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FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
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Majority (202) 225-2927
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**MEMORANDUM**

**May 13, 2015**

**To: Subcommittee on Environment and the Economy Members and Staff**

**Fe: Committee on Energy and Commerce Democratic Staff**

**Re: Subcommittee Markup of H.R. __, the "TSCA Modernization Act of 2015"**

On Thursday, May 14, 2015, at 12:00 p.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Environment and the Economy will convene for a markup of a revised discussion draft of H.R. __, the "TSCA Modernization Act of 2015." The revised draft addresses several concerns raised at the April 14, 2015 legislative hearing, as described below. Background information was provided in the memorandum for the hearing, which is attached.

## I. SUMMARY OF CHANGES TO THE "TSCA MODERNIZATION ACT OF 2015"

The following changes were made to the original "TSCA Modernization Act of 2015" discussion draft, which was circulated on May 12, 2015. These changes, were not included in the discussion draft text that was the subject of the April 14, 2015 legislative hearing on the bill. Formal feedback regarding these changes has not yet been received or submitted for drafting considerations. For this reason, further revisions to the bill may possibly be made.

### A. The Role of Costs in Risk Management

At the April 14th hearing, the Environmental Protection Agency (EPA) testified that the original discussion draft did not make clear the role of cost considerations in risk management, and would need to be clarified to comport with the Administration's principles for TSCA reform. According to the agency, several different provisions in the previous draft and current law contributed to the problem.

The revised discussion draft includes several changes to address this problem. Specifically, section 6(g) would explicitly establish that the decision of whether or not to regulate a chemical should be made purely based on risk, without consideration of costs or other

non-risk factors.[1] The bill also clarifies that EPA would not be required to adopt cost-effective requirements if doing so is not practicable,[2] and includes critical use exemptions to clarify the narrow circumstances in which cost should prevail.[3]

### B. Protections for Vulnerable Populations

The discussion draft included explicit protections for vulnerable populations before EPA could declare that a chemical does not present an unreasonable risk. However, as EPA testified, it did not provide the same explicit protections when EPA finds that a chemical does present an unreasonable risk. The revised draft now contains an explicit requirement that risk management address any identified risks to vulnerable populations.[4]

### C. The Hurdle to Risk Evaluation

At the hearing, EPA testified that the discussion draft would require the agency to meet a substantial hurdle before initiating a risk evaluation for a chemical, essentially having to find risk before beginning the process. Environmental groups shared this concern and testified to the same effect.

To address these concerns, the draft now requires EPA to pursue a risk evaluation based on a finding that a chemical presents a potential hazard and potential route of exposure.[5] Additionally, the bill would allow EPA to move forward on evaluating chemicals listed on its TSCA Work Plan without any additional or duplicative findings.[6]

### D. Scope of Preemption

The bill would preempt state action when EPA either acts to regulate a chemical, or finds that a chemical does NOT present an unreasonable risk. Numerous stakeholders have voiced concerns that overbroad preemption provisions could prevent states from regulating a dangerous use of a chemical substance which EPA has not evaluated. Preemption could also overturn existing state programs to protect air and water quality or that have proven effective in mitigating risks to human health and the environment.

To address these concerns, the revised draft requires EPA to consider all uses of a chemical substance in their risk evaluation, and limits preemption for uses that are not

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[1] H.R. __, the "TSCA Modernization Act of 2015," at 13.

[2] *Id.* at 11.

[3] *Id.* at 13.

[4] *Id.* at 4.

[5] *Id.* at 5.

[6] *Id.*

considered.[7] The revised draft also explicitly protects state laws to protect air and water quality and state laws regarding waste treatment and disposal.[8] Lastly, the draft includes a grandfather clause to preserve state laws that are already on the books, unless they expressly conflict with the federal law.[9]

### E. Setting up a Dedicated Trust Fund

There was consensus at the hearing that user fees collected under the bill, including those paid for manufacturer-initiated risk evaluations, should be deposited in a dedicated trust fund made available to EPA, independent of the appropriations process. Under current law, user fees collected under TSCA are deposited with and held by the U.S. Treasury.

Using the electronic manifest legislation as a model, the bill now establishes a dedicated trust fund for fees collected under TSCA. Although the funds are not exempt from the appropriations process, monies deposited in this fund are reserved for use by EPA in administering TSCA.

### F. Litigation Hooks Related to Science

Opportunities to litigate EPA's use of science have arisen as a major issue in past TSCA reform proposals. Changes in the revised discussion draft reduce potential litigation hooks to ensure that statutory language will not undermine the scientific expertise of the agency. For example, the bill now clarifies that consideration of the factors listed under "scientific standards" are only required where applicable.[10]

### G. Deadlines and Pace

There was consensus at the previous legislative hearing that EPA should be required to initiate a minimum number of risk evaluations every year, and that the deadline for completion of manufacturer-initiated evaluations (180 days) was unrealistic and should be extended. The revised discussion draft requires a minimum of ten EPA-initiated risk evaluations each year,[11] and all risk evaluations are subject to the same three-year completion deadline.[12]

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[7] *Id.* at 21.

[8] *Id.* at 22.

[9] *Id.* at 23.

[10] *Id.* at 29.

[11] *Id.* at 9.

[12] *Id.* at 7.

## H. Expedited Action on Chemicals that are Persistent, Bioaccumulative, and Toxic (PBT)

Expedited action on PBTs has long been a top priority for environmental and public health advocates engaged on TSCA. These chemicals are recognized to be the 'worst of the worst' and to defy traditional risk assessment. Any use of these chemicals carries risk because they remain in the environment forever and build up in our bodies and the food chain. These chemicals are the subject of several international treaties, and have been restricted in EPA's new chemicals program since 1999.

Risk management under a new provision in the discussion draft will seek to minimize likely exposure to the chemicals to the extent practicable.[13] The new provision requires EPA to compile a list of PBT chemicals, excluding PBT metals, within nine months of enactment, and it would subject those chemicals to an expedited review. Those that are found through the expedited review to score high under EPA's methodology used for the TSCA Work Plan for persistence or bioaccumulation and high or moderate for the other, and to have likely exposure will move to expedited risk management.

## I. Inventory Concerns

The original discussion draft included a small change in section 8 of TSCA to require EPA to update the TSCA inventory. The inventory is a list maintained by EPA of all chemicals that were in commerce when TSCA was first adopted, plus all chemicals that have gone through the new chemicals program since it was established. The inventory, which now includes 84,000 chemicals, but it is unclear how many of these chemicals are still actively manufactured, processed or otherwise used in commerce. Because revisions of the inventory are possible under existing authority, this provision has been dropped from the revised discussion draft. The revised draft no longer amends section 8 of TSCA.

## J. Protections for Civil Remedies

The original discussion draft included a savings clause for tort cases and contract suits at the state level. The new discussion draft includes an expanded savings clause explicitly saving all civil remedies under state and federal statutory and common law. It also includes a provision stating the EPA actions under TSCA should not be dispositive in judicial proceedings. This second provision excludes state court cases that expressly conflict with the federal law, an exclusion not included in similar language in other TSCA reform proposals.[14]

[13] *Id.* at 15.

[14] *Id.* at 24.

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**MEMORANDUM**

**April 13, 2015**

**TO: Subcommittee on Environment and the Economy Members and Staff**

**FR: Committee on Energy and Commerce Democratic Staff**

**RE: Legislative Hearing on H.R. __, the "TSCA Modernization Act of 2015"**

On Tuesday, April 14, 2015 at 10:15 a.m. in room 2322 of the Rayburn House Office Building, the Subcommittee on Environment and the Economy will hold a legislative hearing on a discussion draft of the "TSCA Modernization Act of 2015."[15] The discussion draft was circulated by Chairman Shimkus on April 7, 2015, following bipartisan discussions. Continued discussions are expected following the legislative hearing, which will include testimony from the Environmental Protection Agency (EPA) and other stakeholders.

## I. BACKGROUND

The Toxic Substances Control Act (TSCA) was enacted in 1976 to address risks to human health and the environment from chemicals manufactured in the United States and distributed in commerce. TSCA requires EPA to review new chemicals for risk and authorizes EPA to restrict or ban the use of new or existing chemicals that pose an "unreasonable risk" to public health or the environment.[16]

There is broad agreement that TSCA has failed to effectively achieve Congress' goals.[17] Since 2009, the Government Accountability Office included EPA's oversight of toxic chemicals

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[15] H.R. __, the "TSCA Modernization Act of 2015" (online at democrats.energycommerce.house.gov/sites/default/files/documents/Discussion-Draft-EE-HR___TSCA-Act-2015-4-14.pdf).

[16] 15 U.S.C. §2601 *et seq.*

[17] Subcommittee on Commerce, Trade, and Consumer Protection, *Hearing on Revisiting the Toxic Substances Control Act of 1976*, 111th Cong. (Feb. 26, 2009).

in its High Risk Series, concluding that it "limits the agency's ability to fulfill its mission of protecting human health and the environment."[18]

Many stakeholders have laid out principles for TSCA reform, including EPA,[19] the American Chemistry Council (ACC), [20] the Environmental Council of the States, the National Council of State Legislatures, environmental groups, public health groups, and consumer advocacy groups.[21]

Congressional efforts to reform TSCA have been significant and ongoing. Last Congress, this Subcommittee held a series of hearings on TSCA, including two legislative hearings on a prior proposal, the "Chemicals in Commerce Act." TSCA reform proposals have also been introduced in the Senate by Senators Boxer and Markey[22] and Senators Udall and Vitter.[23]

## II. OVERVIEW OF THE TSCA MODERNIZATION ACT OF 2015

The TSCA Modernization Act discussion draft differs significantly from the Chemicals in Commerce Act discussion draft. Unlike past legislative proposals, the "TSCA Modernization Act of 2015" amends only a small subset of provisions in the existing TSCA statute. The included changes address many, but not all, of the significant problems in current law that have been identified in past hearings. The limited scope of the discussion draft avoids some areas that have proven difficult to resolve in other proposals. Problems in current law and other proposals are described below, along with an explanation of whether and how they are addressed in the discussion draft.

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[18] Government Accountability Office, *High-Risk Series: An Update* (Jan. 2009) (GAO-09-271).

[19] U.S. Environmental Protection Agency, *Essential Principles for Reform of Chemicals Management Legislation* (Sept. 29, 2009) (online at www.epa.gov/oppt/existingchemicals/pubs/principles.html).

[20] American Chemistry Council, *Ten Principles for Modernizing TSCA* (online at www.americanchemistry.com/s_acc/sec_article_acc.asp?CID=2178&DID=9939); Consumer Products Specialty Association, *Modernizing the Toxic Substances Control Act* (online at www.cspa.org/advocacy/our-issues/122.html).

[21] Safer Chemicals, Healthy Families, *A Platform to Reform the Toxic Substances Control Act* (online at www.saferchemicals.org/PDF/SCHF_Campaign_Platform.pdf); Business NGO Working Group for Safer Chemicals and Sustainable Materials, *Principles for Safer Chemicals* (Apr. 4, 2013) (online at www.biznGO.org/pdf/BizNGO_Principles_for_Safer_Chems_endorsers_updated_2013_04_04.pdf).

[22] S. 725, the "Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act (online at www.congress.gov/bill/114th-congress/senate-bill/725).

[23] S. 697, the "Frank R. Lautenberg Chemical Safety for the 21st Century Act" (online at www.congress.gov/bill/114th-congress/senate-bill/697).

### A. Challenges Managing Risks from Existing Chemicals

EPA has faced two primary challenges in managing "unreasonable risks" from chemical substances and mixtures that are not new (these are often referred to as "existing chemicals" though that term is not used in the statute). The standard for action under section 6 of TSCA requires EPA to find a reasonable basis to conclude that a chemical substance or mixture presents, or will present, an unreasonable risk of injury to health or the environment.[24] The section 6 standard has long been interpreted as a cost/benefit standard, as opposed to a purely risk based standard. EPA must also choose the "least burdensome" requirements that will adequately protect against the identified unreasonable risk.[25] The combination of these provisions has prevented EPA from using this regulatory authority to manage risks from existing chemicals, including asbestos.[26]

The discussion draft maintains the "unreasonable risk" standard in section 6.[27] This standard is less protective than the "reasonable certainty of no harm" standard that environmental and public health groups have sought. However, the discussion draft explicitly excludes consideration of costs and other non-risk factors during the risk evaluation stage.[28] Thus, the determination of whether or not a chemical substance presents an unreasonable risk would have to be made without consideration of cost, though cost could be considered in connection with risk management.

The discussion draft also removes the problematic "least burdensome" language, and replaces it with a requirement that EPA select regulations and requirements that are "cost-effective."[29]

### B. Challenges in Requiring Testing

EPA has faced two challenges in exercising its testing authority under section 4 of TSCA. The first challenge stems from the requirement that EPA demonstrate that chemicals may pose an unreasonable risk before requiring testing.[30] Many have called this a *catch-22*, because EPA's lack of data is an obstacle to making a demonstration necessary to require data. The second challenge flows from the requirement that EPA engage in notice and comment rulemaking to require any testing, even for a single chemical.[31]

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[24] Toxic Substances Control Act § 6(a); 15 U.S.C. 2605(a).

[25] *Id*.

[26] *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

[27] H.R. __, the "TSCA Modernization Act of 2015,"at 4-12.

[28] *Id.* at 6.

[29] *Id.* at 9-10.

[30] Toxic Substances Control Act § 4(a).

[31] *Id.*

The discussion draft addresses this second challenge, by allowing EPA to require testing through orders.[32] The first challenge, however, has not been addressed in the draft. The discussion draft creates new grounds for requiring testing – to carry out a risk evaluation under section 6 – but EPA must make the equivalent of a "may present" finding before initiating a risk evaluation.[33] The hurdle to requiring testing is therefore preserved.

### C. Funding Challenges

Funding for current TSCA efforts comes through the appropriations process and from user fees collected under sections 4 and 5. Section 26 of current law limits user fees to $2500 or, $100 for small business concerns.[34] These amounts have not changed since 1976.

The discussion draft removes the outdated caps on user fees, and adds additional authority for EPA to collect fees to defray the costs of manufacturer-requested risk evaluations under section 6.[35] While these are positive improvements, the user fees collected by EPA would still be deposited in the U.S. Treasury, and remain subject to appropriations. The amounts of funding that will actually be made available to EPA is therefore unclear.

### D. Challenges to Transparency

Under section 14 of TSCA, EPA is prohibited from sharing information that would qualify as confidential business information (CBI) under the Freedom of Information Act, except under narrow circumstances.[36] Preventing abuse of the CBI process is important to ensure that the public has access to information on the safety of industrial chemicals that end up in their workplaces, communities and consumer products.

Under current law, submitters of information can designate that information as CBI without substantiating their claim.[37] At a hearing before this Subcommittee in the 113th Congress, the Government Accountability Office (GAO) testified that due to constraints on resources, EPA has not routinely challenged companies' CBI claims.[38] It is therefore unclear to what extent CBI claims have been warranted.[39]

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[32] H.R. __, the "TSCA Modernization Act of 2015,"at 3.

[33] *Id.* at 5.

[34] Toxic Substances Control Act § 26.

[35] H.R. __, the "TSCA Modernization Act of 2015," at17-18.

[36] Toxic Substances Control Act § 14(c).

[37] *Id.* at § 14(a); 15 U.S.C. 2613(a).

[38] Testimony of Alfredo Gomez, U.S. Government Accountability Office, Committee on Energy and Commerce Subcommittee on Environment and the Economy, *Hearing on Title I of the Toxic Substances Control Act: Understanding Its History and Reviewing its Impact*, 113th Cong. (June 13, 2013).

[39] *Id.*

The discussion draft requires up-front substantiation of all future CBI claims, and periodic re-substantiation of those claims every 10 years.[40] It does not apply retroactively to CBI claims made in the past, although EPA has recently made progress in reviewing and overturning some unwarranted claims.[41] The discussion draft also grants additional authority to share CBI for purposes of responding to environmental releases and for health diagnosis or treatment.[42]

### E. Challenges Identifying Chemicals in Commerce

There are approximately 84,000 chemicals currently on the EPA TSCA inventory.[43] Although approximately 700 new chemicals are added every year to the list, no chemicals have been removed since the inventory was created following adoption of the 1976 statute. This diminishes the utility of the inventory because it is not clear which chemicals on the inventory are still manufactured or used in commerce.[44]

The discussion draft would address this issue by giving EPA authority to collect information "necessary to remove from the list any chemical substance that is no longer manufactured or processed in the United States, and revise the list accordingly."[45]

### F. Heightened Standard of Judicial Review

EPA actions taken under TSCA must be "supported by substantial evidence in the rulemaking record."[46] This standard is significantly higher than the "arbitrary and capricious" standard common to most other environmental laws and the Administrative Procedure Act. TSCA's heightened judicial review standard played a critical role when a federal appeals court decided to overturn EPA's section 6 rule to ban and phase out asbestos.[47]

The discussion draft does not change the "substantial evidence" standard in TSCA section 19.

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[40] H.R. __, the "TSCA Modernization Act of 2015," at 14-15.

[41] U.S. Environmental Protection Agency, *Declassifying Confidential Claims to Increase Access to Chemical Information* (online at www.epa.gov/oppt/existingchemicals/pubs/transparency-charts.html#progressreview).

[42] H.R. __, the "TSCA Modernization Act of 2015," at 14.

[43] Government Accountability Office, *High-Risk Series: An Update* (Jan. 2009) (GAO-09-271).

[44] Congressional Research Service, *The Toxic Substances Control Act (TSCA): Implementation and New Challenges* (July 23, 2009) (RL34118).

[45] H.R. __, the "TSCA Modernization Act of 2015," at 13.

[46] Toxic Substances Control Act § 19.

[47] *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

## G. Lack of Protections for Vulnerable Populations

Currently, TSCA does not require consideration of risks to vulnerable subpopulations. Children, pregnant women and the elderly may be more susceptible to adverse health effects from harmful chemicals. Others, like those who live near chemical manufacturing or processing facilities, may suffer greater exposures. Even if a chemical presents serious risks to one of these subpopulations, EPA may not be able to show an "unreasonable risk" under current law and would therefore be unable to regulate. The National Academies of Science, in their 2009 report Science and Decisions, recommended that vulnerable populations should receive special attention in all stages of the risk assessment process.[48]

The discussion draft adds a new definition to TSCA section 3 for "potentially exposed subpopulations," defined as those who "due to either greater susceptibility or greater potential exposure, are at greater risk than the general population of adverse health effects from exposure to a chemical substance."[49] Importantly, the discussion draft also revises section 6 to bar EPA from making a finding that a chemical does not present an unreasonable risk if it presents an unreasonable risk for one or more potentially exposed subpopulations.[50]

## H. Lack of Expedited Action for Persistent, Bioaccumulative, and Toxic Chemicals (PBTs)

Exposure to PBTs have been associated with cancer, neurotoxicity, reproductive and developmental toxicity, and genetic mutations. Examples of PBTs include polychlorinated biphenyls (PCBs); certain brominated flame retardants and some perfluorinated compounds; metals such as lead, mercury and cadmium; and fragrances such as musk xylene.

Environmental advocates have long called for expedited action to manage risks from PBTs because traditional risk assessment does not accurately capture the risks they pose. Even with controls to restrict or eliminate their use, they can remain unchanged as long-lasting contaminants in the global environment. The discussion draft does not currently provide expedited action for these chemicals.

## I. Challenges Contained in Other Proposals

Section 18 of TSCA currently preserves all authority of states and political subdivisions to regulate chemical substances, mixtures, and articles, except in narrowly identified circumstances.[51] Specifically, if EPA has promulgated a test rule for a chemical under TSCA section 4, a state is preempted from establishing or continuing a testing requirement for the same

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[48] National Academies of Science, *Science and Decisions: Advancing Risk Assessment* (2009).

[49] H.R. __, the "TSCA Modernization Act of 2015," at 2.

[50] *Id.* at 8-9.

[51] Toxic Substances Control Act § 18(a)(1); 15 U.S.C. 2617(a)(1).

chemical for the same purpose as the Federal rule.[52] Similarly, if EPA has taken action to restrict a chemical substance or mixture under sections 5 or 6 of TSCA, a state is preempted from establishing or continuing a requirement on that chemical substance or mixture that addresses the same risk.

Current law allows states to adopt or continue in effect requirements that are identical to the federal requirement, are adopted under other federal authority (such as the Clean Air Act), or are outright bans on the use of the chemical substance or mixture.[53] This allows states to go beyond federal regulation in cases where such action is warranted. Current law also exempts states from preemption if complying with both the state and federal requirements is possible and the state requirement does not unduly burden interstate commerce.[54]

Debate over past proposals has included a focus on preemption of state authority. Recent proposals have expanded the circumstances leading to state preemption considerably. For example, S. 697 would: (i) preempt state authority when EPA designates a chemical as "low priority," which occurs without a full risk evaluation, and (ii) when EPA has designated a chemical as "high priority" but not yet taken any action to assess or manage its risks. S.697 would also eliminate the ability of states to co-enforce EPA rules by adopting identical requirements.[55]

The discussion draft adds only one additional circumstance in which state authority is preempted. Under the draft, if EPA conducts a risk evaluation and determines that a chemical is safe (i.e., that it does not pose an unreasonable risk), a state will be preempted from establishing or continuing a requirement on that chemical substance.[56] However, EPA's determination of no unreasonable risk is deemed final agency action and therefore subject to judicial review.[57] The discussion draft also expands the scope of preemption by eliminating the ability of states to prohibit the use of the chemical substance or mixture where EPA has already taken action.[58]

Authority to regulate articles has also been a focus of past proposals. S. 697 would create new analytical requirements before EPA can restrict articles.[59] Jim Jones, Assistant Administrator of the EPA with responsibility for TSCA, testified before the Senate Committee on Environment and Public Works in March, that those requirements fail to comport with EPA's

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[52] *Id.* at § 18(a)(2); 15 U.S.C. 2617(a)(2).

[53] *Id.* at § 18(a)(2)(B).

[54] *Id.* at § 18(b).

[55] S. 697, the "Frank R. Lautenberg Chemical Safety for the 21st Century Act" at § 18 (online at www.congress.gov/bill/114th-congress/senate-bill/697).

[56] H.R. __, the "TSCA Modernization Act of 2015," at 16.

[57] *Id.* at 9.

[58] *Id.* at 18.

[59] S. 697, the "Frank R. Lautenberg Chemical Safety for the 21st Century Act" at 17 (online at www.congress.gov/bill/114th-congress/senate-bill/697).

principles for TSCA reform.[60] The discussion draft is intended to express a preference for upstream regulation of chemicals over articles, but does not create additional burdens for EPA. The draft also provides an exemption for existing stocks of replacement parts manufactured prior to the date of enactment, unless those articles contribute significantly to the identified risk.

## III. WITNESSES

The following witnesses are expected to testify:

**Panel One**

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

**Panel Two**

**Dr. Beth Bosley**
President
Boron Specialties, LLC
*On behalf of the Society of Chemical Manufacturers and Affiliates*

**Andy Igrejas**
National Campaign Director
Safer Chemicals, Healthy Families

**Jennifer Thomas**
Senior Director, Federal Government Affairs
Alliance of Automobile Manufacturers

**Michael P. Walls**
Vice President of Regulatory and Technical Affairs
American Chemistry Council

[60] Testimony of Jim Jones, U.S. Environmental Protection Agency, Committee on Energy and Commerce Subcommittee on Environment and the Economy, Hearing on S. 697, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, 114th Cong.(Mar. 18, 2015).