act.

Section 17 of the Discussion Draft preserves State and local laws adopted pursuant to any other Federal law and actions under State law for personal injury, death, or property damage.

J. Section 18: Judicial Review

The Discussion Draft maintains the existing legal standard of "substantial evidence" in order to have a rule promulgated under sections 4, 5, or 6, or an order issued under section 4 or under section 5 set aside.

K. Section 22: Policies, Procedures, and Guidance

Section 22 of the Discussion Draft requires EPA, within one year, to establish policies, procedures, and guidance needed to implement the Act.

The Discussion Draft adds language to implement the new requirements of the Draft and reinforce the use of high quality science in implementing its provisions. Section 22 of the Discussion Draft ensures that the policies, procedures, and guidance employ and rely upon best available science and risk assessment principles and methodologies, including clear articulation of the strength and reliability of the results produced. The Discussion Draft also requires good laboratory practices.

L. Section 27: Preservation of Authority

The Discussion Draft preserves existing TSCA regulations and decisions not otherwise amended by the Draft.

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