April 10, 2015

TO: Members, Subcommittee on Environment and the Economy

FROM: Committee Majority Staff

RE: Hearing entitled "H.R. _____, the TSCA Modernization Act of 2015"

I. INTRODUCTION

On Tuesday, April 14, 2015, at 10:15 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Environment and the Economy will hold a hearing entitled "H.R. _____, the TSCA Modernization Act of 2015."

II. WITNESSES

Panel 1

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

Panel 2

- Mr. Michael P. Walls, Vice President of Regulatory and Technical Affairs, American Chemistry Council;
- Dr. Beth Bosley, President, Boron Specialties, LLC, On behalf of the Society of Chemical Manufacturers and Affiliates;
- Ms. Jennifer Thomas, Senior Director, Federal Government Affairs, Alliance of Automobile Manufacturers; and
- Mr. Andy Igrejas, Director, Safer Chemicals, Healthy Families.

Additional witnesses may be announced later.

III. BACKGROUND

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.

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IV. LEGISLATION

The Discussion Draft is comprised entirely of amendments to Title I of TSCA.

Chemicals Already in Commerce

The Discussion Draft would repeal the requirement in subsection 6(a) that rules prohibiting or restricting chemical substances use "the least burdensome requirements," and repeals subsection 6(b), which authorizes EPA to order chemical manufacturers and processors to describe quality control procedures used in manufacturing or processing, and, if inadequate, to order the manufacturer or processor to give notice of risks or to provide replacement or repurchase.

Risk Evaluations

The Discussion Draft would add a new subsection 6(b) to prohibit EPA from imposing a restriction (or complete prohibition) on a chemical substance before evaluating the substance's risk of injury to human health or the environment. The risk evaluation step provides a new system by which EPA will evaluate risks associated with chemicals already on the market. Before restricting one or more uses of a chemical in order to manage its risk to human health or the environment, EPA must evaluate the risk, applying scientific standards set out below. EPA selects chemical substances for risk evaluations when it finds that there is a reasonable basis for concluding that the combination of hazard from and exposure to a chemical substance has the potential to present an unreasonable risk of injury to human health or the environment. A manufacturer (who is willing to pay the EPA administrative cost of the evaluation) also may designate a chemical for risk evaluation.

The risk evaluation focuses on determining whether a combination of hazard from and exposure to a chemical substance is or is not high enough to present an unreasonable risk of injury to human health or the environment. Duration, intensity, and frequency of exposures are considered along with whether the weight of the evidence supports determination of threshold doses. At this step, cost and other factors not directly related to human health and environment are not taken into account when determining what constitutes an unreasonable risk.

At the conclusion of a risk evaluation, EPA must either decide that the chemical does not present an unreasonable risk or develop a rule to manage the risk under subsection 6(a).

Risk Management Rules

The Discussion Draft would require that EPA, when developing a rule under subsection 6(a):

- 1) consider the effects of the substance (or mixture) on health and the environment, the benefits of the substance, and the economic consequences of the rule;
- 2) determine if the rule is cost-effective;

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- 3) determine whether feasible substitutes will be available when deciding whether to prohibit or restrict the chemical or mixture and when setting a transition period;
- 4) exempt replacement parts manufactured before the rule is effective, unless such parts contribute significantly to the risk; and
- 5) apply restrictions on articles only to the extent necessary to mitigate the risk.

Deadlines for EPA Action

The Discussion Draft also would establish deadlines for certain EPA actions – risk evaluations on chemicals selected by EPA must be completed within 3 years, and risk evaluations initiated by manufacturers must be completed within 180 days. If more information is needed, EPA may extend the deadline by not more than 90 days after receiving such information, or 2 years after initiating the risk evaluation, whichever is shorter. Any subsection (6)(a) risk management rule must follow completion of risk evaluations by 90 days.

Testing Authority for Risk Evaluations

The Discussion Draft would authorize EPA to require testing on chemicals for the purposes of conducting the section 6 risk evaluations.

Inactive Chemicals

The Discussion Draft would require EPA to collect information necessary to remove from the TSCA section 8 inventory any chemical substance that is no longer manufactured or processed in the U.S.

Preemption of State Law

Once EPA makes a final decision on a chemical, either in a rule to manage the risk or in a decision that the chemical poses no unreasonable risk, that decision would apply in all States. This preemption would be as comprehensive as the risk evaluation and the risk management rule. The Discussion Draft contains a savings provision to ensure that interpretation of State tort and contract law is not affected.

Protection of Confidential Business Information

The Discussion Draft would continue to protect confidential business information (CBI) submitted to EPA and allows access to certain State, local, and tribal government officials and health care professionals, subject to the same penalties for unauthorized disclosure that already apply to U.S. government employees. The Discussion Draft would require confidentiality claims made after enactment to be reasserted after 10 years. The Discussion Draft also would clarify that current exemptions from CBI protections for health and safety studies do not include the release of data that would disclose confidential chemical formulas.

Relationship to Other Federal Laws

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The Discussion Draft would require EPA, in deciding whether to take action under TSCA or another law, to compare the risks, estimated costs, and efficiencies of taking action under the different laws.

Fees

The Discussion Draft would replace the cap on fees for data submission under sections 4 and 5, (\$2,500 or, for small businesses, \$100), but would continue to require that fees be reasonable and that fees for small businesses be lower. In addition, EPA would be required to publish (for notice and comment) policies and procedures for setting and charging fees.

Science Standards

Discussion Draft would require EPA to follow detailed requirements when carrying out sections 4, 5, and 6 to ensure that decisions are supported by valid science. These relate to the means used to generate information, the relevance of the information, the clarity and completeness with which data are documented, the extent of uncertainty, and independent verification, validation, and peer review.

The Discussion Draft also would require EPA decisions under sections 4, 5, and 6 to be based on the weight of the scientific evidence.

Publication of EPA Actions

Discussion Draft would require that, subject to section 14, the Administrator publish all notices and actions taken pursuant to the Discussion Draft.

Policies, Procedures and Guidance Deadlines

Within 2 years of the bill's enactment (and every 5 years thereafter to review), the Discussion Draft would require EPA to develop procedures, and guidance to carry out the Discussion Draft.

V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact David McCarthy or Jerry Couri of the Committee staff at (202) 225-2927.