U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

May 11, 2015

TO: Members, Subcommittee on Environment and the Economy

FROM: Committee Majority Staff

RE: Subcommittee Markup of "H.R. ____, the TSCA Modernization Act of 2015"

I. INTRODUCTION

The Subcommittee on Environment and the Economy will meet in open markup session at noon on May 14, 2015, in 2123 Rayburn House Office Building to consider:

- H.R. ___, TSCA Modernization Act of 2015

In keeping with Chairman Upton's announced policy, Members must submit any amendments they may have two hours before they are offered during this markup. Members may submit amendments by email to peter.kielty@mail.house.gov. Any information with respect to an amendment's parliamentary standing (e.g., its germaneness) should be submitted at this time as well.

II. 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.

III. EXPLANATION OF 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 the Environmental Protection Agency (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 have EPA designate a chemical for risk evaluation.

The Discussion Draft adds explicit authority for the Administrator to select for risk evaluation chemicals from the TSCA Work Plan as of date of enactment of the TSCA Modernization Act without being required to make the determination in subsection (b)(3)(A)(i). This provision is intended to take advantage of work already performed on these chemicals prior to enactment of the TSCA Modernization Act.

The risk evaluation itself focuses on determining whether or not a chemical substance presents or will 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 identification of doses below which no adverse effects can be expected. 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 and EPA may not make a determination that an unreasonable risk is not present if the chemical substance presents an unreasonable risk to a vulnerable subpopulation.

If EPA determines that that the chemical presents or will present an unreasonable risk, the legislation requires EPA to develop a rule to manage the risk under subsection 6(a).

The Discussion Draft requires the Administrator, subject to the availability of appropriations, to initiate 10 or more risk evaluations in each fiscal year, beginning in the fiscal year in which the bill is enacted.

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) and their magnitude on health and the environment, the benefits of the substance, and the economic consequences of the rule;
2. impose requirements determined by the Administrator to be cost-effective, except where the Administrator determines that it is not practicable to protect against an unreasonable risk of injury using cost-effective requirements;
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 designed before the rule is published in the Federal Register, unless such parts contribute significantly to the risk; and apply restrictions on articles only to the extent necessary to mitigate the risk.

Critical Use Exemptions

If EPA determines that a requirement, issued under section 6(a), to control a risk from a chemical substance or mixture is not cost-effective, the Discussion Draft permits EPA to grant a five (5) year exemption from that requirement. This waiver, which can be renewed, is only permitted for chemical substances or mixtures whose use EPA finds are needed to avoid significant disruption of the national economy, national security, or critical infrastructure.

Persistent, Bio-accumulative, and Toxic Chemicals

The Discussion Draft permits EPA to take faster action on chemicals that are considered to be persistent, bio-accumulative, and toxic (PBTs). First, the draft requires that EPA identify those chemicals – excluding metals or metal compounds (as well as polychlorinated biphenyls which are already covered by another section of TSCA) – which the Administrator has a reasonable basis to conclude, are persistent, bioaccumulative, and toxic. One year after that, EPA is required to determine which of those substances have a likely exposure to the general population or EPA identified vulnerable subpopulations and score "high" for either persistence and bioaccumulation and "high" or "moderate" for persistence and bioaccumulation pursuant to EPA's February 2012 Methods Document for use in updating the TSCA Work Plan. The Discussion Draft requires EPA, subject to appropriations and not later than two years after making the above determination, to apply one or more requirements under section 6(a) to reduce, to the extent practicable, the likely exposure to the chemical substance. If a risk evaluation under subsection (b) of section 6 is initiated prior to ninety days after the date on which a chemical is listed as a PBT, then it is removed from the PBT list and undergoes the risk evaluation instead.

Deadlines for EPA Action

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

The Discussion Draft deletes language amending TSCA section 8 that would have required 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. The Discussion Draft does not amend section 8.

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, such decision applies in all States. The preemption established in the legislation would be as comprehensive as the risk evaluation and the risk management rule. The Discussion Draft contains provisions saving State-based interpretation of State tort and contract laws; laws regarding admissibility of evidence; any action taken before August 1, 2015 under State or local authority that prohibits or otherwise restricts a chemical substance (unless in conflict with Federal law) or any action taken pursuant to a State law that was in effect on August 31, 2003. State-based treatment of evidence rules are explicitly unaffected by the TSCA provisions on protection of confidential business information.

The Discussion Draft adds to TSCA section 18 a provision that protects state or local requirements for air and water quality and waste treatment and waste disposal (unless in conflict with Federal law). The Draft also clarifies that in the case of a state law requirement that is identical to a Federal one, a State may not assess a penalty for a specific violation if the Administrator has done so first, and if a State has assessed a penalty first, the EPA penalty added to the state penalty may not exceed in total the EPA maximum penalty.

Protection of Confidential Business Information

The Discussion Draft would continue to protect confidential business information (CBI) submitted to EPA and allow 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 designated, substantiated, and reasserted after ten 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 formulas, including molecular structures, for chemical substances and mixtures whose protection as confidential has been justified to EPA.

Relationship to Other Federal Laws

The Discussion Draft would require EPA, in deciding whether to take action under TSCA or another law, to first compare the relevant 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 (for new test data) and 5 (data about a new chemical or new use of a chemical), (currently set at $2,500 or, for small businesses, $100), but would require that fees be "sufficient and not more than reasonably necessary" 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.

The Discussion Draft also creates a "TSCA Service Fee Fund," which would be operated by the U.S. Treasury, where user fees collected for section 4 and 5 data submissions and risk evaluations requested by the manufacturer of a chemical substance would be deposited. Funds deposited would be made available to EPA only for use in administering the provisions of law for which they were collected. The Discussion Draft also requires biannual EPA reports to Congress on fee income and disbursements, as well annual TSCA Service Fee Fund audits by the EPA Inspector General to examine fee reasonableness, Fund management, and the Fund's financial stability.

Science Standards

The Discussion Draft would require EPA, when making science-based decisions in sections 4, 5, and 6, to consider quality of the science it is using. 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, and peer review. After these considerations, the Discussion Draft requires EPA decisions under sections 4, 5, and 6 to be based on the weight of the scientific evidence.

Publication of EPA Actions

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

IV. STAFF CONTACTS

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