

H.R. _____, THE TSCA MODERNIZATION ACT
OF 2015

HEARING
BEFORE THE
SUBCOMMITTEE ON ENVIRONMENT AND THE
ECONOMY
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED FOURTEENTH CONGRESS

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**H.R. _____, THE TSCA MODERNIZATION ACT
OF 2015**

TUESDAY, APRIL 14, 2015

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:15 a.m., in room 2322 of the Rayburn House Office Building, Hon. John Shimkus (chairman of the subcommittee) presiding.

Members present: Representatives Shimkus, Harper, Latta, McKinley, Johnson, Bucshon, Flores, Hudson, Cramer, Upton (ex officio), Tonko, Schrader, Green, DeGette, Capps, McNerney, Cárdenas, and Pallone (ex officio).

Staff present: Charlotte Baker, Deputy Communications Director; Leighton Brown, Press Assistant; Noelle Clemente, Press Secretary; Jerry Couri, Senior Environmental Policy Advisor; David McCarthy, Chief Counsel, Environment and the Economy; Tim Pataki, Professional Staff Member; Tina Richards, Counsel, Environment and the Economy; Chris Sarley, Policy Coordinator, Environment and the Economy; Jessica Wilkerson, Legislative Clerk; Jacqueline Cohen, Democratic Senior Counsel; Rick Kessler, Democratic Senior Advisor and Staff Director, Energy and the Environment; and Ryan Schmidt, Democratic EPA Detailee.

Mr. SHIMKUS. The committee will come to order.

Before I start with my opening statement, I want to recognize my classmate and my friend, Lois Capps, who has announced her retirement, although I imagine she will be a pain in our side for about a year and a half yet, so a very nice thing. So I will recognize myself for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Today marks an important milestone in our effort to modernize TSCA. The more we work together, Member to Member, on a bipartisan basis, the more we understand each other and how much we hope to accomplish. Our subcommittee has put in a lot of hours on TSCA over the past couple years, and actually I would say the past couple weeks, and that effort, we believe, is about to pay off. It is gratifying to work directly with Members on both sides of the aisle who bring so much dedication to the task.

A week ago we unveiled the bill before us today. Besides the bill language itself, that announcement carried a couple other important messages. First, Members have been working together di-

rectly, challenging each other to find common ground, and discovering that we share many policy objectives. Let's talk about some of those policy objectives.

First, I think we all want EPA to do objective, science-based examinations on some of the chemicals that are already on the market. EPA already has some of these in mind to evaluate because EPA thinks they have potential for unreasonable risk of injury to human health and the environment. Meanwhile, if manufacturers want to take a proactive approach and ask the Agency to perform a risk evaluation, we are OK with that as long as it meets the same rigorous science requirements as the ones EPA itself initiates, and the manufacturer is willing to pay the EPA administrative costs of performing the work.

We also want to continue protecting confidential business information, but for CBI claims made after our bill becomes law, we would like manufacturers to reestablish those claims at least once every 10 years. We think EPA should be allowed to mandate testing on a chemical in order to complete a risk evaluation, since the risk evaluation step is new to TSCA.

These are just a few of the provisions that appear in the discussion draft. I think we also agree that the process is, and should be, moving forward. Leading Members on both sides are committed to that momentum. We will listen carefully to stakeholders on what they like in the draft, and we welcome suggestions they have for improvement. We will collect those comments and then we will sit down as a subcommittee and make decisions. Members should plan on a subcommittee markup about a month from now on May 14th.

To facilitate our work, we will publish a revised bill text reflecting consensus revisions in time to use as the subcommittee markup vehicle, and I will be asking Chairman Upton to schedule it for full committee consideration as soon as practicable after the subcommittee has done its work.

I thank all of the witnesses today for their willingness to participate. Assistant Administrator Jim Jones, you are no stranger to this committee. Your agency has already offered some informal technical assistance for which we are grateful, and we expect to continue working with you on it until the final version passes both bodies of Congress and is signed by the President.

We also welcome our second panel of witnesses. You are all also friends to this committee, and we have been grateful for your perspectives in the past. We look forward to hearing from you on this fresh new approach.

Finally, I thank Chairman Upton for his full support on this bill, and my friends, Paul Tonko and Frank Pallone, and the subcommittee members and I would say the subcommittee staff on both sides for all their active participation and partnership in this project. Let's all keep working together to get this vitally important legislation enacted.

[The prepared statement of Mr. Shimkus follows:]

PREPARED STATEMENT OF HON. JOHN SHIMKUS

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Meanwhile, if manufacturers want to take a pro-active approach and ask the Agency to perform a risk evaluation, we are OK with that as long as:

- It meets the same rigorous science requirements as the ones EPA itself initiates; and
- The manufacturer is willing to pay the EPA administrative cost of performing the work.

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Finally, I thank Chairman Upton for his full support on this bill, and my friends, Paul Tonko and Frank Pallone, and subcommittee members on both sides for their active partnership in this project.

Let's all keep working together to get this vitally important legislation enacted.

[Discussion draft H.R. _____ appears at the conclusion of the hearing.]

Mr. SHIMKUS. And with that, I yield back my time and yield 5 minutes to the gentleman from New York, Mr. Tonko.

OPENING STATEMENT OF HON. PAUL TONKO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. TONKO. Thank you, Mr. Chair, and I certainly appreciate the tone. I value the friendship and partnership we have in serving this committee.

Good morning to each and every one of our witnesses and to my fellow panelists here. Thank you, Chair Shimkus, for calling this important hearing, this very important hearing.

Our subcommittee spent a good deal of time on the Toxic Substances Control Act in the last Congress. We had a number of very good hearings covering many of the provisions of the current law,

and although we did not get to an agreement, the exercise provided the members of this subcommittee with a much better understanding of the current law and its associated shortcomings. It is a new Congress. We have another opportunity to develop a bill to address the key problems with current law.

For much of the past 37 years, TSCA served the industry well, but I would caution that TSCA needs to be balanced. It needs to serve all perspectives well. Existing chemicals remain on the market, and new chemicals entered commerce through a limited review process that does not require licensing or compel the production of minimal data sets. Information provided by chemical manufacturers could be labeled as confidential business information with less review of whether the CBI claims were justified or not. Even in the face of strong evidence that a chemical substance indeed presented a significant risk, the Environmental Protection Agency was unable to act.

For all practical purposes, TSCA has no enforceable safety standard. Under the law's standard of unreasonable risk and the requirement to produce substantial evidence, the burden of proof of harm as interpreted by the courts is too high to enable EPA to address even well-characterized risks. In addition, the Agency has insufficient resources and little authority to require manufacturers to produce information for an adequate evaluation of those chemical risks. This is especially true for thousands of older chemicals that remained in commerce with no evaluation from the time the law was passed to the present moment.

The overriding problem with TSCA is that the public has no confidence in this Federal program. As a result, the public does not believe that the presence of a chemical in the marketplace has any relationship to its safety. That is not good for industry and it is not good for the public. The Federal program must have credibility.

The discussion draft that is the subject of today's hearing represents a significant departure from the proposal offered by Senator Vitter and Senator Udall, and I believe that is an important step here in this House. It is also different from the approach taken in the House last year. So I believe that this draft has a number of benefits relative to these two other proposals, and that is a very beneficial thing in this process.

I want to commend the Chair for working with us and demonstrating a desire to discuss and address concerns raised by Democratic members and by different stakeholders and interest groups. I appreciate and applaud the Chair's decision to narrow the scope of this effort and to focus on the key problems with TSCA.

Again, I appreciate the partnership and the friendship, but there is much more work to do, and I am prepared to work with you as are the other members of our subcommittee, Mr. Chair. My hope is that we can produce a bill that all members of our subcommittee can support, one that truly can become law. If we are to do that, the final product must reflect compromise and gain the support of a broad coalition representing all of the major stakeholder groups and it must have the support of the administration. I believe we can get there and that this discussion draft makes a great start toward the goal of passing a law but I do not want to mislead anyone. There are still some tough issues to address. A new TSCA

must do more for public health and the environment than the current law. It must preserve State authority to act to protect their citizens in the absence of meaningful Federal action, and changes in policy alone will not be enough. The Agency must have adequate resources by which to fulfill its obligation to the public and to the regulated community. A reformed TSCA should generate more innovation, not more litigation.

I want to thank all of our witnesses who are participating in today's very important hearing. Your input on this draft legislation will be very important to our efforts as we move forward, and again, I would like to thank you, Mr. Chair, and commend you for tackling this important and very challenging issue. It is not easy. I look forward to working with you and the other members of this subcommittee to complete this very important task.

And with that, I yield back.

Mr. SHIMKUS. The gentleman yields back his time, and you know, without objection, what I would like to do, Mr. Jones, is allow you to go for 5 minutes, and then when Chairman Upton and the ranking member come, after that we will let them give their opening statements, and with that, you are recognized for 5 minutes.

Welcome.

STATEMENT OF HON. JAMES JONES, ASSISTANT ADMINISTRATOR, OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION, ENVIRONMENTAL PROTECTION AGENCY

Mr. JONES. Thank you. Good morning, Chairman Shimkus, Ranking Member Tonko, and other members of the subcommittee. I appreciate the opportunity to join you today to discuss the much-needed reform of chemicals management in the United States and the opportunity to engage early on the recently released discussion draft, the TSCA Modernization Act of 2015.

As you know, chemicals are found in almost everything we buy and use. They contribute to our health, our well-being and our prosperity. However, we believe it is essential that chemicals are also safe.

TSCA gives the EPA the jurisdiction over chemicals produced, used, and imported into the United States. However, unlike laws applicable to pesticides and drugs, TSCA does not have a mandatory program that requires EPA to conduct a review to determine the safety of existing chemicals. In addition, TSCA places burdensome legal and procedural requirement on the EPA before the Agency can request a generation and submission of health and environmental effects data on existing chemicals. As a result, in the more than 3½ decades since the passage of TSCA, the EPA has only been able to require testing on a little more than 200 of the original 60,000 chemicals listed on the TSCA inventory and has regulated or banned only five of these chemicals under TSCA Section 630, the last of which was in 1990. In the 25 years since, the EPA has largely relied on voluntary action to collect data and address risks.

In the absence of additional Federal action, an increasing number of States are taking actions on chemicals to protect their residents, and the private sector is making their own decisions about

chemicals to protect their interest and to respond to consumers, it is clear that even with the best efforts under current law and resources, we need to update and strengthen TSCA and provide the EPA with the appropriate tools to protect the American people from exposure to harmful chemicals.

The EPA believes that it is critical that any update to TSCA include certain components. In September 2009, the administration announced a set of six principles to update and strengthen TSCA.

While the administration does not have a position on the discussion draft, there are several important observations that I would like to offer.

The discussion draft provides the EPA with more effective authority to compel the generation of health and safety data on existing chemicals. The discussion draft should give the EPA authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. The draft includes two means by which risk evaluations could be initiated for existing chemicals. The first is that EPA would be required to conduct a risk evaluation upon a finding that the combination of hazard from and exposure to a particular chemical substance has the potential to create an unreasonable risk of injury to health or the environment. The second allows for a chemical manufacturer to request that EPA conduct a risk evaluation for a particular chemical substance. In practice, this would likely lead to EPA focusing the majority of its limited risk evaluation resources on completing evaluations for chemical substances requested by industry, which, once requested, start the clock ticking on a number of deadlines. This could result in evaluations for the chemicals with the most potential for risk being put off indefinitely while EPA works on the evaluations requested by industry. Additionally, the requirement that EPA make an affirmative finding of the potential for unreasonable risk, prior to initiating a risk evaluation, creates a possible analytical catch-22 in which EPA must make a finding regarding the potential for risk prior to beginning the risk evaluation process. I note that once the EPA is able to conduct an evaluation that finds risk, the discussion draft appears to impose rigorous deadlines for taking regulatory action to reduce those risks. However, in many cases the deadlines in the draft are unreasonably short.

The use of TSCA section 6 to limit or ban a chemical that poses a significant risk has been a major challenge. The discussion draft clearly removes TSCA's requirement that the EPA demonstrate it is using the least burdensome requirements needed to provide adequate protection. The draft appears consistent with Principle 1 in that it specifies that risk assessments should include consideration of information on potentially exposed populations but not information on cost and other factors not directly related to health or the environment. The discussion draft, however, is ambiguous on how EPA is to incorporate cost and other factors into a risk-management rule under section 6(a).

In the current discussion draft, the cap on fees is eliminated; however, there are not provisions that ensure EPA will be given a sustained source of funding for implementation, as articulated in Principle 6. The discussion draft is consistent with the administration principles in the area of transparency and availability of infor-

mation on chemicals, including giving the EPA the ability to share chemical data with State, local, and tribal governments.

Mr. Chairman, thank you again for your leadership on TSCA reform. I will be happy to answer any questions you or other members have.

[The prepared statement of Mr. Jones follows:]

**TESTIMONY OF
JAMES JONES
ASSISTANT ADMINISTRATOR
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
COMMITTEE ON ENERGY AND COMMERCE COMMITTEE
ENVIRONMENT AND THE ECONOMY SUBCOMMITTEE
UNITED STATES CONGRESS**

April 14, 2015

Good morning Chairman Shimkus, Ranking Member Tonko, and other members of the Subcommittee. I appreciate the opportunity to join you today to discuss much needed reform of chemicals management in the United States and the opportunity to engage early on the recently released discussion draft of the "TSCA Modernization Act of 2015."

There continues to be wide agreement on the importance of ensuring chemical safety and restoring the public's confidence that the chemicals used in the products they and their families use are safe. This Administration also believes it is crucial to modernize and strengthen the Toxic Substances Control Act (TSCA) to provide the EPA with the tools necessary to achieve these goals and ensure global leadership in chemicals management.

We continue to be encouraged by the interest in TSCA reform indicated by the introduction of several bills in recent years, the hearings on TSCA related issues that are being held, and the discussions that are taking place. Key stakeholders share common principles on how best to improve our chemicals management programs. We at the EPA remain committed to working with this committee and others in both the House and Senate, members of the public, the

environmental community, the chemical industry, the states, and other stakeholders to improve and update TSCA.

As you know, chemicals are found in almost everything we buy and use. They contribute to our health, our well-being, and our prosperity. However, we believe that it is essential that chemicals are safe. While we have a better understanding of the environmental impacts, exposure pathways, and health effects that some chemicals can have than we did when TSCA was passed in 1976, under the existing law it is challenging to act on that knowledge.

TSCA gives the EPA jurisdiction over chemicals produced, used, and imported into the United States. Unlike the laws applicable to pesticides and drugs, TSCA does not have a mandatory program that requires the EPA to conduct a review to determine the safety of existing chemicals. In addition, TSCA places burdensome legal and procedural requirements on the EPA before the agency can request the generation and submission of health and environmental effects data on existing chemicals.

While TSCA was an important step forward when it was passed almost forty years ago, it has proven to be a challenging tool for providing the protection against chemical risks that the public rightfully expects. It is the only major environmental statute that has not been updated or revised since enactment. We believe the time is now to significantly strengthen the effectiveness of this outdated law.

When TSCA was enacted, it grandfathered in, without any evaluation, about 60,000 chemicals that were in commerce at the time. The statute did not provide adequate authority for the EPA to reevaluate these existing chemicals as new concerns arose or science was updated. The law also failed to grant the EPA effective tools to compel companies to generate and provide toxicity data.

It has also proven challenging in some cases to take action to limit or ban chemicals that the EPA has determined pose a significant health concern. For example, in 1989, after years of study and with strong scientific support, the EPA issued a rule phasing out most uses of asbestos in products. Yet, in 1991, a federal court overturned most of this action because it found the rule had failed to comply with the requirements of TSCA.

As a result, in the more than three and a half decades since the passage of TSCA, the EPA has only been able to require testing on a little more than 200 of the original 60,000 chemicals listed on the TSCA Inventory, and has regulated or banned only five of these chemicals under TSCA's section 6 authority, the last of which was in 1990. In the 25 years since, the EPA has largely relied on voluntary action to collect data and address risks. In the absence of additional federal action, an increasing number of states are taking actions on chemicals to protect their residents and the private sector is making their own decisions about chemicals to protect their interests and respond to consumers.

This Administration is committed to using the current statute to the fullest extent possible but the nature of the statute has limited progress. In the last six years, the EPA has identified more than

80 priority chemicals for assessment under TSCA. We have completed final risk assessments on specific uses of five chemicals. Of these, two show no significant risk. The remaining three show risk. To address the risks identified in these three assessments, the EPA is considering pursuing action under Section 6 of TSCA.

It is clear that even with the best efforts under current law and resources, we need to update and strengthen TSCA and provide the EPA with the appropriate tools to protect the American people from exposure to harmful chemicals. The EPA believes that it is critical that any update to TSCA include certain components.

In September 2009, the Administration announced the attached set of six principles to update and strengthen TSCA. The principles are:

Principle 1: Chemicals Should Be Reviewed Against Safety Standards That Are Based on Sound Science and Reflect Risk-based Criteria Protective of Human Health and the Environment.

Principle 2: Manufacturers Should Provide EPA With the Necessary Information to Conclude That New and Existing Chemicals Are Safe and Do Not Endanger Public Health or the Environment.

Principle 3: Risk Management Decisions Should Take into Account Sensitive Subpopulations, Cost, Availability of Substitutes and Other Relevant Considerations.

Principle 4: Manufacturers and EPA Should Assess and Act on Priority Chemicals, Both Existing and New, in a Timely Manner.

Principle 5: Green Chemistry Should Be Encouraged and Provisions Assuring Transparency and Public Access to Information Should Be Strengthened.

Principle 6: EPA Should Be Given a Sustained Source of Funding for Implementation.

While the Administration does not have a position on the discussion draft, there are several important observations that I would like to offer. As stated in the principles above, we feel strongly that updated legislation should include improvements that will provide the EPA with the ability to make timely decisions if a chemical poses a risk and the ability to take action, as appropriate, to address that risk.

The Administration principles state that priority chemicals should be assessed and acted upon in a timely manner, with clear, enforceable and practicable deadlines for completion of chemical reviews. The discussion draft does provide the EPA with more effective authority to compel the generation of data on existing chemicals. The discussion draft should give the EPA authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. We believe this authority is vitally important to assuring the American public that the chemicals that they find in the products they buy and use are safe.

The discussion draft includes two means by which risk evaluations could be initiated for existing chemicals under section 6. The first is that EPA would be required to conduct a risk evaluation

upon a finding that the combination of hazard from and exposure to a particular chemical substance has the potential to create an unreasonable risk of injury to health or the environment. The second allows for a chemical manufacturer to request that EPA conduct a risk evaluation for a particular chemical substance. In practice, this would likely lead to EPA focusing the majority of its limited risk evaluation resources on completing evaluations for chemical substances requested by industry, which, once requested, start the clock ticking on a number of deadlines. This could result in evaluations for the chemicals with the most potential for risk being put off indefinitely, while EPA works on the evaluations requested by industry.

Additionally, the requirement that EPA make an affirmative finding of the potential for unreasonable risk, prior to initiating a risk evaluation, creates a possible analytical “catch-22” in which EPA must make a finding regarding the potential for risk prior to beginning the risk evaluation process. I note that once the EPA is able to conduct an evaluation that finds risk, the discussion draft appears to impose rigorous deadlines for taking regulatory action to reduce those risks. However, in many cases the deadlines in the draft are unreasonably short, which we would be happy to discuss with committee staff at the appropriate time.

As stated earlier, the use of section 6 of TSCA to limit or ban a chemical that poses a significant risk has been a major challenge. The discussion draft clearly removes TSCA’s requirement that the EPA demonstrate it is using the least burdensome requirements needed to provide adequate protection. Administration Principle 1 states that chemicals should be reviewed against a safety standard based on sound science and risk-based criteria protective of human health and the environment. By this, we mean that assessment of safety should not include consideration of

costs or the availability of substitutes. The draft appears consistent with Principle 1 in that it specifies that risk assessments should include consideration of information on potentially exposed subpopulations but not information on cost and other factors not directly related to health or the environment. The discussion draft is ambiguous on how EPA is to incorporate cost and other factors into a risk management rule under section 6(a).

A chemical safety program is not credible if it is clear that resources are inadequate to do the work that is necessary to determine safety. In the current discussion draft, while the cap on fees is eliminated, there are not provisions that ensure EPA will be given a sustained source of funding for implementation, as articulated in Principle 6.

The discussion draft is consistent with the Administration principles in the area of transparency and availability of information on chemicals, including giving the EPA the ability to share chemical data with state, local and tribal governments.

Mr. Chairman, thank you again for your leadership on TSCA reform. I will be happy to answer any questions you or other members may have.

APPENDIX: Essential Principles for Reform of Chemicals Management Legislation

The U.S. Environmental Protection Agency (EPA) is committed to working with the Congress, members of the public, the environmental community, and the chemical industry to reauthorize the Toxic Substances Control Act (TSCA). The Administration believes it is important to work together to quickly modernize and strengthen the tools available in TSCA to increase confidence that chemicals used in commerce, which are vital to our Nation's economy, are safe and do not endanger the public health and welfare of consumers, workers, and especially sensitive sub-populations such as children, or the environment.

The following Essential Principles for Reform of Chemicals Management Legislation (Principles) are provided to help inform efforts underway in this Congress to reauthorize and significantly strengthen the effectiveness of TSCA. These Principles present Administration goals for updated legislation that will give EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals.

Principle No. 1: Chemicals Should Be Reviewed Against Safety Standards That Are Based on Sound Science and Reflect Risk-based Criteria Protective of Human Health and the Environment.

EPA should have clear authority to establish safety standards that are based on scientific risk assessments. Sound science should be the basis for the assessment of chemical risks, while recognizing the need to assess and manage risk in the face of uncertainty.

Principle No. 2: Manufacturers Should Provide EPA With the Necessary Information to Conclude That New and Existing Chemicals Are Safe and Do Not Endanger Public Health or the Environment.

Manufacturers should be required to provide sufficient hazard, exposure, and use data for a chemical to support a determination by the Agency that the chemical meets the safety standard. Exposure and hazard assessments from manufacturers should be required to include a thorough review of the chemical's risks to sensitive subpopulations.

Where manufacturers do not submit sufficient information, EPA should have the necessary authority and tools, such as data call in, to quickly and efficiently require testing or obtain other information from manufacturers that is relevant to determining the safety of chemicals. EPA should also be provided the necessary authority to efficiently follow up on chemicals which have been previously assessed (e.g., requiring additional data or testing, or taking action to reduce risk) if there is a change which may affect safety, such as increased production volume, new uses or new information on potential hazards or exposures. EPA's authority to require submission of use and exposure information should extend to downstream processors and users of chemicals.

Principle No. 3: Risk Management Decisions Should Take into Account Sensitive Subpopulations, Cost, Availability of Substitutes and Other Relevant Considerations

EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns.

Principle No. 4: Manufacturers and EPA Should Assess and Act on Priority Chemicals, Both Existing and New, in a Timely Manner

EPA should have authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. Clear, enforceable and practicable deadlines applicable to the Agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive sub-populations

Principle No. 5: Green Chemistry Should Be Encouraged and Provisions Assuring Transparency and Public Access to Information Should Be Strengthened

The design of safer and more sustainable chemicals, processes, and products should be encouraged and supported through research, education, recognition, and other means. The goal of these efforts should be to increase the design, manufacture, and use of lower risk, more energy efficient and sustainable chemical products and processes.

TSCA reform should include stricter requirements for a manufacturer's claim of Confidential Business Information (CBI). Manufacturers should be required to substantiate their claims of confidentiality. Data relevant to health and safety should not be claimed or otherwise treated as CBI. EPA should be able to negotiate with other governments (local, state, and foreign) on appropriate sharing of CBI with the necessary protections, when necessary to protect public health and safety.

Principle No. 6: EPA Should Be Given a Sustained Source of Funding for Implementation

Implementation of the law should be adequately and consistently funded, in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that EPA is meeting

that goal. To that end, manufacturers of chemicals should support the costs of Agency implementation, including the review of information provided by manufacturers.

Mr. SHIMKUS. Thank you very much for your opening statement, and I appreciate the comments. I would like to turn to Chairman Upton and thank him for his friendship and support as we move forward, and you're recognized for 5 minutes.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Well, thank you, Mr. Chairman.

It is today an important milestone as we work to bring our chemical safety laws into the 21st century, and I thank Chairman Shimkus for his bipartisan member-to-member work bringing this legislation before the subcommittee. I also commend the ranking member of the full committee, Mr. Pallone, for collaborating across the aisle to develop a proposal that in fact we can all embrace.

We have heard from a diverse cross-section of stakeholders that TSCA needs modernizing. When first enacted nearly four decades ago, the structure was a bit of an experiment. When our predecessors on this committee designed TSCA, they were clearly attempting to reconcile diverse points of view within Congress and with the American public. But our challenge today is the same, but now we have the benefit of experience. Our witnesses include the administration's main point person on chemical regulation, industry experts with global regulatory experience, and a person who manages a chemical business on a day-to-day basis. As someone responsible for meeting the payroll, she may have the most valuable experience of all. We look forward to all of your testimony today as we collectively work together in the days ahead to get the project done.

Last year we spent lots of hours, countless hours, trying to develop bipartisan legislation only to find that we put more issues on the table than we could resolve. Drawing on that lesson, this year's bill is a little bit more focused.

First, it kicks the starting process of selecting chemicals already in commerce for risk evaluation and, if necessary, rulemaking to mitigate that risk. From among chemicals already on the market, EPA selects ones that it sees as potentially posing an unreasonable risk. Second, the bill also lets the market select chemicals for risk evaluation by allowing a manufacturer to ask for and pay for an evaluation. In either case, the risk evaluation must stand up to rigorous scientific standards set out in the legislation. If EPA does identify an unreasonable risk, it must turn immediately to drafting a rule tailored to mitigate that risk. These rules will focus on the danger at hand. Once written, those rules will be shared by all Americans. Rooted in science, the EPA decisions will obviate State-by-State attempts to regulate interstate markets, and everyone from moms in Michigan to consumers around the world will have the confidence that a chemical cleared by EPA won't harm them or their families. So let's continue the bipartisan momentum and get this legislation through the committee and the full House. This is the year for meaningful reform.

I again want to particularly thank Mr. Shimkus for his strong work to get a bill to the plate where we can finally get some runs scored. Yield back.

[The prepared statement of Mr. Upton follows:]

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Let's continue the bipartisan momentum and get this legislation through the committee and the full House. This is the year for meaningful reform.

Mr. SHIMKUS. The gentleman yields back his time. The Chair now recognizes the ranking member of the full committee, Mr. Pallone, for 5 minutes.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

I am pleased to be here today to continue this subcommittee's important work to reform the Toxic Substances Control Act. Chairman Shimkus' new discussion draft, the TSCA Modernization Act of 2015, is a thoughtful and innovative approach that has the potential to move chemical regulation forward. The chairman and the majority staff have worked closely with Democratic members, including our ranking member, Mr. Tonko, to improve this draft, and I am happy to say that our work is ongoing. I look forward to hearing from EPA, affected industries, and environmental stakeholders this morning to plot a course forward and begin to strengthen this draft.

Improving the Federal Government's ability to identify and manage risks from the chemicals that are manufactured and processed in this country is critical. For 6 years now, there has been wide-

spread agreement among industry, labor, and nongovernmental organizations that TSCA needs to be reformed.

In 2009, the EPA Administrator said that TSCA had proven to be “an inadequate tool for providing the protection against chemical risks that the public rightfully expects.” The American Chemical—or I should say, the American Chemistry Council said it wanted to work with stakeholders, Congress, and the administration to make reform a reality. And a coalition of public interest groups said that by updating TSCA, Congress can create the foundation for a sound and comprehensive chemicals policy that protects public health and the environment while restoring the luster of safety to U.S. goods in the world market.

At that time, stakeholders and policymakers pursued a vision of a fully reformed TSCA, ensuring that no chemical would go on the market without being found to be safe. All chemicals in commerce would be subject to minimum testing, and aggressive regulation would ensure to the American public a reasonable certainty of no harm from the chemicals they are unwittingly exposed to every day. Six years later, that vision is still my goal but the risks from toxic chemicals in our environment and the products we use every day are serious and pressing, and progress toward that vision has been elusive.

This new discussion draft does not attempt to realize the goal of a fully reformed TSCA with assurances that all chemicals in commerce are safe but it will give EPA tools to reduce risk now, in a package that I think has the potential to become law, and it will give consumers the ability to choose chemicals and products that have been reviewed for safety against a purely risk-based standard.

Under this draft, EPA would have the ability to require testing through orders, rather than just rulemaking. That is an important step forward, although it won't fix all of the problems in Section 4 of the existing law. The draft would also ensure that EPA's determinations of unreasonable risk under section 6 of current law will be made without consideration of costs and with explicit protections for vulnerable populations. EPA would then be able to move forward with risk management without the paralyzing requirement to select the least burdensome option. These too are essential steps forward, although issues in section 6 still remain.

Additionally, the draft would remove outdated limits on user fees to provide more resources for EPA's activities under TSCA, although it could do more to ensure that EPA actually receives those funds. The draft also would direct EPA to update the TSCA inventory, providing better information to consumers and policymakers on the universe of chemicals in commerce in the United States, and the draft would require substantiation of CBI claims in the future, preventing abuse of CBI claims and ensuring greater transparency. These are all positive changes that would empower EPA to offer greater protections for human health and the environment. Importantly, the draft also avoids some of the significant concerns that have been raised about past proposals, such as limits on the ability of EPA to regulate articles and limits on the ability of States to be partners in enforcement.

This bill reflects robust bipartisan outreach, which I hope to continue in the coming weeks. Mr. Chairman, you deserve credit for

a strong process so far, and a strong product. Some important issues remain to be worked out, such as setting yearly targets for EPA initiated risk evaluations, ensuring that private rights of action are protected, and targeting risks from the worst of the worst chemicals, PBTs. So I hope we can come together to strengthen this proposal and produce a law.

I welcome the testimony from today's witnesses, which will point the way for further work on a bipartisan basis. We have all, Mr. Shimkus, myself, Mr. Tonko and of course Mr. Upton, we really consider this a goal that can be accomplished on a bipartisan basis, and I just want to thank everyone for all their hard work, particularly over the last 2 weeks. You know, we had a recess for 2 weeks but the staff were certainly not in recess. They were working very hard on this bill.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

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I hope we can come together to strengthen this proposal and produce a law. I welcome the testimony from today's witnesses, which will point the way for further work.

Thank you.

Mr. SHIMKUS. Thank you. I also want to thank you for your personal involvement, and we were working. There was a conference call for about an hour, and I think you were on the road somewhere and I was on the road somewhere, and staff was here, and it was a good start, so people were working hard, and I appreciate it.

Now I would like to recognize 5 minutes to start the questions, and Mr. Jones, how many chemicals already on the market is EPA currently assessing on a yearly basis? And I think check the microphone.

Mr. JONES. I am sorry.

Mr. SHIMKUS. That is all right.

Mr. JONES. Thank you. We identified about 80 chemicals several years ago for assessment. We have assessed final assessments for five of them, and we have about 20 under evaluation right now, so it is hard, since we are so early in the early days of attempting to evaluate existing chemicals, it is hard to right now estimate exactly how many per year we are doing. Somewhere in the range between three and eight I would say would be an accurate number.

Mr. SHIMKUS. To evaluate, let's say, 20 chemicals per year, how much many and staff would you need? Do you have—

Mr. JONES. I would think we would need at least twice the existing chemical resources we have right now to do 20 a year.

Mr. SHIMKUS. Would the discussion draft, particularly the section—you kind of highlighted part of this in your testimony—requiring manufacturers to pay all costs related to the requested reviews all you, the EPA, to have more chemicals evaluated?

Mr. JONES. Yes. One of the tricks that we have observed in the way the bill is drafted is that those resources actually don't come to EPA, and so they go to the Treasury, and so we are limited by the appropriated resources that we have, so it doesn't really expand our capacity.

Mr. SHIMKUS. Yes. Is there—and that is why we have the hearing and stuff because—I am being whispered in my ear that you are right, so we obviously—the intent is for—if there are user fees,

the whole intent is for you to be able to get access to it so you can have the ability. And so if there are ways that you get your smart people involved and we get our smart people involved, maybe there is—I don't know what we can do but we need to make sure that that happens. I think that is the intent—what is that, Mr. Chairman? I know I am not the smart guy.

Does the discussion draft improve the agency's ability to require the submission of hazard and exposure data by authorizing the EPA to obtain it by rule, consent agreement, or by issuing an order?

Mr. JONES. Yes, it does.

Mr. SHIMKUS. Does the discussion draft allow EPA to select and do risk evaluations on chemicals whose exposures and hazards have the potential to be high enough to create an unreasonable risk?

Mr. JONES. Well, it is interesting because the language creates an additional step that we don't have today and that we have to—that is why I refer to it as the potential catch-22. We actually have to make a finding before we can initiate a review, and that finding is somewhat related to risk, even though the whole point of a risk evaluation is to determine the risk. So it creates somewhat of a barrier actually to initiating a risk evaluation.

Mr. SHIMKUS. And obviously the intent of the legislation is to be, as was stated in some of the opening statements, a more slimmed-down, more efficient, more simplistic process of getting from A to B to C to judgment ruling, so we want to make sure we have that, and any help you can provide in addressing that, we would be—because look at schematics of current law, and you look at schematics of other possible laws, they are much more complex, and we would like to—our intent is not to be—our intent is just to get the job done.

Mr. JONES. I think that could be achieved.

Mr. SHIMKUS. The discussion draft excludes cost considerations when EPA performs risk evaluations, saving that issue for when and if a risk-management rule is written. Do you agree that the risk evaluation should focus on hazard and exposure?

Mr. JONES. Yes.

Mr. SHIMKUS. You testified that the discussion draft is ambiguous on how EPA is to incorporate cost and other factors into a risk-management rule under section 6A. Can you explain why you said that?

Mr. JONES. Thank you. That is probably one of the most important observations that we have around the discussion draft. So the existing standard of unreasonable risk has been interpreted by courts to be a risk-benefit balancing where the Agency has actually got to demonstrate that the health benefits of the rule literally outweigh the costs imposed by the rule. It is not clear whether or not that interpretation that exists right now would be changed at all. There are some parts of the draft that make it appear that actually cost shouldn't come into consideration in determining the level of protection achieved, but that would conflict with the cost-benefit balancing that previous courts have determined, and then there is the cost-effectiveness language, and so our observation is, it is not clear if this discussion draft is maintaining the existing cost-benefit

balancing, if it is attempting to exclude costs completely from the risk management, or if it wants costs considered but in some general way without being explicit. So it is a clarity issue from our perspective.

Mr. SHIMKUS. Thank you, and my time is expired, but I think you have raised an issue that what is the—you have courts—decisions courts have rendered and then simplistically changing a law, so my guess is, the courts would then have to render judgment under new statutes versus old statutes.

So having said that, I will recognize the ranking member, Mr. Tonko, for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair, and again, much exchange here has cited the hard work done over the last couple of weeks, so allow me to further compliment and thank the staff for their devotion to this effort along with my colleagues.

We need TSCA reform certainly because under current law, the American public is exposed to industrial chemicals without that sufficient bit of safeguard to protect public health. So tens of thousands of chemicals in commerce have never been tested for safety, and EPA does not currently have the necessary authority or resources to tackle this backlog.

So Mr. Jones, what is EPA currently doing to address the highest-priority chemicals under TSCA?

Mr. JONES. Thank you, Congressman Tonko. So we identified—we evaluated the 1,200 or so chemicals with known hazard, and we compared them against criteria that were related to severity of hazard as well as the potential for exposure, and from that priority-setting process, we have identified a little over 80 chemicals that we think are the most important to assess first, and we have now begun to assess those chemicals.

Mr. TONKO. And then would this draft as it currently stands enable that work plan?

Mr. JONES. It sets a little bit of a higher bar than the priority process that we did in making a judgment that there is actually the potential for the exposure to exceed the hazard, which we did not do in our priority—

Mr. TONKO. Any clarification that we need to have in the language that we are proposing?

Mr. JONES. I think we don't want to create a potential unmanageable bar, I think if that might be useful.

Mr. TONKO. OK. The last thing we should do in TSCA legislation is make it harder for EPA to act against the worst chemicals. What changes could we make to ensure that the chemicals EPA thinks are the highest priority get reviewed and addressed?

Mr. JONES. Well, as I mentioned, having a requirement that we make a finding that the exposure may exceed the risk before we have actually done the risk assessment is I think an unnecessary requirement up front. And then as I mentioned earlier, I think it is important that we all have a clear understanding of what the actual risk-management standard is, and I don't think it is clear right now what that standard is, which opens the potential for there to be a lot of litigation after decisions are made.

Mr. TONKO. And adding a minimum number for EPA is a beneficial thing when it comes to initiating reviews?

Mr. JONES. If the Congress wants a certain pace to be achieved, and my experience is that being clear about what your expectations are about how quickly the Agency acts is pretty important.

Mr. TONKO. Let me focus on the role of cost considerations that the Chair was quizzing you about, and using those costs in the effort to assess and manage risks.

This bill includes, as he indicated, explicit language to indicate EPA's risk evaluation cannot take cost into consideration. The language is intended to ensure that EPA's determination of whether or not a chemical presents an unreasonable risk does not include cost considerations but cost analyses are never part of that risk. They are, however, or should be included in an analysis of the options available to reduce identified risks for risk management. So are there—and again, I heard the give and take, the bantering that you and the Chair had, but are there suggested changes that you can share that would make that effort more clear?

Mr. JONES. Yes, and this goes back to the risk-management standard Congress is trying to put into place, and the administration believes the costs are an important consideration in risk management, which is different from saying that the risk-management standard should be a risk-benefit balancing, as I have testified before. In the chemicals arena, that is a very challenging thing to do because the risks that we are looking at are often not quantifiable but the costs almost always are, and what we got out of the Corrosion Proof case was a finding that the Agency had to numerically determine that those benefits literally numerically were larger than the costs, which creates—you end up with a cost-biased standard, which has been one of the problems that we have had. So being clear about whether the Congress is looking for a cost-benefit balancing or you want a standard that requires the consideration of costs, which may not sound like it is a lot different but actually in reality it is quite different, would be very useful.

Mr. TONKO. Well, I think any kind of, you know, suggested changes would be very helpful for the subcommittee as we move forward, and I appreciate your input here today. I yield back.

Mr. SHIMKUS. The gentleman yields back his time. The Chair now recognizes the vice chair, Mr. Harper, for 5 minutes.

Mr. HARPER. Thank you, Mr. Chairman. Mr. Jones, thank you for being here today and shedding some light on a very important subject for us, and we look forward to working together on both sides of the aisle and with you on coming up with a solution that works, and I appreciate your input on the discussion draft today.

You testified that priority chemicals should be assessed and acted upon in a timely manner if the chemical poses a risk. For your work plan chemicals, have you determined that some show an unreasonable risk?

Mr. JONES. So we have demonstrated with the five assessments we have completed that three of them demonstrate risk. Two of them we said were not significant risks. But unreasonable risk under current TSCA has been interpreted by courts to mean that the health benefits outweigh the costs, and so what we are doing right now for the three chemicals where we have demonstrated significant risks were evaluating the health benefits that we have identified and comparing them to the cost of potential regulation

and ultimately we need to come up with a risk management that balances the health benefits with the costs. So that is the part of the process that we are in right now.

Mr. HARPER. So the three of the five that you are moving forward on, you haven't completed that process, correct?

Mr. JONES. That is correct. We are in that process.

Mr. HARPER. So what is the status of the risk-management rules on those particular three chemicals?

Mr. JONES. So we are right now—we have articulated the health benefits, the risk, and we are right now evaluating the cost of potential regulation, which also involves looking at evaluating the risks and the benefits of the alternatives and determining whether or not we have figured out the least burdensome way to adequately protect against the risk.

Mr. HARPER. You know, when you have those five that you were looking at, ruling two of those, did you start the process on all five at the same time?

Mr. JONES. Yes, we did.

Mr. HARPER. And are they supposed to proceed at the same pace, or I assume each one can be at a different level, but are you proceeding—are the three that you are looking at, are they at the same spot in the process?

Mr. JONES. They are actually, although that is a little bit by happenstance because sometimes you run into a difficult issue and it may take a little longer to resolve, but the three that we are looking at, whether or not there is unreasonable risk, they are moving at pretty much the same pace.

Mr. HARPER. Now, you said there are 80 that have been identified.

Mr. JONES. That is correct.

Mr. HARPER. And how many—who determines which ones are looked at next and assessed?

Mr. JONES. That would be me.

Mr. HARPER. OK.

Mr. JONES. We actually had a public process where we identified factors that we wanted to look at. They were factors like carcinogenicity, reproductive toxicity, persistence bioaccumulation, and we also wanted to make sure there was exposure so that we weren't looking at potentially hazardous chemicals for which nobody was being exposed. We had public participation around that at some workshops, and then we finalized the criteria, and then we evaluated about 1,200 chemicals against the criteria that we developed, and these are the ones that came out on top.

Mr. HARPER. So how many assessments do you believe will be completed this calendar year?

Mr. JONES. That is a tricky one because we are taking on some—there are at least three that will be above the five that we have done that is very clear will be completed. We are also looking at some of the most challenging compounds, which are flame retardants, and we are looking at several dozen of those, and they are quite complicated, so it is hard for me at this point to predict how many of the flame-retardant assessments we will complete.

Mr. HARPER. Yield back the balance of my time.

Mr. SHIMKUS. The gentleman yields back his time. The Chair now recognizes the ranking member of the full committee, Mr. Pallone, for 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman.

The testimony we hear today will be essential as we work to move this draft forward, and I know we have heard already today and we will continue to hear from the second panel that there are a number of changes needed to the draft, and I appreciate my colleague, Mr. Tonko, for highlighting some of those changes. I would like to focus briefly on some of the things I think this draft gets right, and if you can to just answer yes or no, but I am not going to restrict you completely. I just want to get through it.

First, I would like to highlight some of the problems in current law that I think this draft addresses. So Mr. Jones, does this draft remove the least-burdensome language that has been an obstacle to EPA action under section 6?

Mr. JONES. Yes.

Mr. PALLONE. Does the draft remove the statutory cap on user fees in existing law?

Mr. JONES. Yes.

Mr. PALLONE. Is it your view that the draft needs to do more to ensure that EPA actually receives adequate resources to carry out this program?

Mr. JONES. Yes, and I would just say it is because the draft as written right now does not allow the fees to come to EPA.

Mr. PALLONE. OK. Would you have any recommendation in that regard?

Mr. JONES. We could work with the committee to figure out how to write that. We have done this before.

Mr. PALLONE. OK. Well, I just hope that we can make changes to ensure that EPA has the resources as we move forward. Otherwise, you know, what goes is it?

Turning back to the draft, does this draft require justification of future CBI claims, unlike current law?

Mr. JONES. Yes.

Mr. PALLONE. And does this draft provide explicit protections to vulnerable populations and therefore improve current law?

Mr. JONES. It is a little ambiguous. It precludes EPA from determining a chemical meets the safety standard unless we have evaluated vulnerable populations but doesn't speak to scenarios where we find that the safety standard is not met.

Mr. PALLONE. OK. I think these are all very important points, and I recognize that the draft is not as comprehensive as some past proposals, but I think it would move the ball forward on chemical regulation and improve current law.

I also wanted to recognize again the subcommittee chairman, Mr. Shimkus, because he has tried to avoid some of the major issues that have stalled proposals in the Senate. So let me ask you about some of that.

Mr. Jones, I know that you raised concerns about article provisions in the Senate bill. Are those concerns addressed here?

Mr. JONES. Yes, they are.

Mr. PALLONE. OK. And you also raised some concerns about the ability of States to co-enforce requirements of EPA TSCA rules and

to regulate chemicals while EPA is evaluating them. Are those concerns addressed here?

Mr. JONES. Yes.

Mr. PALLONE. OK. I think this draft is a good starting point. Obviously we still have a lot of work to do, but we have had a very good process so far, and I look forward to continuing to work with the chairman and Mr. Tonko. And so at this point, I can't believe I am actually yielding back, but I accomplished everything I wanted to accomplish.

Mr. JONES. It was my short answers.

Mr. PALLONE. Thank you.

Mr. SHIMKUS. The gentleman yields back his time, and I hope those answers are helpful to you and I hope they are not harmful to me.

So with that, I would like to yield 5 minutes to the gentleman from Ohio, Mr. Latta, for 5 minutes.

Mr. LATTA. Well, thank you very much, Mr. Chairman, and thanks very much for holding this very important hearing today, and Administrator, thanks for being with us today.

Last year when you testified before the subcommittee, in April, in fact, just about a year ago, I discussed with you the TSCA inventory. You stated how the actual number of chemicals on the TSCA inventory somewhere between 7,000 and 84,000, the 7,000 number being the rough number of chemicals produced in large quantities and overall the 84,000 representing those chemicals that have been on the inventory and how it could be potentially misleading. Let me ask, do you believe that the discussion draft before us would give a more accurate picture of the chemicals actually in commerce on any given date?

Mr. JONES. It would, yes.

Mr. LATTA. OK. And also, how effective do you believe the least-burdensome provision has been under the current law?

Mr. JONES. I think it has created a barrier under the current law.

Mr. LATTA. OK. Could you explain that, how it has created a barrier?

Mr. JONES. So for example, right now there are three chemicals that we have identified as posing significant risk, and before we can move forward regulating them, we have to evaluate about eight different risk-management scenarios that are identified in the statute and show how for each one of them we are selecting the one that poses the least burden on society at large, so we have to analyze each of these potential risk-management options and then just pick the least burdensome one, which as a general matter I don't have a problem with but it is not always necessary to evaluate everything to know which one is going to be the least burdensome ultimately and we are required to do that under the statute.

Mr. LATTA. Let me ask, how much time does that add to the process?

Mr. JONES. Well, you know, we are doing it right now for the first time in 30 years, and so I will have a clearer answer when we have actually finished that analysis, and whether or not a court ultimately upholds did we do enough analysis for each of the risk-management options that are in the statute.

Mr. LATTA. Let me ask about under the proposed draft bill before us is on the deadlines, and you know, the deadlines we are looking at that the administration will conduct and publish risk evaluation under the subsection for chemical substance not later than 3 years after the date on the Administrator makes a finding, 180 days after the date on which the manufacturer requests the risk evaluation, and it also goes on to state that if the Administrator determines that additional information is necessary to make a risk evaluation, a determination under the subsection, there is—it can be extended a date of 90 days after receipt of additional information or 2 years after the original deadline, and with that, you know, where do you see that—do you see that would be a good time frame?

Mr. JONES. You know, I think deadlines are really important for the Government to have, but they are pretty short, and the only one that I think that the Agency has some potential for meeting is the initial assessment if EPA initiates the review, 3 years—our experience so far is that between 2 and 3 years, so having the deadline be the latter end of it seems appropriate.

Us turning an assessment around in 6 months from an industry submission I think is unrealistically optimistic. I would love to be able to do proposed rules within 6 months of a safety evaluation. My experience is that that is also just unrealistic from past experience.

Mr. LATTA. Well, you know, with the 3 years, you know, how long on general—you are saying 2 to 3 but how many different chemicals are out there that have taken more than 3 years for you to do an evaluation on?

Mr. JONES. So it is possible that something that is hugely challenging from an exposure potential or hugely challenging from understanding the hazard that it would take longer than 3 years, I would expect that as a general matter, 3 years is a deadline that could be achieved for the vast majority of the chemicals we would evaluate.

Mr. LATTA. Well, thank you very much, and—

Mr. SHIMKUS. Will the gentleman yield the last 44 seconds?

Mr. LATTA. I yield back.

Mr. SHIMKUS. Under the industry applied evaluation, you will have more data in that process than when you just pick a chemical out of the air and say we have to do this one as our requirement under current law. Is that correct?

Mr. JONES. It is not clear that that would be the case. I assume that that was some of the assumptions that were built into that 6-month deadline. It is not obvious the way it is drafted that we would have more. The other—

Mr. SHIMKUS. Well, if the industry is willing to have you expedite this, my guess is that there would be, you know, a working relationship that—but we will work to clear that up. My assumption would be, they are going to give you what they have to try to get an expedited—I mean, that is the whole benefit of going through this process is coming to a decision.

Mr. JONES. Yes. The draft is written that all they have to do is request it, so they don't have to actually give us anything.

Mr. SHIMKUS. OK. Thank you. I thank my colleague. The Chair now recognizes the gentleman from Oregon, Mr. Schrader, for 5 minutes.

Mr. SCHRADER. Thank you, Mr. Chairman. I appreciate it.

How does the Agency currently and then under your interpretation of the new discussion draft balance individual risk and responsibility versus, you know, absolute risk, if you will, posed by certain chemicals?

Mr. JONES. That is a good question, Congressman. Right now we are looking at a compound that is used as a paint stripper, and it has actually resulted in deaths across the country over the last 15 years, and so arguably—and it results in deaths because people sometimes use it in an enclosed space, and so if you—it is theoretically possible that we could mitigate that risk by a labeling restriction, although when you look there actually is a labeling restriction right now although the fine print is quite fine, and so you try to struggle with the effectiveness of giving people information to protect themselves versus what may be the reality is to whether or not people avail themselves of that, and so it is something that we right now are struggling with, with a chemical that we have made a priority compound because, you know, individuals do have some responsibility with respect to protecting themselves, but at the same time, if past is prologue and giving information may not be effective, we think we have the ability to protect people from themselves.

Mr. SCHRADER. I think one of the struggles this committee is going to have and the Congress writ large is balancing that personal responsibility. If people are allergic to certain things and most people are not allergic to, does that make that a toxic substance generally speaking. So I think we are going to have a lot of work to do to find out what that appropriate balance is. This is still the United States of America and people do bear personal responsibility for their own health and well-being, and labeling, albeit small or large, hopefully adequately, demonstrating what potential harm it may cause to certain subpopulation is important but the real world is anything in excess is probably toxic, in popular terms, carcinogenic. Everything is carcinogenic these days. I think we have to be thoughtful and I would hop the EPA would balance their rulemaking with whatever legislation we have going forward.

I am interested in the cost-effectiveness discussion. You are interested in apparently more leeway than is now granted under this legislation. I would probably be against that. My concern is that costs should be taken into account. We have a Superfund site in my State where EPA's interpretation has gotten to where if one individual sort of maybe could have ingested a certain amount of fish on a daily basis, way in excess of what any person would do, even tribal members, that at a level that is way below the current toxicity standards, that that would pose a significant risk and needs to be mitigated by extremely expensive alternatives, and the judgment I have seen so far from EPA is that they want to have a very expensive alternative to what could be a simpler solution to I think a very exaggerated risk. So I would hope that you would take this into account. I hope that the legislation does not reduce the cost.

In fact, to me it seems pretty clear. You know, when you are determining the risk, OK, cost should not perhaps be part of the discussion, but certainly, certainly, absolutely, 100 percent cost-effectiveness should be part of, a major part of, the solution, and I would fight against any language that said cost should be just a consideration. That, to your point, is a loophole you could drive a truck through at the end of the day. So I hope you would be at least open to the current legislation as currently written.

Mr. JONES. We think it is very important for cost to be considered in the risk management. It is about how it should be considered, and as I was saying, right now it is not clear if it needs to be considered in a literal balancing of cost and benefits, and that we have stated numerous times how challenging that is for chemicals where it is always possible to estimate cost. It is often not possible to give a numeric monetization to the benefit.

Mr. SCHRADER. Well, if you can't monetize it that what can't be measured should probably be done. I mean, at the end of the day, there has to be—everyone is susceptible. There are going to be some persons, some individuals, some child, some remote genetic configuration of any given individual that is going to be at risk with any given chemical or food substance, whether it is deemed safe or not, and I think it is extremely important not to get wrapped around the axle on having completely irrelevant, with all due respect, solutions that are not actually benefit to the population writ large.

As a veterinarian, it is all about epidemiology. You are not going to save everybody at the end of the day, and we have to understand that, and I think America in this 21st century has to become sophisticated enough to understand where is the maximum risk exposure.

With that, I would like to yield the balance of my time to the chairman of the committee—or ranking member. Excuse me.

Mr. SHIMKUS. Yes, you don't want to give it to me—no, you might want to give it to me.

Mr. TONKO. Thank you. I thank the gentleman for yielding.

I would like to turn briefly to a concern I have that the draft is too specific about how the Agency should conduct science. Agency decisions must be transparent including those about science, but in my opinion, these are decisions best left to technical experts. This draft includes requirements that EPA act based on a specific definition of the weight of the scientific evidence and requires EPA to consider a lengthy list of factors including sponsor organizations, uncertainty and more.

So Mr. Jones, when these scientific requirements are included in the statute, does that open EPA's use of science up to litigation?

Mr. JONES. So any requirement that you have to do, you then either—if you don't do it, you are open to litigation. I think that the science requirement that most troubles us is the consideration of a threshold effect, which is something that we do right now, but it is certainly possible that in 10, 15, or 20 years, it is not even part of the scientific, you know, lexicon. And so boxing us into things that may become obsolete in the future scientifically are the kinds of things we would like to generally avoid.

Mr. TONKO. Thank you, and I share those concerns, and I yield back.

Mr. SHIMKUS. The gentleman yields back his time. The Chair now recognizes the gentleman from Ohio, Mr. Johnson, for 5 minutes.

Mr. JOHNSON. Thank you, Mr. Chairman.

Administrator Jones, about a year ago, you testified before this committee on TSCA reform. You may remember at that meeting, I expressed my concern to you that TSCA reporting requirements seemed to incentivize manufacturers, for example, in the electronics industry, to landfill byproducts instead of recycling them, even when those byproducts are rich in recyclable metals and other valuable materials—copper, for example. In other words, we are making it more cost-effective for manufacturers to put that stuff in the dirt than to recycle it, save money, create jobs, and be more environmentally conscious.

You may also remember that last October I sent Administrator McCarthy a letter asking the EPA to complete its analysis of data collected during the 2012 chemical data reporting, or the CDR cycle, with the idea that such an analysis would help EPA reassess the need for CDR information in future reporting cycles. In December I received a response from Administrator McCarthy that the analysis would be completed by early 2015. It is now April, and no analysis has been finalized, and while the EPA has had talks with my staff, and I know that there has been some exchange of information with industry, it has not provided the electronics industry nor the public with any new information for some time now. So because it appears that this analysis is ongoing, I remain hopeful that the EPA still has the opportunity to safely incentivize the recycling of byproducts and render any other options to solve this problem unnecessary.

But the first step must be the release of the analysis of 2012 CDR byproducts. Can you tell me when that data will be released?

Mr. JONES. Thanks, Congressman, and thank you for raising this issue to our attention. We have spent a fair amount of time evaluating the issue that you brought to our attention. We have begun to communicate with your staff as well as the electronics industry the results of our analysis. I would be reluctant to give a date on the release of the analysis before checking with my staff, but we are very close to being able to give an answer to the question that you raised.

Mr. SCHRADER. OK. Administrator McCarthy said early 2015. Is that still a projection? Are looking at the first half of this year or—

Mr. JONES. It is the first half of this year.

Mr. SCHRADER. OK. All right. Well, I look forward to getting that. I appreciate that.

What is the EPA's cost for doing the analysis that they do? Is it pretty consistent, or does the cost vary from chemical to chemical?

Mr. JONES. It is going to vary pretty significantly from chemical to chemical.

Mr. SCHRADER. OK. Can you give us an example?

Mr. JONES. Yes. So the first five chemicals that we looked at, we project that the regulation for those that we think bear consideration of regulation will cost about a million and a half dollars, and the analysis will have been a million dollars. That applies to three of them, and so the chemicals that demonstrated some risk are significantly more expensive to do than the two chemicals which did not demonstrate any risk. So when you find no risk, it is relatively cheap. There we estimated about a million dollars, so actually much of the cost is associated with the regulatory requirements of the analysis necessary to support a regulation.

Mr. SCHRADER. You just said something that maybe I misunderstood you. Why would you be considering regulating a chemical that provides no risk anyway?

Mr. JONES. I am sorry. I must have stated it backwards.

The chemicals that demonstrated risk are the ones that we are doing regulatory analysis for to support a potential regulation.

Mr. SCHRADER. OK. All right.

The discussion draft gives the EPA to select a chemical substance for risk evaluation under TSCA section 6. Would the EPA rely on information that is currently available to the Agency to make those selections?

Mr. JONES. That is now we would intend to—

Mr. SCHRADER. That is how you put those in the risk category?

Mr. JONES. Yes.

Mr. SCHRADER. OK. I think I have only got 34 seconds left, and I can't get this last one in. Mr. Chairman, I will yield back some of my time.

Mr. SHIMKUS. The gentleman yields back his time. The Chair now recognizes the gentleman from Texas, Mr. Green, for 5 minutes.

Mr. GREEN. I am sitting in as the ranking member. Mr. Tonko had to go, although Paul from New York doesn't really want me from Texas doing it.

Mr. SHIMKUS. You better take down that placard because you might hurt him.

Mr. GREEN. Yes, I don't want to get him in trouble.

Thank you for being here. I particularly want to thank Chairman Shimkus and Ranking Member Tonko and our ranking member and Chair of the full committee for working on this issue. It has been frustrated because it has been a law since 1976, and I know for the last two terms this subcommittee has tried to see how we could deal with it, but it sounds like, you know, we will go small and see what we can do and do just problem-solving, which I think is a great way to go.

If enacted, would the TSCA Modernization Act improve EPA's ability to make a risk determination and a risk-management plan for existing chemicals?

Mr. JONES. That is an interesting question. For the way it is structured right now, because the only things—because the way the fees don't come to the Agency for industry-submitted requests, it would absolutely make it clearer what we had to do and how many. We have to do whatever they submitted to us. But because we are not getting the fees, I think it would crowd out our ability to initiate any on our own. Now, if there is a solution that allows

the fees to come to EPA, then I think it would clearly allow us to have more pace to existing chemicals program.

Mr. GREEN. OK. Would the discussion draft retain the current TSCA timing of preemption of State and local action?

Mr. JONES. Basically, yes, it would retain the—it would eliminate the—it would basically be similar to what is currently required in TSCA, marginally different.

Mr. GREEN. Under the discussion draft, would risk determination be based solely on health and safety factors without consideration of cost?

Mr. JONES. The risk evaluation would, yes.

Mr. GREEN. Currently, the EPA is allowed to disclose confidential business information to State and local government officials. Is that part of this package?

Mr. JONES. Currently it is quite difficult to do that but under this provision, the provision in the discussion draft, it would make it quite straightforward to do that.

Mr. GREEN. OK. Will the discussion draft allow EPA to disclose the confidential business information to the—well, strike that. Under current TSCA, is EPA allowed to disclose CBI to a treating doctor or a healthcare professional?

Mr. JONES. It is quite—that is what I was saying. It is quite burdensome for us to do that right now, which is something that—

Mr. GREEN. Would this discussion draft help with that?

Mr. JONES. Yes.

Mr. GREEN. Would the discussion draft authorize the EPA to disclose—well, I take that back again. Under current law, is there any limit to the length of time for confidential business information claim?

Mr. JONES. No.

Mr. GREEN. Under the discussion draft, would there be any time limits?

Mr. JONES. Yes, 10 years.

Mr. GREEN. OK. The discussion draft creates a new term, “potentially exposed subpopulations.” Under the definition provided in the discussion draft, would the thousands of chemical plants that I have and the people that work there and the people that live around it in our district be covered under the definition of potentially exposed subpopulations?

Mr. JONES. It is certainly possible that they would be, yes.

Mr. GREEN. Now, obviously you want those jobs there but we also want to make sure that the products they are producing that our country needs are safe as possible. In your testimony, you note the discussion draft lacks a sustained source of funding for the chemical safety management, which goes back to the funding. Would you recommend to our subcommittee the best way to address that concern?

Mr. JONES. I think it is a relatively straightforward fix that has the funding that is designated here going to the EPA, which right now it would not go to the EPA.

Mr. GREEN. And I think that is something we will consider. Are there current statutes that provide a sustained source of funding that could be used as a model for TSCA reform?

Mr. JONES. Yes, both the drug law—PDUFA is the acronym—or the pesticide law, the Pesticide Registration Improvement Act, both have funding mechanisms.

Mr. GREEN. You state in your testimony that EPA strongly feels that any update to TSCA must provide the agency with the ability to make timely decisions and the ability to take action to address that risk. Do you believe that the discussion draft provides the agency with the needed authority to make those timely decisions?

Mr. JONES. The timeliness is clear. As I said earlier, I think that the ambition is quite impressive and perhaps not manageable. I think the part that I am struggling is looking for more clarity as to exactly what the risk-management standard is so we are not fighting in litigation forever about what it actually means.

Mr. GREEN. And I agree. I would hope when we finish it, we give the clarity that you need so there is no question at all. In fact, EPA is downstairs in the Energy and Power Subcommittee so you all are regular guests here in our committee.

Mr. JONES. We carpooled over.

Mr. GREEN. But any suggestions I know we would all appreciate that. And do you believe the discussion draft gives the EPA the authority to address the identified risk? If not, what changes would we need to ensure the Agency has that authority?

Mr. JONES. Again, that goes back to clarity of what the risk-management standard is is important.

Mr. GREEN. Thank you, Mr. Chairman. I know I am over time. I appreciate it.

Mr. SHIMKUS. The gentleman yields back his time. The Chair will now look to my colleague from Indiana, Mr. Bucshon. Do you waive?

Mr. BUCSHON. I waive.

Mr. SHIMKUS. The Chair now recognizes the gentlelady from Colorado, Ms. DeGette. It is good to have her back. She was very active last Congress, and we are glad to see her here with us.

Ms. DEGETTE. Thank you very much, Mr. Chairman. I really appreciate you having this hearing, but even more so, I appreciate the amount you have worked with Mr. Green, myself, Mr. Tonko and others on really trying to make progress on this path to TSCA reform. It is not easy as we all had been saying. If it was easy, it wouldn't have taken us 30 years to fix it.

And thank you, Assistant Administrator Jones, for coming over to give us some thoughts this morning. I want to start by looking at EPA's ability to require testing of chemicals under the draft. This discussion draft includes an important change to EPA's authority under section 4 of TSCA by empowering the EPA to require testing through order rather than rulemaking.

So if you can talk to us about how order authority will improve your ability to require testing under section 4, that would be great.

Mr. JONES. Sure. Right now we are required to do a rule if we want to compel the generation of health and safety data for a chemical, and we are also required to make a finding that we have some reason to believe there may be an unreasonable adverse effect for such chemicals, so you get into this kind of a catch-22. You want the data because you don't know but you need to know something before you compel it, and then you have to do a rule, and

rulemaking is a very long process and so it can take many, many years. So an order authority would allow us to move much more quickly to require generation of health and safety data.

Ms. DEGETTE. Do you have any sense about on an average how much more quickly that would be?

Mr. JONES. Well, in our pesticides program, we have order authority and have had it for 40 years, and when we find that there is data that we need to require, we are able to issue orders in matters of months as opposed to 4 or 5 years.

Ms. DEGETTE. OK. Now, that change was one that I had sought in section 4 but this draft doesn't seem to address the catch-22 that EPA has long faced, and you talk a little about it. It seems that under this draft, the EPA would still have to find that a chemical might present an unreasonable risk before they were required—before they could require testing, and that is what you were just talking about.

Mr. JONES. So the way we have read the discussion draft, Congresswoman, is that to issue an order, we don't need to make that finding, so that seems to be addressed. It is in the context of to initiate a risk evaluation, we need to have some reason to believe the exposure exceeds the hazard.

Ms. DEGETTE. And so how do you think the language, or do you think the language can be adjusted in this discussion draft to reflect that issue?

Mr. JONES. I think it would be relatively straightforward to do that instead of having some reason to believe exposure exceeds hazard, have some reason to believe there is exposure, have some reason to believe there is hazard.

Ms. DEGETTE. OK. So it is the "exceeds hazard" that is the issue?

Mr. JONES. Yes, I think so.

Ms. DEGETTE. If you could work with us to supplement your response to give us some technical assistance on that, that would be really helpful. We would appreciate it.

In addition to granting the EPA order authority to require testing, the discussion draft also includes a provision to allow manufacturers to request that EPA evaluate their chemicals for safety. The discussion draft requires the EPA to make a finding on any evaluations requested by companies within 6 months. Is that going to be enough time to perform a robust evaluation of a chemical?

Mr. JONES. I don't think so, no.

Ms. DEGETTE. How long does the evaluation of a chemical usually take?

Mr. JONES. It usually takes a couple of years, and this was the conversation the chairman and I were having that the discussion draft doesn't require the manufacturers to submit all the data necessary to do an evaluation. If it did, it would still require a couple of years. And so they could just say I want you to evaluate my chemical. The other thing is that when there is a controversy around the chemical, it is often the case that EPA's interpretation of the data doesn't agree with the manufacturer's.

Ms. DEGETTE. So do you think there is some language we could put together to tighten that up a little bit?

Mr. JONES. It would seem like it is more about how much time the Agency should have to do—

Ms. DEGETTE. So maybe, Mr. Chairman, that is something we can talk about as we go forward.

Mr. SHIMKUS. Would the gentlelady yield?

Ms. DEGETTE. I would be happy to.

Mr. SHIMKUS. I still think there is this debate about what is industry going to provide, and that was the whole part.

Ms. DEGETTE. Right.

Mr. SHIMKUS. If they are providing a lot of data, then the timelines may be legit, so we will visit that.

Ms. DEGETTE. OK. Good. All right.

The last thing is that the discussion draft proposes amending section 9 of TSCA to allow the EPA to set fees to help defray the costs of additional chemical testing but it doesn't flag funds to be used specifically for that purpose. So my question is, does the Office of Chemical Safety and Pollution Prevention have sufficient funds appropriated to undertake additional testing of new chemicals under TSCA?

Mr. JONES. Not as written in the discussion draft.

Ms. DEGETTE. So if we had some kind of a dedicated fund rather than just solely relying on appropriations, would that be of assistance?

Mr. JONES. Yes, it would.

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. SHIMKUS. The gentlelady's time is expired. The Chair now turns to Mr. Cramer from North Dakota for 5 minutes. Do you waive?

Mr. CRAMER. I would yield to Mr. Hudson.

Mr. SHIMKUS. The gentleman has yielded to Mr. Hudson, who is recognized for 5 minutes.

Mr. HUDSON. Thank you, Mr. Chairman.

Thank you for being here today. I appreciate your testimony. It has been very informative.

My first question: TSCA as amended by the discussion draft requires that the agency have a need for testing and exposure information before it imposes a requirement on manufacturers and processors to develop that information. Is that a good requirement?

Mr. JONES. I believe so, yes.

Mr. HUDSON. All right. Last year you asked that each chemical evaluation have a deadline for completion. Are the deadlines in our bill about right for that?

Mr. JONES. I rarely say this: They are a little too short.

Mr. HUDSON. Really? Well, what do you think they ought to be?

Mr. JONES. Well, I think that we can complete assessments within 3 years. I don't think we can even with industry-submitted data complete an industry-submitted assessment in 6 months. As much as I would love to do a rulemaking in 6 months, I think we probably need upwards of 2 years to do a rulemaking.

Mr. HUDSON. EPA has authorized some 90 chemicals as TSCA work plan chemicals. Does the discussion draft require a change to that program?

Mr. JONES. It requires us to make a finding that is above and beyond what we did in the identification of the priority chemicals.

Mr. HUDSON. Well, would work plan chemicals likely be selected for risk evaluations under the House discussion draft?

Mr. JONES. They would likely be but, again, we would have to do one additional step that we have not done heretofore, make a determination that we think it is likely or possible that the exposure exceeds the hazard, which we have not done.

Mr. HUDSON. Gotcha. I have got a question as far as fees, collection of fees currently. How does the Agency currently collect user fees under TSCA?

Mr. JONES. We only have a few right now for the submission of a new chemical under the premanufacturer notification program. Those fees don't come to EPA either, so except for some small businesses, manufacturers when they submit a new chemical to EPA for review submits a fee with that.

Mr. HUDSON. And those go back to the Treasury?

Mr. JONES. They go back to the Treasury.

Mr. HUDSON. What is your budget breakdown by category for individual sections of TSCA?

Mr. JONES. I would need to get back to you on that but we could provide that pretty quickly.

Mr. HUDSON. I would appreciate it if you would do that. What is the EPA budget in both funding and FTEs for chemical review under section 5 and under section 6 of TSCA?

Mr. JONES. Again, that would be part of what we would get back to you on, overall budget breakdown between existing chemicals and new chemicals.

Mr. HUDSON. OK. Well, I would appreciate that information, and I thank you.

Mr. SHIMKUS. Would the gentleman yield?

Mr. HUDSON. I yield back to the chairman.

Mr. SHIMKUS. Just a follow-up. So on new chemicals, you have 90 days, and then with the possibility of an additional 90 days?

Mr. JONES. Um-hum.

Mr. SHIMKUS. And so we are saying on existing chemicals, it will take 3 years? That is just part of the date we are having.

Mr. JONES. Yes.

Mr. SHIMKUS. You will have to explain to me why—not now but you will have to explain to me why that is, and with that, I yield back the time and now, she has been very patient, my colleague from California, Ms. Capps, for 5 minutes.

Mrs. CAPPS. Thank you, Mr. Chairman, first of all, for holding the hearing, and our witness for your testimony.

Under current law, TSCA has used an “unreasonable risk” standard to evaluate the safety of a chemical. This is understood to be a cost-benefit standard, which in effect requires the Agency to balance the economic value of a chemical against the adverse health effects such as cancer, autism. Besides posing serious ethical problems, this approach has also proven to be unworkable.

Mr. Jones, what is the impact of this cost-benefit standard in the context of TSCA?

Mr. JONES. Well, as I have mentioned, it is often very difficult for certain health outcomes to the way in which we do risk assessment to monetize them. Some we are able to. There are some carcinogens which we are able to monetize. There are some pollutants like particulate matter where we are able to monetize. In the case of a chemical that we are looking at right now where death is the

outcome, we can monetize that. There are some outcomes the way our risk assessment is designed, we are not able to monetize them, and so our ability to say that these benefits literally outweigh these costs is challenging. It is not impossible but it creates a challenge for us.

Mrs. CAPPS. So since 2009, there has been widespread agreement that this cost-benefit standard does need to be abandoned. This subcommittee has repeatedly received testimony that TSCA's current safety standard is failing to protect the general public and particularly vulnerable populations. EPA, the American Chemistry Council, even oil refineries have all stated that cost should not be part of safety determinations under TSCA. I welcome the changes in the discussion draft to explicitly exclude costs from risk evaluations but I am not sure they go far enough.

So my question, Mr. Jones, is: do you think changes are needed in this draft to ensure the safety of chemicals as evaluated against a purely health standard?

Mr. JONES. Well, what I said so far today is that right now it is just ambiguous as to what the standard is, and that I think is critically important so we don't spend, if this were to become law, the next 30 years litigating what the standard is. The administration has said that the safety evaluation should be risk-based. but the administration has also said that cost should be a consideration in the risk management.

Mrs. CAPPS. Right. I hope you will work with this committee because we intend to, I hope, move forward to ensure the language gives effect to that kind of intent.

Another important component of the safety standard in any TSCA proposal is protection for vulnerable populations. Vulnerable populations include infants and children, the elderly and disabled, workers, and those living near chemical facilities. In their 2009 report, *Science and Decisions*, the National Academy of Science recommended that vulnerable populations should receive special attention at all stages of the risk assessment process.

Mr. Jones, do you agree that it is important to address risks to vulnerable populations when managing chemical risks under TSCA?

Mr. JONES. Yes.

Mrs. CAPPS. I am pleased to see this draft includes an explicit protection for vulnerable populations blocking EPA from finding that a chemical does not present an unreasonable risk if the agency finds that the chemical presents an unreasonable risk for a vulnerable subpopulation. In other words, if a chemical fails to meet the standard for a subpopulation, it doesn't meet the standard, period.

Mr. Jones, do you think that requirement is going to provide the protection that we need for vulnerable populations?

Mr. JONES. It is interesting, Congresswoman Capps. When we make the determination that a chemical doesn't pose an unreasonable risk, we have to make the finding you described, and this just goes back to the earlier comments for when what the actual safety standard is when we find that there is risk is not clear, and for that reason it is not clear how vulnerable populations would be included in that, so when we find there is a risk.

Mrs. CAPPS. So we need more clarity?

Mr. JONES. There needs more clarity there.

Mrs. CAPPS. Yes. And I appreciate the efforts made in this draft to ensure, and I can see now it is important to emphasize the word "draft." It probably does need to be changed along the way. Costs are left out of safety evaluations and that vulnerable populations are protected. This is sort of we are this far on it but I hope we can continue to work to improve this draft. I applaud the efforts that we have made so far but we have a ways to go to make sure that we move chemical regulation forward, and I yield back.

Mr. SHIMKUS. The gentlelady yields back her time.

Seeing no other members asking for questions, we do want to thank you for, it is obviously not long in congressional time but a legislative hearing, and we want to thank the members for being very diligent and involved and engaging in your responses. We look forward to working with you, and with that, we will dismiss you and ask for the second panel to come forward.

Mr. JONES. Thank you.

Mr. SHIMKUS. We would like to start. We want to thank the second panel for coming and appreciate you sitting through the first round. Hopefully a lot of questions will be generated based upon the comments. The way I would like to do it is, I will just introduce one at a time when their time comes for the opening statements, and again, welcome. A lot of them are familiar faces that we have seen here numerous times, so friends of the committee, I would say.

First, we would like to welcome Mr. Mike Walls, who is the Vice President of Regulatory and Technical Affairs with the American Chemistry Council. Your full statement is in the record. You have 5 minutes, and you are recognized.

STATEMENTS OF MICHAEL P. WALLS, VICE PRESIDENT, REGULATORY AND TECHNICAL AFFAIRS, AMERICAN CHEMISTRY COUNCIL; DR. BETH D. BOSLEY, PRESIDENT, BORON SPECIALTIES, LLC, ON BEHALF OF THE SOCIETY OF CHEMICAL MANUFACTURERS AND AFFILIATES; JENNIFER THOMAS, SENIOR DIRECTOR, FEDERAL GOVERNMENT AFFAIRS, ALLIANCE OF AUTOMOBILE MANUFACTURERS; AND ANDY IGREJAS, DIRECTOR, SAFER CHEMICALS, HEALTHY FAMILIES

STATEMENT OF MICHAEL P. WALLS

Mr. WALLS. Good morning, Mr. Shimkus, Mr. Tonko, and members of the—

Mr. SHIMKUS. And just if you could pull that a little bit closer.

Mr. WALLS. How is that? I don't want to break anybody's eardrums.

Thank you again for the invitation to be here today. I am very happy to testify today in support of the bipartisan discussion draft.

ACC strongly supports efforts to reform TSCA. Over the years, problems with implementation of the current statute have eroded public confidence in the Federal regulatory system, contributed to misperceptions about the safety of chemicals, and created uncertainty throughout interstate commerce.

The discussion draft is a significant milestone in the TSCA reform debate. For the first time, there is now bipartisan reform measures before each House of Congress, and while the debate over TSCA reform certainly doesn't end with this hearing, there is now a very real opportunity to achieve TSCA reform this year, and we at ACC are very encouraged by the very positive comments that members of this subcommittee have made both on the process and the substance of the draft.

Now, in 2009, ACC published a set of 10 fundamental principles for TSCA reform. The discussion draft, like S. 697, which is pending in the Senate, fully addresses all our principles. The draft addresses key issues and shortcomings in TSCA, and among the most important elements are that the draft requires that EPA evaluate risks only on the basis of health and environmental considerations. That was a key problem that has hampered implementation of the current Act to date.

Under the draft, cost and benefit considerations are relevant only in deciding what regulatory option EPA will impose to control risks. We believe the draft strengthens EPA's authority to mandate the generation of new information on chemicals. The draft also protects sensitive commercial information from disclosure while requiring appropriate upfront substantiation of those claims.

The draft also balances the interests of the State and Federal Governments by promoting a robust, uniform national chemical regulatory system.

As the subcommittee continues its discussion, some elements of the draft do require some additional clarifications. We think there is a need for additional detail and direction to EPA on the manufacturer risk initiated—sorry—the manufacturer-initiated risk evaluation process. I think you heard comments to that effect from Mr. Jones. We think it is particularly important that Congress provide clear direction and clearly articulate its expectations for that process, and at a minimum, EPA should be required to promulgate rules or appropriate guidance so that all stakeholders understand how that process can produce risk evaluations that are timely, of high quality and are reliable.

We also think it is necessary to clarify the interplay between section 6A and 6B and the presence or absence of an appropriate risk-management rule. This was one of the elements Mr. Jones mentioned at the conclusion of his testimony.

ACC also believes that EPA must have access to appropriate resources to implement a reformed TSCA. Under the draft, TSCA fee revenue is deposited to the general Treasury. We believe those funds need to be returned to EPA.

The draft also allows State governments to adopt regulations identical to those promulgated by EPA in certain cases. It would be helpful if the degree to which States may depart from the Federal approach in enforcing those regulations, if at all, should be clarified.

Again, the bipartisan discussion draft is a significant step toward achieving TSCA reform this year. We look forward to working with all members of this subcommittee to ensure that TSCA reform builds confidence in the U.S. chemical regulatory system, protects health and the enforcement from significant risks, and meets the

commercial and competitive interests of the U.S. chemical industry and the national economy.

Thank you again for the opportunity to testify. I am happy to respond to questions.

[The prepared statement of Mr. Walls follows:]



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

**Before the
U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Environment and the Economy
Regarding a Hearing on
“H.R. ____, the TSCA Modernization Act of 2015.”**

April 14, 2015

**American Chemistry Council
700 2nd Street, N.E.
Washington, D.C. 20002**

**TESTIMONY OF MICHAEL P. WALLS
ON BEHALF OF THE
AMERICAN CHEMISTRY COUNCIL**

Chairman Shimkus, Ranking Member Tonko, and members of the Subcommittee: I am Mike Walls, the Vice President for Regulatory and Technical Affairs at the American Chemistry Council. I am very happy to testify today in support of the bipartisan discussion draft of the TSCA Modernization Act of 2015. We particularly welcome the significant effort of Mr. Pallone and Mr. Shimkus to produce this discussion draft.

The discussion draft, like S. 697 under consideration in the Senate, represents significant progress toward the objective of TSCA reform this year. We are 6 ½ years into a debate on changes to a major federal environmental statute that has not been significantly amended since it was enacted nearly 40 years ago. It is well past time that TSCA reform moves forward; the discussion draft is a major milestone toward that goal.

The discussion draft addresses the key issues and questions that have been raised by stakeholders in long debate on TSCA reform. In ACC's view, the discussion draft:

- Ensures that the Environmental Protection Agency (EPA) evaluates the risks of priority chemical substances under their conditions of use.
- Accelerates the evaluation of chemical substances in commerce by providing manufacturers an opportunity to submit the hazard, use and exposure and other information necessary for EPA to efficiently evaluate risks, while ensuring a source of funds to review that information.
- Establishes aggressive deadlines for EPA decisions on risk evaluations and to adopt any necessary regulatory measures.
- Mandates that risk evaluations be made only on the basis of health and environmental considerations.

- Clarifies that cost and benefit considerations are relevant only in deciding what risk management measure should be imposed to ensure the use of a substance does not pose unreasonable risks.
- Ensures that potentially exposed subpopulations are fully considered in evaluating the risks of priority chemicals under their conditions of use and in any necessary risk management measures.
- Strengthens EPA's ability to require the generation of new information on chemicals.
- Requires EPA to make decisions on the basis of the best available scientific information, on the basis of the weight of the evidence.
- Provides appropriate protection to confidential business information.
- Appropriately balances the interests of the state and federal governments by establishing a robust national chemical regulatory program and maintaining the ability of state governments to act when EPA has not.

The notice for today's hearing requested comment on elements of the discussion draft that need additional consideration. ACC believes that the following elements of the discussion draft would benefit from additional discussion and clarification:

- The elements of the manufacturer-initiated risk evaluation process are not entirely clear, and additional detail may be helpful in order to provide clear direction to EPA on Congress' expectations for the program, as well as clear guidance to the manufacturing community. That detail would help clarify how the relatively short review deadline is consistent with a robust review of the hazards, exposures and risks of a chemical substance.

- The draft prohibits an EPA finding that a substance does not pose an unreasonable risk any time there is an exposure to one or more subpopulations. It is not clear how this provision fits with other provisions that require that a finding of unreasonable risk be based on the integration of hazard and exposure information, or the imposition of a risk management rule intended to ensure no unreasonable risks are present.
- Under the draft, TSCA fee revenue is deposited in the general treasury. All TSCA funds should be returned to EPA to support implementation of the program.
- EPA's authority to "reset" the TSCA inventory to better reflect chemical substances actually in commerce should be clarified. Under the draft as published, EPA would remove the substances from the inventory -- which would force manufacturers to submit new pre-manufacturing notices if they wanted to begin manufacturing again.
- The degree to which State governments may adopt regulations identical to EPA actions under sections 5 and 6, and any limitations applicable to enforcement of those regulations, should be clarified.

Mr. Chairman, as I noted before, the bipartisan discussion draft represents a significant milestone toward the objective of TSCA reform this year. ACC and its member companies look forward to working with you and other Subcommittee members to ensure that Congress adopts, and the President signs into law, TSCA reforms that build confidence in the U.S. chemical regulatory system, protect health and the environment from significant risks, and meets the commercial and competitive interests of the U.S. chemical industry and the national economy.

Thank you again for the opportunity to testify in support of the discussion draft. I would be happy to respond to any questions.

Mr. SHIMKUS. Thank you.

Next I would like to turn to Dr. Beth Bosley, President of Boron Specialties, on behalf of the Society of Chemical Manufacturers and Affiliates. She has testified before. Welcome back, and you are recognized for 5 minutes.

STATEMENT OF BETH D. BOSLEY

Ms. BOSLEY. Thanks very much. Good morning, Chairman Shimkus and Ranking Member Tonko, and everyone on the subcommittee, and thanks also for having me back to Washington to discuss TSCA, one of my favorite subjects. It has been really refreshing to hear so many positive statements being put forth by both the Democrats and Republicans on this issue, and we really applaud all the efforts to modernize TSCA. It covers such a wide variety of chemicals and applications, and it really impacts a huge swath of our economy, so it is really important, and given the range of interested parties, it is remarkable how much alignment has been achieved. It is a very complicated statute, and you have worked pretty hard not to make it more complicated, so I applaud that as well.

I would just like to highlight a few things that I think are important in the discussion draft. The safety standard, as we have already heard today, corrects the fundamental flaw in the current TSCA that requires you to take cost into account. In this case, protection of human health and the environment is really the only driver for the safety standard, and that is a great improvement. EPA will make very different decisions under section 6 now than it has before, and it will allow policy and emerging science to inform protective determinations regarding these chemicals.

For new chemicals, I have talked quite a bit I think here before that I think the new chemicals process works very well, and I would like it to remain basically as it is. It is one of the more important parts of the statute. It drives protection of our environment and our economy. Experience has taught us that new chemicals can be greener, and of course, we must continue to innovate because we live in a global economy now. If we want to promote innovation and develop greener chemistries, section 5 really must remain efficient, predictable, and affordable.

We are also interested in timely access to the market, and the 90-day review window has proven sufficient in most cases. In some cases, EPA has to suspend or give itself another 90 days, but in fact EPA often completes its review after day 22, which is really very early. It depends on how much information they are given, but after day 22 is often. We would certainly like to be able to go to market after day 22 as well.

One area that TSCA hasn't worked, and we have heard about this a number of times already this morning, is with existing chemicals, but I think the discussion draft goes a long way to really solve the problems with existing chemicals. It can ask for data under section 4 really whenever it thinks it is necessary to conduct the risk evaluation. It doesn't have to make a finding, and that is a really great improvement.

We do support a more comprehensive review of existing chemicals, and since there is no detailed screening process outlined in

the bill, we are assuming EPA would go forward with its work plan chemicals as it has to date.

We do also support deadlines for this review. I am not sure how long it takes, but I would say EPA probably has a good estimate of how long existing chemicals take to review. We know that deadlines work well in new chemicals, so they should work well in existing chemicals, but the deadlines and the workload really have to be achievable.

Under section 8 for the reporting requirements, one of the most important factors we see there is an inventory reset. As we have heard already today, again, there are over 80,000 chemicals on the inventory, but only 7,700 were reported on in the most recent CDR. That is a big disparity between what is in commerce and what is not in commerce.

Currently, as a manufacturer, I report on exposures of chemicals to my employees, but then I also have to estimate exposures to my customers' employees, and that is pretty hard for me to do, especially as a small business. So I would think process of reporting would be very important to add to this—requiring process of reporting would be very important language to add.

Confidential business information is really important for all U.S. manufacturers, but especially small businesses like mine. CBI allows us to pursue research and market development without advertising to the world exactly what we are doing. Even so, we really appreciate that we must proceed with as much transparency as possible, and I think that resubstantiation after 10 years is an excellent addition to the current draft.

Resources and fees: As we have all heard, EPA needs more resources, and getting those fees to EPA instead of the Treasury is really important. I also appreciate, as you might imagine, that you have given the provision for small-business reduced fees, and I wholeheartedly support that.

So in general, just very much supportive of the bill. We think it fixes a lot of the problems with the current TSCA statute, and I am sure other issues will be raised, but we look forward to working through them with you.

[The prepared statement of Ms. Bosley follows:]



Testimony
of
Beth D. Bosley

President
Boron Specialties LLC

On behalf of the

Society of Chemical Manufacturers & Affiliates

Before the

U.S. House of Representatives

Energy and Commerce Committee
Subcommittee on Environment and the Economy

On the

“TSCA Modernization Act of 2015”

April 14, 2015

Good morning, Chairman Shimkus, Ranking Member Tonko, and members of the Subcommittee. My name is Beth Bosley, and I am the President of Boron Specialties in Pittsburgh, Pennsylvania. Boron Specialties is a specialty chemical manufacturer and a woman-owned small business.

I am pleased to be back in Washington on behalf of the Society of Chemical Manufacturers and Affiliates to share my perspective on the April 7 discussion draft of the TSCA Modernization Act. At the outset, I would like to applaud the great work you and your staff have been doing on advancing TSCA reform – and your bipartisan approach. It has been refreshing to hear such positive statements coming from both Republicans and Democrats in the leadership. We are hopeful this tone can be maintained. We also appreciate your outreach to stakeholders, and your interest in SOCMA's perspectives on TSCA.

After many years of failed attempts, this appears to be an excellent opportunity for TSCA reauthorization. While these past efforts may have been frustrating, they have also been educational. We have identified what parts of TSCA required the most work. We also have a better idea what approaches are realistic and achievable for the universe of chemicals that fall under its scope. TSCA covers a wide variety of chemicals and applications and impacts a huge swath of the economy. Given the wide range of interested parties, it is truly remarkable how much alignment on issues has been achieved this time around. I hope that, working together, we can continue to expand this support.

To borrow an expression from chemistry, the draft TSCA Modernization Act passes the Litmus Test: It maintains the provisions that have worked well, and it fixes provisions that have been blamed for TSCA not working well. This bill has real potential for attracting substantial bipartisan support. In some areas, the bill challenges EPA and stakeholders to make more of existing law than EPA has in the past. We are interested to hear others' views on whether it does enough in that regard. There remain a number of ways that we believe the bill could be improved upon, or clarified, but this is what the legislative process is for.

TSCA is a complicated statute, and you've been careful not to make it more so; not to unfix areas that have worked well, and not to give EPA more authority where it already has enough. This bill really focuses on the essentials. I will now talk about some them.

Safety Standard. The bill retains the language of the current TSCA safety standard, but it corrects its fundamental flaw by preventing cost from playing a role. As a result, the standard is purely based on human health and environmental concerns. The bill also requires specific consideration of vulnerable subpopulations, to protect individuals with greater susceptibility.

There is no question, therefore, that EPA could make very different decisions under Section 6 than it has (or more accurately, has not) in the past. As a practical matter, any differences will be determined in practice as EPA makes policy decisions about specific chemicals informed by evolving science. But we don't think EPA has to be given any new words to interpret in order to make protective decisions. In particular, it simply would not work for EPA to be forced to use a safety standard that is borrowed from laws governing pesticides or food and drugs. Those laws



cover much narrower fields of chemicals that are intended to be bioactive, and that have easily defined and managed applications. Most industrial chemicals have different exposure pathways than pesticides, food or drugs and many of these are used exclusively within industrial settings.

New Chemicals. For many years, SOCMA has advocated for TSCA Section 5 to remain, basically, as it is. We have heard from many other stakeholders that this is the one section of TSCA that has worked very well. It also happens to be the most important part of the statute for the future of our environment and our economy. Experience has taught us that new chemicals tend to be greener. If we want to promote innovation and the development of greener chemistries, Section 5 must remain efficient, predictable and affordable.

Timely access to market is crucially important for innovation. It is especially important to specialty chemical manufacturers, who often have to manufacture custom chemicals on demand, on a batch-to-batch basis. In fact, the one change we would urge to Section 5 would be to eliminate the one source of delay under the new chemicals program. Currently, even if EPA concludes its review of a new chemical in less than 90 days, the statute requires the chemical submitter to wait the full 90 days. EPA should be authorized to allow commencement of manufacture upon EPA's decision to "drop" from further review (which often occurs on or about day 22), indicating that a new chemical will not present an unreasonable risk of injury to human health or the environment.

Testing of Existing Chemicals. While the new chemicals program has worked well, the same cannot be said about reviews of existing chemicals. Two main problems have been identified with Section 4 – and the draft bill fixes both:

- First, currently EPA has to establish that a chemical poses a risk before it can seek the data to enable it to make that determination. The bill adds a new provision stating simply that EPA can seek data under Section 4 whenever that data "is necessary to conduct a risk evaluation," and it *requires* EPA to conduct a risk evaluation whenever it has "a reasonable basis for concluding that the combination of hazard from and exposure to the chemical substance under the intended conditions of use has the potential to be high enough to present an unreasonable risk."
- Second, current TSCA requires EPA to act by rulemaking – a resource intensive and time consuming process. EPA has dealt with this problem quite successfully by utilizing enforceable consent agreements and voluntary efforts. But that is only a partial solution. Under this bill, EPA would be authorized to issue orders and enter into consent decrees, much the same way as it does with new chemicals – in addition to promulgating rules.

The most notable omission from the bill's treatment of Section 4 is a detailed prioritization or screening process for existing chemicals. We support a more comprehensive review of existing chemicals and with the other improvements made by the bill (including access to greater financial resources) there is arguably nothing to prevent EPA from continuing a risk-based prioritization process similar to the current Work Plan chemicals initiative, which has been generally supported. EPA can also review the information it gets from periodic reporting under the Chemical Data Reporting rule. With all the tools at EPA's disposal under the bill to collect

data and conduct risk evaluations, EPA should be able to establish its own, de facto, high priority chemicals – it should not need a specific legislative direction to do that.

The real issue is whether this and future EPAs can muster the necessary resources (which will require political support from the White House and Congress) to step up the review of existing chemicals. SOCMA supports legislative specification of workload requirements and deadlines, if they turn out to be necessary as a practical matter. Specific review timelines have worked well in the new chemicals program; we believe they could work for existing chemicals as well. What is key, however, is that EPA has adequate resources and sufficient tools to review existing chemicals – and this bill addresses those shortcomings of the current program.

Risk Evaluations and Risk Management. One of the most contentious aspects of TSCA implementation has been EPA's ability under Section 6 to impose restrictions on existing chemicals that "present or will present an unreasonable risk." As noted earlier, the bill changes that standard by excluding cost considerations, making it a purely safety-based exercise. Should EPA make an unreasonable risk finding, it would also be freed from having to choose the "least burdensome" restrictions. The bill also eliminates the requirement that Section 6 rulemakings include public hearings whenever requested. These are all huge improvements. Furthermore, a manufacturer can offer to pay the costs of an evaluation, which should help with EPA resource constraints, provide additional data, and increase the throughput of chemical evaluations. We would support going further and requiring EPA to consider industry drafted risk evaluations, as the Senate bill does. That bill leaves to EPA's discretion how much weight to give such work, which can be guided by objective criteria such as compliance with Good Laboratory Practice standards and use of EPA-approved test methods.

Reporting Requirements. The principal change in Section 8 is to establish an inventory reset. This is an essential improvement since understanding the universe of chemicals in commerce will help to focus EPA's efforts. We ask that you take this a step further and include a list of inactive chemicals in commerce like the Senate does. SOCMA would also like to see additional reporting to enhance the data available to EPA. We acknowledge that EPA already has authority to require reporting from downstream processors, but we also support language requiring processors to report use and exposure data when EPA concludes that such reporting would materially improve their understanding of actual exposures, a necessary part of the risk equation. This would not have to be identical to manufacturer reporting, but it could be helpful in certain cases. We understand that processor reporting is a politically challenging issue (and could be logistically challenging as well). But we believe information from processors (who are in the best position to report on exposure patterns during use) will be crucial to evaluate the need for additional test data and in generating well-informed risk assessments. We urge you to consider this issue.

As I have mentioned in prior testimony, the bill should also authorize submission of non-adverse data under Section 8(e) and to require EPA to take such data into account in evaluating chemicals. Currently EPA accepts what it calls "FYI" submissions, but it is criticized by some for doing so. The bill defines "weight of the scientific evidence" to mean "the results of an approach that gives appropriate weight to all relevant information in an integrative and objective

manner that takes into account the strengths and limitations associated with each type of information.” The only way for EPA to do that is to consistently consider all information that bears on the health effects of a chemical, both positive and negative. Such an enhancement would greatly increase the amount of data submitted under Section 8(e), which can only improve EPA’s understanding of chemical hazards.

Finally, we would also like to see the bill include a section on statutory mixtures to recognize certain nomenclature for specialty chemicals, including color pigments. Much can be gleaned from the Senate bill in this regard.

Confidential Business Information. As I’ve stated previously, CBI is essential to US manufacturers, especially small businesses like mine; protection of CBI allows us to pursue research and market development without disclosing details of these activities to the public (and by extension, to our competitors). While we wish to keep certain aspects of our new product development efforts confidential, we appreciate that we must proceed with as much transparency as possible. Section 14 is where these competing values are balanced. The biggest shortcoming with current law is that industry can claim a trade secret and essentially have it stay that way in perpetuity, unchecked. The bill addresses this problem by requiring upfront substantiation and re-substantiation every ten years. The bill also addresses another common criticism of Section 14 by allowing disclosure to states, emergency responders and treating physicians. These are major improvements. Additionally, we would like to see chemical identity explicitly protected as CBI in health and safety studies, when the claim can be adequately substantiated. I would never advocate keeping the hazard or the study confidential, only the specific chemical ID. We believe that robust generic names could give enough information to stakeholders while still maintaining confidentiality for business sensitive chemical IDs. We would also like to see some more specificity about exactly what kinds of trade secrets need to be substantiated and re-substantiated. The Senate bill declares a list of types of information to be presumptively confidential, so that substantiation is focused on chemical identity, which has been the principal source of transparency concerns. There are many types of CBI and having to substantiate obviously sensitive things like manufacturing processes or market information could turn into a highly and unnecessarily burdensome exercise.

Preemption. This topic has become the main source of controversy over the Senate bill. As noted above, the House bill has no mandatory prioritization process, so the issue of whether prioritization decisions should be preempted is avoided. In retaining Section 18 of current law, state co-enforcement would remain unpreempted. The section also clarifies that state tort law is not preempted. However, if EPA determines that a substance presents no unreasonable risk, state laws that are prohibitions would no longer be preserved from preemption. These are fair and reasonable provisions. We are still assessing this section, but it does address the biggest controversies that have emerged in discussions over the years on preemption.

Resources and Fees. Inadequate EPA resources has become another hot-button issue. The bill lifts the \$2,500 cap on fees for submissions under Sections 4 and 5 currently imposed by Section 26. As with EPA’s workload under Section 4, this simple change would seem to allow EPA to structure a fee program comparable to that contained in the Senate bill. The bill would also require EPA to set lower fees for small businesses, a very good thing from the perspective of



SOCMA's membership, 70% of which are small businesses. Manufacturers can also offer to pay all costs of a risk evaluation, as noted earlier.

We do have some concerns about this part of the bill:

- Because it works with existing law, under the bill, fees associated with certain submissions would go to the Treasury, and would not necessarily alleviate EPA's resource problems. The bill should establish a dedicated fund to which fees would be directed and which could only be used to support the TSCA program.
- The Senate caps fees at \$18 million, with a goal of covering 25% of the TSCA program. This bill should include some comparable cap.
- We are concerned about the potential for new chemical fees to be used to subsidize other parts of the program. Pre-manufacture notices (PMNs) are mandatory and are filed with great regularity, thus offering a tempting target for fee increases – whereas EPA has no obligation to impose any Section 4 requirements, so fees from implementation of this section are a less certain funding stream. In our opinion, fees for new chemical submissions should be used for the new chemicals program and should not be prohibitive – PMNs filed represent innovation, usually encompassing chemicals that pose fewer hazards than their existing chemical predecessors. Keeping new chemical fees reasonable ensures that manufacturers are incentivized to develop newer, greener chemistries.
- We also believe there should be no fees for exemption notifications, such as the low volume exemption. We are pleased this bill does not mention this prospect, unlike the Senate bill. Remarkable innovation often occurs with low volume chemicals. Furthermore, these sorts of notices tend to be extremely restrictive in volume, manufacturing methods, and end use applications, and therefore do not raise the same concerns that larger volume chemicals do. Additionally, exemption notices have shorter review times and do not require as many resources from EPA as a PMN review does.
- Finally, the bill should clarify that EPA cannot charge higher fees for submissions that include CBI claims – this would be a deterrent to innovation and to the protection of intellectual property.

Conclusion. To conclude, the bill generally maintains the most effective and politically sensitive parts of current law and fixes the areas that have been most problematic. It takes some notably different approaches than its Senate counterpart. Many of the most controversial parts of the Senate bill are not present in this bill, particularly given the absence of a prioritization scheme. Given my experience, I am sure new controversies will emerge, or take new form. Either way, as an optimist, I see this an improvement over the status quo and a promising vehicle for a bipartisan solution.

We appreciate your intense focus on TSCA reauthorization and remain committed to helping in any way we can.

Thank you again for this opportunity to share SOCMA's perspective. I look forward to your questions.



Mr. SHIMKUS. Thank you very much.

Now I would like to recognize Ms. Jennifer Thomas, Director of Federal Government Affairs with the Alliance of Automobile Manufacturers, again, another returnee. Welcome, and you have 5 minutes.

STATEMENT OF JENNIFER THOMAS

Ms. THOMAS. Thank you, Chairman Shimkus, Ranking Member Tonko. My name is Jennifer Thomas, and I am here on behalf of the Alliance of Automobile Manufacturers, which is a trade association of 12 automakers, and together they account for approximately 75 to 80 percent of all new vehicle sales here in the United States. The last time I was before this committee, I was beamed in from Europe, so I am very happy to be here in this person this time, so thank you for giving me the opportunity to share our views on the draft TSCA Modernization Act of 2015.

We commend Chairman Shimkus, Chairman Upton, and Ranking Member Pallone for their bipartisan efforts to reform TSCA for the first time since it was enacted in 1976.

Automakers work diligently to identify and reduce substances of concern in automobiles. We have eliminated the use of mercury switches and lead wheel weights. We continue to phase out the use of the flame retardant deca, and we are eliminating copper from brake pads.

Autos are also one of the most recycled consumer products. Nearly 90 percent of a vehicle's material content is recycled or reused.

But clearly there is more work to do to protect the public and environment from harmful chemical substances, and we want to be part of the solution. We welcome this discussion draft and believe it will enhance EPA's ability to more effectively regulate potentially harmful chemicals while providing industry a clear and consistent regulatory environment.

Let me take a moment to highlight some specific areas of interest to our industry. First, we support the manner in which this draft seeks to regulate chemicals and articles. This approach is consistent with existing EPA policy, which has traditionally recognized the complexity of regulating chemicals and articles by exempting them from most TSCA requirements. We understand the potential need to regulate articles in certain circumstances but this should be based on risk of exposure to the chemical in question. For example, there is a clear difference between the risk of exposure to a chemical substance in a baby bottle versus an engine component underneath the hood of a car.

Secondly, we believe that vehicles should be serviced with parts as produced, meaning those service parts used the material that were acceptable when the vehicle was designed, certified and warrantied. Replacement part demand is very small. It is generally 1 to 5 percent of all vehicle parts, and it declines over time as a vehicle fleet is retired. But since the average age of a vehicle on the road today is 11 years, replacement parts must be available for many years so that those vehicles can be serviced and maintained.

There is often some confusion of how vehicle replacement parts are produced, so let me briefly explain this model. Automakers typically put a marginal supply of those parts in stock while the

vehicle is still in production, and to the extent that customers need replacement parts beyond that initial stock, there is a production-on-demand market, and suppliers continue to produce them using the same materials, the same production process, and the same engineering specifications as for the original vehicle. So while replacement parts might theoretically be able to be redesigned for vehicles no longer in production, there are technical and logistical barriers that often make such redesign infeasible if not impossible.

I would also note that similar laws regulating chemical substances have examined this issue and have opted to exempt replacement parts.

Finally, we appreciate this draft's simplified approach to State preemption, which ensures that any EPA final determination will preempt State chemical regulations. However, we do recommend that the committee also consider suspending any new State action while EPA decides a chemical substance is a candidate for a risk evaluation. We are aware of the concern expressed about the passage of time while EPA considers regulatory action and are supportive of expedited time frames for EPA action.

Thank you again for inviting me to be here and discuss this important issue with you today. Congress is on the cusp of reforming TSCA for the first time in nearly 40 years, and we strongly believe that the final bipartisan product will more effectively regulate harmful chemicals in a way that protects the health and safety of all Americans while providing industry the certainty and the clarity that it needs. We look forward to working with you as this draft moves through the legislative process.

I thank you again, and I would be happy to answer any of your questions.

[The prepared statement of Ms. Thomas follows:]



AUTO ALLIANCE

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STATEMENT

OF

THE ALLIANCE OF AUTOMOBILE MANUFACTURERS

BEFORE THE:

**ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY
U.S. HOUSE OF REPRESENTATIVES**

April 14, 2015

PRESENTED BY:

Jennifer Thomas
Senior Director, Federal Government Affairs

Summary

The Alliance of Automobile Manufacturers welcomes the draft TSCA Modernization Act of 2015. The Alliance believes it will enhance EPA's ability to more effectively regulate chemical substances, while providing industry with a clear and consistent regulatory environment. Automakers have a long history of corporate stewardship with regard to identifying and reducing specific chemicals or "substances of concern" in automobiles, but they recognize that more can be done to protect the public and environment from potentially harmful chemical substances.

The Alliance supports the manner in which the draft TSCA Modernization Act of 2015 seeks to regulate chemicals in "articles," as defined by EPA in its TSCA regulations and believes it is consistent with existing EPA policy. Automakers are not advocating that articles be exempt from regulation under TSCA, but rather we believe that legislation to modernize TSCA should consider the unique concerns of article manufacturers.

Additionally, we support an exemption of vehicle replacement parts, including the limited exemption contained in this discussion draft. Vehicles should be serviced with parts "as produced" – using the materials that were acceptable when the vehicle produced. Similar laws with goals to replace potentially harmful substances have opted to exempt vehicle replacement parts.

Finally, this draft recognizes the need for a single national regulatory program for chemical management by ensuring that any EPA action would then apply in all the states. However, we recommend the Committee also include language suspending any new state action when EPA decides a chemical substance is a candidate for a risk evaluation to allow EPA the necessary time to conduct a robust, science-based risk and ensure that any final decision take into account the range of possible use and exposure considerations.

Congress is on the cusp of reforming this important environmental statute for the first time in nearly 40 years. The Alliance stands ready to work with the Committee as this discussion draft proceeds through the legislative process.

Testimony

Thank you, Chairman Shimkus, Ranking Member Tonko and members of the Subcommittee. The Alliance of Automobile Manufacturers (Alliance) is a trade association of twelve car and light truck manufacturers comprised of BMW Group, FCA US LLC, Ford Motor Company, General Motors Company, Jaguar Land Rover, Mazda, Mercedes-Benz USA, Mitsubishi Motors, Porsche Cars, Toyota, Volkswagen Group and Volvo Cars. Together, Alliance members account for roughly three out of every four new vehicles sold in the U.S. each year.

On behalf of the Alliance, I appreciate the opportunity to offer our views on the draft TSCA Modernization Act of 2015. We applaud Subcommittee Chairman Shimkus, Chairman Upton and Ranking Member Pallone for the thoughtful approach taken in this bipartisan discussion draft. This streamlined product reflects the hard work this Subcommittee has conducted on this important issue throughout the past two years. We remain encouraged by this process and believe a strong bipartisan approach provides for the best opportunity to reform the Toxic Substances Control Act for the first time since it was enacted in 1976.

The automobile industry is a massive employer -- reaching well beyond the iconic names of auto companies familiar to us all. Auto manufacturing depends on a broad range of parts, components and materials provided by thousands of suppliers, as well as a vast retail network of dealers, service providers and repairers around the globe. In the United States alone, eight million workers and their families depend on the auto industry. Each year, the industry generates \$500 billion in paychecks, and accounts for \$205 billion in tax revenues across the country.

Automakers have a long history of corporate stewardship with regard to identifying and reducing specific chemicals or "substances of concern" in automobiles. For more than a decade, automakers have maintained an industry-focused global declarable substance list and a sophisticated tracking database to actively reduce industry-wide use of substances of concern in global production. The auto industry has invested more than \$30 million on this system, which now tracks more than 3,000 substances used in automotive components to ensure that restricted substances are not in our products. By way of example: automakers have eliminated the use of

mercury-containing switches and lead wheel weights from automobiles; we continue to phase out the use of the flame retardant decaBDE; and we are eliminating copper in brake pads¹. Most notably, automobiles are among the most recycled consumer products. In the U.S., 95% of retired cars are processed for recycling annually, and approximately 86% of a vehicle's material content is recycled, reused or used for energy recovery.²

But automakers recognize that more can be done to protect the public and environment from the risk of harmful exposures to chemical substances and we want to be part of the solution. Despite decades of rapid advancement in the science and technology of chemical use and management, TSCA remains the only major federal environmental statute that has not been substantively revised since its enactment. We welcome the draft TSCA Modernization Act of 2015 and believe it will enhance EPA's ability to more effectively regulate chemical substances in a way that better protects public health and the environment, while providing industry with a clear and consistent regulatory environment.

The Alliance supports the manner in which the draft TSCA Modernization Act of 2015 seeks to regulate chemicals in "articles," as defined in TSCA. The approach taken is consistent with existing EPA policy, which has traditionally recognized the complexity of regulating chemicals in articles by exempting articles from most TSCA requirements. This discussion draft will allow EPA to regulate chemical substances in articles, but "only to the extent necessary to mitigate the identified risk."

Automakers are not advocating that articles be exempt from regulation under TSCA. Rather, we believe that any legislative efforts to modernize TSCA should consider the unique concerns of article manufacturers or assemblers. The average automobile has 30,000 unique components and each individual component is comprised of multiple materials, including a range

¹ Memorandum of Understanding on Copper Mitigation in Watersheds and Waterways between U.S. EPA and Motor Equipment Manufacturers Association, Automotive Aftermarket Suppliers Association, Brake Manufacturers Council, Heavy Duty Manufacturers Association, Auto Care Association, Alliance of Automobile Association, Association of Global Automakers, Truck and Engine Manufacturers Association, and Environmental Council of the States, January 21, 2015, http://water.epa.gov/polwaste/npdes/stormwater/upload/copper_brakepads_mou.pdf.

² "Vehicle Recycling, Reuse, and Recovery: Material Disposition from Current End of Life Vehicles," Society of Automotive Engineers (SAE), 2011.

of chemicals and mixtures. Most of these components never come into contact with people or the environment during use. Each automaker works with a global, multi-tiered network of more than 1,000 suppliers, spanning multiple sectors from electronics to textiles. Most automotive components are obtained from suppliers as finished products, which are then integrated into the vehicle. Regulating the construction and assembly of automobiles on a component-by-component basis is burdensome, inefficient, and unnecessary to effectively manage chemicals.

Again, we understand the potential need to regulate articles in some circumstances; however, this should be based on risk of exposure to the chemical in question. For example, there is a clear and dramatic difference between the risks of exposure to a chemical substance found in a baby bottle versus an engine component under the hood of a car. In the event EPA determines it is appropriate to regulate chemicals in articles, feasible alternatives must be available and EPA should allow sufficient lead-time to implement the necessary changes. The Alliance supports the language in this discussion draft that allows for these operational constraints to be considered.

Additionally, automakers support the “repair as produced” concept – and the exemption of vehicle replacement parts, including the limited exemption contained in this discussion draft. Vehicles should be serviced with parts “as produced,” meaning the service parts should use the materials that were acceptable when the vehicle was designed, certified, and warranted, even if manufactured after the effective date of a restriction on use of a chemical contained in those parts. To be clear, we are not advocating that all *automobile* parts be exempt from TSCA requirements. Rather, we are seeking an exemption for replacement parts used to service in-use vehicles that were designed prior to the effective date of chemical restrictions – a much smaller universe of auto parts.

Each major automaker carries over 250,000 active replacement parts, with roughly 20,000 new service parts added annually (~3,000 for each new vehicle introduced). Replacement part demand is small -- generally 1% to 5% of the production volume of all vehicle parts -- and declines over time. Since the average age of vehicles on the road today is more than 11 years and many vehicles last much longer, replacement parts must be available for many years so that vehicles already purchased by consumers can continue to be maintained.

The basic economic business model for replacement parts is that manufacturers put a marginal supply of these parts in stock while a vehicle is in production. However, not all replacement parts are produced at the end of production of a vehicle. To the extent that customers need replacement parts beyond what is initially stocked, there is a “production-on-demand market” whereby suppliers continue to produce replacement parts typically using the same materials, production processes and engineering specifications as for the original vehicle. While replacement parts theoretically might be redesigned for vehicles no longer in production, there are technical, economic, and logistical barriers that often make such redesign infeasible, if not impossible, in most cases. Similar laws with goals to replace potentially harmful substances have examined this issue and have opted to exempt vehicle replacement parts. (See, e.g., European Union End-of-Life Vehicle Directive, Directive 2000/53/ELC; Canada Consumer Product Safety Act; California’s standards on motor vehicle brake friction materials, Cal. Health and Safety Code § 25250.50 *et seq*; Washington state’s motor vehicle brake pads standards, Wash. Rev. Code Chapter 70.285; and Maryland’s standards governing decaBDE in various products, MD Code § 6-1201.)

Finally, the draft TSCA Modernization Act of 2015 recognizes the need for a single national regulatory program for chemical management by ensuring that any EPA final determination on a chemical substance will preempt state chemical restrictions. We appreciate this new and simplified approach to state preemption. However, we recommend the Committee also include language suspending any new state action when EPA decides a chemical substance is a candidate for a risk evaluation. This “pause” would allow EPA the necessary time to conduct a robust, science-based risk evaluation. It should be structured to ensure state participation in the risk evaluation process, so that any final EPA decision takes into account the range of possible use and exposure considerations.

Because automakers sell the same products across all 50 states, one state’s chemical restriction or ban is, in effect, a *de facto* U.S.-wide (and possibly even global) requirement. Therefore, preemption of state law after an EPA regulation is finalized may come too late to provide relief from inconsistent or ill-considered state restrictions because automakers may already have had to comply with the state restriction. Preemption, or a “pause” on additional

state legislation/regulation, should begin once EPA begins the assessment process. We are aware that some have expressed concern about the passage of time while EPA considers regulatory action. In response, we support language in this draft setting forth an expedited timeline for EPA action. We cannot support a situation in which a state regulates a chemical substance while EPA is considering whether to regulate the same substance, and may regulate in a different manner than the state does. In such cases, the most stringent regulation quickly becomes the default standard for the industry.

As an example of the compliance challenges posed by a state-by-state approach, both California and Washington have environmental protection laws to restrict heavy metals and asbestos in brake friction material. Although the two states have made conscious efforts to collaborate on their approaches, there are still conflicting differences between their laws and implementing regulations. For example, while both states ultimately require brakes to contain less than 0.5% copper, each state has its own deadlines and regulatory processes. In California, the copper reduction goal must be accomplished by 2025; however in Washington, the deadline is eight years following the state's determination that a viable alternative exists. Both states allow manufacturers to make an application for an extension from their respective requirements, but, the applications and timing for applying are not identical, and, each state has its own process for determining whether to grant these extensions, which means one state could grant an extension while the other does not.

Imagine this scenario multiplied across 48 additional states. Compliance would be both labor-intensive and costly, and inefficient to have to go through processes of this kind on a state-by-state basis. We are noticing a significant trend towards state legislation and regulations targeting not just chemicals but consumer products (i.e., articles) containing specified substances. In 2014, at least 43 broad-reaching chemical regulation bills were introduced by state legislatures across the country. Even if the states attempt to harmonize their requirements – an effort that usually falls short to one degree or another – automakers will still have to spend considerable time and resources monitoring multi-state regulations, submitting multiple reports, satisfying individual state notification and approvals, etc.

We appreciate the opportunity to offer our views on the draft TSCA Modernization Act of 2015. Congress is on the cusp of reforming this important environmental statute for the first time in nearly 40 years. We are encouraged by the significant progress that has been made on this issue in this Committee, as well by the action occurring simultaneously in the Senate. We strongly believe that the final, bipartisan product will more effectively regulate harmful chemical substances in a way that protects the health and safety of all Americans, while providing industry the certainty and consistency it needs. The Alliance stands ready to work with the Committee as this discussion draft proceeds through the legislative process. Thank you again and I will be happy to answer any of your questions.

Mr. SHIMKUS. Thank you very much.

The Chair now recognizes Mr. Andy Igrejas, Director of Safer Chemicals, Healthy Families. Welcome back. You are recognized for 5 minutes.

STATEMENT OF ANDY IGREJAS

Mr. IGREJAS. Thank you very much, Mr. Chairman and Mr. Tonko. I am pleased to be here as like the other witnesses are.

Safer Chemicals, Healthy Families is a coalition of 450 organizations and businesses. It ranges from the Learning Disabilities Association, the Steelworkers Union, large health providers like Dignity Health, and the major national environmental organizations.

We all came together to reform TSCA in 2009, and we definitely want to have it happen sooner than later, and we are glad to work with the committee toward that end.

I want to highlight what we see as positive in the draft, what is missing, and some ideas for how to move forward. I want to also say up front that we think the more targeted approach you have taken does hold a lot of promise. There is a lot that it potentially solves and points the way forward, and also to identify some of the elements that are in there that we support.

The absence of a complicated prioritization scheme we think is wise. It avoids the downside of the low-priority loophole that a lot of us are concerned about. You also heard from EPA that they already have prioritization criteria they have gone through that had public input, et cetera.

The approach to preemption by preserving more of TSCA's existing preemption, you avoid the controversy of the void or the suspension whereby States are blocked just because EPA is looking at something, and we appreciate that. The draft also doesn't roll back EPA's authority on products or imports, so we think you have threaded the needle on the issue of products and don't take away authority on some of these other areas. It doesn't make it easy to require toxicity testing. It does remove the least-burdensome requirement, which was an issue in the asbestos decision, and vulnerable populations are addressed though there is some clarification potentially needed around the rulemakings.

I want to focus on the issue of cost and see if I can add some value. It was talked about a lot. We basically agreed with where EPA came down on this, that we don't see that issue as solved in this draft, and to try to put it simply, I think in our vision, you want the risk evaluations to clearly identify the risk including the vulnerable populations and you want the rulemaking to have to protect against that risk very clearly. And then the cost considerations including cost-effectiveness comes into play with how EPA does that, which can mean longer time frames for implementing some particularly costly piece of the risk management. It can include choosing a more cost-effective way of addressing the risk over another way. But you don't want it to be a limitation on whether the risk is addressed at all, and that is the key distinction that we still see as potentially not solved. So it literally comes down to, will you have a risk hanging out there that EPA has identified and at the end we will be able to tell the story that the public is now protected from that risk and have that be true, or we potentially have

the story that EPA winds up saying we actually didn't protect against the risk because a court found that we couldn't prove that the cancer cases and the hospital visits, the lost work, et cetera, outweighed the costs to the companies to move to the safer alternative. That is the difference that this hinges on, and so I am not sure if we have a difference of intent or of interpretation of the language, but that is the key thing we would like to see solved is that the risk management has to protect against the risk.

We also would agree with what has been said about the imbalance between industry assessments and the assessments that EPA would undertake under its own power under the draft. Really, the industry assessments are the only thing driving EPA activity under this draft. They have to agree to these requests and they have to undertake them, and on the flip side, they have to go through some hoops before they can undertake an assessment, and that creates an imbalance that we think could lead to them looking more at the chemicals that are already being managed well or that are already safe that have a lot of data instead of the ones that are causing problems out in the real world right now. And so we think if you got rid of those extra barriers put in place—this issue came up of 20 chemicals a year, a requirement perhaps to do that. That is a nice round number. Maybe giving them a deadline to complete work on the chemicals that have been talked about, the 90 work plan chemicals, then we are on the way to driving some EPA action on the chemicals in addition to having this industry-initiated assessments.

We agree with what has been said about fees. I have mentioned some other issues in more detail in the written testimony around the science provisions in the bill. We think that you could take—if you are going with less is more, you can go all the way and not direct EPA to take a position on some of these scientific questions, but if you are going to do that, there are places in the bill where what you are calling for is stuff that the National Academy of Sciences has actually said EPA shouldn't do and there are some things the National Academies have said EPA should do that aren't in there, and so I would say pull back or go further with what the National Academies would like to do.

Persistent bioaccumulative toxins—these are the chemicals that are like PCBs. One of the only success stories of the original TSCA, there is a limited number of them, chemicals that are like that, identifying them early and requiring action.

So I will stop there but I will just say that we think all the issues that we have identified are things that could be solved in the draft. We wouldn't support the draft in its current form. But with the changes that we have talked about, it could be getting in shape where you would have a genuine public health achievement here.

[The prepared statement of Mr. Igrejas follows:]



**Testimony of Andy Igrejas, Director
Safer Chemicals, Healthy Families**

**Environment and the Economy Subcommittee
Energy and Commerce Committee
U.S. House of Representatives**

April 14, 2015

Thank you, Mr. Chairman and Ranking Member Tonko, for the opportunity to testify.

Safer Chemicals, Healthy Families is a coalition of public health, community, parent, and labor organizations as well as small businesses. We came together in 2009 to pursue meaningful and effective reform of the Toxic Substances Control Act and have been working diligently toward that end.

The Discussion Draft takes a narrower approach to TSCA reform that holds some promise. The implicit idea seems to be that by doing less and focusing on the fundamentals, a way forward can be found that enjoys broad support. There is merit in that approach.

However, in our analysis, some of the fundamentals are still missing. I discuss several of them in this testimony. They will need to be addressed for this effort to draw support from the public health and environmental community, including our coalition.

First, I want to make clear what we see as several positive elements of the draft:

In testimony last year we highlighted concerns about the "low priority" category as creating a potential loophole for many chemicals to escape scrutiny based on a murky standard. The Discussion Draft wisely eliminates that category.

Last year, we highlighted the need to protect vulnerable populations. The draft requires risk evaluations to address populations that are disproportionately exposed or susceptible to harm from a chemical.

Last year, we raised concern about when and how states were preempted compared with current law. The Discussion Draft retains key elements of current law including the timing of preemption, the ability of states to co-enforce, a workable waiver provision, and the savings clause.

The draft also allows EPA to require toxicity testing through an administrative order instead of only through the current cumbersome process of a formal rulemaking.

Finally, unlike the Senate bill recently introduced by Senators Udall and Vitter, S.697, the Discussion Draft does not propose to weaken TSCA sections dealing with exports, imports, nomenclature, or regulation of articles.

We appreciate this responsiveness to several concerns we raised in the debate last year.

Key Barrier to EPA Action Remains

Our first concern about the draft is that it does not, in our analysis, fix the fundamental barrier in current law to EPA imposing risk management on an unsafe chemical.

As you know, the death knell for the TSCA program on existing chemicals is widely recognized to be the decision in *Corrosion Proof Fittings*, whereby a federal appellate court struck down EPA's proposed regulation of asbestos.

The court interpreted TSCA as requiring EPA to prove with substantial evidence that the risks of asbestos outweighed its benefits to the economy. It found that EPA failed to do so. It also found that EPA failed to demonstrate it had chosen the "least burdensome" way of addressing asbestos's risks, which TSCA also required.

The draft makes targeted changes that appear designed to address the issues from the court case. It specifies that risk evaluations are to exclude cost and other non-risk factors. It eliminates the "least burdensome" requirement. It also prohibits EPA from finding that a chemical poses no unreasonable risk if it poses such a risk to any potentially exposed or susceptible population. Those are all positive changes.

However, the language in 6(c), including the cost-effectiveness requirement, combined with the baggage of the phrase "unreasonable risk" would, in our interpretation, still outweigh these changes. It would limit EPA's ability to impose risk management to those measures that could pass a cost-benefit and cost-effectiveness test.

While this may seem like a fine point, it is fundamental. Stakeholders broadly agree on a risk-based system for TSCA reform. In such a system, cost considerations should be reserved for the question of *how* to mitigate the risk, not *whether* to mitigate it. As it stands, we believe the draft would allow a major risk – such as a chemical that causes cancer or birth defects – to remain unmitigated if it was deemed too expensive to do so. That is a very different outcome than mitigating the risk in a cost-effective way.

This problem in the bill is fundamental but it could potentially be solved with small changes to the language. The bill needs to ensure the public is protected from the identified risk and that cost-effectiveness analysis is used only to choose among approaches that clearly protect the public.

Imbalance in Assessments

A second fundamental problem is the imbalance between the industry-initiated and EPA-initiated assessments under the bill.

We do not flatly oppose the idea of industry-initiated assessments as proposed in the bill because the chemicals are held to the same standard of safety.

As drafted, however, this provision would likely overpower the public health imperatives of TSCA reform. EPA is required to undertake a risk evaluation if industry requests it. There is no wiggle room. On the flip side, if EPA wants to undertake a risk evaluation of a chemical for its own reasons of public health and safety, it has to make a number of findings to justify the evaluation. There is no cap on the number of industry-initiated evaluations, and no minimum schedule for the EPA-initiated evaluations. Also, EPA is under a much tighter deadline to complete the industry-initiated assessments.

Instead, to provide balance, EPA should have the discretion to turn down an industry request and to initiate its own assessments without having to make multiple findings. There should be a minimum schedule of EPA-initiated risk evaluations to ensure steady progress in public health and environmental protection. EPA should be able to levy fees to fund the assessments it initiates, and not just the fees allowed for the assessments industry initiates.

One way to structure the program would be to give EPA a deadline to complete risk evaluations on the chemicals it has already prioritized using the Work Plan process under current law and then require it to initiate a minimum number of evaluations per year after that. The industry-initiated evaluations should be limited in relation to the EPA ones in any year.

The absence of a complicated prioritization scheme is a key feature that we support in the draft. The changes we propose would ensure steady progress on chemicals to benefit public health and the environment while also providing companies that step forward with the opportunity, if deserved, for the imprimatur of safety.

Persistent and Bioaccumulative Toxic Chemicals

One of TSCA's only clear areas of success was the elimination of the production and distribution of polychlorinated biphenyls (PCBs), which were explicitly named in the law. The chemicals were widely used at the time in electrical transformers. Their high concentration in fish and even in the breast milk of nursing mothers raised public health concerns and drove Congressional action on chemicals.

PCBs were a particular problem because in addition to being toxic, they were also *persistent* – they did not break down in the environment – and *bioaccumulative* – they built up in the food chain. The phase-out of PCBs by TSCA was a clear public health success. The Centers for Disease Control and Prevention has tracked the steady decline of the chemicals in Americans. However, it is a sign of just how problematic these qualities are that almost 40 years after PCBs were banned, people continue to be exposed to the chemicals.

Dozens of other existing chemicals are known or suspected to have these same properties. EPA has the ability to screen for them and routinely does so as part of the new chemicals

program. The lesson of PCBs in original TSCA is that early detection and expedited risk management were needed to realize public health benefits years later. We should apply that lesson to TSCA reform by requiring similar expedited action on chemicals with the same properties as PCBs.

Scope of Preemption

As noted above, we support the Discussion Draft's retention of current TSCA regarding the timing of preemption, co-enforcement, the waiver, and the savings clause. It is important to note, however, that the draft does expand the preemption in current law by eliminating the ability of states to ban a chemical outright if EPA has imposed risk management and by applying preemption to states when EPA has made a finding of "no unreasonable risk."

The draft needs a grandfather clause to preserve the state laws enacted in the intervening years since TSCA passed. These laws have generally become settled matters of public health policy and preserving them would ensure there is no backsliding.

In addition, the preemption appears to apply broadly to any state action on a chemical even if a federal evaluation addressed only one source of exposure to the chemical or one type of hazard. The draft would prohibit a state from taking action on a chemical in a toy, for example, if EPA only examined the use of the chemical in furniture or looked only at acute health effects and not at chronic effects like cancer or reproductive toxicity. Further clarification on the scope of preemption is needed.

Science Policy Prescriptions

The draft contains several provisions that direct how EPA should consider scientific evidence and sets limits on what studies the agency can rely upon in assessing the safety of chemicals. We are concerned that several of these provisions are overly proscriptive – and may improperly tie EPA's hands from considering information important for accurately assessing the potential risks of a substance, as well as create multiple hooks for litigation. In addition, the draft directs EPA to use a concept – "Weight of the Evidence" – that the National Academies of Sciences have specifically rejected. It fails to require approaches – including aggregate assessment – that the National Academies have specifically recommended. If the bill is going to depart from the "less is more" philosophy in the area of science policy, it should adhere to the approaches recommended by our most authoritative scientific body.

Judicial Review Standard

The standard for judicial review under TSCA – "substantial evidence" – departs from virtually every other environmental statute and played a role in the fateful court decision around asbestos. It places a greater evidentiary burden on EPA for its decisions than the more common "arbitrary and capricious" standard. Since a goal of TSCA reform is to ensure EPA can implement necessary risk management for unsafe chemicals, the judicial review standard should finally be changed.

Confidential Business Information

The draft explicitly recognizes the obligation of companies to substantiate claims of confidential business information. This is long overdue. However, in order to respond to widespread concern about abuses and to ensure the availability of public information, EPA should be required to review such claims by a set deadline. And given the large volume of existing chemicals and existing claims, the effect of these changes would be significantly enhanced if they applied substantiation and review to past claims. Under the draft as now written, substantiation would be limited to information submitted after enactment of the new law. Also, we should be sure that EPA is authorized to disclose information to the full range of first responders, state, local and tribal officials, and medical professionals in emergency and public health situations.

Conclusion

We appreciate that the draft addresses several of the concerns we have raised over the course of the TSCA reform debate. Our goal for reform is a clear improvement in public health and environmental protection at the federal level, with no backsliding from rollbacks or undue preemption. The recommendations we've made today would help the legislation achieve that goal. We continue to analyze the legislation and look forward to working with the committee as you consider TSCA modernization.

Mr. SHIMKUS. I thank you for your opening statement, and I will turn to myself for the start of the first round of questions and recognize myself for 5 minutes.

Mr. WALLS, under section 6 of the House discussion draft, EPA must determine that a substance presents or will present in the absence of risk-management measures and unreasonable risk of injury to health or the environment. Do you believe the discussion draft establishes a workable process for evaluating risk and identifying necessary risk-management measures?

Mr. WALLS. Yes.

Mr. SHIMKUS. Do you believe the discussion draft provides clear direction to EPA to consider only health and environment considerations in evaluating the risk of chemical substances?

Mr. WALLS. Yes.

Mr. SHIMKUS. And then Dr. Bosley, do you agree with the bill's provision that breaks out risk evaluation, analysis of hazard and exposure as a separate question from the details of how to restrict a chemical by rulemaking?

Ms. BOSLEY. Yes, I do.

Mr. SHIMKUS. You have previously testified that Congress should include deadlines in TSCA. The updated discussion draft contains enforceable deadlines. Does the way that the discussion draft handles this matter satisfy you?

Ms. BOSLEY. It does. I would like to see clearer deadlines that can be achieved by EPA.

Mr. SHIMKUS. Are you concerned that deadlines might force EPA into making decisions to meet a deadline?

Ms. BOSLEY. I am sorry. What was—

Mr. SHIMKUS. Do you think—well, the deadline issue, which is obviously a debatable question, would force them to make a quicker decision because of the deadline versus the science I guess is a better way to put it. Do you think the deadlines will force them to make bad—

Ms. BOSLEY. A bad call?

Mr. SHIMKUS. Yes.

Ms. BOSLEY. I don't think so. The scientists and engineers at the EPA are very talented, and I think given what we have seen with new chemicals, they are able to make decisions in a very timely manner, and I think with the correct resources for existing chemicals—I think it all hinges on that as to how quickly they can address, so with correct resources, they should be able to—

Mr. SHIMKUS. What about the debate from the business perspective and the issue of litigation on missing a deadline or the like?

Ms. BOSLEY. Yes. So I guess if it were up to me to write the bill, I would give EPA the ability to say, "Look, this happened, and so we need this much more time, we need another 3 months." So I would give them that ability. We wouldn't want that to go on for years and years, but I would give them the ability to say, "Well, there is this unforeseen circumstance, and we need a little more time."

Mr. SHIMKUS. The discussion draft permits a manufacturer to request EPA to conduct a risk evaluation of a chemical substance. Do you agree that this process can help EPA accelerate their review of existing chemicals in commerce?

Ms. BOSLEY. I should think it would, yes.

Mr. SHIMKUS. In your business, do you conduct a basic risk evaluation of your chemical products and could that information inform EPA's review of a substance?

Ms. BOSLEY. We do. We don't do a reaction in the lab without performing a risk evaluation beforehand.

Mr. SHIMKUS. So it kind of addresses some of the questions we had to Mr. Jones on definitive timelines, and I guess to you and then I will go to Mr. Walls, talk about what would industry do if they are going to pay a fee to have a chemical reviewed? Would you think that there would be then a partnership that the sectors would be trying to work together or do you think they would just do that without providing information?

Ms. BOSLEY. Oh, no, I would think that they would work together.

Mr. SHIMKUS. Because that would help you expedite the system. You could check your—

Ms. BOSLEY. In my case, for a small business, I would suspect we would have less to add than maybe a larger business, because I don't have any toxicologists on staff, for instance. So I would rely on EPA toxicologists. So it may differ between the actual business and the actual circumstance how much information would be given, but we would always try to participate very heavily with EPA.

Mr. SHIMKUS. And Mr. Walls?

Mr. WALLS. Mr. Shimkus, I think what has been the hallmark of section 5 right now, the new chemical review provision, has been that it has promoted a dialog between the industry and EPA. I would see the same sort of circumstance applying here in the manufacturer-initiated process.

Mr. SHIMKUS. And that again back to you, Mr. Walls and Dr. Bosley, and in this process under new chemicals, are you confident that confidential business information as you are going through this process with the EPA is currently being protected? Obviously that is a concern that we try to address a little bit.

Mr. WALLS. EPA has very rigorous controls to protect confidential information, yes.

Ms. BOSLEY. I am confident all of our information is protected.

Mr. SHIMKUS. Great. I think that is all I have, so with that—and Mr. Igrejas, we look forward to continuing to work with you because obviously we are moving forward. There is some bipartisan interest, and we want to continue to be open, so let's keep working together.

With that, I yield back my time and turn to the ranking member, Mr. Tonko.

Mr. TONKO. Thank you, Mr. Chair, and thank you again to all the members of the panel. Your testimony is obviously very helpful, and we appreciate your participation.

I would like to follow up on the earlier questions I had of the first panel member, and under the draft, manufacturers would have unlimited ability to require EPA to conduct risk evaluations, and there is no required number of EPA-initiated risk evaluations.

Mr. Igrejas, do you find that to be a concern?

Mr. IGREJAS. We do. I would share the concern that Mr. Jones raised, that they really don't have the ability to—the discretion to

turn down the request and then they have to complete it under an expedited time frame. I imagine that those risk evaluations would be valuable to a number of companies. There are a number of companies who have developed data and they would bring that forward. And even if that is all on the up and up, in other words, even if EPA agrees and we would agree looking at the data, if that winds up being most of what they do, you are really not dealing with the chemicals that are causing a problem for public health and the environment right now. So even if you take the process at the most positive view of it—but I think there is another element too which is as far as I can tell, the burden of proof would still be on EPA, so they have to undertake this evaluation but then the burden of proof is still on them if they find an unreasonable risk to prove with substantial evidence, et cetera, et cetera. So it is not that—they are not—they would be doing it a little bit under the gun in that sense. It is not like the drug burden of proof that we have.

Mr. TONKO. And Mr. Jones spoke about the need for clarification to ensure that determinations as a risk must be acted on would not include cost considerations. Do you agree that EPA's determinations of whether a chemical substance needs risk management should be made without cost considerations?

Mr. IGREJAS. We would agree with what he said, that they should identify the risk cleanly, health only, is this causing an unreasonable amount of risk, cancer, learning disabilities, birth defects, et cetera, and then the rule should be required to adequately protect against the risk, and then the cost considerations should be sort of behind that line, how you do that, how quickly can we phase in alternatives, how quickly can we impose these restrictions. That is where the role of cost should come in. And the draft, we would agree with him that it is a judgment call and we are concerned that a court could find that the old balancing still applies. As we know from the asbestos decision, that was where you had risks that were so severe, you had an unusual level of quantifiableness to the health cost of asbestosis and mesothelioma, and the court still find that EPA couldn't prove that those quantifiable costs outweighed the benefits that asbestos brought to the economy. So it is a very—it is a big issue that has to be gotten right.

Mr. TONKO. So I am hearing a little clarification needed in the language of the draft.

What about our other panelists in that regard to the cost language?

Ms. BOSLEY. Oh, yes, I think that clarification there to give EPA guidance would be very helpful. We wouldn't want it to end up in the courts as well.

Mr. WALLS. Mr. Tonko, I think the discussion draft reflects a desire to ensure that EPA continues to have the discretion, a considerable amount of discretion in managing the process, et cetera. I don't think that the language in and of itself mandates that EPA adopt a process that raises the very same problems we have under current law. I think the intent is clear to do something different if it takes an additional clarification to get there. I hesitate—

Mr. TONKO. If left as is, does it invite additional litigation?

Mr. WALLS. It might, but I think the clear intention here is that, you know, EPA ought to be taking a very reasonable approach in looking at what are the costs and efficiencies related to the regulatory options under discussion.

Mr. TONKO. But I think we can agree that we all want to avoid any threat of additional litigation.

Ms. Thomas?

Ms. THOMAS. I would agree with Mr. Walls, and just add that, you know, as an end user of chemicals, we strongly believe that cost should be a factor in the risk-management process.

Mr. TONKO. And if we could turn to the use of science, Mr. Igrejas, do you have concerns about the requirements to use the weight of the scientific evidence as defined in this draft?

Mr. IGREJAS. Yes, we do. Even though that phrase sounds innocuous, the National Academy of Sciences weighed in a report that Congress requested saying that the phrase was ambiguous and were concerned that it could cause some needless delays and potentially litigation hooks over what kind of information was included and referred to be EPA in an assessment.

Mr. TONKO. Thank you. With that, I yield back, Mr. Chair.

Mr. SHIMKUS. The gentleman's time is expired. The Chair now recognizes the vice chair of the subcommittee, Mr. Harper, for 5 minutes.

Mr. HARPER. Thank you, Mr. Chairman, and thanks to each of you for being here.

Ms. Thomas, if I may ask you a few questions, what is the typical lead time from, say, the design to the time that a new car is going to show up on the showroom floor?

Ms. THOMAS. Thank you for your question, and, you know, it varies amongst automakers but generally lead time is 5 to 7 years for a new production model. It is obviously longer for advanced technologies like electric vehicles. But that goes back to the articles debate and why, if EPA were to take action on a chemical substance in an article there should be, you know, lead time should be considered in that process.

Mr. HARPER. So when EPA is looking at what they are going to do in a situation, that is something you believe they should take into account is that significant lead time on what they are going to try to do?

Ms. THOMAS. Absolutely, because we need that time to obviously make the necessary changes and suitable alternatives should also be available.

Mr. HARPER. What are some practical examples from your members that help illustrate why you are seeking these changes to TSCA?

Ms. THOMAS. So, you know, our top priority is one single national program for chemical management, and that it be implemented at the Federal level. You know, a patchwork of inconsistent, conflicting State requirements just imposes a huge burden on complex durable-goods manufacturers like automakers. We manufacture vehicles to meet customer needs and to be sold in all 50 States, and inconsistent requirements, like, for example, there is—California and Washington State have brake friction standards to eliminate heavy metals and asbestos, and as much as they have tried to har-

monize those regulations, there is still inconsistencies that we require a lot of resources and significant time obviously.

Mr. HARPER. So you can't have 50 different cars—the same car designed 50 different ways to sell in each State?

Ms. THOMAS. No, that would be quite challenging.

Mr. HARPER. Although sometimes you feel like that is what you might have to do.

Please explain the technical, economic and logistical barriers that often make such redesigned replacement parts infeasible if not perhaps impossible to achieve.

Ms. THOMAS. Sure. So like I indicated, there is a lot of confusion around this area. You know, we are not talking about all automobile parts, and we certainly don't believe that they should be exempt from TSCA requirements. We are talking about a small universe of parts, 1 to 5 percent of vehicle production parts, and it is critical that those parts are needed to servicing and maintaining the existing fleet and, you know, the average age of a car is 11 years old. We are making vehicles that last longer these days and so we have to be able to repair them and service them and so that is why that exemption is necessary.

Mr. HARPER. Thank you very much.

Ms. BOSLEY, you have long been an advocate for maintaining section 5 and ensuring strong CBI protections. Does this updated discussion draft appropriately handle those sections to your satisfaction?

Ms. BOSLEY. It does. We are very happy with maintaining the CBI with substantiation, and we are also happy to resubstantiate or not after a certain amount of years. Section 5 works very well. The deadlines are adequate, and EPA can always extend if they need it, so we are very happy with section 5.

Mr. HARPER. Do you believe that generic names and unique chemical qualifiers or identifiers will provide the public concrete enough information about your chemical without giving away your intellectual property?

Ms. BOSLEY. I think so. I think that manufacturers work with EPA to provide robust generic chemical names that might identify the portion of the molecule that is causing the concern or the hazard, and that is where we need to get to.

Mr. HARPER. Thank you, and I yield back the balance of my time.

Mr. SHIMKUS. The gentleman yields back his time. The Chair recognizes the ranking member of the full committee, Mr. Pallone, for 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman.

As I discussed with the first panel, I see some areas for improvement but I also think there are a lot of strong points in the chairman's discussion draft, so let me start with Mr. Igrejas.

I am particularly interested in your analysis that leaving the unreasonable-risk language in place along with the heightened standard of judicial review could perpetuate the problems EPA has faced in regulating dangerous chemicals. So do you think an important measure of any TSCA reform proposal is whether it empowers EPA to regulate known dangerous chemicals like asbestos, for example?

Mr. IGREJAS. Certainly. I think that is the main lesson from the asbestos decision.

Mr. PALLONE. OK. Do you think it is important that any TSCA reform proposal provide for expedited action to manage the risks from chemicals that are persistent, bioaccumulative and toxic?

Mr. IGREJAS. Absolutely.

Mr. PALLONE. And why is this expedited action important for those chemicals?

Mr. IGREJAS. The lesson from TSCA's action on polychlorinated biphenyls, which is something TSCA originally did, is that those qualities taken together mean the chemical is around for a longer time and the risk winds up compounding because it builds up in the food chain. So the levels go up for the end user, for people, over time and so you need to identify them earlier and take more aggressive action to restrict them earlier even to see the public health improvements 20 years later, and that is the story of PCBs.

Mr. PALLONE. Well, going back to PCBs, do you think that naming those chemicals in the statute helped move risk management forward, and would you support something similar for PBT chemicals?

Mr. IGREJAS. Well, we certainly would. We have supported that in the past. That is the simplest way of having them in the draft. You could also put in criteria for PBTs and require EPA to do the identification but naming this is fastest.

Mr. PALLONE. And I hope that we can work with the chairman as we move forward to include authorities for, you know, the way you suggested. I believe the draft shows the chairman's intent to ensure that the problems identified in Corrosion Proof Fittings are addressed, and that is an intent I share.

I just wanted to, if I could, in the time I have left, if I could just call attention to some of the strengths in this draft, which reflect points of strong agreement between stakeholders, and I just wanted to go down the line, you know, and as much as possible just answer yes or no, and I ask each of you to answer each of these questions.

Do you support removing the least-burdensome language that has been an obstacle to EPA action under section 6? Mr. Walls?

Mr. WALLS. Yes.

Mr. BOSLEY. Yes.

Ms. THOMAS. Yes.

Mr. IGREJAS. Yes.

Mr. PALLONE. Is the reporter able to get that? All right.

Do you support giving EPA authority to require testing through orders, not just rulemaking? Mr. Walls?

Mr. WALLS. Yes.

Mr. BOSLEY. Yes.

Ms. THOMAS. Yes.

Mr. IGREJAS. Yes.

Mr. PALLONE. OK. I don't want to go too fast. Do you all support upfront substantiation of future CBI claims?

Mr. WALLS. Yes.

Mr. BOSLEY. Yes.

Ms. THOMAS. Yes.

Mr. IGREJAS. Yes.

Mr. PALLONE. OK. Do you all support explicit protections for vulnerable populations?

Mr. WALLS. Yes. I think the discussion draft appropriately acknowledges the need to address potentially exposed populations.

Mr. PALLONE. Dr. Bosley?

Mr. BOSLEY. I do as well.

Ms. THOMAS. Yes, we do.

Mr. IGREJAS. Yes.

Mr. PALLONE. OK. Do you all see these changes in the draft as valuable?

Mr. WALLS. Yes, although I wouldn't necessarily agree, Mr. Pallone, with Mr. Igrejas' comments regarding asbestos and PBTs because the discussion draft limits in no way EPA's discretion to identify true priorities. But other than that, yes, we support changes.

Mr. PALLONE. Dr. Bosley?

Mr. BOSLEY. We support as well.

Mr. PALLONE. Ms. Thomas?

Ms. THOMAS. We support as well.

Mr. IGREJAS. Yes.

Mr. PALLONE. OK. And well, again, I got through this fairly quickly. I guess when you ask yes or no questions, it is easier to get through everything quickly.

So I just want to again thank the chairman for working with us as we move forward to get this done. Thanks again. I yield back.

Mr. SHIMKUS. The gentleman yields back his time. The Chair now recognizes the gentleman from Oregon, Mr. Schrader, 5 minutes.

Mr. SCHRADER. I pass, Mr. Chairman.

Mr. SHIMKUS. The gentleman passes, and the Chair recognizes the gentleman from California, Mr. McNerney, for 5 minutes.

Mr. MCNERNEY. Well, thank you, Mr. Chairman. I just want to say I appreciate your bipartisan work in getting this draft ready.

Mr. SHIMKUS. Don't let that information out.

Mr. MCNERNEY. OK. I will be careful not to.

Mr. Igrejas, I am going to ask about the catch-22 provision here. I don't think that has been asked yet.

The "may present unreasonable risk", could you explain why that is a catch-22 and what we can do about that in the draft?

Mr. IGREJAS. Sure. I think the lesson of TSCA, and because of the approach in this draft, I think it got a lot of us looking back at original TSCA more, and you read it, and there are a lot of things that sound reasonable, they sound like they should have worked, and it just turned out that when a court got into them and EPA anticipating that, they didn't. They really turned out to be significant barriers to EPA acting, and I think this would be in this category. On its face, it sounds like before EPA should get started, shouldn't they decided well, this might be something that is a problem, but the history I think of this statute and of EPA interpreting is that it could trip them up substantially. If they really have to show that it may before they undertake the evaluation to see if it does, it seems unnecessary in the spirit of the more stripped-down approach in expediting them taking action.

Mr. MCNERNEY. OK. Now, the heightened standard of judicial review, EPA actions taken under TSCA must be supported by substantial evidence in the rulemaking record, and that is a substan-

tially higher—well, that is significantly higher than the “arbitrary and capricious” standard that is normally used for EPA rules. Could you comment on how that could be improved in the TSCA?

Mr. IGREJAS. We think taking it out would be the improvement in having “arbitrary and capricious” apply to this statute as well. One of the things I think is lost is, it is not just that the court threw out the EPA rulemaking on asbestos but that because of substantial evidence, it took EPA 10 years to put together that record. I think it was a 40,000-page record. And so it has an impact on how much time—how much EPA feels it has to put under its feet in order to go forth and make a rulemaking in addition to the risk of something getting thrown out of court. So I feel it being removed would put it in line with other environmental laws.

Mr. MCNERNEY. Well, my understanding is, the “supported by substantial evidence in the rulemaking record” is what prevented the rules on asbestos from being implemented.

Mr. IGREJAS. That is right.

Mr. MCNERNEY. And that is clearly, you know, a disadvantage.

Mr. IGREJAS. It was the third leg of the stool, so to speak, in preventing EPA from taking action on asbestos.

Mr. MCNERNEY. OK. Thank you, Mr. Chairman. I yield back.

Mr. SHIMKUS. The gentleman yields back his time.

Seeing no other members present, I want to thank the panel for coming. It was a pretty good hearing. I think there are things that we want to continue to discuss. I did announce a date for a subcommittee mark, and the only thing I will say too is, as we move forward, we don't have to get it perfect right the first bite. We have subcommittee, we have full committee. Then hopefully the Senate will move something. We go to conference. There are going to be a lot of opportunities. But I appreciate the positive comments from all my colleagues. I understand the issues that they have concerns on. We look forward to really having an opportunity to get this thing done, and we look for your input to be able to do that.

So I will dismiss the second panel, and I will ask unanimous consent that all members of the subcommittee have five legislative days to submit opening statements for the record.

I also ask unanimous consent that the following letters to the subcommittee regarding the discussion draft at our hearing today be included in the record. The letters are from the American Cleaning Institute, the Environmental Working Group, the Bipartisan Policy Center, Society of Toxicologists, the American Alliance for Justice, and a statement by Dr. Paul Locke. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. SHIMKUS. And I will adjourn the hearing.

[Whereupon, at 12:15 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

[DISCUSSION DRAFT]114TH CONGRESS
1ST SESSION**H. R.** _____

To modernize the Toxic Substances Control Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVESM. _____ introduced the following bill; which was referred to the
Committee on _____**A BILL**To modernize the Toxic Substances Control Act, and for
other purposes.1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “TSCA Modernization Act of 2015”.6 (b) **TABLE OF CONTENTS.**—The table of contents of
7 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Definitions.
- Sec. 3. Testing of chemical substances and mixtures.
- Sec. 4. Regulation of hazardous chemical substances and mixtures.
- Sec. 5. Reporting and retention of information.

Sec. 6. Relationship to other Federal laws.
Sec. 7. Disclosure of data.
Sec. 8. Effect on State law.
Sec. 9. Administration of the Act.
Sec. 10. Conforming amendments.

1 **SEC. 2. DEFINITIONS.**

2 Section 3 of the Toxic Substances Control Act (15
3 U.S.C. 2602) is amended—

4 (1) by redesignating paragraphs (7) through
5 (14) as paragraphs (8) through (10) and (12)
6 through (16), respectively;

7 (2) by inserting after paragraph (6) the fol-
8 lowing:

9 “(7) The term ‘intended conditions of use’ means the
10 circumstances under which a chemical substance is in-
11 tended, known, or reasonably foreseen to be manufac-
12 tured, processed, distributed in commerce, used, and dis-
13 posed of.”;

14 (3) by inserting after paragraph (10), as so re-
15 designated, the following:

16 “(11) The term ‘potentially exposed subpopulation’
17 means a group of individuals within the general population
18 who, due to either greater susceptibility or greater poten-
19 tial exposure, are at greater risk than the general popu-
20 lation of adverse health effects from exposure to a chem-
21 ical substance.”; and

22 (4) by adding at the end the following:

1 “(17) The term ‘weight of the scientific evidence’
2 means the results of an approach that gives appropriate
3 weight to all relevant information in an integrative and
4 objective manner that takes into account the strengths
5 and limitations associated with each type of information.”.

6 **SEC. 3. TESTING OF CHEMICAL SUBSTANCES AND MIX-**
7 **TURES.**

8 Section 4 of the Toxic Substances Control Act (15
9 U.S.C. 2603) is amended—

10 (1) in subsection (a)(1)—

11 (A) in subparagraph (A)(iii), by striking “;
12 or” and inserting a semicolon;

13 (B) in subparagraph (B)(iii), by striking “;
14 and” and inserting “; or”; and

15 (C) by adding at the end the following:

16 “(C) testing of a chemical substance is nec-
17 essary to conduct a risk evaluation under section
18 6(b); and”; and

19 (2) in the matter following subsection (a)(2), by
20 inserting “, order, or consent agreement” after “by
21 rule”.

1 **SEC. 4. REGULATION OF HAZARDOUS CHEMICAL SUB-**
2 **STANCES AND MIXTURES.**

3 (a) SCOPE OF REGULATION.—Section 6(a) of the
4 Toxic Substances Control Act (15 U.S.C. 2605(a)) is
5 amended—

6 (1) by striking “finds that there is a reasonable
7 basis to conclude” and inserting “determines under
8 subsection (b)”; and

9 (2) by striking “using the least burdensome re-
10 quirements”.

11 (b) RISK EVALUATIONS.—Section 6(b) of the Toxic
12 Substances Control Act (15 U.S.C. 2605(b)) is amended
13 to read as follows:

14 “(b) RISK EVALUATIONS.—

15 “(1) IN GENERAL.—The Administrator shall
16 conduct risk evaluations pursuant to this subsection
17 to determine whether or not a chemical substance
18 presents or will present, in the absence of require-
19 ments under subsection (a), an unreasonable risk of
20 injury to health or the environment as described in
21 subsection (a).

22 “(2) APPLYING REQUIREMENTS.—The Adminis-
23 trator shall apply requirements with respect to a
24 chemical substance through a rule under subsection
25 (a) only if the Administrator determines through a
26 risk evaluation under this subsection that the chem-

1 ical substance presents or will present, in the ab-
2 sence of such requirements, an unreasonable risk of
3 injury to health or the environment as described in
4 subsection (a).

5 “(3) CONDUCTING RISK EVALUATION.—The
6 Administrator shall conduct and publish the results
7 of a risk evaluation under this subsection for a
8 chemical substance if—

9 “(A) the Administrator finds a reasonable
10 basis for concluding that the combination of
11 hazard from and exposure to the chemical sub-
12 stance under the intended conditions of use has
13 the potential to be high enough to present an
14 unreasonable risk of injury to health or the en-
15 vironment; or

16 “(B) the manufacturer of a chemical sub-
17 stance requests such a risk evaluation.

18 “(4) REQUIREMENTS.—In conducting a risk
19 evaluation under this subsection, the Administrator
20 shall—

21 “(A) integrate and assess information on
22 hazards and exposures for the intended condi-
23 tions of use of the chemical substance, includ-
24 ing information that is relevant to specific risks
25 of injury to health or the environment and in-

1 formation on potentially exposed subpopula-
2 tions, but not including information on cost and
3 other factors not directly related to health or
4 the environment;

5 “(B) take into account, where relevant, the
6 likely duration, intensity, frequency, and num-
7 ber of exposures under the intended conditions
8 of use of the chemical substance;

9 “(C) describe the weight of the scientific
10 evidence for identified hazard and exposure;

11 “(D) consider whether the weight of the
12 scientific evidence supports the identification of
13 threshold doses of the chemical substance below
14 which no adverse effects can be expected to
15 occur; and

16 “(E) in the case of a risk evaluation re-
17 quested by a manufacturer under paragraph
18 (3)(B), ensure that the costs to the Environ-
19 mental Protection Agency, including contractor
20 costs, of conducting the risk evaluation are paid
21 for by the manufacturer.

22 “(5) DEADLINES.—

23 “(A) RISK EVALUATIONS.—The Adminis-
24 trator shall conduct and publish a risk evalua-

1 tion under this subsection for a chemical sub-
2 stance not later than—

3 “(i) 3 years after the date on which
4 the Administrator makes a finding under
5 paragraph (3)(A); or

6 “(ii) 180 days after the date on which
7 a manufacturer requests the risk evalua-
8 tion under paragraph (3)(B).

9 “(B) SUBSECTION (a) RULES.—If, based
10 on a risk evaluation conducted under this sub-
11 section, the Administrator determines that a
12 chemical substance presents or will present, in
13 the absence of a rule under subsection (a), an
14 unreasonable risk of injury to health or the en-
15 vironment as described in subsection (a), the
16 Administrator shall—

17 “(i) propose a rule under subsection
18 (a) for the chemical substance not later
19 than 90 days after the date on which the
20 risk evaluation regarding such chemical
21 substance is published under subparagraph
22 (A); and

23 “(ii) publish in the Federal Register a
24 final rule not later than 180 days after
25 such publication date.

1 “(C) EXTENSION.—If the Administrator
2 determines that additional information is nec-
3 essary to make a risk evaluation determination
4 under this subsection, the Administrator may
5 extend deadlines under subparagraph (B) ac-
6 cordingly, except that the deadline under sub-
7 paragraph (B)(i) may not be extended to a date
8 that is later than—

9 “(i) 90 days after receipt of such ad-
10 ditional information; or

11 “(ii) 2 years after the original dead-
12 line.

13 “(6) DETERMINATIONS OF NO UNREASONABLE
14 RISK.—

15 “(A) NOTICE AND COMMENT.—Not later
16 than 30 days before publishing a final deter-
17 mination under this subsection that a chemical
18 substance will not present an unreasonable risk
19 of injury to health or the environment, the Ad-
20 ministrator shall make a preliminary determina-
21 tion to such effect and provide public notice of,
22 and an opportunity for comment regarding,
23 such preliminary determination.

24 “(B) POTENTIALLY EXPOSED SUBPOPULA-
25 TIONS.—The Administrator shall not make a

1 determination under this subsection that a
2 chemical substance will not present an unrea-
3 sonable risk of injury to health or the environ-
4 ment if the Administrator determines that the
5 chemical substance, under the intended condi-
6 tions of use, poses an unreasonable risk of in-
7 jury to 1 or more potentially exposed sub-
8 populations.

9 “(C) FINAL ACTION.—A final determina-
10 tion under this subsection that a chemical sub-
11 stance will not present an unreasonable risk of
12 injury to health or the environment shall be
13 considered a final agency action.”.

14 (e) PROMULGATION OF SUBSECTION (a) RULES.—
15 Section 6(e) of the Toxic Substances Control Act (15
16 U.S.C. 2605(e)) is amended—

17 (1) by amending paragraph (1) to read as fol-
18 lows:

19 “(1) REQUIREMENTS FOR RULE.—In promul-
20 gating any rule under subsection (a) with respect to
21 a chemical substance or mixture, the Administrator
22 shall—

23 “(A) consider and publish a statement with
24 respect to—

1 “(i) the effects of the chemical sub-
2 stance or mixture on health and the mag-
3 nitude of the exposure of human beings to
4 the chemical substance or mixture;

5 “(ii) the effects of the chemical sub-
6 stance or mixture on the environment and
7 the magnitude of the exposure of the envi-
8 ronment to the chemical substance or mix-
9 ture;

10 “(iii) the benefits of the chemical sub-
11 stance or mixture for various uses; and

12 “(iv) the reasonably ascertainable eco-
13 nomic consequences of the rule, including
14 consideration of the likely effect of the rule
15 on the national economy, small business,
16 technological innovation, the environment,
17 and public health;

18 “(B) impose requirements under the rule
19 that the Administrator determines, consistent
20 with the information published under subpara-
21 graph (A), are cost-effective;

22 “(C) based on the information published
23 under subparagraph (A), in deciding whether to
24 prohibit or restrict in a manner that substan-
25 tially prevents a specific use of a chemical sub-

1 stance or mixture and in setting an appropriate
2 transition period for such action, determine
3 whether technically and economically feasible al-
4 ternatives that benefit health or the environ-
5 ment, compared to the use so proposed to be
6 prohibited or restricted, will be reasonably
7 available as a substitute when the proposed pro-
8 hibition or restriction takes effect;

9 “(D) exempt replacement parts that are
10 manufactured prior to the effective date of the
11 rule for articles that are first manufactured
12 prior to the date of publication in the Federal
13 Register of the rule unless the Administrator
14 finds such replacement parts contribute signifi-
15 cantly to the identified risk; and

16 “(E) in selecting among prohibitions and
17 restrictions to address an identified risk, apply
18 prohibitions or restrictions to articles on the
19 basis of a chemical substance or mixture con-
20 tained in the article only to the extent necessary
21 to mitigate the identified risk.”;

22 (2) in paragraph (2)—

23 (A) by inserting “PROCEDURES.—” before
24 “When prescribing a rule”;

1 (B) by striking “provide an opportunity for
2 an informal hearing in accordance with para-
3 graph (3); (D)”;

4 (C) by striking “, and (E)” and inserting
5 “; and (D)”;

6 (D) by moving such paragraph 2 ems to
7 the right;

8 (3) by striking paragraphs (3) and (4) and re-
9 designating paragraph (5) as paragraph (3); and
10 (4) in paragraph (3) (as so redesignated)—

11 (A) by striking “Paragraphs (1), (2), (3),
12 and (4)” and inserting “APPLICATION.—Para-
13 graphs (1) and (2)”;

14 (B) by moving such paragraph 2 ems to
15 the right.

16 (d) EFFECTIVE DATE.—Section 6(d)(2)(B) of the
17 Toxic Substances Control Act (15 U.S.C. 2605(d)(2)(B))
18 is amended by adding at the end the following: “Any rule
19 promulgated under subsection (a) shall provide for a rea-
20 sonable transition period.”.

21 **SEC. 5. REPORTING AND RETENTION OF INFORMATION.**

22 Section 8(b) of the Toxic Substances Control Act (15
23 U.S.C. 2607(b)) is amended by adding at the end the fol-
24 lowing:

1 “(3) The Administrator shall periodically collect in-
2 formation under this subsection as necessary to remove
3 from the list any chemical substance that is no longer
4 manufactured or processed in the United States, and re-
5 vise the list accordingly.”.

6 **SEC. 6. RELATIONSHIP TO OTHER FEDERAL LAWS.**

7 Section 9(b) of the Toxic Substances Control Act (15
8 U.S.C. 2608(b)) is amended—

9 (1) by striking “The Administrator shall coordi-
10 nate” and inserting “(1) The Administrator shall co-
11 ordinate”; and

12 (2) by adding at the end the following:

13 “(2) In making a determination under paragraph (1)
14 that it is in the public interest for the Administrator to
15 take an action under this title rather than under another
16 law administered in whole or in part by the Administrator,
17 the Administrator shall compare the relative risks, esti-
18 mated costs, and efficiencies of the action to be taken
19 under this title and an action to be taken under such other
20 law to protect against such risk.”.

21 **SEC. 7. DISCLOSURE OF DATA.**

22 Section 14 of the Toxic Substances Control Act (15
23 U.S.C. 2613) is amended—

24 (1) in subsection (a)—

1 (A) by striking “or” at the end of para-
2 graph (3);

3 (B) by striking the period at the end of
4 paragraph (4) and inserting a semicolon; and

5 (C) by adding after paragraph (4) the fol-
6 lowing new paragraphs:

7 “(5) may be disclosed to a State, local, or tribal
8 government official upon request of the official for
9 the purpose of administration or enforcement of a
10 law; and

11 “(6) shall be disclosed upon request—

12 “(A) to a health or environmental profes-
13 sional employed by a Federal or State agency in
14 response to an environmental release; or

15 “(B) to a treating physician or other
16 health care professional to assist in the diag-
17 nosis or treatment of 1 or more individuals.”;

18 (2) in subsection (b)(1), in the matter following
19 subparagraph (B), by striking “discloses processes”
20 and inserting “discloses formulas or processes”;

21 (3) by amending subsection (c)(1) to read as
22 follows:

23 “(c) DESIGNATING AND SUBSTANTIATING CON-
24 FIDENTIALITY.—(1)(A) In submitting information under
25 this Act after date of enactment of the TSCA Moderniza-

1 tion Act of 2015, a manufacturer, processor, or distributor
2 in commerce shall designate the information which such
3 person believes is entitled to protection under this section,
4 and submit such designated information separately from
5 other information submitted under this Act. A designation
6 under this subparagraph shall be made in writing and in
7 such manner as the Administrator may prescribe, and
8 shall include—

9 “(i) justification for each designation of
10 confidentiality;

11 “(ii) a certification that the information is
12 not otherwise publicly available; and

13 “(iii) separate copies of all submitted infor-
14 mation, with 1 copy containing and 1 copy ex-
15 cluding the information to which the request
16 applies.

17 “(B) Designations made under subparagraph (A)
18 after the date of enactment of the TSCA Modernization
19 Act of 2015 shall expire after 10 years, at which time the
20 information shall be made public unless the manufacturer,
21 processor, or distributor in commerce has submitted a re-
22 quest for renewal, made in writing and in such manner
23 as the Administrator may prescribe, including all of the
24 elements required for the initial submission.”; and

1 (4) by adding at the end the following new sub-
2 section:

3 “(f) PROHIBITION.—No person who receives informa-
4 tion as permitted under subsection (a) or (b) may use such
5 information for any purpose not specified in such sub-
6 section, nor disclose such information to any person not
7 authorized to receive such information.”.

8 **SEC. 8. EFFECT ON STATE LAW.**

9 Section 18(a)(2) of the Toxic Substances Control Act
10 (15 U.S.C. 2617(a)(2)) is amended—

11 (1) in subparagraph (A), by striking “; and”
12 and inserting a semicolon; and

13 (2) by striking subparagraph (B) and inserting
14 the following:

15 “(B) if the Administrator makes a final deter-
16 mination under section 6(b) that a chemical sub-
17 stance will not present an unreasonable risk of in-
18 jury to health or the environment under the intended
19 condition of use, no State or political subdivision
20 may, after the date of publication of such determina-
21 tion, establish or continue in effect any requirement
22 that applies to such chemical substance under the
23 intended conditions of use and is designed to protect
24 against exposure to such chemical substance under
25 the intended conditions of use; and

1 “(C) if the Administrator imposes a require-
2 ment, through a rule or order under section 5 or 6,
3 that applies to a chemical substance or mixture
4 (other than a requirement described in section
5 6(a)(5)), no State or political subdivision may, after
6 the effective date of such requirement, establish or
7 continue in effect any requirement that applies to
8 such chemical substance or mixture (including a re-
9 quirement that applies to an article because the arti-
10 cle contains the chemical substance or mixture) and
11 is designed to protect against exposure to the chem-
12 ical substance or mixture, unless the requirement of
13 the State or political subdivision—

14 “(i) is identical to the requirement imposed
15 by the Administrator; or

16 “(ii) is adopted under the authority of a
17 Federal law.”.

18 **SEC. 9. ADMINISTRATION OF THE ACT.**

19 Section 26 of the Toxic Substances Control Act (15
20 U.S.C. 2625) is amended—

21 (1) in subsection (b)(1)—

22 (A) by inserting “, or who requests a risk
23 evaluation under section 6(b)(3)(B),” before “to
24 defray the cost”; and

1 (B) by striking “Such rules shall not pro-
2 vide for any fee in excess of \$2,500 or, in the
3 case of a small business concern, any fee in ex-
4 cess of \$100.” and inserting “Such rules shall
5 provide for lower fees for small business con-
6 cerns.”; and

7 (2) by adding at the end the following:

8 “(h) SCIENTIFIC STANDARDS.—In evaluating infor-
9 mation from studies and tests, and in carrying out sec-
10 tions 4, 5, and 6 to the extent that the Administrator
11 makes a decision based on science, the Administrator shall
12 consider, among other applicable factors—

13 “(1) the extent to which the scientific and tech-
14 nical procedures, measures, methods, or models em-
15 ployed to generate the information are reasonable
16 for and consistent with the intended use of the infor-
17 mation;

18 “(2) the extent to which the information is rel-
19 evant for the Administrator’s intended use;

20 “(3) the degree of clarity and completeness with
21 which the data, assumptions, methods, quality assur-
22 ance, sponsoring organizations, and analyses em-
23 ployed to generate the information are documented;

24 “(4) the extent to which the variability and un-
25 certainty in the information, or in the procedures,

1 measures, methods, or models, are evaluated and
2 characterized; and

3 “(5) the extent of independent verification, vali-
4 dation, and peer review of the information or of the
5 procedures, measures, methods, or models.

6 “(i) WEIGHT OF SCIENTIFIC EVIDENCE.—The Ad-
7 ministrator shall make decisions under sections 4, 5, and
8 6 based on the weight of the scientific evidence.

9 “(j) AVAILABILITY OF INFORMATION.—Subject to
10 section 14, the Administrator shall make available to the
11 public all notices, determinations, findings, rules, and or-
12 ders of the Administrator under this title.

13 “(k) POLICIES, PROCEDURES, AND GUIDANCE.—

14 “(1) DEVELOPMENT.—Not later than 2 years
15 after the date of enactment of the TSCA Moderniza-
16 tion Act of 2015, the Administrator shall develop
17 any policies, procedures, and guidance the Adminis-
18 trator determines are necessary to carry out the
19 amendments to this Act made by the TSCA Mod-
20 ernization Act of 2015.

21 “(2) REVIEW.—Not later than 5 years after the
22 date of enactment of the TSCA Modernization Act
23 of 2015, and not less frequently than once every 5
24 years thereafter, the Administrator shall—

1 “(A) review the adequacy of the policies,
2 procedures, and guidance developed under para-
3 graph (1), including with respect to animal,
4 nonanimal, and epidemiological test methods
5 and procedures for assessing and determining
6 risk under this title; and

7 “(B) revise such policies, procedures, and
8 guidance as the Administrator determines nec-
9 essary to reflect new scientific developments or
10 understandings.

11 “(l) SAVINGS.—Nothing in this title shall be con-
12 strued to affect either the tort law or the law governing
13 the interpretation of contracts of any State.”.

14 **SEC. 10. CONFORMING AMENDMENTS.**

15 (a) SECTION 4.—Section 4 of the Toxic Substances
16 Control Act (15 U.S.C. 2603) is amended—

17 (1) in subsection (b)—

18 (A) in paragraph (1), by striking “rule”
19 each place it appears and inserting “rule, order,
20 or consent agreement”;

21 (B) in paragraph (2)(B), by striking
22 “rules” and inserting “rules, orders, and con-
23 sent agreements”;

1 (C) in paragraph (3), by striking “rule”
2 each place it appears and inserting “rule, order,
3 or consent agreement”; and

4 (D) in paragraph (4)—

5 (i) by striking “rule under subsection
6 (a)” each place it appears and inserting
7 “rule, order, or consent agreement under
8 subsection (a)”;

9 (ii) by striking “repeals the rule” each
10 place it appears and inserting “repeals the
11 rule or order or modifies the consent
12 agreement to terminate the requirement”;
13 and

14 (iii) by striking “repeals the applica-
15 tion of the rule” and inserting “repeals or
16 modifies the application of the rule, order,
17 or consent agreement”;

18 (2) in subsection (c)—

19 (A) in paragraph (1), by striking “rule”
20 and inserting “rule or order”;

21 (B) in paragraph (2)—

22 (i) in subparagraph (A), by striking
23 “a rule under subsection (a) or for which
24 data is being developed pursuant to such a
25 rule” and inserting “a rule, order, or con-

1 sent agreement under subsection (a) or for
2 which data is being developed pursuant to
3 such a rule, order, or consent agreement”;
4 (ii) in subparagraph (B), by striking
5 “such rule or which is being developed pur-
6 suant to such rule” and inserting “such
7 rule, order, or consent agreement or which
8 is being developed pursuant to such rule,
9 order, or consent agreement”; and
10 (iii) in the matter following subpara-
11 graph (B), by striking “the rule” and in-
12 serting “the rule or order”;
13 (C) in paragraph (3)(B)(i), by striking
14 “rule promulgated” and inserting “rule, order,
15 or consent agreement”; and
16 (D) in paragraph (4)—
17 (i) by striking “rule promulgated”
18 each place it appears and inserting “rule,
19 order, or consent agreement”;
20 (ii) by striking “such rule” each place
21 it appears and inserting “such rule, order,
22 or consent agreement”; and
23 (iii) in subparagraph (B), by striking
24 “the rule” and inserting “the rule, order,
25 or consent agreement”;

1 (3) in subsection (d), by striking “rule” and in-
2 serting “rule, order, or consent agreement”; and

3 (4) in subsection (g), by striking “rule” and in-
4 serting “rule, order, or consent agreement”.

5 (b) SECTION 5.—Section 5 of the Toxic Substances
6 Control Act (15 U.S.C. 2604) is amended—

7 (1) in subsection (b)—

8 (A) in paragraph (1)(A)—

9 (i) by striking “rule promulgated”
10 and inserting “rule, order, or consent
11 agreement”; and

12 (ii) by striking “such rule” and insert-
13 ing “such rule, order, or consent agree-
14 ment”;

15 (B) in paragraph (1)(B)—

16 (i) by striking “rule promulgated”
17 and inserting “rule or order”; and

18 (ii) by striking “the date of the sub-
19 mission in accordance with such rule” and
20 inserting “the required date of submis-
21 sion”; and

22 (C) in paragraph (2)(A)(ii), by striking
23 “rule promulgated” and inserting “rule, order,
24 or consent agreement”; and

1 (2) in subsection (d)(2)(C), by striking “rule”
2 and inserting “rule, order, or consent agreement”.

3 (e) SECTION 7.—Section 7(a)(1) of the Toxic Sub-
4 stances Control Act (15 U.S.C. 2606(a)(1)) is amended,
5 in the matter following subparagraph (C), by striking “a
6 rule under section 4, 5, 6, or title IV or an order under
7 section 5 or title IV” and inserting “a rule under section
8 4, 5, or 6 or title IV, an order under section 4 or 5 or
9 title IV, or a consent agreement under section 4”.

10 (d) SECTION 8.—Section 8(a)(3)(A)(ii)(I) of the
11 Toxic Substances Control Act (15 U.S.C.
12 2607(a)(3)(A)(ii)(I)) is amended by striking “or an order
13 in effect under section 5(e)” and inserting “, an order in
14 effect under section 4 or 5(e), or a consent agreement
15 under section 4”.

16 (e) SECTION 9.—Section 9(a) of the Toxic Sub-
17 stances Control Act (15 U.S.C. 2608(a)) is amended by
18 striking “section 6” each place it appears and inserting
19 “section 6(a)”.

20 (f) SECTION 11.—Section 11(b)(2)(E) of the Toxic
21 Substances Control Act (15 U.S.C. 2610(b)(2)(E)) is
22 amended by striking “rule promulgated” and inserting
23 “rule promulgated, order issued, or consent agreement en-
24 tered into”.

1 (g) SECTION 15.—Section 15(1) (15 U.S.C. 2614(1))
2 is amended by striking “(A) any rule” and all that follows
3 through “or (D)” and inserting “any requirement of this
4 title or any rule promulgated, order issued, or consent
5 agreement entered into under this title, or”.

6 (h) SECTION 18.—Section 18(a)(2)(A) of the Toxic
7 Substances Control Act (15 U.S.C. 2617(a)(2)(A)) is
8 amended—

9 (1) by striking “rule promulgated” and insert-
10 ing “rule, order, or consent agreement”; and

11 (2) by striking “such rule” each place it ap-
12 pears and inserting “such rule, order, or consent
13 agreement”.

14 (i) SECTION 19.—Section 19 of the Toxic Substances
15 Control Act (15 U.S.C. 2618) is amended—

16 (1) in subsection (a)—

17 (A) in paragraph (1)(A)—

18 (i) by striking “(A) Not later than 60
19 days after the date of the promulgation of
20 a rule” and inserting “Not later than 60
21 days after the date on which a rule is pro-
22 mulgated”;

23 (ii) by inserting “or the date on which
24 an order is issued under section 4,” before
25 “any person”;

- 1 (iii) by striking “such rule” and in-
2 sserting “such rule or order”; and
3 (iv) by striking “such a rule” and in-
4 sserting “such a rule or order”;
5 (B) by striking paragraph (1)(B);
6 (C) in paragraph (2), by striking “the
7 rule” and inserting “the rule or order”; and
8 (D) in paragraph (3)—
9 (i) in subparagraph (A), by striking
10 “the rule” and inserting “the rule or
11 order”;
12 (ii) in subparagraph (B), by striking
13 “a rule under section 4(a)” and inserting
14 “a rule or order under section 4(a)”;
15 (iii) in subparagraph (C), by striking
16 “such rule” and inserting “such rule or
17 order”;
18 (iv) in subparagraph (D), by striking
19 “such rule” and inserting “such rule or
20 order”; and
21 (v) in subparagraph (E)—
22 (I) by striking “such rule” and
23 inserting “such rule or order”; and
24 (II) by striking “the date of the
25 promulgation of such rule” and in-

1 serting “the date on which such rule
2 is promulgated or such order is
3 issued”;

4 (2) in subsection (b)—

5 (A) by striking “review a rule” and insert-
6 ing “review a rule, or an order under section
7 4,”;

8 (B) by striking “such rule” and inserting
9 “such rule or order”;

10 (C) by striking “the rule” and inserting
11 “the rule or order”;

12 (D) by striking “new rule” each place it
13 appears and inserting “new rule or order”; and

14 (E) by striking “modified rule” and insert-
15 ing “modified rule or order”; and

16 (3) in subsection (c)—

17 (A) in paragraph (1)—

18 (i) in subparagraph (A)—

19 (I) by striking “a rule” and in-
20 serting “a rule, or an order under sec-
21 tion 4”; and

22 (II) by striking “such rule” and
23 inserting “such rule or order”; and

24 (ii) in subparagraph (B)—

28

- 1 (I) in the matter preceding clause
2 (i), by striking “a rule” and inserting
3 “a rule or order”; and
4 (II) in clause (i)—
5 (aa) by inserting “or an
6 order under section 4,” before
7 “the standard for review”;
8 (bb) by striking “such rule”
9 inserting “such rule or order”;
10 and
11 (cc) by striking “the rule”
12 and inserting “the rule or order”;
13 and
14 (B) in paragraph (2), by striking “any
15 rule” and inserting “any rule or order”.
- 16 (j) SECTION 20.—Section 20(a)(1) of the Toxic Sub-
17 stances Control Act (15 U.S.C. 2619(a)(1)) is amended
18 by striking “order issued under section 5” and inserting
19 “order issued under section 4 or 5”.
- 20 (k) SECTION 21.—Section 21 of the Toxic Substances
21 Control Act (15 U.S.C. 2620) is amended—
22 (1) in subsection (a), by striking “order under
23 section 5(e) or (6)(b)(2)” and inserting “order
24 under section 4 or 5(e)”; and
25 (2) in subsection (b)—

1 (A) in paragraph (1), by striking “order
2 under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)”
3 and inserting “order under section 4 or 5(e)”;

4 (B) in paragraph (4)(B)—

5 (i) in the matter preceding clause (i),
6 by striking “order under section 5(e) or
7 6(b)(2)” and inserting “order under sec-
8 tion 4 or 5(e)”;

9 (ii) in clause (i), by striking “order
10 under section 5(e)” and inserting “order
11 under section 4 or 5(e)”;

12 (iii) in clause (ii), by striking “or an
13 order under section 6(b)(2)”.

14 (l) SECTION 24.—Section 24(b)(2)(B) of the Toxic
15 Substances Control Act (15 U.S.C. 2623(b)(2)(B)) is
16 amended—

17 (1) by inserting “and” at the end of clause (i);

18 (2) by striking clause (ii); and

19 (3) by redesignating clause (iii) as clause (ii).

20 (m) SECTION 27.—Section 27(a) of the Toxic Sub-
21 stances Control Act (15 U.S.C. 2626(a)) is amended by
22 striking “rules promulgated” and inserting “rules, orders,
23 or consent agreements”.

24 (n) SECTION 30.—Section 30(2) of the Toxic Sub-
25 stances Control Act (15 U.S.C. 2629(2)) is amended by

- 1 striking “rule” and inserting “rule, order, or consent
- 2 agreement”.



April 14, 2015

Honorable John Shimkus
Chairman
Environment and the Economy Subcommittee
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Honorable Paul Tonko
Ranking Member
Environment and the Economy Subcommittee
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

RE: Subcommittee Hearing on the TSCA Modernization Act of 2015

Dear Chairman Shimkus and Ranking Member Tonko:

The American Cleaning Institute® (ACI) supports and has actively worked for the modernization of TSCA. ACI is the trade association representing the \$30 billion U.S. cleaning products market. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers.

ACI and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. These products provide essential benefits to consumers while protecting human health and the environment. ACI's mission is to support the sustainability of the cleaning products industry through research, education, outreach and science-based advocacy.

ACI commends the Subcommittee for its release of a bipartisan discussion draft of the *TSCA Modernization Act of 2015*. ACI urges prompt action on the measure. This draft legislation, along with the bipartisan legislation in the U.S. Senate, *The Frank R. Lautenberg Chemical Safety for the 21st Century Act* (S. 697), are important milestones in the effort to strengthen and modernize our nation's premier chemical management law.

A modernized TSCA has the potential to promote product innovations that our members have long used in developing sustainable cleaning products. In many ways, TSCA has fostered innovative developments in the U.S. and globally. A modernized TSCA would help contribute to public confidence in the chemicals used to manufacture consumer products and packaging. A strengthened TSCA has the potential to promote even greater innovation in the development of evermore sustainable cleaning products.

ACI urges Congress to ensure that updates to TSCA result in a credible and workable program for the EPA and industry; one that allows EPA to meet its regulatory obligations without unduly delaying or burdening innovation. The U.S. chemical management system must be risk-based and use the best science so as not to waste or misdirect resources. Improvements in the law should reflect recent progress in science and technology and advance further innovations. It is important that a modernized TSCA allow scientific developments and advances that enable EPA to use important information developed by industry to be incorporated into chemical safety assessments and determinations.

The modernization of TSCA is important to the cleaning products industry because a robust and credible federal program is crucial to the national uniformity that industry requires. Without this, the ability to be

responsive to concerns that may be raised about chemicals in cleaning products — especially those concerns not based on reliable science — is significantly hampered.

TSCA must continue to provide robust, effective and predictable CBI protection and the discussion draft contains needed updates balanced with reasonable protections. This will provide industry confidence that it will be able to reap the benefits of its expenditures of both time and resources in research and development leading to the creation of more sustainable products. Limits on the ability of industry to preserve CBI and prevent illegitimate use of intellectual property would discourage innovation and hinder the introduction of safer chemical alternatives.

New products and greener chemistries get to U.S. consumers as fast as innovation allows because of the efficient method TSCA provides to accomplish this task. The TSCA premanufacture program is a better constructed process than any command and control regime which demands reams of data, irrespective of any health or safety concern. Hallmark features of the program that set the U.S. system apart from other regimes around the world include minimal delays, robust interactions between government and industry, and data flows all designed to meet key health and environmental goals. ACI applauds the decision to recognize the strength of the program reflected in the discussion draft.

ACI remains committed to a bipartisan, bicameral dialogue to advance the modernization of TSCA. ACI appreciates the opportunity to engage as a direct participant with you on the most critical issues related to updating the law in order to promote the safe use of chemicals; build public confidence in the chemical management system; protect American jobs, and maintain the U.S. global leadership role in chemical innovation.

Respectfully submitted,

A black rectangular redaction box covering the signature of Ernest S. Rosenberg.

Ernest S. Rosenberg
President & CEO

cc: Members of the Subcommittee on Environment and the Economy

www.ewg.org

April 14, 2015

Chairman John Shimkus
House Committee on Energy and Commerce
Subcommittee on the Environment and the Economy
2217 Rayburn House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Ranking Member Paul Tonko
House Committee on Energy and Commerce
Subcommittee on the Environment and the Economy
2463 Rayburn House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Shimkus and Ranking Member Tonko:

Although we strongly support efforts to modernize the federal Toxic Substances Control Act of 1976, EWG opposes the discussion draft of the "TSCA Modernization Act."

Simply put, the discussion draft would fail to ensure that chemicals are safe, fail to ensure that the Environmental Protection Agency quickly evaluates and regulates dangerous chemicals like asbestos, fail to set deadlines for chemical restrictions or bans, and fail to provide the EPA with needed resources. In addition, the discussion draft would fail to preserve important steps already taken by states to protect the public from dangerous chemicals.

In particular, the discussion draft would fail to ensure that chemicals regulated under TSCA are as safe as the chemicals used in and on food -- that is, that chemicals pose a "reasonable certainty of no harm." Instead, the discussion draft would continue the present policy of allowing chemicals to be used so long as they pose "no *unreasonable* risk of injury" to people and the environment. Rather than requiring that safety determinations exclude considerations of cost, the discussion draft explicitly requires the EPA to consider the economic consequences of proposed actions and to impose only those restrictions that would be cost-effective.

In addition, the discussion draft would fail to require quick action to protect Americans from dangerous chemicals, including toxic chemicals that persist in the environment and build up in people's bodies. The EPA has identified approximately 1,000 chemicals that require urgent assessment and regulation, but the discussion draft would not direct the agency to make the most dangerous chemicals a priority for evaluation, would not provide the resources needed to conduct such a review, and would not require deadlines for agency action to review, regulate or ban chemicals.

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MIDWEST OFFICE 103 E. 6th Street, Suite 201 Ames, IA 50010 | P: 515.598.2221

Instead, the discussion draft proposes a fee system that would give priority consideration and expedited action to chemicals deemed a priority by the chemical industry. Under this system, reviews of the most dangerous chemicals would be subject to the mercy of Congressional appropriators.

The discussion draft fails to require quick action on asbestos and fails to remove all of the serious legal obstacles that prevented the EPA from banning asbestos more than two decades ago. Although the draft would no longer demand adoption of the "least burdensome" alternative, it would retain the "no unreasonable risk" safety standard and then would subject EPA decisions to the heightened "substantial evidence" standard of judicial review.

Finally, the discussion draft fails to preserve important actions taken by states to protect the public from dangerous chemicals. In the absence of federal leadership, more than 30 states have enacted more than 150 laws to regulate or restrict dangerous chemicals. Any efforts to reform TSCA should preserve a role for the states.

The discussion draft proposes some important improvements, including expanded EPA authority to order chemical testing. But the draft falls far short of what is needed to ensure that chemicals are safe and that the most dangerous chemicals are quickly reviewed and regulated.

We appreciate the opportunity to share our comments and welcome the opportunity to work with you to modernize TSCA.

Sincerely,

A black rectangular redaction box covering the signature of Scott Faber.

Scott Faber
Vice President of Government Affairs
EWG



BIPARTISAN POLICY CENTER

April 14, 2015

The Honorable Fred Upton
Chairman
Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Energy and Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20515

The Honorable John Shimkus
Chairman
Subcommittee on Environment
and the Economy
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Paul Tonko
Ranking Member
Subcommittee on Environment
and the Economy
2232A Rayburn House Office Building
Washington, DC 20515

Dear Chairmen Upton and Shimkus and Ranking Members Pallone and Tonko:

I am writing to commend your leadership on legislation to reauthorize the Toxic Substances Control Act (TSCA). There is widespread agreement that the 39 year old law has not worked as intended. I applaud your effort to update the regulatory framework to achieve greater public health protections. More broadly, I am encouraged by the substantive, open and collaborative process the Committee has pursued.

The committee led efforts reveal a broader point about the importance of the committee process. In 2013, the BPC launched the Commission on Political Reform (CPR) to examine the causes and consequences of our political gridlock and develop recommendations for alleviating the impasse. Key to the commission's recommendations are several proposals aimed at restoring the role of congressional committees in legislative development and oversight. Committees have always been the engines of the democracy where legitimate partisan instincts are mediated by substantive expertise, common interests and shared constituencies.

The legislative discussion draft, hearing schedule and efforts to solicit broad stakeholder input have been critical to anchoring a productive public discussion on this complex and controversial subject and provides an excellent example of how the system can and should work. It is encouraging to see bipartisan efforts moving in both the House and the Senate to update and improve upon one of our nation's most important environmental and public health statutes.

The BPC stands ready to offer any assistance as you move forward in this important endeavor.

Sincerely,

Jason Grumet, President
Bipartisan Policy Center



2014-2015 COUNCIL April 13, 2015

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The Honorable John Shimkus, Chairman
The Honorable Paul D. Tonko, Ranking Member
House Energy and Commerce Subcommittee on Environment and the
Economy
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Shimkus and Ranking Member Tonko:

The Society of Toxicology (SOT) is pleased to provide comments on the current bipartisan discussion draft of the TSCA Modernization Act. SOT remains committed to further scientific review of future drafts of TSCA Reform legislation with the hope that a revised TSCA bill will have strong, objective, scientific underpinnings and will protect public health for years to come. Please include this letter in the official record for your subcommittee's April 14, 2015, hearing.

As Congress considers revising the Toxic Substances Control Act of 1976 (TSCA; P.L. 94-469), the Society of Toxicology, with more than 5,000 toxicology professionals in the United States and nearly 8,000 worldwide from 61 nations, strongly urges Congress to ensure the language used in TSCA reform legislation:

1. Affords flexibility in selection of the best available science for generating and evaluating information used in the safety and risk assessment process.
2. Protects the authority of the US Environmental Protection Agency, working with the scientific community, to judge when and how to apply new techniques and methods.
3. Ensures the terms and concepts used in the legislative language that apply to the science of toxicology are consistent, accurate, and unambiguous.

Specific comments:

Discussion Draft of the TSCA Modernization Act

Page 2, lines 16-21 "Potentially Exposed Subpopulation"

The previous bill substituted 'vulnerable subpopulation' for "potentially exposed population." We were supportive of that change and commented that vulnerable individuals/subpopulations could be more susceptible or more highly exposed. While this concept seems to have been covered in the new bill language, the definition has reverted to the 'potentially exposed subpopulations.' While susceptibility alone might not be a concern without sufficient exposure, it seems that 'potentially vulnerable subpopulations' would be the scientifically preferred descriptor for either more susceptible or more highly exposed subpopulations.

Page 3, lines 1-5 "Weight of the Scientific Evidence"

The SOT TSCA Task Force supports the inclusion of this definition of "weight of the scientific evidence." Considering all relevant information in an integrative and objective manner is consistent with the use of the best science for regulatory decision-making.

Page 4-5, lines 23-4 "Applying Requirements"

This language requires a risk evaluation and a positive finding of "unreasonable risk of injury..." to invoke regulation. Unlike other TSCA Reform bills, this language is a bit different than presenting a safety assessment and a safety standard of "no unreasonable risk of harm..." First, we are supportive of the concept of performing a "risk evaluation" as opposed to a safety assessment" and there appears to be no presentation of a "safety standard" in the bill, per se. Second, "injury" may be viewed by some as different from "harm," particularly when referring to impact on the environment. Other bills all seem to have settled on "harm" as the appropriate term and we would support that perspective.

Page 5, lines 5-17 Conducting Risk Evaluation

Conduct of a risk evaluation seems limited to an Agency action or a request by the manufacturer. In the spirit of openness and transparency of the nomination process, it seems that there should be an opportunity for other informed parties, such as states or other non-manufacturer entities, to make such a request. Since the bill puts the onus on the manufacturer to pay for the risk evaluation if they request it, this language as presented may place limitations on who could afford to request an evaluation and might negatively affect who would or could make such requests.

Page 6, lines 11-15 Threshold Doses

11 "(D) consider whether the weight of the
12 scientific evidence supports the identification of
13 threshold doses of the chemical substance below
14 which no adverse effects can be expected to
15 occur; and

Under the section on requirements for a risk evaluation, the statement above is included. It would be better stated if it used the approach that EPA uses for describing a reference dose...an estimate, with uncertainty spanning perhaps an order of magnitude, of a daily (oral) exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime. As stated in the discussion draft, the language is suggesting the ability to identify a dose where no effect occurs without specifying length of exposure or who is exposed.

Page 6-7, lines 23-8 Risk Evaluations

It is unclear why, and potentially problematic, that there should be a difference in the time required for the assessment depending on who requests it or is paying for it. In our experience, if the EPA, or any scientific body for that matter, is conducting the assessments, the 3 year deadline may be difficult enough to meet, given the complexity of the topics, and the requirements for peer engagement in the process. A six month deadline would be impossible for most chemicals, given past experience.

Page 8-9, lines 13-8 Determinations of No Unreasonable Risk

It is unclear why these two sections are separated. The concept of "...including vulnerable subpopulation(s)" should just be added into the first section regarding a negative finding. See comment above about "vulnerable" versus "potentially exposed" subpopulations.

Page 10-11, lines 22-8 Alternatives

The SOT Task Force is supportive of inclusion of the language regarding evaluation of alternatives, or replacement chemicals. However, we want to acknowledge the challenges, both logistical (how to identify alternatives and who will do it?) and technical (how to estimate risk with different levels of information?) in requiring such an evaluation.

Page 18-19, lines 8-5 Scientific Standards for Information

The SOT Task Force is supportive of this type of clarity around what constitutes good science and the processes and judgments for getting there. However, we caution the authors that writing this level of detail into the law opens up the possibility for procedural challenges if someone believes that one of these steps was inadequate.

We thank you again for addressing our previous comments and appreciate your consideration of our comments on this latest draft as well. We look forward to the next draft and the opportunity to work with you and your colleagues to comment further on subsequent iterations.

For the Society of Toxicology TSCA Task Force

Most Sincerely,



SOT 2014–2015 President

cc: The Honorable Fred Upton, Chairman, House Energy and Commerce Committee
The Honorable Frank Pallone, Jr., Ranking Member, House Energy and Commerce Committee



April 14, 2015

The Honorable John Shimkus
Chairman
Subcommittee on Environment and
Economy
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Paul Tonko
Ranking Member
Subcommittee of Environment and
Economy
House Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Re: The TSCA Modernization Act of 2015

Dear Chairman Shimkus and Ranking Member Tonko:

The American Association for Justice (AAJ), formerly the Association of Trial Lawyers of America (ATLA), hereby submits comments in relation to the Energy and Commerce Committee Subcommittee on the Environment and the Economy's hearing on the "TSCA Modernization Act" of 2015, draft legislation that would update the current Toxic Substances Control Act (TSCA).

AAJ, with members in United States, Canada and abroad, is the world's largest trial bar. It was established in 1946 to safeguard victims' rights, strengthen the civil justice system, promote public safety, and protect the constitutionally mandated right to a trial by jury. As advocates for people harmed by toxic chemicals, AAJ strongly supports efforts to reform TSCA to better protect American families from the harmful chemicals which are found in everything from our drinking water to children's toys and consumer products. These chemicals often pose significant and often deadly risks, especially to children, pregnant women, workers and the elderly.

Unfortunately, the draft legislation that is the subject of today's hearing, the "TSCA Modernization Act," rolls back the rights of states to protect their own citizens and wipes out civil justice protections. Accordingly, AAJ strongly opposes the "TSCA Modernization Act" as it is currently drafted.

The TSCA Modernization Act of 2015 contains loopholes that threaten the rights of victims of toxic exposures to chemicals like lead, formaldehyde, and asbestos. Under this draft, if the EPA makes a determination and an individual is later injured or killed by that toxic chemical, he or she would be unable to hold the chemical corporation accountable under his or her own state law. This not only unnecessarily wipes out individual rights under state law, but would also leave taxpayers on the hook to pay for the costs of chemical injuries.

The failure of The TSCA Modernization Act to specifically and clearly preserve fundamental rights under state law threatens the safety of all Americans by effectively immunizing chemical corporations for harms caused by toxic chemicals. If negligent chemical corporations know they will never be held accountable for selling dangerous products to the American people, what incentives do they have to ensure safety?

AAJ looks forward to working with the committee to enact meaningful TSCA reform that ensures a federal scheme truly protective of the public health, while preserving the authority of state enforcement entities and the civil justice system to promote and effectively protect public health and the environment from the risks of toxic chemicals.

Sincerely,



Linda A. Lipsen
Chief Executive Officer
American Association for Justice

cc: The Honorable Fred Upton The Honorable Frank Pallone
 Chairman Ranking Member
 House Committee on Energy and House Committee on Energy and
 Commerce Commerce
 2125 Rayburn House Office Bldg. 2322A Rayburn House Office Bldg.
 Washington, DC 20515 Washington, DC 20515

Testimony of Dr. Paul A. Locke

Associate Professor at John Hopkins Bloomberg School of Public Health,

Department of Environmental Health Sciences

Submitted to the House Energy and Commerce Subcommittee on Environment and the Economy

Hearing on TSCA Modernization Act

Tuesday, April 14, 2015, at 10:15 a.m.

Room 2322 of the Rayburn House Office Building

Chairman Shimkus, Ranking Member Pallone, and members of the subcommittee:

Thank you for the opportunity to submit testimony on the TSCA Modernization Act and the important issues of toxic chemical evaluation, advancing scientific research and efficiency and implementing public health protections.

As Congress seeks to find consensus on reforming our outdated TSCA law, it will be helpful to keep in mind important areas where agreement can and has been reached in recent years. One area of consensus is the goal of advancing the science of regulatory toxicology by implementing the recommendations made to EPA by the US National Academy of Sciences (NAS) about how to improve its testing methodologies. In its report entitled "Toxicity Testing in the Twenty-first Century: A Vision and a Strategy," the NAS advised EPA to move from a testing system based on animal models to one that is based on human biology, using cell lines and other methods that provide information about the pathways that lead to diseases caused or contributed to by chemical exposures.

Stakeholders in the issue of chemical regulation have long agreed that improving regulatory toxicology by advancing innovative testing methods, especially those that do not use animals, would be in the best interest for all involved. Industry has embraced the concept of non-animal testing, or in vitro testing, as a way to cut costs and learn about toxic cellular reactions. Animal testing can be very expensive and slow to produce usable data. Environmental and public health advocates have argued that advancing non-animal testing would provide useful data in a timely fashion that regulators could use to help make decisions that protect public health and welfare. Animal welfare advocates have also pushed for less reliance on animal tests as a way to improve and advance humane science.

Recent scientific advances offer to fundamentally change the way chemicals are tested for human health risks. These advances, which include in vitro testing, make it possible to rely less heavily on animal studies and instead focus on evaluating chemicals' effects on biological processes in cells and organs. Scientists can generate improved data to evaluate risks and expand the number of chemical assessments while taking less time and money and using fewer animal subjects. Several federal agencies — the Environmental Protection Agency, the Food and Drug Administration and the National Institutes of Health — embraced this approach and are working hard to further develop the science to make this vision a reality.

Existing chemical regulations place the burden of risk assessment on the EPA, and that is a heavy burden. More than 80,000 chemicals are registered for use in the United States and an estimated 2,000 new ones are introduced each year for use in everyday items such as foods, personal care products, prescription drugs, household cleaners, and lawn care products. TSCA has not been effective in generating chemical toxicity information for the vast majority of these chemicals. In March 2013, a Government Accountability Office report evaluated the EPA's efforts to strengthen its management of chemicals. The GAO found that the lack of data is one of the biggest impediments the EPA encounters in attempting to ensure chemical safety, even on substances prioritized for risk assessment.

It is encouraging that The TSCA Modernization Act contains at least some provisions that recognize the value of in vitro testing for regulatory decision-making. While these provisions could be stronger in this bill and other bills, the fact that they have been a common link shows that this is a fertile opportunity to build consensus. Strengthening the focus on in vitro, innovative science will increase the likelihood for consensus and put the bill on the path of employing the innovative toxicological methods that the NAS and others have recommended.

Congress has made clear its pursuit of advancing alternative methods of chemical testing as a means toward the development of better chemical safety data that is thorough, efficient and applicable to human exposure concerns. Last year, as part of the FY 2015 Interior, Environment and Related Agencies Appropriations bill (passed as part of the FY 2015 Omnibus Appropriations bill), Congress directed EPA to report on the modernization of risk assessment protocols and the incorporation of the recommendations from the National Academy of Sciences. In that directive, Congress requested that EPA report on (1) progress to date to research, develop, validate and translate innovative chemical testing methods that characterize toxicity pathways, (2) efforts to coordinate across federal agencies, and (3) future plans to continue to implement the toxicity testing vision and strategy in the NAS report. This report is expected to be submitted to Congress from EPA later this year.

A strong system of in vitro testing will help provide the necessary data for a risk assessment regime that is more efficient, accurate and effective in evaluating chemicals for toxicity and safety. It is a common sense approach that will offer all Americans a more risk-free environment. This is a real opportunity to build consensus that has been elusive as Congress has sought to modernize TSCA over the years. I hope that any legislation passed by Congress will include strong provisions that will build consensus and help build a model for a modern chemical safety testing that we can all believe in.



Andrew N. Liveris
Chairman and Chief Executive Officer

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April 14, 2015

The Honorable Fred Upton
Chairman, House of Representatives Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton,

The chemical industry plays an essential role in Michigan's and our Nation's economy and quality of life. As you know, The Dow Chemical Company is headquartered in Midland, Michigan, and employs nearly 6,000 people throughout the state of Michigan. Midland is home to our corporate center and one of our global strategic manufacturing sites, Michigan Operations, which consists of 24 plants that provide products to customers in over 55 countries on six continents. Michigan is home to one of Dow's largest research and development centers, housing over 440 scientists and engineers working to provide innovative solutions in consumer, agricultural, transportation, and building and construction sectors.

For these reasons, I wanted to personally thank you for your support of the discussion draft of the bipartisan *Toxic Substances Control Act (TSCA) Modernization Act of 2015*. It is vital to Michigan's and our Nation's future that we modernize TSCA, the law that oversees the regulation of chemicals in commerce. It has been almost 40 years since TSCA first passed Congress. While the law established a robust regulatory system, over time, confidence in critical chemical management mechanisms under TSCA has eroded.

Thanks to your leadership and the leadership of Ranking Member Pallone and Subcommittee Chairman Shimkus, the TSCA Modernization Act (Act) is a meaningful and important step forward to reforming TSCA in a way that will improve safety and bring renewed credibility to our chemical regulatory system. As additional steps are taken towards enhancing the discussion draft, I appreciate your recognition of the importance in preserving the ability of Dow and other manufacturers to innovate and compete in the global marketplace.

Chairman Upton, your leadership will be critical for successful and meaningful TSCA reform, and Dow supports your efforts. I request that this letter be added to the record for the April 14, 2015, hearing on the TSCA Modernization Act.

Thank you,

Andrew Liveris