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ASSESSING THE EFFECTIVENESS OF U.S. CHEMICAL SAFETY LAWS

HEARING

BEFORE THE

SUBCOMMITTEE ON SUPERFUND, TOXICS AND ENVIRONMENTAL HEALTH

OF THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS UNITED STATES SENATE

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

FEBRUARY 3, 2011

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C O N T E N T S

ASSESSING THE EFFECTIVENESS OF U.S. CHEMICAL SAFETY LAWS

THURSDAY, FEBRUARY 3, 2011

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON SUPERFUND, TOXICS AND ENVIRONMENTAL HEALTH,
Washington, DC.

The committee met, pursuant to notice, at 10 o'clock a.m. in room 406, Dirksen Senate Office Building, Hon. Frank R. Lautenberg, (chairman of the subcommittee) presiding.

Present: Senators Lautenberg, Vitter, Whitehouse, Johanns, and Boozman.

STATEMENT OF HON. FRANK R. LAUTENBERG, U.S. SENATOR FROM THE STATE OF NEW JERSEY

Senator LAUTENBERG. Good morning. This is the first hearing of the year of the Subcommittee on Superfund, Toxics and Environmental Health.

In this hearing, we will examine the effectiveness of our chemical safety laws, a critical issue that touches the lives of all Americans. In this Congress, our goal must be to build on our progress during the last progress. Progress. Notice I didn't say achievement, I said progress. Over the course of four hearings, we uncovered dangerous and costly deficiencies in the Toxic Substances Control Act, known as TSCA. This subcommittee heard from the Centers for Disease Control, who told us that their scientists found 212 industrial chemicals, including 9 carcinogens, coursing through American bodies.

We heard from everyday Americans who shared their heartbreaking stories, including two young mothers. One of those mothers, Molly Gray, testified about the fear and the uncertainty that she experienced when testing revealed that she had dozens of industrial chemicals in her body while she was pregnant. Twice we heard from EPA Administrator Lisa Jackson, who told us under current law that her Agency lacks the tools it needs to regulate hazardous chemicals.

TSCA is so severely flawed that the non-partisan Government Accountability Office testified that it is a "high risk area of the law." With the Federal Government unable to act and families growing more concerned about health risks, at least 18 States have adopted their own chemical safety laws. In a hearing last February, Dow and Dupont, two major chemical companies, testified in support of reform, in part because of the difficulties they face oper-

ating under different rules in different States. Since our most recent hearing on this issue last October, the political landscape has shifted somewhat.

But as we will hear today, the urgent need to fix our Country's broken chemical safety system has not changed. The longer we wait to modernize TSCA, the longer businesses face uncertainty about the future, and the longer families will have concern about the risks, which products are safe and which are not.

The highly successful global companies represented on our second panel today are as eager as we are to give people more confidence in the safety of their products. Make no mistake about it: chemicals play a crucial role in modern life. They are essential to everything from cleaning products that kill germs in our homes, schools and workplaces to renewable energy sources that reduce our dependence on dirty fuels.

Most chemicals improve lives around the globe, and they do so with no toxic side effects. But some have been linked to serious health problems. Studies show that as much as 5 percent of childhood cancers, 10 percent of neurobehavioral disorders, and 30 percent of childhood asthma cases are associated with hazardous chemicals.

The National Institute of Environmental Health Science recently held a 3-day discussion on links between certain toxic chemicals and obesity and diabetes. That is why we need scientists to evaluate chemicals, determine which uses are safe and which are not. That is why we are here today. The companies represented have strong standards for evaluating the safety of their products.

SC Johnson & Son was founded 125 years ago, and its continued success depends on keeping toxic chemicals out of the company's products. Same principle applies to BASF, and many other chemical companies. But we must hold all companies to a high standard of safety.

That is why I committing to move TSCA's reform legislation in this Congress. In 1996, our pesticides law and the Safe Drinking Water Act passed a Republican Congress, and were signed into law by a Democratic President. I am confident that this Committee can come together to improve our chemical laws while allowing the U.S. chemical industry to continue to lead the world.

When I introduced my Safe Chemicals Act last year, the vice president of Dupont said that we carefully listened to a range of diverse views and sought to strike a thoughtful balance. That is what we want, a thoughtful balance. But we want a thorough review.

My colleague, Senator Inhofe, has been very helpful in fostering a meaningful dialog with the chemical industry and our friends in the other party. I am eager to continue working with him and other Senators to develop a risk-based system, built on sound science, that protects the health and allows companies to continue to thrive.

I also look forward to continuing to work with responsible companies like SC Johnson and BASF that offer constructive ideas for modernizing the law. I want to be clear: the status quo is not acceptable. We simply must reform our chemical laws. I look forward

to moving this issue forward in this Congress, beginning with today's hearing.

So I thank those of you who are being witnesses here today, and those of you who are here for specific interest. We need your help, all of you, and it is not without very deep personal interest, I am sure, in all of our lives. I have a grandchild who has asthma. Before my daughter takes him to play ball, he is a very athletic young man, she checks to see where the nearest emergency clinic is. So that is a threat that overhangs us, and it should not be. We can do better. I thank you all for being here.

With that, I turn to Mr. Steve Owens, and please introduce yourself, Steve, and tell us, give us your testimony.

[The prepared statement of Senator Lautenberg follows:]

STATEMENT OF HON. FRANK R. LAUTENBERG, U.S. SENATOR FROM THE STATE OF NEW JERSEY

Good morning. This is the first hearing of the year of the Subcommittee on Superfund, Toxics and Environmental Health. In this hearing, we will examine the effectiveness of our chemical safety laws—a critical issue that touches the lives of all Americans. In this Congress, our goal must be to build on our progress during the last Congress. Over the course of four hearings, we uncovered dangerous and costly deficiencies in the Toxic Substances Control Act, known as TSCA.

This subcommittee heard from the Centers for Disease Control, who told us their scientists found 212 industrial chemicals—including 6 known carcinogens—coursing through Americans' bodies. And we heard from everyday Americans who shared their heartbreaking stories—including two young mothers. One of those mothers—Molly Gray—testified about the fear and uncertainty she experienced when testing revealed she had dozens of industrial chemicals in her body while she was pregnant.

Twice we heard from EPA Administrator Lisa Jackson, who told us under current law her agency lacks the tools it needs to regulate hazardous chemicals. TSCA is so severely flawed that the non-partisan Government Accountability Office testified that it is a "high risk area of the law." With the Federal Government unable to act—and families growing more concerned about health risks—at least 18 states have adopted their own chemical safety laws.

In a hearing last February, Dow and DuPont—two major chemical companies—testified in support of reform, in part because of the difficulties they face operating under different rules in different states. Since our most recent hearing on this issue last October, the political landscape has shifted somewhat. But as we'll hear today, the urgent need to fix our country's broken chemical safety system has not changed. The longer we wait to modernize TSCA, the longer businesses face uncertainty about the future, and the longer families will face confusion about which products are safe and which are not. The highly successful, global companies represented on our second panel are as eager as we are to give people more confidence in the safety of their products. Make no mistake: Chemicals play a crucial role in modern life. They are essential to everything from cleaning products that kill germs in our homes, schools and workplaces, to renewable energy sources that reduce our dependence on dirty fuels. Most chemicals improve lives around the globe—and they do so with no toxic side effects. But some chemicals have been linked to serious health problems.

Studies show as much as 5 percent of childhood cancers, 10 percent of neurobehavioral disorders and 30 percent of childhood asthma cases are associated with hazardous chemicals. And the National Institute of Environmental Health Science recently held a 3-day discussion on links between certain toxic chemicals and obesity and diabetes. That's why we need scientists to evaluate chemicals and determine which uses are safe—and which are not.

As we will hear, the companies represented today have strong standards for evaluating the safety of their products. SC Johnson and Sons was founded 125 years ago—and its continued success depends upon keeping toxic chemicals out of the company's products. The same principle applies to BASF and many other chemical companies. But we must hold all companies to a high standard of safety. This is why I am committed to moving TSCA reform legislation in this Congress.

In 1996, our pesticides law and the Safe Drinking Water Act passed a Republican Congress and were signed into law by a Democratic President. I am confident that this committee can come together to improve our chemical laws while allowing the

U.S. chemical industry to continue to lead the world. When I introduced my Safe Chemicals Act last year, the vice president of DuPont chemical company said that we "carefully listened to a range of diverse views and sought to strike a thoughtful balance."

My colleague Senator Inhofe has been very helpful in fostering a meaningful dialog with the chemical industry and our friends in the other party. I'm eager to continue working with him and other Senators to develop a risk-based system—built on sound science—that protects health and allows companies to continue to thrive. I also look forward to continuing to work with responsible companies like SC Johnson and BASF that offer constructive ideas for modernizing the law. Let me be clear: the status quo is not acceptable. We simply must reform our chemical laws.

I look forward to moving this issue forward in this Congress, beginning with today's hearing.

STATEMENT OF STEVE OWENS, ASSISTANT ADMINISTRATOR, OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION, ENVIRONMENTAL PROTECTION AGENCY

Mr. OWENS. Good morning, Senator Lautenberg. I am Steve Owens, I am the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention at the U.S. Environmental Protection Agency.

Thank you for the opportunity to be with you here today to discuss modernizing the Toxic Substances Control Act. We appreciate your leadership on this issue. As the father of a son who has asthma, I very much appreciate your interest in that issue as well, Senator.

As you know, Senator, TSCA regulates chemicals manufactured and used in this Country. While TSCA was an important step when it was first passed in 1976, it is the only major environmental statute that has not been reauthorized since its initial passage. TSCA is clearly showing its age, and its limitations. Unlike the laws for drugs and pesticides we have in this Country, TSCA does not have a mandatory program by which EPA must review the safety of chemicals. In addition, TSCA places legal and procedural requirements on EPA's ability to request the generation and submission of health and environmental data on chemicals.

When TSCA was enacted in 1976, it grandfathered in without evaluation whatsoever the more than 60,000 chemicals that existed at that time. More than 24,000 additional chemicals have been produced since then, with the result that our TSCA inventory now lists more than 84,000 chemicals, very few of which have actually been studied by EPA for their risks to families and children.

Indeed, TSCA does not provide EPA with adequate authority to reevaluate existing chemicals as new concerns arise, or science is updated. It does not give EPA full authority to require companies to produce toxicity data. As a result, over the last 35 years, EPA has been able to require testing on only around 200 of the more than 84,000 chemicals that are on the TSCA inventory.

It has also been very difficult for EPA to take meaningful action on chemicals found to cause unreasonable risk to human health or the environment. Even if EPA has substantial data and wants to protect the public against known risks, the law creates obstacles to quick and effective regulatory action.

For example, in 1989, after years of study and nearly unanimous scientific opinion, EPA issued a rule phasing out most uses of asbestos in products. Yet a Federal court held that the rule did not

comply with the very complex requirements of section 6 of TSCA and overturned most of the Agency's actions. EPA has not taken an action under section 6 of TSCA since that time, more than 20 years ago.

In fact, since 1976, only five chemicals have been successfully regulated under TSCA's authority to ban chemicals. That is 5 out of more than 84,000.

The problems with TSCA are so significant, as you noted, Senator, that the Government Accountability Office has put the law on its list of high risk items needing urgent attention. TSCA must be updated and strengthened if EPA is to do its job to protect public health and the environment. The Obama administration has developed a set of principles to help modernize TSCA. Let me summarize them briefly. The full texts of those principles are attached to the written testimony that I submitted, Senator. This is a brief summary of those.

First, 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.

Second, the responsibility for providing adequate health and safety information should rest on industry, and EPA should have the necessary tools to quickly and efficiently require testing or obtain other information from manufacturers without the delays and obstacles that are currently in place in the law, and without excessive claims of confidentiality.

Third, 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.

Fourth, EPA should have clear authority to set priorities for conducting safety reviews of chemicals.

Fifth, we must encourage innovation and green chemistry and support strategies that will lead to safer and more sustainable chemicals and processes.

Finally, Senator, implementation of the law should be adequately and consistently funded. Chemical manufacturers should support the cost of agency implementation, including the review of information provided by manufacturers.

Mr. Chairman, as you noted, the time has come to bring TSCA into the 21st century and give the American people the protection against chemical risks they expect and deserve. EPA Administrator Lisa Jackson and I look forward to working with you and other members of this subcommittee and Congress on this very important issue. I will be happy to answer any questions you may have.

[The prepared statement of Mr. Owens follows:]

TESTIMONY OF

STEVE OWENS
ASSISTANT ADMINISTRATOR
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
U.S. ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE
SUBCOMMITTEE ON SUPERFUND, TOXICS, AND ENVIRONMENTAL HEALTH
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

February 3, 2011

Good morning Chairman Lautenberg, Ranking Member Inhofe, and other members of the Subcommittee. Thank you for the opportunity to be with you today to discuss the reform of chemicals management in the United States. I am pleased to be able to testify about EPA's strong interest in reforming and updating the Toxic Substances Control Act (TSCA). Ensuring chemical safety in a rapidly changing world, restoring public confidence that EPA is protecting the American people, and promoting our global leadership in chemicals management are top priorities for EPA Administrator Lisa Jackson and the Agency.

On behalf of Administrator Jackson, I want to thank you, Chairman Lautenberg, as well as members of your Subcommittee, for your leadership on this very important issue and for your efforts to bring about comprehensive reform of TSCA. As you know, the time has come to bring TSCA into the 21st Century and give the American people the protection from harmful chemicals they expect and deserve.

While chemicals have improved our lives in many ways, there are still significant scientific gaps in our understanding of the health risks of many chemicals. That's why, increasingly, the public is demanding that the government provide an assurance about the long term safety of these chemicals.

TSCA, which was enacted in 1976, gives EPA jurisdiction over chemicals produced and used in the United States. TSCA is the only major environmental statute that has not been reauthorized. The TSCA Inventory currently contains over 84,000 chemicals, few of which have been studied for their risks to children. Unlike the laws applicable to drugs and pesticides, TSCA does not have a mandatory program where EPA must conduct a review to determine the safety of existing chemicals. In addition, TSCA places legal and procedural requirements on EPA before the Agency can request the generation and submission of health and environmental effects data on existing chemicals.

TSCA was an important step forward at the time. But over the years, not only has TSCA fallen behind the industry it is intended to regulate, it has also proven an inadequate tool for providing the protection against chemical risks that the public rightfully expects.

When TSCA was enacted, it grandfathered in, without any evaluation, all chemicals in commerce that existed in 1976. Further compounding this problem, the statute never provided adequate authority for EPA to reevaluate existing chemicals as new concerns arose or science was updated, and failed to grant EPA full and complete authority to compel companies to provide toxicity data. As a result, in the nearly 35years since TSCA was passed, EPA has only been able to require testing on just a little more than 200 of the 84,000 chemicals listed on the TSCA Inventory, and has regulated or banned five of these chemicals under Section 6 of TSCA.

It has also proven difficult in some cases to take action to limit or ban chemicals found to cause unreasonable risks to human health or the environment. Even if EPA has substantial data and wants to protect the public against known risks, the law creates obstacles to quick and effective regulatory action. For example, in 1989, after years of study and nearly unanimous scientific opinion about the risk, EPA issued a rule phasing out most uses of asbestos in products. Yet, a federal court overturned most of this action because it found the rule had failed to comply with the requirements of TSCA.

Today, advances in toxicology and analytical chemistry are revealing new pathways of exposure. There are subtle and troubling effects of many chemicals on hormone systems, human reproduction, intellectual development and cognition, particularly in young children. It is clear that in order to properly protect public health and the environment, TSCA must be updated and strengthened, including providing the appropriate tools to protect the American people from exposure to harmful chemicals.

In September 2009, EPA Administrator Lisa Jackson announced a set of principles that articulate the Administration's goals for updating TSCA that would enable EPA to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals.[1] She also announced that while the legislative reform process is underway, EPA intends to take steps to enhance its current chemical management program.[2] As part of this effort, EPA has developed a number of action plans that communicate the Agency's initial review of readily available use, exposure, and hazard information on a select number of chemicals, outline the Agency's concerns with the chemicals, and identify the steps EPA is considering to address those concerns. We are also taking steps to increase the public's access to chemical information that is provided to the Agency. This has included greater web access to a wider range of chemical information and implementing a series of steps to reduce claims of confidentiality, while recognizing that there can be legitimate business needs to protect information on chemicals.

As previously mentioned, the Administration has released a set of principles for TSCA reform that I would like to again briefly highlight:

First, 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 the clear authority to establish safety standards based on risk assessments, while

[1] http://www.epa.gov/opptintr/existingchemicals/pubs/principles.pdf and attached as an appendix.
[2] http://www.epa.gov/oppt/existingchemicals/pubs/Existing.Chem.Fact.sheet.pdf

recognizing the need to assess and manage risk in the face of uncertainty.

Second, the responsibility for providing adequate health and safety information should rest on industry. Manufacturers must develop and submit the hazard, use, and exposure data demonstrating that new and existing chemicals are safe. If industry doesn't provide the information, EPA should have the necessary tools to quickly and efficiently require testing, or obtain other information from manufacturers that is relevant to determining the safety of chemicals, without the delays and obstacles currently in place, or excessive claims of confidential business information.

Third, 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. Both EPA and industry must include special consideration for exposures and effects on groups with higher vulnerabilities – particularly children. For example, children ingest chemicals at a higher ratio relative to their body weight than adults, and are more susceptible to long-term damage and developmental problems.

Fourth, EPA should have clear authority to set priorities for conducting safety reviews. on existing chemicals based on relevant risk and exposure considerations. In all cases, EPA and chemical producers must act on priority chemicals in a timely manner, with firm deadlines to maintain accountability. This will not only assure prompt protection of health and the environment, but provide business with the certainty that it needs for planning and investment.

Fifth, we must encourage innovation in green chemistry, and support research, education, recognition, and other strategies that will lead us down the road to safer and more sustainable chemicals and processes. All of this must happen with the utmost transparency and concern for the public's right to know.

Finally, 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. Chairman, TSCA needs to move toward the vision embodied in these principles. We should require that all chemicals be reviewed against a safety standard based on sound science and that reflects risk based criteria protective of human health and the environment, including the health of children and other vulnerable populations. We should squarely place the burden on industry to provide data to demonstrate that chemicals are safe. Legislative reform should give EPA significantly greater authority to require any data necessary to assess the safety of chemicals and to quickly take action on chemicals which cause harm. The substantial increase in information available on toxic chemicals would vastly improve the understanding of chemical risks and greatly enable government and the public to make better informed decisions about the chemicals that are in the products we use daily. These key elements represent a significant change in the approach the U.S. has historically taken in regulating chemicals and would substantially update and modernize TSCA.

Further, legislative reform of TSCA should address a number of other areas the Administration believers are important in modernizing this nation's chemicals management efforts, such as encouraging the development and use of green chemistry and adoption of safer alternatives. It should impose stricter requirements for assertion of confidentiality claims while allowing the sharing of critical data – with appropriate safeguards – with state governments also regulating chemicals.

Mr. Chairman, we greatly appreciate your efforts to help us bring TSCA into the 21st Century, and we look forward to continuing to work with you and your Committee as you move forward. I will be happy to answer any questions you 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.

Senate Committee on Environment and Public Works
Subcommittee on Superfund, Toxics, and Environmental Health
Hearing on "Assessing the Effectiveness of U.S. Chemical Safety Laws"
February 3, 2011
Questions for the Record

Chairman Barbara Boxer, California

Boxer 1A. In 2009, the EPA initiated a chemical action plan for existing chemicals. Could you please describe the reasons for these plans, benefits of this type of action and any difficulties that the agency has experienced when developing and implementing the plans?

Answer: The EPA created the chemical action plans under the EPA's Enhanced Chemical Management approach announced by Administrator Lisa Jackson in September 2009. This announcement included the release of a set of administration principles to help guide Toxic Substances Control Act (TSCA) reform and a comprehensive approach to enhance the EPA's chemical management program using the agency's existing authorities under TSCA to achieve the following goals:

- Identify chemicals that pose significant risk and take action to address those risks;
- Obtain information to fill gaps in health and safety data on chemicals; and
- Make more information on chemicals transparent and accessible to the public.

In selecting chemicals for action plan development, the agency accessed readily available information on hazard, use, and exposure. The initial chemicals selected were chosen on the basis of multiple factors, including, among others:

- Chemicals identified as persistent, bio-accumulative, and toxic;
- High production volume chemicals;
- Chemicals in consumer products;
- Chemicals potentially of concern for children's health because of reproductive or developmental effects;
- Chemicals subject to review and potential action in international forums;
- Chemicals found in human bio-monitoring programs; and
- Chemicals in categories generally identified as being of potential concern in the new chemicals program.

Between December 2009 and April 2011, the EPA developed and made public ten Action Plans addressing various chemicals or groups of chemicals with potential risks to human health or the environment. The Action Plans summarize the potential risks from the chemicals and identify steps the agency may take to address those risks and/or gather additional data on the chemicals. These actions include a range of approaches under TSCA including requiring the submittal or development of data needed to help assess risks under TSCA Sections 4 and 8, requiring notification to the EPA under Section 5 before new uses of the chemicals that might increase

exposure and risk, and consideration of control measures under Section 6. The Action Plans also consider identification of safer alternatives to some of the high risk chemicals and uses.

Boxer 1B. Please also describe:
A. How the creation of these plans and the generation of information resulting from these plans can be expedited;
B. Any gaps in information needed to protect public health that may remain following the completion of these plans; and
C. Whether this type of information, and any additional information, should generally be provided for other chemicals, including new chemicals if the Toxic Substances Control Act is modified during reauthorization.

Answer: While the EPA is moving as expeditiously as possible to develop rules using current TSCA authorities to the greatest extent possible to develop the actions necessary to address the risks identified in the Action Plans, the 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.

The Administration Principles released in 2009 broadly outline the tools the EPA needs, 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. Manufacturers should be required to provide sufficient hazard, exposure, and use data for a chemical to support review by the agency. Exposure and hazard assessments from manufacturers should be required to include a thorough review of risks to sensitive subpopulations. The EPA's authority to require submission of use and exposure information should extend to downstream users of chemicals.

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 subpopulations. The EPA should have the authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations.

Outlined below is the complete set of the Administration Principles for TSCA Reform:

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.**

   The 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.

2. **Manufacturers Should Provide the 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, the 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 are relevant to determining the safety of chemicals. The 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. The EPA's authority to require submission of use and exposure information should extend to downstream processors and users of chemicals.

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

   The 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.

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

   The 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 subpopulations.

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. The 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.

6. **The 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 the 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.

Additionally, the EPA is taking steps to implement various items outlined in the Action Plans. Those proposals are currently undergoing interagency review.

Boxer 2: In 2008, the EPA issued a safeguard to address the threats to human health, including children's health, from lead chips and dust during and following renovation and repair work. Please describe the expected benefits of the agency's implementation of the Lead, Repair and Renovation safeguards, how implementation is progressing, and the steps that the agency has taken to ease implementation for small businesses.

Answer: Exposure to lead paint (above 5 ug/dL) affects over one million children today, with children under the age of six at the greatest risk. The benefits of the rule result from the prevention of adverse health effects attributable to lead exposure. Neurotoxic effects in children and cardiovascular effects in adults are known to occur at very low blood-lead concentrations (at or below 5 to 10 μg/dL). These categories of effects are and the potential effect levels are well substantiated and currently of greatest public health concern.

The EPA promulgated the Lead Renovation, Repair and Painting (LRRP) rule in 2008 pursuant to the requirements of the Residential Lead-Based Paint Hazard Reduction Act of 1992 to help reduce potential exposure to lead-based paint hazards, including toxic lead paint dust, created by renovation activities. In 2010 the LRRP was amended to cover all pre-1978 housing, making it more protective.

As of September 21, 2011, the EPA has accredited 573 training providers (including 346 traveling trainers) who have conducted more than 34,000 classes, training an estimated 725,000 people in the construction and remodeling industries to use lead-safe work practices. The EPA has approved 92,631 firms (110,460 firms including those approved by authorized states).

The Agency has taken many steps to ease implementation for small businesses. Prior to developing the proposed rule, the EPA organized a Small Business Advocacy Review (SBAR) panel, which included representatives from the EPA, the Small Business Administration, and the Office of Management and Budget. The SBAR panel consulted with small entities on cost and economic implications of the proposed regulation for small entities. As a result of this consultation with small businesses, the EPA sought a quick, inexpensive, reliable, and easy to perform alternative to a requirement for laboratory lead-dust testing ("clearance") as a means of determining that the renovation job was complete. The LRRP rule's cleaning verification process ensures that leaded dust created by renovations is adequately cleaned up without the expense and time required for laboratory testing.

Also, the LRRP rule was finalized in 2008, and allowed two years before the rule became fully effective and renovators were required to follow the work practices. To further assist small businesses who expressed concern about their ability to obtain worker training and the EPA certification, shortly after the rule became effective the EPA provided renovation firms and workers additional time to obtain the necessary training and certification in order to comply with the new rule. The rule also allows for flexibility in a number of areas that should be particularly helpful to small businesses; for example, certified renovators are not required to be on site at all times. Additional flexibility is provided by allowing on the job training to allow for hiring flexibility (e.g., temporary/day laborers). In the first year of the program, the EPA's focus has been on compliance assistance, rather than penalty enforcement. In addition, the EPA also issued a regulation as part of the recent amendments to the LRRP rule, which became effective

on October 5, 2011, that allows renovators the flexibility of taking paint chip samples as another method of determining the presence of lead-based paint.

Ranking Member James M. Inhofe, Oklahoma

Inhofe 1. Please describe your view of the "new chemicals program." Does the program allow companies to send dangerous chemicals into the stream of commerce without any controls or restrictions?

Answer: The EPA believes that the new chemicals program has effectively used the tools available under TSCA to allow the agency to review new chemicals prior to introduction into the marketplace. The EPA's New Chemicals Program helps manage the potential risk to human health and the environment from chemicals new to the marketplace. The program functions as a "gatekeeper" that can identify conditions, up to and including a ban on production, to be placed on the use of a new chemical before it is entered into commerce. Anyone who plans to manufacture or import a new chemical substance for a nonexempt commercial purpose is required by section 5 of TSCA to provide the EPA with notice before initiating the activity. Because of limitations in the data generally available for new chemicals, it is possible that some health risks to workers, consumers, and the general population as well as ecological risks to aquatic and terrestrial organisms may not be identified during premanufacture reviews. TSCA does not require a safety determination for new chemicals, except for exemptions under TSCA section 5(h)(4).

Inhofe 2. Could you describe what information is required to be submitted under the new chemicals program when a company submits a premanufacture notice? After this information is submitted to the agency, does the EPA analyze it or conduct any sort of assessment? If so, after an assessment is conducted, does the EPA have the ability to prohibit or limit manufacture of the substance or ask the company to develop and submit additional data?

Answer: Premanufacture notices (PMNs) and exemption applications must include information such as specific chemical identity, use, anticipated production volume, exposure and release information, and any existing test data in the control or possession of the notice submitter. TSCA does not require that new chemical notices accompanied by basic hazard, exposure, and use data that would allow the agency to make a positive determination that a new chemical will not present an unreasonable risk of injury to health or the environment. However, as explained in the following paragraphs, the EPA can require the development of such information by the submitter of the PMN if the EPA makes certain determinations under TSCA Section 5(e).

Based on the information provided, PMNs and exemption applications are reviewed by the EPA to evaluate whether the substance may present an unreasonable risk of injury to human health or the environment or whether the substance, if produced in substantial quantities, may be anticipated to enter the environment in substantial quantities or result in substantial or significant exposure to the substance.

The EPA can take regulatory action under TSCA section 5(e) or section 5(f) to prohibit or limit the manufacture, processing, distribution in commerce, use, and disposal of a new chemical substance if the EPA determines that:

- There is insufficient information to evaluate the human health and environmental effects of the substance; and
- The substance may present (section 5(e)) or will present (section 5(f)) an unreasonable risk of injury to human health or the environment; or

- The substance will be produced in substantial quantities and may be anticipated to enter the environment in substantial quantities or there may be significant or substantial human exposure.

In such cases, section 5(e) orders are almost always issued as consent orders that are signed by both the EPA and the chemical manufacturer. Given the insufficient information finding, most section 5(e) orders require the PMN submitter to develop and submit to the EPA certain toxicity or fate tests before exceeding a specified production volume ("test trigger") designed to allow sales of the chemical to generate enough revenue to pay for the testing. Exposure-based section 5(e) orders consist primarily of a requirement to conduct triggered testing (plus recordkeeping and "risk notification" in case the test data indicates a risk.) Risk-based section 5(e) orders, depending on the type of concerns identified by the EPA for a given PMN substance, typically also require exposure controls such as gloves, goggles, respirators, specified disposal technologies or restrictions on releases to water, and hazard communication such as material safety data sheets (MSDS), labels, and training. The EPA typically issues Significant New Use Rules (SNURs) for PMNs with risk-based consent orders to ensure that other future manufacturers and processors of chemicals under consent orders are subject to the same terms and conditions of the consent order.

The EPA also has the authority to issue SNURs without a §5(e) Consent Order if the EPA determines that activities other than those described in the PMN may result in significant changes in human exposure or environmental release levels and/or that concern exists about the substance's health or environmental effects. SNURs typically identify testing that the EPA recommends be submitted with any SNUN to enable the EPA to better evaluate the potential risks associated with a new use.

Inhofe 3. If the agency is able to make either of these findings based on the available information, the EPA may take action under TSCA section 5(e) to prohibit or limit the manufacture, processing, distribution in commerce, use, and disposal of a new chemical substance, pending the development of additional information. How is the EPA striking the proper balance between protecting confidential business information and providing the public with information they need?

Answer: Over the past two years, the EPA has taken a number of significant steps to increase the public's access to chemical information and increase transparency by reducing unwarranted claims of confidentiality. For example, on November 28, 2011, the EPA announced that the agency has made publicly available hundreds of studies on chemicals that had previously been

treated as Confidential Business Information (CBI). These efforts are part of the EPA's efforts to make public chemical information that is not entitled to CBI status.
The EPA's efforts to promote transparency in no way affect how legitimate CBI is handled or protected by the EPA. The agency has long established, well developed processes for the management and handling of all materials claimed by submitters as CBI and regulations which implement TSCA section 14 (disclosure of data). CBI may only be declassified through the regulatory processes provided at 40 CFR Part 2 and also the TSCA specific regulations at 40 CFR 700 et seq. A copy of the November 28, 2011 announcement can be found at: http://yosemite.epa.gov/opa/admpress.nsf/a543211f64e4d199852573590040444 2/5b93eda1f3ee7bba852579510075728f!OpenDocument.

Inhofe 3A. With six IRIS risk assessments currently being delayed and reviewed due to concerns over the lack of "scientific integrity," what steps has the EPA taken to ensure that chemicals are properly reviewed using the best available science to get accurate and unbiased results?

Answer: In June 2010, the EPA became aware of the results of a report written by the National Toxicology Program (NTP), a program administered by the National Institute of Environmental Health Sciences (NIEHS), which outlined a review of research completed by the Ramazzini Institute, a lab in Italy that conducts animal testing to evaluate the potential cancer-causing effects of chemicals. The report discussed findings from an NTP assessment of an animal study on methanol and recommended that further pathology reviews by carried out to resolve differences of opinion between NTP scientists and the Ramazzini Institute in the diagnoses of certain cancers reported in the study.

To ensure the highest level of scientific integrity in its work, the EPA undertook a thorough review of all ongoing and previous chemical assessments to determine which, if any, relied substantially on cancer testing from the Ramazzini Institute. The EPA found six assessments, four of which were in draft form, that relied substantially on Ramazzini data. The four draft assessments are methanol, methyl tertiary-butyl ether (MTBE), ethyl tertiary-butyl ether (ETBE), and acrylonitrile, and the two final assessments are vinyl chloride and 1,1-dichloroethylene. Out of an abundance of caution, in the spirit of scientific integrity, and to ensure the agency's chemical assessments are grounded in the soundest possible science, the EPA placed the four draft assessments on hold pending further review.

In April 2011, the EPA announced its plan for addressing the four draft Integrated Risk Information System (IRIS) assessments that were placed on hold in June 2010, pending a review of some of the underlying studies relied on in the assessments.

The EPA and the NIEHS decided to jointly sponsor an independent Pathology Working Group (PWG) review of selected studies, including the methanol cancer assessment study on which the original NTP report was based. The review is nearing completion. The results will be made public and the four draft assessments will remain on hold until its completion.

The EPA will evaluate the results of the PWG review to inform conclusions about Ramazzini Institute tumor findings for the four draft assessments and two final assessments. These steps

will ensure that the agency is basing its assessments on the best possible scientific information and adhering to the strongest principles of scientific integrity.

Inhofe 4. Many advocates of TSCA reform, including the EPA, argue regularly that the current TSCA law does not "provide the tools" necessary "to adequately protect human health and the environment." Recently, the EPA has drafted an "Inventory Update Reporting" rule to expand industries reporting requirements under TSCA; announced a new general practice of reviewing confidential business information claims under TSCA; mandated that manufacturers of 19 chemicals or large volume conduct testing and provide data to the agency using TSCA authority; drafted multiple chemical action plans; and stepped up efforts to regulate articles under TSCA. Based on these and other examples, it would appear that part of the problem with TSCA is that a number of its authorities have not been utilized rather than the law itself lacking the necessary "tools". Are there other authorities in TSCA currently not being used? Are there authorities that have been hindered by legal decisions or interpretations that could be clarified with simple legislation?

Answer: Current TSCA authorities place 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, and take regulatory action. It has also proven difficult in some cases to take action to limit or ban chemicals found to cause unreasonable risks to human health or the environment. Even if the EPA has substantial data and wants to protect the public against known risks, the law creates obstacles to quick and effective regulatory action. For example, in 1989, after years of study and nearly unanimous scientific opinion about the risk, the EPA issued a rule phasing out most uses of asbestos in products. Yet, a federal court overturned most of this action because it found the rule had failed to comply with the requirements of TSCA. To date, the EPA has only been able to require testing on just more than 200 of the 84,000 chemicals listed on the TSCA Inventory, and has regulated or banned five of these chemicals under Section 6 of TSCA.

Nonetheless, the EPA has a responsibility to do all that it can under current authority to assess chemicals and take appropriate action to protect human health and the environment. The EPA is attempting to utilize the array of tools under TSCA to gather adequate data on and address any potential risks presented by chemicals. TSCA needs to be updated 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.

This much needed legislative reform should give the EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals.

Inhofe 5. If TSCA was reformed to mandate the testing of all chemicals in commerce, new and old, how would the EPA deal with the massive new administrative burden? How could the agency ensure that chemicals are reviewed in a timely enough manner not to stifle innovation and hurt industries? How could the EPA ensure that all the new testing required would be done accurately using the best available science?

Answer: It is difficult to fully determine the impact that a new bill will have on the EPA's ability to address new mandates.

The Administration Principles for TSCA Reform state that 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, and that the EPA should have clear authority to establish safety standards that are based on scientific risk assessments. Further, 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. Where manufacturers do not submit sufficient information, the principles state that the 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 are relevant to determining the safety of chemicals. 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 subpopulations.

The principles also state that the EPA should be given a sustained source of funding for implementation in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that the EPA is meeting that goal.

Inhofe 6. Would there be meaningful public health benefits or environmental gains if the EPA created a minimum data set for chemicals that have been extensively studied and toxicity and exposure levels are well known?

Answer: Currently, the EPA lacks basic information on the potential health and environmental effects of many chemicals. While chemicals which demonstrate high toxicity and result in exposure above levels of concern should obviously be the focus of risk management efforts, one of the challenges the proposed legislation is seeking to address is a lack of available data needed to determine which chemicals are safe at current use levels and which should have controls in place. Rectifying this lack of data is an important goal of TSCA reform legislation.

Different classes and categories of chemicals may require different data sets, given differing characteristics and uses. Input from interested parties will help identify the requirements which should be put in place. If required data exist, the EPA would seek to avoid duplication and redundant reporting.

Inhofe 7. A comparison is often made between TSCA and laws such as FIFRA or FFDCA, which regulate pesticides, to highlight a perceived lack of proper authority and safety standards to regulate chemicals. Isn't there a clear distinction in many cases between the products these laws regulate –TSCA regulating thousands of often innocuous chemicals used in everyday life—while FIFRA and FFDCA regulate products specifically manufactured to be, in many instances, poisonous? Doesn't it make sense to look at these categories of chemicals and products through different lenses?

Answer: The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) provide the federal government with effective authority to require manufacturers to provide the data necessary for review and approval as well as effective authority to remove risky products from the marketplace. The EPA recognizes that not all chemicals should be subject to the same level of scrutiny or regulation but it is important that

these chemicals be evaluated using the best available data and a more complete understanding of the exposure pathways and scenarios. It is also important that the EPA have the regulatory tools it needs to determine if these chemicals are being used safely as well as the ability to take action if they are not. The EPA has effectively implemented FIFRA and FFDCA and applied the safety standards set forth in those statutes for many years.

Senator LAUTENBERG. Thank you very much.

Nothing destroys confidence more than laws that are on the books that don't really work. While TSCA was a, I think, a good idea, and helped marginally, but therein lines a very serious problem, of course, and that is that we haven't been able to make progress that would, again, ease the minds of people in the Country who are at a stage of pregnancy or frailty at the moment, and know that it was caused by something that might not have been there.

Well, we are glad to have you here, Mr. Owens. We have your testimony. What we will do is we will permit you to go for the moment unscathed, and we will submit our questions in writing and get to our next panel. We thank you very much for being here.

Mr. OWENS. Mr. Chairman, I hope this serves as a model for future hearings in which I participate.

[Laughter.]

Mr. OWENS. I appreciate your interest.

Senator LAUTENBERG. This isn't a reorganization of the way we function here. It is to be another version of TSCA, far less harmful, but having a law that doesn't cover the bases.

I want to just ask one question. That is, is it possible to really fulfill the mission that we have with TSCA in its current form?

Mr. OWENS. Well, no, Senator, we do not believe so at EPA, and the Administration does not believe so. That is why we developed the statement of principles that I mentioned, and that we submitted for the record here today. As I mentioned, there are a number of problems with the way the law is written, the number of obstacles it creates to our ability to, in the first instance, gather data about potential risks presented by chemicals, and then to take action on chemicals, if we determine that there are risks there.

In addition, there are challenges with the way the law works in terms of the findings that we have to make under the law before we can take action. In addition, there are very serious problems with the way that the provisions relating to the submission of confidential business information are treated in the law, and the way that the Agency has to deal with CBI, as it is called, once it is submitted to us.

Senator LAUTENBERG. Yes, the recommendations made seem particularly obvious, not the least of which is to provide the resources for the Agency that conducts the program that it does, to make this reform attempt effective.

I said I wasn't going to, but you are someone who speaks with authority and experience. I just want to be sure. There are 18 States I mentioned in my comments that have laws governing chemicals, and 30 have already announced a new chemical legislation for 2011. In a State by State approach like this, do we risk having so much confusion around the Country that we will not be able to effectively do what we want to do, and that is to make sure that people aren't endangered by chemicals that are in products and so forth? I see this as a problem, not only for the reality that we face, if people are worried about their offspring and about their own health, but also for businesses who want to develop products and that may face challenges in the courts, litigation, et cetera, and

brought in different States because one is thought to be an easier target there than in another place. Is that a concern?

Mr. OWENS. Yes, Senator. As you know, the Administrator is a former State environmental agency director, I am a former State environmental agency director. We and others at the agency have a great deal of respect for the interests of States in protecting the health and safety of their citizens. We think that one reason why States are stepping up to the plate and beginning to take action on chemicals is because the Federal Government hasn't done so. The reason we haven't done so to a significant degree is because of the shortcomings of the existing Toxic Substances Control Act.

We want to ensure that when TSCA reform is being discussed by Congress that the States have a seat at the table. They are perfectly capable of representing their interests here and making sure that the reasons for their actions are taken into account. But until we have TSCA reform, and until EPA has the ability to do the job that the American people expect us to do, I think we are going to continue to see action by States on chemicals across the Country.

Senator LAUTENBERG. The question arises also, what might be the influence on the American economy if we get the system working as we would like to have it operate? Can there be a salutary effect?

Mr. OWENS. Senator, we think that it will have a positive effect on industry and on the economy if we have an effective Act that reviews chemicals in this Country, subject to a risk-based safety standard, and gives the EPA the ability and the tools we need to do the job the American people expect.

I know for example, a lot of discussions have centered on how to not only maintain but encourage innovation, for example, and less toxic substances and green chemistry in products that the American people are demanding to have now. Many consumer products, manufacturers, many retailers are asking that the manufacturers provide safer substances for inclusion in those products, because their customers are demanding them.

We believe that the more we have the ability to provide safer chemicals, the more EPA has the ability to give the American people assurances that the chemicals that they and their children are exposed to every day and the products that include those chemicals are in fact safe, the better off we will be, certainly from a health and safety perspective, but also from an economic perspective as well.

Senator LAUTENBERG. The reason that I turned around is that we knew that, we learned that Senator Vitter was on his way, and I wanted to give him a chance to make a statement, then ask a question, if we don't take too much time.

Senator Vitter.

STATEMENT OF HON. DAVID VITTER, U.S. SENATOR FROM THE STATE OF LOUISIANA

Senator VITTER. Thank you, Mr. Chairman. I apologize to everyone for being late. I was rushing back from the National Prayer Breakfast.

Thank you, Mr. Chairman, and thank you for holding this important hearing. I appreciate the opportunity to discuss with you and the witnesses this important topic.

Like Senator Lautenberg's home State, mine, Louisiana, owes a significant number and portion of very good-paying jobs to this industry. So again, I would like to thank everyone here for their work.

The first thing I would like to do is ask unanimous consent that the written testimony of the National Petrochemical and Refiners Association and that of the Society of Chemical Manufacturers be submitted for the record.

Senator LAUTENBERG. Without objection.

Senator VITTER. Thank you.

[The referenced information follows on page 113.]

Senator VITTER. As we move forward with this discussion, the main priority I want to stress is the importance of basing everything on sound and rigorous science. We must ensure the best possible protection of U.S. citizens in an effort to achieve the overarching goals of ensuring human health and safety in a safe environment. We also must ensure that we remain and become more competitive in the industry and the global marketplace, because that is our challenge now, not competition between States, but competition in the global marketplace, certainly including China and India. The key to achieving all of these goals has to be sound and rigorous science.

With that in mind, I have been highlighting and stressing, and will continue to, six principal, overarching concepts that I think need to be at the heart of TSCA reform. Very briefly, they are these.

No. 1, I think EPA needs to redo its inventory of chemicals in commerce. That inventory now is 80,000 chemicals. There aren't 80,000 chemicals in significant commerce. It is probably closer to a quarter of that. So we need to figure out what those 20,000 or so are, and then focus on that, which is the real universe of challenge and problem.

No. 2, I think a European registration, evaluation and authorization of chemical substances, a REACH-style program, would threaten to kill innovation in the United States, and is a real recipe for hamstringing small- and medium-size manufacturers in particular.

No. 3, I think assuming that REACH is somehow the wave of the future is really premature, and could actually impair human health and safety by preventing critical positive, safe products from entering into the marketplace.

No. 4, if EPA ever decides to use any given study as a reason for limiting or terminating the use of certain chemicals, I think the results of that study, absolutely need to be repeatable and proven in supporting research.

No. 5, I think the peer review process needs to ensure that the peers are absolutely independent. This means that cherry-picking of research by activists in Federal agencies needs to end as well.

No. 6, if EPA is going to decide to utilize resources to re-review a chemical prior to the otherwise established scheduled review period, as it has recently, that needs to be, again, to come back to my central theme, based on sound science, not simply a *New York*

Times article that quite frankly uses politicized science. I am specifically referring to what I think happened in the episode about atrazine.

So I hope these six principles will help guide us in this important challenge of TSCA reform, and I look forward to working with the Chairman on that challenge. Thank you, Mr. Chairman.

Senator LAUTENBERG. Thank you, Senator Vitter.

Senator Boozman, welcome. We know that you are brand new here. I was once brand new here. The buildings were about the same, but little else.

[Laughter.]

Senator LAUTENBERG. We invite you to take 5 minutes, please, and use it either for an opening statement or for asking questions.

Senator BOOZMAN. Thank you, Mr. Chairman. It is a pleasure to be here, and we do appreciate your leadership.

I think what I would like to do is just ask some questions, if that is OK. I would like to start off with a fairly broad question, and then hope that you will address it. Maybe you can followup for the record with more specifics.

I would like to get at one of my fundamental concerns, and that is, how can we update TSCA to ensure EPA has the ability to protect human and environmental health but also protect jobs, small businesses and the ability of manufacturers to compete against China and other countries? As you know, this is really, I think, one of the overriding problems that we are facing. Where do you draw the balance?

Mr. OWENS. Thank you, Senator, for the question. Thank you, Senator Vitter, for your statement as well.

I think you will hear some discussion of that on the next panel, with the representatives from industry and others that are here. We have had a lot of very good conversations with them about not only the process, but the specifics of reforming the Toxic Substances Control Act.

As I mentioned in my oral statement and I submitted with my written statement, the Administration has developed a set of principles, roughly half a dozen or so principles that outline what we think are, in very broad terms, the concepts that should be embodied in a modernized Toxic Substances Control Act. One of those principles talks about encouraging innovation and ensuring that we take a variety of considerations into account when we are conducting a risk-based safety review of chemicals. That includes costs, that includes impacts on disproportionately affected populations.

But also understand that we are in a globally competitive environment in terms of the issues that we need to be considering when we are looking at chemical manufacturing in this Country. I don't believe you were in the room when Senator Lautenberg asked a similar question a moment ago, but we believe that a reformed TSCA that, as you indicated, does protect the health and safety of the American people is in the best interest of industry. That is why the ACC and the Consumer Specialty Products Association and individual companies that are here today have endorsed TSCA reform, have articulated their own principles.

We have different perspectives on specific issues related to TSCA reform, but we believe that because of the way that we think that innovation can be encouraged, to produce safer chemicals, to invest in green chemistry and to meet consumer demand that is growing in this Country, that we have products that the American people have confidence in, that a revitalized and reformed TSCA will be good for the economy and good for American industry.

Senator BOOZMAN. So I guess a little bit more specific, then, are there any specific problems that you can tell us related to TSCA that you would like to get fixed? If we don't pass a bill, what kind of legal authority and direction does EPA have to address those kinds of problems?

Mr. OWENS. Thank you, Senator, for the question.

The principles that the Administration has developed identify, as I indicated, broad areas within TSCA that we think need to be addressed. I think first and foremost, the safety standard, the review standard under which chemicals are evaluated by EPA needs to be addressed. I think there is broad agreement, certainly among industry and the environmental community that there needs to be some sort of risk-based standard there, in contrast to the current law, which really has no safety standard in it.

That EPA needs to have the ability to get information from industry more efficiently and more effectively than we currently have. Right now, there is no obligation on the part of manufacturers of chemicals to provide information to EPA, and if we decide that we need information in order to better evaluate a chemical, we have to go through a lengthy, formal rulemaking process that can take years before we even get basic data on chemicals.

There are issues associated with the way the confidential business information is submitted. We absolutely respect and understand the need to keep certain types of information confidential to protect trade seekers, to protect formulation processes and things like that. But it has been grossly over-used, so much now that we have a list called the TSCA inventory, which now has 84,000 chemicals. One of the things we do have to look at, as Senator Vitter said, is how we make that list more realistic. But there are 84,000-plus chemicals on that list.

The identify of 17,000 of those chemicals is currently considered confidential. There are lots of reasons for that, but if you stop and think about that, the identity of almost a fifth of all the chemicals on the Toxic Substances Inventory are confidential, the American people don't know what they are, you don't know what they are unless you go through all the training for reviewing CBI and things like that.

Then last but not least, we need to have an effective way for funding the kinds of safety reviews and other operations that will be needed if we are going to revitalize the Toxic Substances Control Act. We have had some very productive discussions with the business community, including many of the people who will be testifying here today about a fee structure or something like that. What would be a reasonable fee would depend in part on what the requirements are for the Agency and what the expectations are.

But I think there is a general agreement that we need to figure out a better way to provide the kind of resources that we are going to need to do the job the American people expect us to do.

Senator BOOZMAN. Thank you, Mr. Chairman.

Senator LAUTENBERG. Thanks very much, Senator Boozman.

I didn't mean to cut you short, but we have several witnesses that are going to testify. Of course, you can submit questions in writing, which will be, I assure you, will be properly taken care of.

Thank you very much, Mr. Owens. I have a couple more questions I will also submit for the record.

I now would like to call up the second panel. That would include, my competent assistant has adopted the role of being my microphone alert person. I am neglectful, because I always think I talk too loud. My wife confirms that, by the way.

[Laughter.]

Senator LAUTENBERG. But welcome. We would ask Kelly Semrau, Steve Goldberg, Frances Beinecke and Cal Dooley and Dr. Lynn Goldman to come to the table. We welcome you.

I will take a moment and I want to enter into the record two letters in support of reforming TSCA. The first comes from CEOs of trade associations representing over 300 companies that together do at least $2 trillion in revenue every year. The second comes from a wide range of faith groups, including Presbyterian, Episcopal and United Methodist churches, and the Union for Reformed Judaism. One of the things that I am going to look to you for as we go through is to ask in broad terms whether or not it is believed if you have any contact with companies that operate abroad, in Europe in particular, and ask you if their standards, the question is being raised now, but their response is not necessary until we get to the question period, whether or not standards for safeguarding people against dangers from chemicals are any less demanding than that which we might have for America, despite that fact that so many of these companies are operating at record levels with record profits to support that.

Now with that unbiased question, I ask you, Ms. Semrau, to testify. We thank you very much. You are vice president for Global Corporate Affairs, Communication and Sustainability, for SC Johnson & Son. We thank you for being here.

STATEMENT OF KELLY M. SEMRAU, SENIOR VICE PRESIDENT, GLOBAL CORPORATE AFFAIRS, COMMUNICATION AND SUSTAINABILITY, SC JOHNSON & SON, INC.

Ms. SEMRAU. Thank you, Chairman Lautenberg and members of the subcommittee. I am very pleased to be here today to support modernizing U.S. chemical management policies.

My name is Kelly Semrau, and I am senior vice president of Global Corporate Affairs, Communication and Sustainability at SC Johnson. I am also a mother of two beautiful children, one of whom is an asthmatic.

One hundred twenty-five year-old, SC Johnson is a family-owned and managed company, with the fifth generation of the Johnson family, Dr. Fisk Johnson, as our Chairman and CEO. We are one of the world's leading manufacturers of home cleaning, home storage, air care and insect control products. We market such leading

brands as Glade®, Off®, Pledge®, Raid®, Scrubbing Bubbles®, Shout®, Windex® and Ziploc® in the United States and beyond.

We employ 12,000 people globally with many employees based here in the United States. We market our products in virtually every country around the world. Hopefully, many of you are already familiar with our company. If you are, then you know that doing what is right for consumers by working to safeguard the environment and protect human health has been a part of our company's ethic for generations. It is a value we live by every day.

Let me cite two brief examples for you. In 2001, we launched our patented, award-winning Greenlist™ process to enable us to select ingredients for our products that have a more desirable human health and environmental profile. Today, we use Greenlist™ to rate more than 95 percent of our ingredients across 19 different ingredient categories, and our scientists are continually exploring adding additional categories.

In 2009, we announced an industry-leading ingredient disclosure program that grew out of Greenlist™ and is designed to bring transparency to our products by sharing ingredient information with consumers through our Website, on product labels and a toll-free telephone number. Yet by no means are we a perfect company. Our commitment to putting the health and well-being of our consumers first is what informs the work we do every day at SC Johnson, and the perspectives we are developing on TSCA modernization.

While we review TSCA as a chemical statute and not a product-related statute, we strongly support efforts to modernize the current law for several reasons. We believe it makes good business sense to update the law while protecting the spirit of innovation that lies at the heart of SC Johnson, our industry and the U.S. economy. First, our products are probably in every home, and on hundreds of thousands of store shelves across the Country. But more important to us is the fact that the Johnson family name is on every company product, and has been for five generations.

Since we go to great lengths to evaluate the ingredients that go into our products and study their related exposures, consumers and their families can be confident about using our products. But some gaps exist in the data that is available to us about chemicals used in commerce. Modernizing TSCA would enable us to examine where these data gaps occur and how they can be filled most effectively.

Second, in the absence of Federal legislative action, the States have begun to adopt their own chemical management programs. We market products in all 50 States. Complying with as many as 50 different State chemical management policies will only create uncertainty in our markets and costly inefficiencies. We believe a modernized Federal TSCA statute will lessen the perceived need for chemical regulation on a State-by-State basis.

Third, chemical regulation is changing rapidly around the globe. Just look at Europe's REACH, countries like Canada and China. We need to be on pace with such global developments, and our Government must be a global leader in chemical policy. Others on the panel will describe industry positions on other key areas of the debate, including the need to prioritize chemical assessments, up-

date the safety standard, and apply the best available science. We too, believe, these are vital elements and urge you to consider them as you develop legislation to update TSCA.

In closing, I would like to thank the Chairman and members of the subcommittee for this opportunity to share our views. SC Johnson pledges to work with you to develop responsible, workable changes to TSCA that will garner broad public and industry support and make the United States a global leader in chemical management policy.

For the record, I am providing the subcommittee with a more comprehensive written statement regarding SC Johnson's history, sustainability programs and rationale for supporting TSCA reform. I look forward to your questions.

[The prepared statement of Ms. Semrau follows:]

SC Johnson
A FAMILY COMPANY

WRITTEN STATEMENT
OF
KELLY M. SEMRAU
SENIOR VICE PRESIDENT –
GLOBAL CORPORATE AFFAIRS, COMMUNICATION & SUSTAINABILITY
S. C. JOHNSON & SON, INC.
BEFORE THE SUBCOMMITTEE ON SUPERFUND, TOXICS,
AND ENVIRONMENTAL HEALTH
OF THE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE
FEBRUARY 3, 2011

"ASSESSING THE EFFECTIVENESS OF U.S. CHEMICAL SAFETY LAWS"

Chairman Lautenberg and members of the Subcommittee, I am very pleased to be here today to support modernizing U.S. chemical management policies. My name is Kelly Semrau and I am Senior Vice President of Global Corporate Affairs, Communication, and Sustainability at S. C. Johnson & Son, Inc. (SC Johnson). Among my responsibilities, I oversee the company's diverse global sustainability programs and initiatives, some I will describe for you today. Many programs are directly linked to understanding, evaluating, and making informed decisions about the chemicals we use to formulate our consumer products. Thus, we have a great interest and a stake in the congressional debate over whether and how to modernize the Toxic Substances Control Act (TSCA) and bring it into the 21st Century.

125 years old in 2011, SC Johnson is family-owned and managed with the fifth generation of the Johnson family, Dr. Fisk Johnson, as our Chairman and Chief Executive Officer. Our business is dedicated to creating and marketing innovative, high-quality products to make consumers' lives easier, better and healthier. We have a particular emphasis as well on excellence in the workplace and enduring generational commitment to the environment. We also believe that the communities in which we operate should be better because we are there. Our international headquarters is in Racine, Wisconsin, where the company was originally founded.

SC Johnson is one of the world's leading manufacturers of products for cleaning, home storage, air care, and insect control. We market leading brands such as GLADE®, OFF!®, PLEDGE®, RAID®, SCRUBBING BUBBLES®, SHOUT®, WINDEX®, and ZIPLOC® in the U.S. and beyond, and among the brands we market outside the U.S. are AUTAN®, BAYGON®, BRISE®, KABIKILLER®, and MR. MUSCLE®. We market our products in virtually every country around the world. We employ 12,000 people globally, yet with many of our employees in the U.S. Please visit our website at *www.scjohnson.com* to learn much more about the company and our values.

Doing What's Right for Consumers

First let me explain what motivates our appearance before the Subcommittee today. Some of you may already be familiar with our company. Perhaps you have seen our television commercials, particularly our most recent ones featuring Fisk Johnson, talking about the importance of doing what's right for our consumers by being more open and transparent about what's in our products. That message – doing what's right for consumers – is what SC Johnson is all about, and it's not just a tag-line in a commercial or slogan in a company brochure. It is a value that we live every day.

Doing what's right for consumers by working to safeguard the environment and protect human health has been a part of our company's ethic for generations. For example, we switched to water-based aerosols from petroleum-based aerosols in 1955. We were leaders in the industry in 1975 as the first company to remove CFCs (chlorofluorocarbons) from all aerosol products, doing so voluntarily and unilaterally three years before the federal mandate. We launched our patented, award-winning Greenlist™ process in 2001 to enable us to select ingredients for our products with the most preferred environmental impact. And in 2009, we announced a broad ingredient communication program that was a logical extension of Greenlist™, designed to bring more transparency to our products by sharing product ingredients with consumers through (1) a dedicated website; (2) product labels; and (3) a toll-free number. Some of these decisions were difficult and expensive but, in each case, SC Johnson felt it was the right thing to do.

While SC Johnson may be a large global company, we pride ourselves on being a *family* company. And everything we do has families in mind. We are always working to make products that consumers know they can trust. For a family company, earning and keeping consumers' trust is paramount. Yet by no means are we a perfect company. However, our commitment to put the health and well-being of our consumers first is what informs the work we do every day at SC Johnson, as well as the perspectives we are developing on TSCA modernization.

SC Johnson Supports TSCA Modernization

While we view TSCA first and foremost as a chemical statute, and not a product-based statute, SC Johnson strongly supports efforts to modernize the 35-year-old law. For many years, TSCA was viewed as an appropriate tool for regulating industrial chemicals, but the statute has not been substantively amended in more than a generation. Yet, the science behind much of chemical management in the U.S. – including the sciences of risk assessment and management – has greatly evolved, and as a result, so have many of our own business practices. We believe it simply makes good business sense to bring TSCA into the 21st Century, while still protecting and enhancing the spirit of innovation that lies at the heart of SC Johnson, the consumer products industry, and the U.S. economy. There are several reasons why we believe there is a compelling business case for modernizing TSCA:

First, formulators like SC Johnson are in many respects the public face of the U.S. chemical industry. Our chemically-formulated products are in every home and on store shelves around the country. Yet, more important to us, the Johnson family name is on every one of our company's products – and has been for five generations. Maintaining a high level of consumer confidence in the safety and performance of every one of our products is a responsibility we take very seriously. Because we go to great lengths to evaluate the ingredients that go into SC Johnson products and study their related exposures, we believe consumers and their families are and can be very confident about using our products. But, we acknowledge that some gaps exist in the data that is available about chemicals that are used in commerce. We believe a TSCA modernization process would give us the opportunity to objectively examine where those data gaps occur and how they can be filled in the most effective and economically responsible manner. Modernizing TSCA may not be the only solution or even the best solution, but the debate opens the door to addressing this fundamental concern.

Second, companies like SC Johnson and others in the chemical industry face tremendous pressure at the state level, as state legislatures and regulatory authorities seek to develop and implement their own chemical management programs in the absence of action at the federal level. These various state initiatives could have the undesirable effect of establishing differing sets of requirements for evaluating chemicals, assessing potential alternatives, and if necessary, eventually substituting chemicals. Since we market products in all 50 states, the prospect of manufacturing products to as many as 50 different sets of state chemical management requirements, no matter how well intentioned, will result in significant uncertainty and inefficiencies. It will also depress innovation. While we respect the belief in the states as "laboratories of democracy," we believe an appropriately modernized and confidence-inspiring federal TSCA statute will ultimately lessen the perceived need for regulation of chemicals on a state-by-state basis.

Third, chemical regulation is changing rapidly and significantly around the globe. Like many of our competitors, SC Johnson is an international company. We comply with the rigorous requirements of Europe's REACH regulation for the Registration, Evaluation, Authorization, and Restriction of Chemical Substances. Added to that are the new Canadian Chemicals Management Program and China's recent revisions to its chemical management program. We believe it is essential for the U.S. chemical management system to keep pace with global developments – including leveraging data and findings for new international chemical management regimes – and that our government be a global leader in chemical regulatory policy.

For these reasons, we believe TSCA should be modernized. We fully intend to play a constructive role to help develop meaningful, effective, and, above all, workable reforms. We will continue to engage Congress, the Administration, EPA, leading non-governmental organizations, and within our own industry to motivate and build support for improving U.S. chemical management practices. This is consistent with the essential principles and building blocks we and our industry developed for a successful chemical management regulatory framework.

Building Blocks of TSCA Modernization

As you think through how best to modernize TSCA, there are issues we believe are critically important:

1. Balanced Transparency: We strongly support transparency, but in a way that balances our genuine desire to inform, and empower our consumers, with the need to protect legitimate confidential business information. We need legitimate confidential business information (CBI) to ensure continued innovation and success in the competitive marketplace. To compete on a global scale, some information must remain a trade secret. Otherwise, U.S. manufacturers will have little or no incentive to expend the research and development resources to innovate. Companies would lose their competitive edge, jeopardizing precious American jobs. With that in mind, however, we are prepared to support reasonable changes in CBI treatment under TSCA, including:

    a. Last year, the EPA asked us to review older files containing CBI claims that we submitted to EPA and to strictly limit such claims in any future TSCA filings. We support EPA's efforts to improve transparency of chemical data. We are committed to undertaking an internal review of our past TSCA submissions with the goal of declassifying information that we conclude no longer merits CBI protection. We also will review our overall TSCA compliance policies concerning future CBI-related claims.

    b. In addition, one of the legislative reforms that has been suggested is to facilitate greater sharing of CBI between governments, whether between the states or between nations. We would support this goal, with proper protections.

    c. We do not object in principle to the suggestion that companies should provide substantiation for CBI claims when the information is submitted to the EPA, provided there is real transparency in the standards under which that substantiation will be evaluated.

    d. There also have been proposals to place time limits on claims of CBI. We can support this approach, provided there is a means to renew the CBI protection where information warrants it.

2. Providing Adequate Use, Exposure and Toxicity Information: We urge EPA to work with chemical manufacturers and downstream users to ensure that EPA has timely and adequate information on chemical hazards, exposures, and uses, including use in children's products. By committing to provide such use and exposure information, formulators like SC Johnson are agreeing to a new reporting responsibility – but one we believe is necessary to properly inform the chemical safety evaluation process. As we evaluate chemical ingredients for use in our products, we find that there are

gaps in the available data. We work very hard to address these gaps and mitigate the risks by working with our suppliers and utilizing peer-reviewed research.

3. Promoting Greener Chemistries: SC Johnson invests in green chemistry. Whether through our Greenlist™ process or our partnership with EPA's Design for the Environment (DfE) program, we see green chemistry as an avenue for motivating the selection of better, safer raw materials. Any TSCA modernization effort should promote the transition to more sustainable alternatives, not hinder manufacturers' ability to formulate out of one ingredient and into another with a more beneficial environmental and human health profile.

4. Ensuring Adequate Time to Respond to New Requirements: We recognize the need to move ahead with TSCA modernization in a timely fashion. We also must ensure that the chemical industry has sufficient time to transform itself and implement the technological and scientific tools needed to accomplish the mission of TSCA modernization. It is vitally important for policymakers to understand and appreciate the fact that manufacturers cannot "flip a switch" and be exactly where we wish to be at a time-certain. I think our Greenlist™ process has put us ahead of the curve for some of the anticipated changes to TSCA, and we are willing to make additional changes that may result from legislation. However, we need a reasonable amount of time to integrate such changes responsibly – those that are less critical priorities where more time can be taken to implement them.

In addition, some other suggestions from industry that we encourage you to consider as you develop legislation include:

1. Promote Innovation: Any changes to current TSCA should promote innovation by chemical manufacturers and their customers by emphasizing simplicity, flexibility, and appropriate protection of intellectual property.

2. Address Prioritization: We believe an effective priority-setting process must be risk-based, taking into consideration a chemical's hazard characteristics and potential exposures to all relevant populations. Prioritization is essential for EPA to focus on the most critical chemicals first, and will in turn bolster public confidence that chemicals of most concern are being addressed first. Neither our resources nor EPA's are limitless. Prioritization will help ensure we proceed in an economically responsible manner.

3. Update the Safety Standard: EPA should establish a risk-based methodology to determine whether a priority chemical is reasonably expected to be safe for its intended use. This will entail the use of exposure data in conjunction with hazard data to make risk-based determinations. Safety determinations should consider the likelihood and potential exposure to the intended population, including children and other sensitive sub-populations, as well as the anticipated benefits from use of a chemical and the availability of suitable alternatives.

4. Leverage and Integrate Chemical Reviews: Policymakers should leverage chemical management programs and reviews undertaken by other nations and integrate, when it makes sense to do so, the patchwork of national laws governing chemical management. This includes accepting validated data generated to meet another country's requirements, so as to minimize duplication of animal testing.

5. Use the Best Available Science: It is essential for policymakers and regulators alike to rely on the best available, scientifically valid data and information, regardless of its source, and to discourage the kind of hype and misleading information that we have seen in recent years.

SC Johnson Sustainability Initiatives

Our perspectives on modernizing TSCA are greatly informed by our own chemical-related innovations and sustainability initiatives. We are very proud of three programs in particular that directly relate to chemical evaluation and selection, and transparency with our customers. These include our Greenlist™ environmental classification process, our ingredient communication initiative, and our ongoing partnership with the EPA Design for the Environment (DfE) program.

Greenlist™

The cornerstone of our company's sustainability efforts is our Greenlist™ process. We implemented Greenlist™ globally in 2001 to classify ingredients considered for use in our products by their impact on human health and the environment. Today, SC Johnson scientists have a computerized, global system that helps them select ingredients with better environmental footprints and to strive to improve our products continually. Our now-patented Greenlist™ process includes ratings for more than 95 percent of the ingredients we use in our products. Among the 19 ingredient categories we have rated under Greenlist™ are chelants, dyes, fragrances, insecticides, packaging, propellants, preservatives, resins, solvents, and surfactants, and our scientists are continually exploring other categories to add. Each type of ingredient is judged based on key criteria, such as toxicity and biodegradability. Greenlist™ scores also take into account whether our suppliers demonstrate their own high environmental performance, such as receiving ISO 14001 certification.

Using the Greenlist™ process, each potential ingredient that goes into an SC Johnson product receives a rating from 3 to 0. An ingredient with a 3 rating is considered "Best," 2 is "Better," 1 is "Acceptable," and 0-rated materials are for restricted use only, when there is no viable alternative. This means that while 0-rated materials may be legal to use, we deem them to be unacceptable against our Greenlist™ program criteria compelling us to work proactively to replace them with those that have a more preferable environmental and human health profile. When SC Johnson scientists create a new product or reformulation, they work to select raw materials rated "Better" or "Best." When existing products are reformulated, the scientist must include ingredients that have combined ratings equal to or higher than the original formula.

Our goal with Greenlist™ is that beyond meeting the legal and regulatory requirements for our products, we increase year-on-year the percentage of our ingredients that are most preferred for their environment impact. In our latest reporting year – 2008/09 – SC Johnson's use of "Better" and "Best" ingredients reached 44% versus 18% in 2000/01. And despite sales growth, our use of the lowest-rated materials in 2008/09 remained at a low 1%. As a result of Greenlist™, we have been able to continuously improve our products, going beyond legal or regulatory requirements to replace less desirable ingredients with those that we believe have a better environmental or human health profile.

Here are a few examples of how Greenlist™ enables us to move away from using certain less desirable ingredients in our products:

- In 2002, we eliminated polyvinyl chloride (PVC) from all of our packaging because it is not biodegradable and has been linked to health problems and other issues.

- Also in 2002, we eliminated chlorine-bleached paperboard packaging because the chlorine can cause contamination of air and water.

- In 2004, we eliminated the organophosphate insecticide DDVP because of links to human health and environmental risk.

- Also in 2004, we eliminated halogenated polymers (PVDC and PVC) from SARAN WRAP® and replaced them with polyethylene (PE).

- In 2006, we acted ahead of regulatory requirements by eliminating another insecticide, propoxur, because of its toxicity and persistence in the environment.

We developed Greenlist™ according to rigorous scientific best practices. It is built on input from recognized experts, such as the UK's Forum for the Future and the U.S. EPA, as well as with help from suppliers, university scientists and other organizations. To this day, we continue to look for ways to improve the Greenlist™ process. It has been scientifically reviewed by organizations like the Society of Environmental Toxicology and Chemistry and the World Wildlife Fund, and has received third-party validation from the Green Chemistry Institute, a division of the American Chemical Society, which is dedicated to promoting and advancing green chemistry. I am proud to note that SC Johnson also has been recognized with multiple awards, including the Presidential Green Chemistry Challenge Award and the Ron Brown Award for Corporate Leadership – both in recognition of our work on Greenlist™.

We are committed to sharing Greenlist™ because we believe other organizations can benefit from the work we have done. We will license Greenlist™ to other companies royalty-free. Because the Greenlist™ process is highly flexible and adaptable, companies licensing it can adapt it to reflect their unique chemicals and materials. Licensees also get a proven management system for establishing, evaluating, and

reporting on performance against measurable objectives. Just as important, they must agree to uphold the responsibility and transparency that's fundamental to operating sustainably. Companies that license the Greenlist™ process must be willing to establish measurable goals and report them annually.

Ingredient Communication

In March 2009, SC Johnson announced a broad ingredient communication program that was a logical extension of Greenlist™. Knowing that families want to understand more about the products they use in their homes, we decided to go beyond the parameters of the ingredient disclosure and "right to know" program launched by our industry in January 2010, which SC Johnson helped develop .Our program goes beyond the industry model by listing dyes (by their trade name), preservatives, and fragrance ingredients for the public to access and review. For fragrances, we will provide a listing of all ingredients that could *potentially* be included in the fragrance, in order to protect the proprietary details of individual fragrance formulations, which are a trade secret. Plus, we continue making our information available to consumers through not just one, but three sources: online at www.whatsinsidescjohnson.com, on product labels, and via a toll-free number that connects customers to our 24-hour Consumer Resource Center.

Additionally, our program focuses on using a single naming system – the International Nomenclature of Cosmetic Ingredients (INCI). This drives simplicity and clarity, as many consumers are already accustomed to seeing INCI terms on personal care product labels. And, we are not just listing, but also defining ingredients and explaining their purpose in the product.

Since that 2009 announcement, we have achieved three key milestones in the implementation of our disclosure program:

- In November 2009, just eight months after announcing our plans, we populated our U.S. ingredient website, www.whatsinsidescjohnson.com. The site contains more than 200 air care, home cleaning and home storage products and the hundreds of ingredients they include.

- In December 2009, SC Johnson Canada launched its own ingredient site in both English and French.

- In March 2010, SC Johnson became the first company in our industry to offer a Spanish-language ingredient site. Just like its English-language counterpart, the site offers easy-to-access and easy-to-understand information about the ingredients in SC Johnson's U.S. air care and home cleaning products. Phone support is available for Spanish-speaking callers, as well.

Transparency with our consumers, as well as with federal and state regulators, is something we take very seriously, and we are looking forward to expanding and enhancing our ingredient communication program in the months ahead. I encourage

members of the Subcommittee to visit our ingredient communication site and share any feedback you may have.

Design for the Environment (DfE)

Finally, we are particularly pleased to be part of the EPA Design for the Environment (DfE) program. In fact, SC Johnson was the first major consumer packaged goods company to partner with DfE. For us, it was a natural fit, as DfE's goals are very much aligned with our Greenlist™ process. Both programs focus on evaluating the safety of numerous cleaning product raw materials. Both place the environment and human health at the center of product development and formulation. And both share a commitment to promoting continuous improvement.

As you consider changes to TSCA, we urge you to preserve our ability to design, implement and expand upon the kinds of sustainability initiatives and programs I described. We need to drive innovative product improvements through the timely evaluation and selection of chemicals that make up our products. And we believe changes to TSCA must be driven by sound science, include realistic timelines for action – for both industry and EPA – and seek to achieve objectives in the least burdensome, most economically responsible manner.

In closing, I would like to thank Chairman Lautenberg and members of the Subcommittee for this opportunity to share our views. SC Johnson pledges to work with you and your colleagues in the other body to develop responsible and workable changes to TSCA that will garner broad public and industry support, and make the U.S. a global leader in chemical management policy.

I look forward to your questions.

Environment and Public Works Subcommittee Hearing
February 3, 2011
Follow-Up Questions for Written Submission

Questions for Kelly M. Semrau

Questions from: Senator James M. Inhofe

What are the real world business implications of states developing and implementing their own chemical regulations?

In the absence of credible TSCA modernization at the federal level, an increasing number of states have taken action on their own to address perceived inadequacies in the way chemicals are regulated. This is a cause for concern among manufacturers, suppliers and retailers as new and differing requirements spring up around the country. The growth of such inconsistent and potentially conflicting regulatory initiatives from state-to-state detracts from the regulatory certainty and workability that are critical to the success of U.S. businesses. Because we market products in all 50 states, the prospect of having to comply with as many as 50 different sets of state chemical management requirements, no matter how well intentioned they may be, will result in significant uncertainty for business investment and ultimately drive up the cost of production and distribution. It also will hamper innovation and new product development by complicating and increasing the cost of R&D activities, as we will be forced to devote more time to assessing and analyzing each new state chemical management regulation and determining which standards we will be required to follow, rather than focusing our energy and resources on developing and marketing innovative new products that improve consumers' lives and achieve real environmental benefits. In the end, consumers will suffer as manufacturers, who must sell nationally, will be forced to comply with the strictest state regulations for every ingredient in their products, thereby downgrading the performance of their products.

While we respect the time-honored role of the states as "laboratories of democracy," we believe a robust, modernized, and confidence-inspiring federal TSCA statute will ultimately lessen the need for regulation of chemicals on a state-by-state basis. Under an appropriately modernized federal chemical regulatory system, U.S. businesses will know what lies ahead and can plan, invest and hire for the future – and states and localities will no longer feel motivated to act on their own, which contributes to an inefficient regulatory patchwork that disrupts national commerce and ultimately hampers our ability to compete in the global marketplace. In fact, we would encourage a federal-state dialogue on chemical management policy reform as you further consider improvements to current TSCA.

In your testimony, you noted the need for TSCA reform to protect legitimate confidential business information and mentioned that, among other negatives, not properly protecting CBI could result in American companies losing their competitive edge and jeopardizing American jobs. What are some other aspects of TSCA reform, which if not executed properly, could result in the exportation or elimination of American jobs?

As I discussed in my Feb. 3 testimony, SC Johnson is committed to pursuing reasonable, workable changes to TSCA that will improve consumer confidence in the safety of chemicals used in household consumer products. To successfully achieve this goal in a manner that enables innovation, inspires public confidence, and creates greater regulatory certainty for businesses, we believe it will be very important for any final legislative proposal to:

- Protect the ability of formulators to safeguard legitimate confidential business information, subject to appropriate substantiation, while meeting public safety and transparency concerns; this is vital to shielding our significant investments in intellectual property from competitors, both here and abroad;
- Establish clear, achievable timelines/deadlines for conducting chemical assessments;
- Ensure that a revamped TSCA system is sufficiently resourced and operates efficiently so that new products can be brought to market in a timeframe that meets global demand; and
- Ensure that prioritization and standard-setting – including development of a potential new safety standard – are appropriate, achievable, and both science- and risk-based.

It is equally important for any final legislation to give formulators sufficient time to respond to new regulatory requirements. While we recognize the need to move ahead with TSCA reform in a timely fashion, we also must ensure that the chemical industry – from raw material suppliers to end-use product manufacturers – has adequate time and flexibility to transform itself and develop/implement the scientific and technological tools needed to comply with an updated TSCA system. Policymakers must understand and appreciate the fact that manufacturers cannot simply "flip a switch" and be exactly where we wish to be at a time-certain. For SC Johnson, our Greenlist™ process has put us ahead of the curve for some of the anticipated changes to TSCA, and we are willing to make additional changes that may result from Congressional action. However, we will need a reasonable amount of time to integrate such changes responsibly.

You also discussed SC Johnson's investment in green chemistry, a decision your company chose to make without any government mandates. Is it true that, for some important chemicals or mixtures, there is no "green" alternative, or one that could materialize in the near future? How could improperly eroding CBI provisions affect the future advancement of green chemistry?

Formulating consumer products is a complex process. While we strive to identify and use raw materials that have reduced impacts on the environment and human health, sometimes we are challenged to find "greener" alternatives that deliver the same level of performance that consumers have come to expect from our products. And in some cases, we have found that a seemingly "greener" option can turn out to be less environmentally preferable. Through our Greenlist™ process, however, we have found it possible to work with our suppliers to improve the human health and environmental profile of the majority of ingredients considered for use in our products. Under Greenlist™ some ingredients may receive a "0" rating – indicating they are considered for use only when there is no viable alternative, even if they are not restricted by government regulatory requirements. In such cases, we continue to work proactively and vigorously to replace them with ingredients that have a more preferable human health and environmental profile. For example, between the baseline years of 2000/01 and 2008/09, we reduced the percentage of 0-rated ingredients from 10 percent to 1 percent – further evidence that

by working closely with our suppliers we have been able to identify suitable alternative ingredients that deliver desired levels of product performance, while having the least impact on the environment and human health. Like any good scientific process, Greenlist™ is all about continuous improvement, and we are continually working on tools that help our scientists more easily identify and evaluate potential options for a particular ingredient or product function.

As your question also points out, the ability to protect legitimate confidential business information is critical to new product – and new ingredient – innovation and no doubt will have an impact on the future growth of green chemistry and engineering. Enabling companies to protect legitimate trade secrets will help spur industry innovation toward the development and use of safer alternatives. Without such protection, manufacturers will have little incentive to invest resources in R&D efforts dedicated to developing sustainable innovations, and we will risk losing valuable intellectual property and other types of sensitive information to domestic and international competitors.

Current TSCA does not reward the development of newer, safer alternatives, thus we believe TSCA reform legislation should include provisions that create market incentives for developing and transitioning to the use of "greener," safer alternatives to existing chemical substances. To incentivize the development and use of such alternatives, we encourage Congress to consider tools that support companies' efforts to innovate in this area, including the use of limited exemptions from certain regulatory requirements and faster assessments that ultimately aid speed-to-market. With our Greenlist™ experiences as a guide, we would be pleased to work with you, Senator Lautenberg, and other Committee members to facilitate the expansion and commercialization of green chemistry.

Senator LAUTENBERG. Thank you very much.
Now, Mr. Steve Goldberg.

STATEMENT OF STEVEN J. GOLDBERG, VICE PRESIDENT, REGULATORY LAW AND GOVERNMENT AFFAIRS, BASF CORPORATION

Mr. GOLDBERG. Thank you, Mr. Chairman and members of the Committee. Thank you for the opportunity to testify today. My name is Steve Goldberg, and I am vice president and Associate General Counsel for Regulatory Law and Government Affairs at BASF Corporation.

BASF Corporation, headquartered in Florham Park, NJ, Mr. Chairman, is the North American arm of BASF SE, the world's largest chemical company. Senator Vitter, our largest single manufacturing site is in Louisiana, as you well know.

In the United States, BASF has operations in 31 States and has over 15,000 employees. Mr. Chairman, thank you for your kind words about BASF. We do believe that safety of our products is of paramount importance, and one of our principal pillars for BASF globally is sustainability. Sustainability as it relates to safety, environment and also economic sustainability.

BASF strongly supports modernization of TSCA. It is necessary to ensure consumer confidence in the products of our industry, to avoid the proliferation of State and local laws that can inhibit commerce, and to bring TSCA into the 21st century with its new technologies and scientific techniques.

In short, TSCA modernization is a business need as well as a societal one.

Modernization, however, must reflect, as you have said, Senator Lautenberg, the importance of the chemical industry to society and the need to maintain and indeed, encourage, innovation. Solutions to some of the key societal issues we face, climate, health, energy efficiency, alternative energy and feeding a growing population sustainably come from the products of the business of chemistry.

TSCA modernization needs to be informed by what works well and does not work well in TSCA now, as well as by what works and doesn't work in other chemical management systems around the world. BASF as the world's leading chemical company, is willing to devote its expertise and experience on these points to help inform Congress as it works toward modernizing TSCA.

Most importantly, I believe that there is more than unites various stakeholders in the TSCA debate than divides them when it comes to TSCA modernization. I have set forth in more detail in my written testimony those points that I think do have consensus among stakeholders. These are based upon principles, documents that have already been put forth. There are a number out there. Mr. Owens talked about EPA, American Chemistry Council, Consumer Specialty Products Association, American Cleaning Institute, and the principles enunciated by Richard Dennison at EDF. I have looked at these, and while the language is my own, I haven't necessarily asked for concurrence from these groups, but I do believe within broad parameters, those principles provide a basis for recognition of the common goals that unite rather than divide stakeholders.

My purpose in setting these forth is not to think that principles are an end in themselves. I am not naive and I do understand that the devil is in the details. But if we are to reach bipartisan consensus and end up with TSCA modernization that succeeds, it is vital that it be based on common goals that stakeholders from all sides share. This can only help to crystallize the issues that need to be addressed in Congress.

Let me highlight just a few of those principles that I think unite stakeholders, and many of them were talked about by Mr. Owens and the committee. First, I think there is strong support for a strong Federal system of chemical regulation and for the important role that EPA must play in chemical safety assessment. From my view, this can reduce or eliminate the need for multiplicity of State or local actions and most especially, provide confidence to consumers in the products they use.

There is consensus that safety assessment should be risk-based, that is, taking into account both toxicological properties and exposure. In this regard, a number of the downstream associations we work with have come forth with concrete proposals on providing use data to inform the safety assessment of chemicals.

Finally and most importantly, TSCA modernization must be done in such as way as to allow it to succeed. Modernization that fails to provide consumer confidence in the products of the business of chemistry does industry no good. Nor will TSCA modernization succeed if it fails to provide resources needed to achieve its ends, or is so overly ambitious that it cannot meet its goals. It will not succeed if it is not based on sound science and risk assessment principles, nor if it stifles innovation or unreasonably delays access to needed technologies.

This is a most urgent need, that TSCA modernization be practical, achievable, protective, and if I may use that perhaps overly used word these days, sustainable.

Thank you for the opportunity to testify. I look forward to your questions.

[The prepared statement of Mr. Goldberg follows:]

Testimony of Steven J. Goldberg
Vice President, Regulatory Law & Government Affairs
BASF Corporation

Assessing the Effectiveness of U.S. Chemical Safety Laws

Subcommittee on Superfund, Toxics, and Environmental Health
Committee on Environment and Public Works
United States Senate

February 3, 2011

Good morning, Mr. Chairman. My name is Steve Goldberg, and I am employed by BASF Corporation as the company's Vice President for Regulatory Law & Government Affairs. Among my responsibilities within BASF, I am charged with ensuring the company's compliance with the Toxic Substances Control Act and other similar statutes, such as those governing pesticides, foods and pharmaceuticals. I have been active in discussions on TSCA modernization during the last two years through trade associations, such as the American Chemistry Council, Consumer Specialty Products Association and American Cleaning Institute, and I have maintained a dialogue with non-governmental organizations, including the Environmental Defense Fund and Natural Resources Defense Council.

BASF Corporation supports modernization of TSCA. While TSCA remains an effective statute in many ways, to ensure the confidence of the American public in the products of chemistry, TSCA needs to be updated. Toxicology, environmental science and risk assessment processes have also advanced considerably since TSCA was enacted in 1976. And new scientific methods are being used to assess the safety of chemicals as to both human health and the environment. Modernization of TSCA needs to ensure the safety of the products of chemistry; but it must also ensure the ability for the U.S. chemical industry and its customers along the value chain to innovate in order to meet the growing complexity and challenges faced by our society, including climate protection, health care, and related concerns.

TSCA modernization will not be an easy task. It will first require consensus around a set of principles. ACC, CSPA and ACI, the three groups that I have worked with, have put forth principles for TSCA modernization. BASF supports these principles. We have also seen principles put forth by NGOs, most specifically those set forth by EDF.

On many fronts, I believe that the regulated and the NGO communities are closer than one might think. As with so many issues, however, the difficulty lies in the details. This hearing will likely not delve into most of these details, but I do hope that it will help us to crystallize the principles that will eventually lead U.S. chemical regulation into the 21st Century.

About BASF

At BASF Corporation, *We create chemistry.* We are the U.S. subsidiary of German-based BASF SE, the world's largest chemical company. Our portfolio includes chemicals, plastics, performance and agricultural products and fine chemicals. As a reliable partner, BASF helps its customers in virtually all industries to be more successful. With our high-value products and intelligent solutions, BASF plays an important role in finding answers to global challenges such as climate protection, energy efficiency, nutrition and mobility. In the United States, BASF employs nearly 13,500 people and has facilities in more than half of the states.

What TSCA Does Right

It was not until 1976 when Congress passed and the president signed TSCA into law that the U.S. had a true chemical regulation program designed, as the statute says, "to ensure that chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."

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First and foremost, TSCA appropriately established a role for the federal government in the regulation of chemicals and it provided those of us in the regulated community with guidance to develop products that are safe for their intended use. The statute requires, for example, an inventory of existing chemicals and provides that new substances are to be added to the inventory after they are reviewed and approved by EPA. EPA has authority to collect data from manufacturers and processors and can require testing of a chemical if it finds that the chemical "may present an unreasonable risk to health or the environment." In addition, TSCA was given built in flexibility, recognizing that not all chemicals are alike and allowing EPA to use different types of assessments depending on the chemical in question. Finally, TSCA gives EPA regulatory authority to impose risk management measures on chemicals found to present an unreasonable risk to health or the environment. These risk management measures include bans, warnings and labeling requirements.

Second, TSCA has promoted innovation. While establishing an appropriate role for government regulation, TSCA makes clear that such regulation "should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation." If one were to look at the role chemistry plays today and the products that we all enjoy as a result of chemistry, TSCA has not only promoted safety, but also ensured economic growth and the creation of new technologies. It is estimated by ACC that over 96% of manufactured goods are directly touched by the business of chemistry. The chemical industry supplies its products into markets for consumer goods, transportation, pharmaceuticals, healthcare, paper, energy, housing and construction and numerous others. It is a leader in meeting the needs of a changing society, looking to enhance sustainability in areas such as energy and construction.

And third, TSCA has ensured the protection of confidential business information. Intellectual property is a company's most valuable intangible asset. Like other forms of intellectual property (patents, trademarks, and copyrights), CBI represents a substantial investment of time and dollars. And, it must be safeguarded carefully from competitors. TSCA allows EPA to solicit and receive CBI, but at the same time correctly establishes criminal penalties for wrongful disclosure by the agency and its personnel.

Why We Need TSCA Modernization

While BASF believes that TSCA is protective of health and the environment, the statute is nearly 35-years-old and was adopted during a different era, one where the economy, science, and technology were not nearly as complex as they are today.

For example, newer forms of testing are rapidly being developed. This includes high throughput screening of chemicals and use of non-animal testing models for toxicity. In addition, biomonitoring, which measures human exposure to natural and manmade chemicals based on sampling of tissues, blood, and other fluids, has become more sophisticated. Scientists are now able to measure smaller and smaller amounts of chemicals in the human body.

And, as science and society have progressed, people's understanding and expectations of chemistry have progressed along with it. Because of new media like the Internet, Americans have greater

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access to information, and misinformation, about chemistry as well as what goes into the products they purchase. Americans want to know more and have confidence in the safety of the products of chemistry and in the federal government's regulatory role ensuring safety. At the same time, industry needs a more predictable, scientifically-based and efficient federal management system to avoid a multiplicity of state and local laws that inhibit innovation.

Most importantly, while EPA has an effective program to review the safety of new chemicals under TSCA, it has lacked an organized, systemic program for reviewing chemicals that were part of the original TSCA inventory.

Principles for Legislation

As noted previously, I have worked on principles for the modernization of TSCA with ACC, CSPA and ACI. Examining them, as well as principles set forth by EDF, suggests that there is commonality in the following areas:

(1) A strong federal system is necessary to ensure the safety of chemicals in commerce. From the industry perspective, it is also necessary to avoid the multiplicity of state and local laws that inhibit commerce.

(2) Chemicals should be safe for their intended use, and EPA should have authority to make appropriate safety determinations.

(3) An appropriate TSCA safety standard should be risk-based, taking into account both hazard and exposure data to assess safety.

(4) Industry should have the burden to come forth with information demonstrating the safety of chemicals for their intended uses for both new and existing chemicals.

(5) Companies that manufacture, import, process, distribute or use chemicals should be required to provide EPA with information necessary to make appropriate safety determinations. Information needs to come not just from manufacturers but from others in the chain in order to make appropriate risk-based assessments.

(6) EPA should systematically prioritize existing chemicals for the purpose of reviewing their safety. Given the large number of chemicals potentially in commerce, EPA should focus on specific chemicals of concern. How this prioritization would occur and what the basis of that prioritization would be under a modernized TSCA remains one of those important details I referenced earlier in my statement.

(7) Considerations of costs and availability of alternatives should be separate from the risk assessment process. Questions of feasibility, cost, or availability (or lack thereof) of alternatives needs to be considered when a product is determined to require some risk management to be used safely. However, it must be recognized that manufacturers of chemicals and chemical products regularly use risk management tools to ensure that their

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products are used safely. Examples of such measures include labeling, safety data sheets, packaging and protective equipment. Existing risk management measures must in fact be considered in determining whether a chemical is safe for its intended use.

(8) EPA should have the authority to impose a range of risk management measures to ensure that chemicals can be used safely in commerce as well as work with other agencies having jurisdiction over chemical products

(9) Potential risk to children should be an important factor in safety assessments.

(10) Safety data regarding chemicals should generally be available to the public. Methods to limit claims of confidentiality to truly confidential business information should be established.

(11) A modernized TSCA should encourage technological innovation, including the promotion of modern advances in science and the development of better products onto the market.

(12) A modernized TSCA should ensure the scientific validity of information from all sources on which regulation relies and establish specific criteria to address the quality, reliability and relevance of scientific information.

(13) EPA needs to be provided with the tools necessary to fulfill the mandates under a modernized TSCA.

(14) EPA should be empowered to share with and receive information from state and foreign governments in order to foster a greater understanding of chemistry and promote cooperation for the good of public health and economic growth and innovation. That said, there should be provision to ensure that these governments continue to keep confidential the CBI data they receive from EPA.

(15) Modernizing TSCA must be done in such a way as to allow it to succeed. Legislation that would bring innovation to a halt or would be unachievable with the resources available benefits no one.

Conclusion

Thank you, Mr. Chairman, for the opportunity to testify. BASF Corporation looks forward to working with this subcommittee and interested stakeholders on developing legislation for TSCA modernization. I would be pleased to answer your questions.

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BASF
The Chemical Company

Legal Department

STEVEN J. GOLDBERG
Vice President & Associate General Counsel
Regulatory Law and Government Affairs

August 22, 2011

Barbara M. Boxer, Chairman
James M. Inhofe, Ranking Member
Committee on Environment and Public Works
United States Senate
Washington, DC 20510-6175

Dear Chairman Boxer and Ranking Member Inhofe:

I am pleased to respond to your letter of September 3 following up on the hearing of February 3, 2011 and to the questions for the record submitted by Senator Inhofe. BASF appreciates the committee's interest in this important area and in soliciting input from the chemical industry as one of the key stakeholders in modernization of the Toxic Substances Control Act (TSCA). As I noted in my testimony, BASF Corporation supports sensible and effective modernization of TSCA.

Our replies to your questions follow.

1. **Question**: "Mr. Goldberg, given that you are part of a chemical company that employs people and contributes to our economy, what are some specific areas of current TSCA law that you feel are working and are not in major need of reform?"

   Response: We appreciate the recognition of the importance of the chemical industry to the economy of the U.S. The chemical industry is critical not only for the jobs in the industry, but because virtually all other industries depend upon the products of the business of chemistry. It is estimated that over 95% of manufactured goods touch upon the business of chemistry.

   We do believe that there are specific areas of TSCA that are working well and are protective of health and the environment. As noted by Dr. Lynn Goldman, former Assistant Administration for Pesticides and Toxics in the Clinton Administration, the new chemicals program works extremely well and is not in need of major reform. In the new chemicals program, EPA makes safety assessments of new chemicals, and, where appropriate, puts limitations on use of such chemicals.

   BASF believes that most of the data collection provisions of TSCA under Section 8, such as those calling for report of studies and reporting of potential adverse effects and update of the TSCA inventory, also function well to provide EPA with a wealth of information on chemicals.

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2. **Question**: "Could you please describe some of the real world consequences associated with TSCA modernization the wrong way, in a manner that imposes severe costs and new regulatory burdens?"

   Response: The business of chemistry is one of the key drivers of the economy, and supports many of the country's downstream industries, from consumer goods to pharmaceuticals, to road and building construction, electronics, and numerous others. The chemical industry provides the innovation to address some of the most challenging societal issues, such as energy and climate. Those industries, and thus the business of chemistry, depend upon a stable and predictable regulatory system, and, most importantly, one that promotes and advances innovation. In order to meet customer needs, companies such as BASF are constantly looking to bring to market new products, or variations of older products (that themselves may, due to slight molecular variations, be "new chemicals"). Reform done incorrectly, for example by substantially delaying the new chemical review process, would have a devastating impact on this innovation, both in the business of chemistry and in our customers' businesses. If customers cannot get the products they need here in the United States, then their only alternative is to move operations overseas where they can. Similarly, if the costs of introducing new chemicals are simply beyond what can be paid to cover those costs, innovation will similarly dry up.

   In addition, careful attention is required to make sure that truly confidential business information (CBI) is maintained as confidential. While, as noted below, we believe CBI is an area in which TSCA can be improved, it must be done carefully. Any loss of industry's confidential information runs the great risk of halting needed innovation and potentially driving business towards countries with much less investment in innovation than the United States.

3. **Question:** "What are the areas that, in your view, are not working well, that really do need to be changed? Could a few specific issues be addressed to satisfy much of the need for TSCA reform without a complete overhaul? If so, could you give a few examples?"

   Response: Whether through judicial or agency interpretation, EPA has appeared hamstrung in TSCA in its ability to call for new data for chemicals for which there may be concerns. Modernizing TSCA Section 4 to provide sufficient authority to call for data under appropriate circumstances would do much to advance the understanding of EPA and the public in the safety of chemicals.

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A second area is the ability of EPA to share information with state and foreign governments. TSCA currently puts substantial limitations on EPA's ability to share data. Proper reform of TSCA should be able to accommodate both legitimate business confidentiality issues while increasing the access EPA has to foreign data, and that states have to data in the possession of EPA. In light of the substantial information likely coming out of the EU's REACH regulatory scheme, this is an important issue to get right.

BASF also believes that the confidentiality provisions of TSCA can be improved to ensure that only truly business confidential information is being protected while making health and safety data more available.

BASF strongly supports modernization of TSCA. This, however, does not mean throwing out the statute and starting over. Rather, we can build upon the successful portions of TSCA and improve those sections that should be improved. BASF believes, however, that critical to successful modernization of TSCA is ensuring that the public has confidence in the products of our industry. This depends upon the public having confidence that EPA has the tools to review chemicals and make safety assessments. Reforming TSCA must be done in a thorough enough fashion to provide that consumer confidence. Sensible but comprehensive TSCA modernization will, hopefully, limit or foreclose the "balkanization" of chemicals management we currently see, with numerous state jurisdictions seeking their own approach to individual chemicals and chemicals management policy.

4. **Question:** "Are there any authorities under TSCA that you feel are being misused or underutilized by EPA? By that I mean: is EPA using all the legal discretion it has under TSCA to ensure the safety of chemicals but also ensuring that you and others trying to make a living can actually do so?"

   Response: Through its process of developing chemical management plans and prioritizing chemicals for review in that process, EPA is utilizing authority which BASF believes it has not utilized in the past, perhaps out of fear of legal challenge. While supportive of EPA's use of this authority, we believe that EPA needs to be fully transparent as to the basis of selection of chemicals for review, and rely on best available science and the weight of the evidence in making assessments and any needed risk management decisions.

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On the issue of misused authority, we are a bit concerned by EPA's program of removing confidentiality claims in any submission to EPA for all substances on the public TSCA inventory. The fact that a compound is on the public inventory does not mean that particular uses, or the chemical identity in a particular study, is not confidential (where, for example, it might disclosure confidential process information). Such flat rules about confidentiality do not comport with the requirements of the Freedom of Information Act for protection of confidential business information.

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Senator LAUTENBERG. Thank you, Mr. Goldberg.

Ms. Beinecke, we welcome you, and note that you are the president of the Natural Resources Defense Council. Thank you for doing that task, and thank you for being here today. Please proceed with your testimony.

STATEMENT OF FRANCES BEINECKE, PRESIDENT, NATURAL RESOURCES DEFENSE COUNCIL

Ms. BEINECKE. Thank you, Chairman Lautenberg and members of the committee. Thank you for inviting me to appear this morning. My name is Frances Beinecke, and I am the president of the Natural Resources Defense Council.

I am pleased that this hearing is being held so early in the 112th Congress. Achieving meaningful reform of TSCA is a high priority for NRDC, and we look forward to working with members of this committee, individual companies, and other key stakeholders to fix this broken law.

The truth is, whether or not Congress is able to enact TSCA reform legislation, the landscape of chemical regulation is already changing dramatically in the United States and around the world. Over the last several years, 18 States have adopted controls on toxic chemicals, nearly all with strong bipartisan support. More than 30 States will consider additional protections this year.

The rest of the world is moving ahead as well, with reform efforts planned or already underway in the European Union, Japan, China, Canada, Taiwan, South Korea and Israel.

TSCA has many serious flaws that have made it one of the greatest failures of our modern environmental laws. These include the original grandfathering of 62,000 chemicals as safe, severe constraints on EPA's ability to require testing by chemical manufacturers, even greater limits on EPA's ability to take action to protect the public from chemicals known to cause harm, limits on EPA's ability to obtain the information necessary to review a new chemical's safety, and little or no publicly available information about most chemicals, including their uses, potential effects on human health, or the environment, and likely sources of exposure.

Meanwhile, over the last 35 years, as EPA has been largely paralyzed, our understanding of the impacts of chemicals in our bodies has greatly expanded. This includes the recognition that children, pregnant women and the fetus are more vulnerable to exposure to toxics, the understanding that some chemicals can alter our hormonal systems, even in very small doses, the scientific realization that the timing of exposure can be as important as the dose, and the potential for the effects of chemical exposure to be passed to future generations.

We made a mistake 35 years ago when we grandfathered those 62,000 chemicals with no requirement of meeting a health standard or being subject to future testing. Two generations later, we find ourselves with hundreds of chemicals in our bodies, some already known as carcinogens or neurotoxins, and with rising rates of cancer, development and learning disabilities, reproductive problems, birth defects and other disorders.

I want to focus a moment on the disease with which I have direct personal experience, cancer. The statistics on cancer are shocking.

It is the second leading cause of death in the United States. One of every two men will develop an invasive cancer during their lifetime, while one in four will die from their cancer. In women, one in three will develop a cancer over their lifetime, and one in five will die.

The issue of cancer is very personal for me, as I know it is for probably everyone in this room. Ten years ago, I was diagnosed with breast cancer. I had chemo, radiation, went through the treatment. My husband at the same time was diagnosed with proState cancer. So we had two of the most common cancers that the American public experiences.

For 10 years, I have had a conversation with my oncologist on what are the causes, and how to prevent exposures for the American public. It is an ongoing conversation. I grew up in Summit, NJ. I have no cancer in my family, no history of cancer. So I am one of the one in three, and I am one of the lucky ones, because I am here to tell my story. I feel fortunate that not only can I tell my story, but I can be an advocate for reform as we go forward.

I suspect few people here today have not lost someone they love to cancer. The point of course is that not all of these cases of cancer are caused by toxic chemicals. But we do know that there are a significant number of cancer-causing chemicals produced in high volumes to which people are widely exposed, and under TSCA, EPA can do almost nothing about them. The American people do not want to be exposed to chemicals linked to cancer, leaning disabilities or infertility, and then take the chance that there won't be a problem 10, 20 or 30 years down the road, or down the road for their children or grandchildren. Your action may not help my daughters who are at reproductive age, but I certainly hope they will help their children.

We now face a tall order. We need to determine which chemicals that are used in commerce are safe. We need to break free of the legal restrictions and red tape that have prevented EPA from quickly reducing exposure to those that have strong evidence of harm and widespread exposure. States will continue to act in the face of inaction at the national level while public trust in the safety of numerous products will continue to decline. That prospect should be enough to keep everyone at the table until we can reach agreement on how to reform this law.

I view this hearing as part of the effort to tackle TSCA reform, and I want to thank you again for being invited to testify and participate. I look forward to working with colleagues across both the environmental community and in industry to work toward a solution to this. Thank you very much, and I look forward to your questions.

[The prepared statement of Ms. Beinecke follows:]

TESTIMONY OF

FRANCES BEINECKE

PRESIDENT

ON BEHALF OF:

NATURAL RESOURCES DEFENSE COUNCIL

BEFORE THE U.S. CONGRESS

SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

SUBCOMMITTEE ON SUPERFUND, TOXICS AND ENVIRONMENTAL HEALTH

AT HEARING ENTITLED:

ASSESSING THE EFFECTIVENESS OF U.S. CHEMICAL SAFETY LAWS

FEBRUARY 3, 2011

Chairman Lautenberg, Ranking Member Inhofe and members of the Committee, thank you for inviting me to testify today on "Assessing the Effectiveness of U.S Chemical Safety Laws." My name is Frances Beinecke. I am the President of the Natural Resources Defense Council (NRDC). NRDC is a national, nonprofit organization of scientists, lawyers, and environmental specialists dedicated to protecting public health and the environment. Founded in 1970, NRDC has more than 1.3 million members and online activists nationwide, served from offices in New York, Washington, Los Angeles, San Francisco, Chicago, and Beijing.

We appreciate being included in today's discussion on the importance of reforming our chemical safety laws to protect the public from unsafe chemicals and promote innovation toward the production and use of safer chemicals. NRDC is a member of the Safer Chemicals, Healthy Families campaign a coalition of nearly 300 local, state-based and national organizations including environmental, health, consumer and justice groups that have united around a common platform for reforming the flawed and outdated Toxic Substances Control Act (TSCA). NRDC is also a member of the Blue Green Alliance, a national strategic partnership between ten labor unions and four environmental organizations dedicated to expanding the number and quality of jobs in the green economy. The Blue Green Alliance is a strong proponent of TSCA reform to increase health protections for workers and their families.

I am particularly pleased that this hearing is being held so early in the 112th Congress, signaling a continued commitment to address this issue, and seek workable legislative solutions to TSCA's long-standing problems. In the 111th Congress, both this Committee and the House Energy and Commerce Committee held a number of hearings on various aspects of TSCA reform, providing a range of views and opportunities for discussion and identification of key issues that need to be addressed. In addition, the Safe Chemicals Act introduced by Senator Lautenberg, as well as legislation introduced in the House, provided good frameworks for discussion and negotiation on the details of TSCA reform. I hope that we can build upon the momentum created in the last Congress and advance legislation in this Congress.

While much of the political discussion inside and outside Washington is about how the recent elections changed the Congressional landscape for addressing a range of problems, recent public opinion research clearly confirms that protecting the public from exposure to unsafe chemicals has strong, bi-partisan support with the public, and all will benefit from moving forward with strong, workable reforms, no matter who is in charge. Achieving meaningful reform of TSCA is a high priority for NRDC, and we look

forward to working with members of this committee, and the rest of the Congress, as well as individual companies – both chemical manufacturers and downstream users – and other key stakeholders – to establish an effective system for protection for public health and the environment.

The truth is, whether or not Congress is able to enact TSCA reform legislation, the landscape of chemical regulation is already changing dramatically, and it will continue to do so even in the face of Congressional inaction. Among the drivers of this change is adoption at the state and local level of controls on the use of specific chemicals (such as bisphenol A and some phthalates), classes of chemicals (brominated flame retardants), as well as broader reform initiatives. In the last 8 years, 18 states have adopted 71 such measures.[1] Significantly, virtually all of these measures commanded strong bi-partisan support from state legislatures, and were signed into law by Democrat, Republican, and Independent governors. That trend is likely to continue. Just last month, legislators in more than 30 states introduced or announced plans to introduce chemical safety legislation this year. Of course not all of these efforts will succeed in the current legislative year, but they reflect the broad and continuing widespread support for reform, and a recognition that the current federal system fails to adequately protect the public. Further evidence of the state-level support for reform, are the adopted resolutions calling for TSCA reform from the Environmental Council of States (ECOS), the National Conference of State Legislatures (NCSL), and the Association of State Drinking Water Administrators (ASDWA). Those calls for reform have been by echoed by medical, science, and public health organizations including the American Medical Association, the American Public Health Association, and the American Nurses Association.

The unprecedented state and local level activity in this area has also been reflected more directly in the marketplace. Numerous large retailers, including Walmart, Toys "R" Us, and Target have acted recently to drop from their shelves products containing chemicals for which there is growing concern, including bisphenol A, phthalates, lead and cadmium. Downstream users and formulators of chemicals are also developing their own chemical safety policies and practices, and are engaged in efforts to disclose more information to the public about the chemicals used in their products and to ensure that those chemicals are safe for all their uses. SC Johnson has been a leader in this regard. I have previously applauded SC Johnsons' efforts to eliminate certain toxic chemicals from their products and expand its disclosure of the chemicals used in its products, and its leadership in working to expand the public's right to know

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[1] See *"Healthy States: Protecting Families From Toxic Chemicals While Congress Lags Behind"* by Mike Belliveau, November 2010, http://www.saferchemicals.org/PDF/reports/HealthyStates.pdf.

about chemicals to which they may be exposed. Downstream users of chemicals, as well as the public, will undoubtedly benefit from federal-level reform that will expand the information about chemicals available to the market as well as the public; provide consumers with the confidence that chemicals have been assessed for safety based on modern scientific methods; and ensure that EPA has the ability (and duty) to take action to protect the public from those chemicals that are unsafe, particularly from everyday products found in homes, schools and the workplace.

While we applaud the steps taken at the state level and in the marketplace to fill the vacuum left by the ineffectiveness of TSCA, we recognize that it is an imperfect alternative to strong reform at the national level. In the first place, state-by state protections cannot themselves meet the larger purpose of protecting all Americans from unsafe chemicals. Second, part of what is needed in national reform is a systematic review of the safety of chemicals in commerce, to ensure that eliminating the use of one unsafe chemical doesn't lead to substitution with another that is equally bad or worse. Third, we need a national chemical safety policy to keep pace with the rest of the developed world that is already pulling ahead in its efforts to strengthen health protections and promote innovation and development of safer chemicals. The most obvious example is the European Union, which just passed a significant milestone in its implementation of REACH: the deadline for submitting registration dossiers on the first set of chemicals to be manufactured or imported into the Union. But the EU isn't alone. Reform efforts are planned or already underway in a host of other countries including Japan, China, Canada, Taiwan, South Korea, and Israel. In short, our broken chemical safety system is getting passed up by our international competitors.

The Committee has heard in previous hearings from EPA and other experts about some of the fundamental problems with the current system under TSCA that have led to the explosion of activities at the state level and in the marketplace to address public concerns about toxic chemicals. These include:

- The absence of any systematic, prioritized, and deadline-driven review of the 62,000 chemicals grandfathered under the original Act to determine whether they meet a safety standard. As a result, the Government Accountability Office (GAO) estimates that fewer than 2% of those chemicals have been fully reviewed by EPA in 35 years;

- The inability to require upfront the information necessary for EPA to adequately review the safety of new chemicals. As a result, 85% of the notices EPA receives for new chemicals contain no health data, and 95% contain no ecotoxicity data. The U.S. is alone in the developed world in not requiring a minimum set of data for new chemicals to assess their safety;

- Severe constraints on EPA's ability and authority to obtain testing or other information from chemical manufacturers – such that fewer than 300 chemicals have been required to be tested under TSCA. As a result, we are still very much in the dark about the potential health or environmental effects of thousands of chemicals that are used in commerce;

- Even higher hurdles for EPA to clear before it can take action to protect the public from chemicals, even those well known to be unsafe and for which there is widespread human exposure (like asbestos). As a result, only 5 of the original 62,000 chemicals have been partially regulated by EPA under TSCA in 35 years. The one most extensively addressed has been PCBs, production of which was banned by Congress under TSCA in 1976. Yet, we still face widespread contamination by PCBs in the environment, in schools, and in our bodies. This is due in part to its persistence in the environment and its ability to build up in the food chain, but also because TSCA did not ban all uses of PCBs. The exemption of certain uses has resulted in continued releases to the environment and ongoing exposure;

- A lack of publicly available information about most chemicals – including their uses, their potential effects on human health or the environment, and likely sources of exposure. This is due in no small part due to TSCA's Confidential Business Information (CBI) provisions that, among other problems, allows companies to make nearly unlimited claims of CBI, without requiring any upfront justification or EPA review, and without any date of expiration or requirement for periodic renewal and justification of such claims;

- A failure to incorporate and act upon advances in our scientific understanding of how chemicals can affect health, and how to best assess the risk posed by chemicals.

Just a small sample of the areas where scientific understanding and technology have increased since TSCA was enacted in 1976 include: a greater recognition that some populations, including children, pregnant women, and the fetus are more vulnerable to the effects of exposure to toxic chemicals; that the timing of exposure to chemicals can be as important as the dose of exposure; expanded understanding of chemical exposures in our bodies through bio-monitoring -- some of which are inside nearly everyone in the population; the impacts some chemicals may have on our hormonal systems with potential implications for rising rates of infertility, learning and developmental problems, cancer, diabetes, obesity and other disorders; the potentially serious effects of exposure to even low doses of some chemicals; and the potential for the effects of chemical exposure to be passed down from one generation to the next.

I am particularly concerned about some communities across this country that are facing a legacy of environmental contamination on a daily basis. I have visited the community of St. Charles, Louisiana, downwind from major refineries and struggling with a long history of serious air quality problems and high rates of illness. In Dickson, Tennessee, a low-income African-American community unknowingly drank water laced with the known carcinogen, trichloroethylene (TCE), for years, even though the contamination was known to Federal agencies. Now people there are suffering from high rates of cancer and other illnesses. One of NRDC's top institutional priorities is to fight environmental injustice, and I feel strongly that it is unfair to allow continued disparities in exposure to toxic pollution that subject many of the poorest and most disenfranchised communities in this country to the greatest health burdens. Meaningful TSCA reform must identify and address these environmental injustices, and must also deal with the legacy pollutants that persist in our environment and pose threats across the generations. The old persistent, bioaccumulative toxicants (PBTs), such as the PCBs, must be cleaned up in communities, and new chemicals that otherwise would become the PBTs of the future should not be allowed on the market because they are simply too dangerous.

This expanded understanding about the potential of toxic chemicals to affect the human body comes as we are also learning, thanks to the science of biomonitoring, that all of us are routinely exposed to hundreds of toxic chemicals, chemicals to which our grandparents were never exposed. This rise in chemical exposures has occurred concurrently with a rise in incidence of certain serious chronic disease and illness, including prostate and breast cancer, asthma, Alzheimer's, and learning and developmental disabilities, including steep rises in ADD/ADHD and autism. Last year, this Committee received testimony summarizing some concerning trends regarding the reproductive health of the U.S.

population. These include a doubling in the percent of women reporting that they had difficulty in conceiving and maintaining a pregnancy; a more than 3-fold increase since the 1980s in the number of babies born prematurely, and a decline in birth weights over the past 25 years.[2] Other disturbing trends include declines in testosterone levels and sperm quality in the United States.[3]

The rise in incidence of these chronic illnesses cannot be solely attributed to genetic factors or improved surveillance and detection. Other factors are also involved, and there is legitimate reason for public concern that ongoing exposure to a mix of chemicals, some of which we already know to be carcinogenic, or neurotoxic, or endocrine disrupting, and others about which we frankly know very little, are playing a part. A growing body of laboratory studies and some epidemiology studies of people demonstrate that chemicals to which we are exposed can cause the very kinds of diseases and disorders that are rising in the human population, often at levels of exposure comparable to those found in people through biomonitoring.

The Committee has received expert testimony on many of these advances in scientific understanding and health trends in hearings over the past year.[4]

As Dr. Federica Perera of Columbia University noted in her testimony before this subcommittee last October, the CDC estimates that 5-17% of children in the United States have been diagnosed with a learning or attention disorder. Dr. Perera's work has focused on the relation between early life exposure to toxic substances and neurodevelopmental disorders. Dr. Perera and her colleagues at the Columbia University Center for Children's Environmental Health have identified widespread exposure to several endocrine-disrupting chemicals, including bisphenol A, phthalates and brominated flame retardtants (PBDEs), which pose serious concern because they can potentially effect hormonal systems and development at very low levels of exposure. In the Center's study of women from the NYC greater metropolitan area who were pregnant on September 11, 2001 and their children, they found that

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[2] Testimony of Tracey J. Woodruff, PhD, MPH before U.S. Senate Committee on Environment and Public Works on "Current Science on Public Exposures to Toxic Chemicals" February 4, 2010.

[3] See Safer Chemicals Healthy Families, *The Health Case for Reforming the Toxic Substances Control Act,* January 2010, http://www.saferchemicals.org/.

[4] Testimony of Frederica Perera, MPH, DrPH, before the Senate Field Hearing on Toxic Chemicals and Children's Health, October 26, 2010; Testimony of Ted Schettler MD, MPH, Hearing on EPA's Efforts to Protect Children's Health March 17, 2010; Testimony of Gina Solomon, MD, MPH, before the Senate EPW Hearing "Protecting Children From Environmental Threats" March 17, 2010; Testimony of Linda Birnbaum, Ph.D, DABT, ATS before the Senate EPW Subcommittee o Superfund, Toxics and Environmental Health "Oversight Hearing on the Federal Toxic Substances Control Act" December 2, 2009.

children exposed to higher levels of PBDEs had significantly impaired psychomotor and mental development as well as lowered IQ for virtually all neurodevelopment assessments conducted between 1-6 years of age.

In three recent reports, the National Academy of Sciences (NAS) has called upon EPA to revise the way it conducts safety assessments on chemicals. Some of the most significant recommendations by the NAS include abandoning the assumption that there are levels below which chemicals are presumed not to have effects other than cancer; recognizing and accounting for the range of potential vulnerabilities amongst the population in estimating the risks posed by chemicals; using scientifically-based default assumptions that will protect health when data gaps exist; and developing the tools to account for the aggregate exposures to a chemical, and the cumulative effects of exposure to multiple chemicals. EPA must incorporate these recommendations into its safety assessments of chemicals, if they are going to be recognized as credible and health-protective, and to provide the confidence in consumer products that the public wants and needs.

The rapidly growing body of science linking exposure to toxic chemicals to a host of chronic illnesses and disabilities, along with the advancement in our analysis of how to better assess the risks posed by exposure to hundreds or thousands of such chemicals in everyday life, comes at the same time as calls for reform are being made by independent science and policy observers. In 2009, EPA's chemicals management program under TSCA was one of only three federal programs added to the GAO's biennial list of "high risk" federal programs, due to its wholesale failure to protect the public from unsafe chemicals.[5] The designation came after years of reports by the GAO outlining the many problems with TSCA. Last year, for the first time in more than 40 years, the President's Cancer Panel addressed the role of environmental contamination in cancer incidence. The report opens with the observation that "...the true burden of environmentally induced cancer has been grossly underestimated." The panel called for a comprehensive agenda to address environmental contaminants and protection of human health. The report specifically identified the Toxic Substances Control Act (TSCA) as "the most egregious example of ineffective regulation of chemical contaminants" and called for the law to be strengthened so that EPA could take action to protect the public from cancer-causing chemicals.

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[5]United States Government Accountability Office (GAO), Report to the Congress, "High-Risk Series: an Update" January 2009.

The statistics on cancer in America are shocking:

- The lifetime chance of a man developing an invasive cancer is about one in two, and approximately one in four men die from cancer. For women, the lifetime chance of developing an invasive cancer is one in three, and one in five will die.
- Cancer is the second most common cause of death in the U.S., exceeded only by heart disease. More than 1.5 million people were diagnosed with new cases of cancer in 2009.
- In 2009, cancer cost the nation $243.4 billion–$99 billion for direct medical costs, $19.6 billion for cost of lost productivity due to illness, and $124.8 billion for cost of lost productivity due to premature death.

But it doesn't take awareness of these national statistics to know that the personal and social costs of cancer are enormous. Millions of Americans are living with cancer, and millions more are affected by the devastating toll a cancer diagnosis takes on an individual and a family. As we continue our national efforts to reduce smoking, and educate the public about the health risks of obesity, including the links to cancer, we must also move quickly to address the threat posed by toxic chemicals.

Let's just stipulate that chemicals have thousands of important uses that are valuable to society, and that our lives have been improved in many ways by the use of chemicals. We can also agree that the production and use of industrial chemicals is so widespread that the chemical industry touches a large part of our economy. In fact, that is part of the reason it is so important that we have a regulatory structure in place to ensure that the chemicals people are exposed to day in and day out – in the home, at school, in the workplace, and the marketplace -- are safe. It is why we need to restructure our regulatory system of toxic chemicals to promote a shift away from the use of those chemicals that may cause cancer, or developmental disabilities, or harm our ability to reproduce, or that persist in the environment and bioaccumulate up the food chain, *and* to promote the innovation necessary to create safer substitutes for those chemicals.

Reforming TSCA is not simple. The truth is a significant mistake was made 35 years ago when all of the chemicals then in commerce were grandfathered under the law, with no requirement of meeting a health standard, or even being subject to further testing. Two generations later, we find ourselves with

hundreds of chemicals in our bodies, *even at birth*, some of which are known to be carcinogens, or neurotoxicants, and rising rates of multiple types of cancer, developmental and learning disabilities, reproductive problems and hormone-related disorders. We now face a tall order: we need to determine which chemicals that are used in commerce are safe (and under what conditions), and we need to break free of the legal restrictions and red tape that have prevented EPA from quickly reducing exposure to those chemicals for which we already have strong evidence of both harm and widespread exposure. States are and will continue to act in the face of inaction at the national level, while public trust in the safety of numerous products will continue to decline. That prospect should be enough to keep everyone at the table until a deal can be reached. I view this hearing as part of the effort to "tackle" TSCA reform, and I want to thank you again for being invited to testify and participate.

Senator LAUTENBERG. Thank you very much, Ms. Beinecke. Forgive the break in the routine, but you were correct, obviously, in an observation that so many of us have experienced directly or indirectly, have experienced the onset of cancer. My father died when he was 43, and he was pure about conditions that surrounded his health and well-being. But he worked in the factory. People who worked there often came down with cancer, as did my father's brother, my uncle and my grandfather.

What I experienced, something with lymphoma last year, and I am told by the doctor the only thing that remains is a change in hairstyle. But other than that, everything else is pretty good.

Thank you very much.

Mr. Dooley, may I invite you to give your testimony.

STATEMENT OF CAL DOOLEY, PRESIDENT AND CEO, AMERICAN CHEMISTRY COUNCIL

Mr. DOOLEY. Thank you, Mr. Chairman and members of the committee. I am Cal Dooley, I am president and CEO of the American Chemistry Council.

First let me State very clearly that the American Chemistry Council supports the modernization of the Toxic Substance Control Act. The member companies of ACC and the chemical industry at large are proud of our commitment to the safe use of the chemicals we manufacture that are in 96 percent of consumer products. We are proud of our leadership in developing the innovations that enhance the quality of lives of citizens around the world, and the role our products play in enabling everyone to live more environmentally sustainable lifestyles. We are proud of the 800,000 high-paying, high-skilled jobs that our industry provides in the United States, and our industry's almost $675 billion contribution to our GDP.

ACC has been joined by a broad coalition of value chain partners, including manufacturers and retailers, that chemical management policy is essential to innovation and growth in every sector in our economy. A modern TSCA must be based on today's technology and should be crafted as new technologies and developments in science emerge. It should incorporate scientific objectivity, prioritize so we identify data and information needs, meet and assess risk based on what chemical is actually used for. We should maintain a foundation of TSCA's review of new chemicals. We should protect intellectual property but provide for greater transparency, so consumers, policymakers and the industry can make sound decisions. We need to remove the motivation for States and cities to pass individual laws that are creating a disjointed national market.

But we must get it right. We must strike the right balance. I don't know how many of you read the *Wall Street Journal* yesterday, but there was an article that kind of summed up this challenge. The title of it was, "U.S. Firms-China Locked in a Major War Over Technology". I also have recently become aware of what has happened in the application for patents for chemicals. The United States historically has been the leader in securing chemical patents. But just in the last couple of years, we have been eclipsed by China. So when you look at the challenge we face here, it is how

can we establish as balanced an approach to the modernization of TSCA that also protects our ability to lead.

The divergence that has happened in our current regulatory environment, if we create a system that adds inappropriate regulatory burdens and creates even greater uncertainty, we are going to see this trend increase and accelerate between our ability to maintain our innovation and competitiveness with China. Modernizing TSCA is the right way, is an opportunity to do that and help the United States maintain its leadership.

So much of the discussion to date has pitted innovation against safety. That is simply not the right way to look at it. We can do both. The principles that ACC put forth are a framework for doing that, and ensuring that the U.S. chemical industry can compete internationally.

At the core of our principles is the need for a risk-based safety standard that assess chemicals based on what they are actually used for. We shouldn't hold a chemical that might be used in a solar cell similar to this that is going to be installed in someone's roof and used in maybe hundreds of other industrial applications to the same standard applied to a chemical that is used in a pharmaceutical, or in a pesticide that is applied to the food that we are going to consume.

We should assess the safety of industrial chemicals based on the exposure resulting from their intended use. This is the kind of rational, reasonable approach that will ensure safety and will also mean innovations developed by U.S. companies will ultimately make it through the regulatory process in a timeframe that global competition requires. Our competitors aren't going to wait for us.

In the next year or so, the world's population will increase to 7 billion people. In 20 or 30 years, we will add another 2 billion people to our planet. We are facing critical challenges to provide the water, food and energy that will be required to meet this growing demand. Chemistry and the chemical industry will be critical to meeting this tidal wave of demand. Chemicals will make water supplies safe for consumption, chemicals will play an instrumental role in increasing agriculture productivity. The chemical industry will continue to be at the forefront of the development of innovations and ensure our houses, offices, factories and cars are more energy-efficient.

The chemical industry will continue to develop the innovations that allow solar panels and other alternative energy technologies to more efficiently capture energy from the sun. The chemical industry will be the single greatest contributor to improving the health and life spans of the world's population. The chemical industry will play a critical role in empowering today's and future generations to live more sustainable lifestyles that will help conserve natural resources and enhance the quality of the global environment.

I am confident that the leaders of ACC and the Members of Congress have a common objective. We want, to the greatest extent possible, ensure that U.S. companies, U.S. scientists and researchers and U.S. workers are developing the innovations, technologies and products that meet and respond to global demand and challenges. We are starting from a strong position. TSCA provides a strong foundation to buildupon. But we need a system that fully

capitalizes on the advancements in science that will allow us to more effectively and efficiently assess and manage the risks of chemicals in commerce.

We are committed to being a constructive force in achieving that goal. Thank you.

[The prepared statement of Mr. Dooley follows:]

Testimony of
The Honorable Cal Dooley
President and CEO
American Chemistry Council
700 Second Street NE
Washington, DC 20002

Before the
Subcommittee on Superfund, Toxics and Environmental Health of the
Senate Committee on Environment and Public Works

"Assessing the Effectiveness of U.S. Chemical Safety Laws"

February 3, 2011

It's Time to Modernize TSCA

The American Chemistry Council and our member companies support modernization of the Toxic Substances Control Act. It is time to update and refresh our 35 year-old chemical management system.

Last week in the State of the Union, President Obama laid out an agenda to ensure that America can "win the future," in his words. We couldn't agree more that we need strong, sound, efficient policies that will not get in the way of the ability of American companies to innovate and create jobs.

This is particularly important for an industry like ours. Chemistry is the source of many of the new technologies that will help create jobs in the future, drive economic growth and achieve the goals articulated by the President including clean energy; improved infrastructure; efficient transportation options; medical advancements that bring down the cost of health care; and even a strong defense.

And we employ nearly 850,000 people directly in high-paying, high-skill jobs. These are the kind of jobs that not only put food on the table, but boost consumer spending, send kids to college, allow families to own homes, and save for retirement.

The business of chemistry is vital not only to achieving national goals, but also to meeting the needs of a growing and changing world. The earth's population is expected to reach approximately 9 billion people in the coming decades. The greatest growth will occur in the developing world, and with it will come the continued explosion of a middle class in those nations. All these people will require food, clean water, energy supplies, and medicines. As standards of living improve, there will be greater demand for automobiles, electronics, appliances and other modern conveniences that Americans now take for granted. It is only through the innovation and products of chemistry that the world will be able to meet those needs in a sustainable way.

The question is not whether the business of chemistry will identify and develop solutions to meet these challenges – have no doubt that we will. The real question is where these innovations will occur – here or in places like China, where patent applications in recent years have surpassed those of the United States.

That is why the issue of TSCA modernization is so critical and the stakes are so high. The continued competitiveness of America's chemical manufacturers will rely in part on our ability to craft a modern regulatory program that

- enables innovation;
- creates greater certainty so businesses have the confidence to expand and hire;
- provides scientifically-sound answers about chemical safety and how to manage risks;
- operates efficiently so new products can be brought to market in a timeframe global commerce demands; and

- inspires confidence among the public that their children, their homes and their environment are being protected.

TSCA Modernization Done Right is Good for Everyone

Simply stated, TSCA modernization done right is good for consumers, good for jobs and good for American businesses.

Before going further, it's important to say that safety is the top priority for ACC and its member companies. If we didn't believe our products were already safe for their intended uses, we wouldn't be making them.

In spite of that fact, there is a fundamental lack of confidence in our nation's chemicals management system. It has led to the frequent spread of misinformation, unnecessary product de-selection by consumers and retailers, litigation, and ill-conceived state and local laws to regulate or ban chemicals. Taken together these factors have created an uncertain business environment for the American chemistry industry and our value chain partners.

In practice, multiple state and local laws regarding chemicals create confusion among manufacturers, retailers and consumers, hamper the development of new products, close off markets, and ultimately prevent business growth and new hiring, all without significantly improving public safety.

America's chemical manufacturers are truly national and global in nature. The engineered materials we produce can change hands numerous times and travel from state to state, or country to country, as they are incorporated into other materials and end products. There is little question that the chemistry industry engages in the kind of interstate commerce that our founders gave Congress, rather than the states, the authority to regulate.

The business of chemistry is also highly complex. It is a 21st century industry founded on science, engineering and continuous innovation; it's what brings us our medicines, cell phones, computers, hybrid automobiles, and all the other essential products of today's world. This is not a job for state or local governments that understandably lack the scientific expertise or resources to make well-informed regulatory decisions.

Only by creating a scientifically-disciplined, efficient and focused federal chemicals management system can we ensure a uniform national market, provide American businesses the certainty they need to justify new investment and hiring here rather than nations like China and India, and give state governments and consumers confidence.

ACC has been joined by a broad coalition of our value chain partners including manufacturers and retailers to call for good TSCA modernization. The breadth of the coalition reflects the fact that sound national chemicals management policy is essential to innovation and growth in nearly every sector in our economy. And conversely, a misguided policy would threaten far more than just chemical manufacturers.

What a Modernized TSCA Should Look Like

Around eighteen months ago, ACC released ten principles for modernization which I have submitted for the record.

These principles provide the right foundation upon which Congress can define a modern chemicals management program that leverages what we already know, focuses time and resources on the highest priority chemicals and deploys a cost-effective program that will reach conclusions, manage risks, and get information to the public and industry in a timely way.

A modern TSCA must be based on today's technology and should be crafted to evolve as new technologies and developments in science emerge. It should incorporate scientific objectivity. It must prioritize so we identify data and information needs, meet them and assess risks based on what a chemical is actually used for. It must operate efficiently so that new chemical products can be reviewed and brought to the market in a time frame that our global customers demand. It must protect intellectual property so we don't enable piracy, but provide for greater transparency so consumers, policymakers and industry can make sound decisions.

We must also learn from what's working and not working in Canada and the EU, which have both implemented new chemicals management regimes in recent years. The U.S. always has been and must remain the global leader by updating TSCA to be the first-in-class system that other countries will want to emulate. As part of this, we must acknowledge there are important elements of the current TSCA program that have stood the test of time and work well such as the process to evaluate and approve new chemicals.

We believe implementing these kinds of enhancements that balance regulation with job creation and innovation is exactly the kind of regulatory reform that is being pursued by the President and this Congress.

Conclusion

Congress has the opportunity to define a modernized TSCA program that if done right, will enable a future where consumers can feel confident; where our chemicals management program is more efficient and focused; where the government spends less over time, but gets more value; where American businesses know what's ahead and can plan, invest and hire; and where states and cities are no longer motivated to act on their own leading to a disjointed and inefficient regulatory patchwork that disrupts national commerce and hampers our ability to compete in the global marketplace.

We hope to work together with stakeholders and Congress to update TSCA to be balanced, protect jobs, foster innovation and reassert our nation's leadership not only in developing ideas, but also in producing the goods that come from them.

Thank you again for having me here today, and I look forward to taking your questions.

American® Chemistry Council

10 Principles for Modernizing TSCA

The American Chemistry Council and its members support Congress' effort to modernize our nation's chemical management system. Such a system should place protecting the public health as its highest priority, and should include strict government oversight. It should also preserve America's role as the world's leading innovator and employer in the creation of safe and environmentally sound technologies and products of the business of chemistry.

The current chemical management law, the Toxic Substances Control Act (TSCA), is more than 30 years old. It should be modernized to keep pace with advances in science and technology. Moreover, the law must provide the Environmental Protection Agency with the resources and the authority to do its job effectively.

We have previously offered general concepts on which to base a modern chemical management system. This document expands upon those concepts and begins to provide more detail, which we hope will be useful to policy makers. We will continue to refine the details of our principles for modernizing TSCA and are committed to working with all stakeholders toward enactment of effective legislation.

1. Chemicals should be safe for their intended use.
    - Ensuring chemical safety is a shared responsibility of industry and EPA.
    - Industry should have the responsibility for providing sufficient information for EPA to make timely decisions about safety.
    - EPA should have the responsibility for making safe use determinations for high priority chemicals, focusing on their most significant uses and exposures.
    - Safe use determinations should integrate hazard, use, and exposure information, and incorporate appropriate safety factors.
    - Consideration of the benefits of chemicals being evaluated, the cost of methods to control their risks, and the benefits and costs of alternatives should be part of EPA's risk management decision-making, but should not be part of its safe use determinations.
    - Other agencies, such as FDA and CPSC, should continue to make safety decisions for products within their own jurisdictions.
2. EPA should systematically prioritize chemicals for purposes of safe use determinations.
    - Government and industry resources should be focused on chemicals of highest concern.
    - The priorities should reflect considerations such as the volume of a chemical in commerce; its uses, including whether it is formulated in products for children; its detection in biomonitoring

programs; its persistent or bioaccumulative properties; and the adequacy of available information.

3. EPA should act expeditiously and efficiently in making safe use determinations.

   - Since a chemical may have a variety of uses, resulting in different exposure potentials, EPA should consider the various uses and focus on those resulting in the most significant exposures.

   - EPA should complete safe use determinations within set timeframes.

4. Companies that manufacture, import, process, distribute, or use chemicals should be required to provide EPA with relevant information to the extent necessary for EPA to make safe use determinations.

   - Companies throughout the chain of commerce should be responsible for providing necessary hazard, use, and exposure information.

   - EPA should be authorized to require companies, as appropriate, to generate relevant new data and information to the extent reasonably necessary to make safe use determinations without having to prove risk as a prerequisite or engaging in protracted rulemaking.

   - Testing of chemicals should progress to more complex and expensive tests through a tiered approach as needed to identify hazards and exposures of specific concern.

   - To minimize animal testing, existing data should be considered prior to new testing, and validated alternatives to animal testing should be used wherever feasible.

   - Existing data and information should be leveraged in EPA's safe use determinations, including data and information from other mandatory and voluntary programs such as REACH and the U.S. High Production Volume challenge.

5. Potential risks faced by children should be an important factor in safe use determinations.

   - Safe use determinations should consider the effects of a chemical on children and their exposure to the chemical.

   - Safe use determinations should consider whether an extra margin of safety is needed to protect children.

6. EPA should be empowered to impose a range of controls to ensure that chemicals are safe for their intended use.

   - The controls could range from actions such as labeling, handling instructions, exposure limits and engineering controls to use restrictions and product bans.

   - The controls should be appropriate for managing the risk, taking into account alternatives, benefits, costs, and uncertainty.

7. Companies and EPA should work together to enhance public access to chemical health and safety information.

- EPA should make chemical hazard, use, and exposure information available to the public in electronic databases.

- Other governments should have access to confidential information submitted under TSCA, subject to appropriate and reliable protections.

- Companies claiming confidentiality in information submittals should have to justify those claims on a periodic basis.

- Reasonable protections for confidential as well as proprietary information should be provided.

8. EPA should rely on scientifically valid data and information, regardless of its source, including data and information reflecting modern advances in science and technology.

   - EPA should establish transparent and scientifically sound criteria for evaluating all of the information on which it makes decisions to ensure that it is valid, using a framework that addresses the strengths and limitations of the study design, the reliability of the test methods, and the quality of the data.

   - EPA should encourage use of good laboratory practices, peer review, standardized protocols, and other methods to ensure scientific quality.

9. EPA should have the staff, resources, and regulatory tools it needs to ensure the safety of chemicals.

   - EPA's budget for TSCA activities should be commensurate with its chemical management responsibilities.

10. A modernized TSCA should encourage technological innovation and a globally competitive industry in the United States.

    - A new chemical management system should preserve and enhance the jobs and innovative products and technologies contributed by the business of American chemistry.

    - Implementation of TSCA should encourage product and technology innovation by providing industry certainty about the use of chemicals.

American Chemistry Council (ACC) Responses to Follow-up Questions from Feb. 3, 2011 EPW Subcommittee Hearing on TSCA
August 19, 2011

Questions from Senator James M. Inhofe for Cal Dooley, ACC:

1. **Q: As we continue to discuss TSCA reform legislation, what are some specific areas of the current law that you feel are working well and/or in need of reform?**

   A: The new chemicals program of TSCA (Section 5) has balanced both the need for EPA to assure new chemicals do not pose risks, with the need to assure that our regulation of new chemicals does not stifle innovation. EPA has completed over 36,000 risk assessments for new chemical submissions prior to their entrance into commerce with 23,000 new chemicals added to the TSCA Inventory. In addition, almost 3,000 substances have been regulated by a TSCA Consent Order or Significant New Use Rule (SNUR). Further evidence that the new chemicals program works is that the US is a global leader in patent applications on chemicals.

   Two areas of TSCA top the list of those aspects of TSCA in need of the most reform: prioritization and confidential business information (CBI). EPA currently has no systematic, science based process to prioritize existing chemicals for further reviews. A modernized TSCA must include a prioritization approach that is based on the hazards, uses, and exposures of chemicals so that EPA can focus its resources on those chemicals that are of highest priority for safety assessment.

   It is critical that all information, other than health and safety data, that is exempt from mandatory disclosure under exemption (b)(4) of the Freedom of Information Act (FOIA) be protected from discretionary disclosure provided that the submitter of the information can substantiate its eligibility for protection on a case-by-case basis under the criteria in 40 C.F. R. §2.208. This includes chemical identity, provided it can be substantiated, but a requirement to disclose structurally-descriptive generic names for chemical identities that qualify for protection from disclosure so that the public can access relevant toxicological literature is appropriate.

   A modernized TSCA should require disclosure of confidential chemical identity to medical professionals who request the information in emergency situations, subject to a signed confidentiality agreement. Additionally, a modernized TSCA should permit EPA to share CBI with other governments, contingent upon the recipient's written adoption of enforceable CBI standards and procedures that are at least as protective of CBI as those EPA has adopted and implemented. EPA should also be permitted to share CBI with appropriate foreign governments, in consultation with the Department of State, where there is a bilateral agreement with reciprocity of protection accorded to the CBI to prevent unauthorized disclosure. Currently, TSCA does not permit the Agency to share or receive confidential business information from foreign governments even when that information might be relevant to an EPA review.

2. **Q: Could you describe how chemistry and chemicals affect our nation's economy, and further, what could happen to the economy if we fail to modernize TSCA the right way? It would be helpful if you could talk specifically about impacts on jobs – both on those employed now and the ability to hire people in the future – as well as our ability to compete with China and other nations in the global marketplace.**

   A: The products of chemistry are critical to the US economy. Over 96% of manufactured goods are directly touched by the business of chemistry. In other words, nearly everything produced by the manufacturing sector contains or is processed with chemical products. The US chemical industry is a $720 billion enterprise and a leading exporter. The US exported $171 billion in chemical products in 2010 and accounted for more than 10 cents of every dollar in US merchandise exports.

   The industry directly employs nearly 800,000 workers who earn on average $82,000 per year. Including suppliers and expenditure-induced jobs, the industry generates more than 4.3 million jobs in the US economy. The business of chemistry is knowledge intensive. More than 45% of the industry workforce is in "knowledge based" professions, such as management, research, IT, marketing, etc. More than 10% of the industry workforce is in science and engineering professions. One in five US patents is chemistry or chemistry-related.

   Modernizing TSCA the "right way" will lead to more productive use of industry resources through the use of new tools and streamlined procedures. In addition, greater regulatory certainty will encourage investment in both physical and human capital. Both developments will allow the industry to allocate more resources to innovation which is shown to be a growth driver not only for the chemical industry, but the economy as a whole. A recent ACC analysis found that advances in knowledge account for a third of economic growth. Of that, advances in chemistry knowledge account for 20% of the knowledge growth component. A modernization of TSCA that allows greater development of chemistry knowledge will grow the industry and the economy. Innovation and differentiation will be key factors in American industry competitiveness in world markets.

3. **Q: Are there any voluntary initiatives that industry has taken to supply EPA with additional information or ensure the safety of products not required under TSCA? If so, could you describe those for us? How can we, as policy makers, ensure that any modernization we do with regards to TSCA doesn't hurt any voluntary efforts and continues to build on this cooperative framework?**

   A: Through ACC's Responsible Care® program, our industry has a proven product stewardship responsibility for its products. To become and remain an ACC member, all companies MUST complete a third-party certified management system audit on environment, health, safety, and security processes. Additionally, above and beyond Responsible Care, our industry participated in EPA's High Production Volume Challenge (HPV) program. Under the HPV Challenge Program, ACC members made commitments to provide hazard screening information on chemicals identified as HPV (manufacture or import in excess of 1 million pounds per year) based on EPA's 1990 Inventory Update Rule (IUR). HPV chemicals

represent 95% of chemicals in US commerce by volume. Industry met this Challenge with an extraordinary response, providing robust summaries on approximately 1,500 chemicals to EPA and committing to another 800+ chemicals through the International Council of Chemicals Associations (ICCA) HPV program. EPA maintains the HPV Information System (HPVIS), a web-based source for HPV information, at http://www.epa.gov/hpv/hpvis/index.html. The HPV program has been a cornerstone of industry's commitment to product stewardship and performance since its inception in 1998. Industry's unprecedented proactive approach to chemical evaluation through HPV resulted in dramatic cost savings and illustrated that voluntary industry approaches can work.

As policy makers look to modernize TSCA, the best practices, lessons, data, and information from such programs are a valuable resource. For example, the concepts of "tiering" chemical evaluation frameworks and the importance of "data needs" vs. "data gaps" have evolved through ACC's participation in Responsible Care's product stewardship program, the HPV Challenge program, and EPA's Voluntary Children's Chemical Evaluation Program. In our view, voluntary programs can serve as a very useful complement to regulatory mandates; a modernized TSCA should give EPA the flexibility to adopt such programs when they make sense.

4. **Q: During your testimony you mentioned that REACH is still in the early stages of implementation and we do not yet know all the potential pitfalls of such a chemical policy. Has the European Chemicals industry suffered any negative effects as a result of REACH thus far? If so could you share some examples? Also, is there any reasonably expected ill effects expected in the future from REACH that you could describe for us?**

A: Unfortunately, it is still too early to determine with specificity the impact of REACH (Registration, Evaluation, and Authorization of Chemicals) on the European Chemicals Agency (ECHA) or the broader European chemicals industry. REACH has been in force for five years, and there have certainly been some significant milestones achieved in its implementation.

For example, manufacturers of high-volume chemical substances and certain other high-hazard chemicals completed the first registration process in November, 2010. The public REACH information submitted to the Agency is now becoming available on the Internet, and some time and effort will be required to assess what information is available and how useful it might be. In June, 2011, the European Commission launched a survey to assess the impact of the REACH registration process on EU businesses, but the results of that survey are not yet available.

There is no question that significant transactional costs and burden were incurred in the development of REACH dossiers. The REACH process requires the use of a Substance Information Exchange Forum (SIEF), a mechanism by which companies with interests in a particular substance might identify themselves and share data relevant to a registration dossier. Some SIEFs contained thousands of companies, and there have been reports that data sharing and compensation agreements have been particularly difficult in some instances. ACC member companies also report having made substantial investments in new information

Senator LAUTENBERG. Thank you very much, Mr. Dooley.

Now we have Dr. Lynn Goldman, who is dean of the George Washington School of Public Health. Dr. Goldman was also the head of EPA's office that implements TSCA and other environmental health laws during the Clinton administration. We look forward to your testimony.

STATEMENT OF LYNN R. GOLDMAN, M.D., M.P.H., DEAN, PROFESSOR, ENVIRONMENTAL AND OCCUPATIONAL HEALTH, THE GEORGE WASHINGTON UNIVERSITY SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES

Dr. GOLDMAN. Mr. Chairman and members of the Committee on Environment and Public Works, I thank you for this opportunity to testify about the Toxic Substances Control Act.

As you know, I have written testimony that I would like to submit for the record. I think it is important that as everybody said here today, that chemicals play a vital in the United States and world economy, and to human welfare, and at the same time, that regulation is required to make sure that they are used safely.

It is 35 years since the enactment of TSCA, and much has changed since that time, including much that has changed in the science and our understanding about the toxicology of chemicals. A fundamental overhaul of TSCA is well overdue, and I have described some points about that in detail in my written statement.

To summarize, EPA needs to be able to assess and manage existing chemicals, but yet, their ability to do that has been hindered by an out of date statute that fails to provide the impetus for the generation of information about chemical hazards and exposures, and does not provide EPA with adequate tools to manage the risks.

Also, TSCA does not give explicit recognition of unique exposures and susceptibilities of children and other vulnerable populations and of course, as a pediatrician, I have been particularly concerned about that.

The current statute actually penalizes industry for studying chemical hazards, because it creates an undue advantage for a chemical about which we know nothing. If you learn something about the hazards of a chemical, there is a blemish on the record for that chemical. When you know nothing about the hazard, as has been already said, it is presumed to be safe.

Now that the European Union has established its REACH legislation, our companies are generating massive quantities of information about chemicals that needs to be made available to the EPA for its assessment. As a former official in State government, I used to work for the State of California, I think that the confidential business information provisions that do not even give State authorities the ability to find out about names of chemicals and locations where they are manufactured certainly needs to be overhauled.

Other positive developments have occurred since 1976. We now have a science of green chemistry that didn't even exist in 1976, opening the possibilities for pollution prevention approaches that could be wrapped into TSCA. We could actually reward companies that do research and development and innovate and bring forth newer and safer alternatives. Also, we have newer approaches to

toxicology, using computational methods that can predict risks, and with less costly procedures and procedures that were not even thought about in 1976.

Likewise, in 1976, the United States was clearly in the lead. But now we have seen newer approaches in Canada and Europe and elsewhere that we need to look at very carefully.

So last year, I got together with three other individuals who have been responsible for EPA's chemicals programs in the past, and we wrote a paper for the ABA. I have put that into the record. Two of them served under Republican administrations, one a career official who has been in many administrations, another who was in the Administration for President George W. Bush. It is interesting that we had fundamental agreement about a number of points.

One is that we should take a very practical approach to the amendment of TSCA. We can look at statutes such as the Food Quality Protection Act, especially the safety standard in that statute. But we need to understand that for chemicals, we need to have flexibility and a prioritized system, so that we can reasonably address the tens of thousands of industrial chemicals.

Second, EPA's TSCA program frankly has limited organizational capacity and limited resources, and that needs to be understood and addressed. Third, all chemicals are not created equally. We would hate to see a numbers game where all EPA has to do is run through a certain number every year, because of all the chemicals on the market, it is our belief that it is a small proportion, 5 or 10 percent of about 6,200 that are actually produced in significant quantities that are of concern. EPA should be directed to put the first attention to those chemicals, rather than simply running through and getting numbers. Factors like exposures, use patterns, potential to cause cancer and other adverse effects, those are the kinds of factors that EPA should use to prioritize them.

Fourth, certainly there is much in the current system that needs to be sustained and strengthened and not simply replaced with a new statute. Finally, the international management of chemicals needs to be understood, needs to be incorporated in any approach, that it is not only the fact that there is a REACH system, but also the globally harmonized system that has been developed, the global strategic approach to international chemicals management and conventions, such as the Stockholm Convention on Persistent Organic Pollutants, needs to be incorporated into a TSCA reform process.

Finally, we would caution against efforts to prescribe how the regulatory science is conducted under TSCA. No matter how well motivated, science has a way of changing very quickly. TSCA has a way of changing very slowly. So we urge that Congress be very cautions about making any prescriptions to EPA about how to do the science, but rather to encourage EPA to keep pace with the sciences it develops.

I think this is a pivotal time. When I look around this table, I am amazed to see the consensus among all of these parties, that this is a statute that needs to be reformed. I don't think that we have seen this before. So at this juncture, I think there is an opportunity for Congress to act. Not only the EPA, but also these stakeholder group who are at the table have brought forth principles for

reform. All the principals don't say the same thing, but I think Congress could bring the parties together to craft a reasonable science-based and health protective overhaul of TSCA.

Thank you very much.

[The prepared statement of Dr. Goldman follows:]

Testimony
Toxic Substances Control Act

Senate Environment and Public Works Committee
Lynn R. Goldman, M.D., M.P.H.

Dean
Professor, Environmental and Occupational Health
The George Washington University, School of Public Health and Health Services
February 3, 2011

Mr. Chairman and members of the Committee on Environment and Public Works, it is my honor to testify today about the Toxic Substances Control Act.

I am Dean of the School of Public Health and Health Services at The George Washington University School of Public Health and Health Services. I am a pediatrician and an epidemiologist, and serve on the Board for the Children's Environmental Health Network and as a member of the Board of Trustees of the Environmental Defense Fund. From 1993-98, I served as Assistant Administrator for Prevention, Pesticides and Toxic Substances at the US Environmental Protection Agency (EPA). While serving in that position I was responsible for the implementation of the Toxic Substances Control Act. Prior to joining the EPA I worked for eight years in public health with the California Department of Health Services. However, my testimony represents my own views and not the views of these other organizations.

When TSCA was passed in 1976, there were great expectations that it would improve our understanding of chemical risks and address these risks in a comprehensive multi-media framework. But, for a variety of reasons, TSCA has not been able to fully live up to these expectations. The people in the Toxics program at the EPA do an excellent job with the tools that they have but they have neither the legislative tools nor the resources that are needed. There are several symptoms that all is not well with TSCA. First is the rising tide of chemicals being regulated on a state-by-state basis. While I support the right of states to take action to protect their citizenry only federal actions protect all US citizens. Second is the enormous gap that is forming between TSCA and the new chemicals legislation (REACH) in the European Union. And third is the dwindling away of personnel and resources in the EPA devoted to core TSCA efforts.

Today, I will focus on a discussion of a number of areas of concern – and opportunity for change. These include: risk evaluation, protection of vulnerable populations, risk management, precaution, new chemicals, right to know, pollution prevention, international management of chemicals and priority-setting.

Risk Evaluation:

To evaluate risk requires the availability of data on hazards and exposures. The Chemical Testing Program was established to carry out the policy expressed in TSCA that adequate data should be developed with respect to the health and environmental effects of chemical substances and that the development of these data should be the responsibility of chemical manufacturers and processors. Unfortunately the analytic burden required of EPA to write TSCA 4 Test Rules and to defend them from litigation has resulted in a situation such that, repeatedly, over the past two decades, the Government Accountability Office (GA0), the Congress, and others have noted a lack of productivity and the absence of a clear agenda for testing. EPA has tried to overcome this problem in a number of ways, including: use of Enforceable Consent Agreements rather than test rules; development of a Master Testing List and voluntary approaches for screening high volume chemicals in cooperation with the chemicals industry and the OECD (Organization for Economic Cooperation and Development). These voluntary

programs are good programs but it is not at all clear how and when EPA will move from screening to more extensive testing of chemicals for adverse endpoints.

Another important information gathering provision is TSCA Section 8(e), a critically important information-gathering tool that serves as an "early warning" mechanism for keeping the Agency apprised of significant new chemical hazards and exposures, and for satisfying the public's right to know about these hazards. EPA's longstanding policy has been, appropriately, that if certain serious health effects are discovered, that information should be considered for immediate reporting to EPA without further evaluation. Over and over again, across the decades, it comes to pass that companies may misinterpret TSCA Section 8(e) and EPA's corresponding policy. EPA has tried to remedy this situation in several ways including by providing guidance documents and via the voluntary Compliance Audit Program (CAP) which, in 1992, allowed participating companies to submit delinquent Section 8(e) information and pay stipulated penalties up to a $1 million ceiling. Yet, this problem has recurred again and again. Some recent examples of significant information being withheld from EPA include: chromium, diacetyl and PFOA.

EPA collects little to no information about chemical exposures yet such information is essential to the evaluation of risk. TSCA needs to be reformed to give EPA clear expectation for testing of risks of existing chemicals. TSCA also needs to provide for exposure monitoring, by EPA or in collaboration with others such as the CDC. The structure of TSCA should reward companies for the generation of information about chemicals and exposures, through more rapid approvals and/or avoidance of penalties.

Protection of Vulnerable Populations

TSCA does not require the protection of sensitive populations, including children. Several other statutes, the Clean Air Act, the Safe Drinking Water Act and the Food Quality Protection Act all contain provisions making it clear that such populations should be protected. Children are often more highly exposed to chemicals in the environment, via diet, inhalation, crawling on the floor, mouthing hands and objects in the environment, and route such as transfer from mother to baby in utero or in breast milk. Children are often more susceptible. "Windows of exposure" during development cause susceptibly to irreversible effects like birth defects, neurobehavioral outcomes, and other developmental alterations, and cancer. Parents are not aware that the products in their homes are made with chemicals, many of which have not been assessed at all for risks to children (or even adults). Because the fetus and child are often more exposed and can be more susceptible to adverse effects of chemicals during critical life stages, this is a particularly important vulnerable group. Other groups include people who have genetic differences in response or metabolism of chemicals; the elderly, and people with preexisting conditions. TSCA should explicitly require the protection of vulnerable populations. Exposure and response patterns of vulnerable populations should be included in risk analyses for chemicals and additional uncertainty factors employed where such information is both missing and relevant.

Risk Management

In terms of managing the risks of toxic chemicals, the EPA never has recovered from the Fifth Circuit Court of Appeals decision to remand the 1989 Asbestos Ban and Phaseout Rule to EPA. In this case, the court's decision imposed a burden of proof on EPA that significantly increased the level of analysis on potential substitutes and on identifying the least burdensome approach for any future Section 6 action. Second, the court's interpretation of least burdensome alternative under Section 6 appears to define end-of-pipe solutions, where toxic substances are controlled after they are distributed into the environment, as less burdensome than pollution prevention solutions, where toxic substances are reduced or eliminated at their source. End-of-pipe solutions are in conflict with the pollution prevention approach and are more costly over time. EPA needs for Congress to restore its ability to take regulatory action to manage risks of chemicals. Strengthening EPA's ability to manage chemicals risks is this is the single most effective way that Congress could turn the tide on state-by-state regulatory actions on chemicals.

Precaution

Decisions about chemical risks should be made based on a stronger, more health based safety standard or goal. The current safety standard is to avoid "unreasonable risk to health or the environment", which means that decisions are based on risk benefit balancing. The standard for pesticides in food is one of a "reasonable certainty of no harm". This is a public health standard. Such a standard is needed for chemicals to which we are exposed in our daily lives, just as it is needed to protect us from residues of pesticides in food. Additionally, existing chemicals on the market should be reviewed to assure that they are safe. Certain categories of chemicals, such as persistent chemicals should be given highest priority (as has been done by Canada). Such a precautionary approach would tend to shift the "burden of proof" onto manufacturers, to prove that chemicals are safe rather than on EPA to prove that they are unsafe. Such an approach is in contrast t the "least burdensome" provision of current law, which made the banning of asbestos impossible.

New Chemicals

Section 5 of TSCA requires that anyone who intends to manufacture or import a new chemical substance in the United States notify EPA 90 days before commencing that activity. The EPA new chemicals program has over the years reviewed thousands of new chemical substances. In many cases EPA has made decisions to prevent risk before a harmful substance enters commerce. The U.S.'s new chemicals program is unique in that it requires review of chemicals prior to manufacture rather than prior to marketing as in most other countries with such systems. I think that there is general agreement among the chemicals regulators worldwide that what would make more sense is a system that gives different types of approvals for R&D and for marketing chemicals. This would help the EPA focus more efficiently on the chemicals which are actually destined for the market. In the case of TSCA, the thousands of chemicals that are submitted and the 90-day review period are challenging. On top of that, the new chemicals program in the United

States does not require any testing prior to PMN submission and therefore over half of all PMNs are submitted without any test data. Ever resourceful, the Agency has developed tools to use Structure Activity Relationships (SAR) to predict and assess the fate and effects of new chemicals. Other systems, most notably the "pre-REACH" Pre-marketing Notification scheme used in the European Union (EU), require a "base set" of testing on new chemicals. In the 1990s the US and EU evaluated the utility of SAR and found that it worked for some endpoints but not others, particularly a number of chronic health effects. Today the EPA and others have been working on the development of new tools to predict toxicity using computational modeling. These new approaches will allow the EPA to even more accurately predict the hazards of new chemicals but only if they are able to request the information that is needed to conduct the modeling.

When EPA determines that there is a risk associated with a PMN it has tools that can be used to manage those risks. TSCA Section 5 gives EPA the ability to require additional tests or other measures such as disposal controls and worker protection. Over the years, the new chemicals program has made wonderful efforts to inform the chemical industry about the criteria used to assess chemicals. These efforts have encouraged development of safer chemicals, and I believe have caused the industry to screen out "bad actors" before presenting them to the EPA in the first instance.

TSCA's new chemical provisions would be improved if EPAs effort were focused premarket rather than premanufacture approvals and would benefit greatly from the addition of risk related data to the agency's determinations.

Right to Know

Empowering the public with information is a powerful tool for environmental progress. The creation of the Toxics Release Inventory (TRI), established in Section 313 of the Emergency Planning and Community Right-to-Know (EPCRA), led the way to a new era of public disclosure and a more constructive dialogue between citizens and industry on emissions reduction and pollution prevention. For a toxic chemicals program, it is almost inevitable that the "right to know" ethic will expand to other chemical information. The public release of environmental data gives everyone the ability to participate in the broader national effort to set a toxics agenda and address chemical issues based on the extent of risk posed. The states, local governments, industry, labor unions, public interest groups and grass-roots community groups are increasingly finding ways to work together on environmental improvements. All problems of chemical management cannot be solved through direct EPA action. As one example of this, the EPA has unsuccessfully attempted to foster and enhance the participation of individual states in chemical management by providing them with TSCA derived chemical data. As a former state regulator, I know the value of site specific information in risk assessment and priority setting. Yet, the language of the law has been interpreted to say that such information cannot be shared with state officials if it has been declared as "confidential business information". In relation to this problem, there is a large amount of information reported to the EPA under TSCA information claimed as confidential business information; studies have found that much of which does not deserve such protection.

EPA has attempted to reform the CBI process but such efforts have foundered on resource limitations and the language of the law, which gives manufacturers too much leeway. Some examples from a survey of the data conducted by EPA in 1998:

- In 1998, more than 65 % of the information filings directed to the Agency through TSCA were claimed as confidential.
- Submissions under the former Inventory Update Rule show that about 20 % of facility identities were claimed as confidential.
- In 1998, 40 % of Section 8(e) substantial risk notices had chemical identity claimed as confidential.

There is a need to reform the CBI provisions in TSCA. Also Congress needs to rethink the role of the states, which has expanded greatly since 1976, and identify ways to provide them not only with more information but also with more opportunities to participate in chemicals management efforts

Pollution Prevention

Preventing pollution offers significant opportunities for protecting the environment and public health in a cost effective manner. The adoption of a pollution prevention ethic is a logical development in a toxic chemicals program, given the focus on improving environmental protection through changes in the manufacture, processing and use of chemicals in our society. Fundamentally, we need to encourage use of safer chemicals and processes in our industrial sector. In order to achieve this TSCA would need to be altered in a number of fundamental ways. First, EPA needs stronger coordination among its "media" offices when it comes to chemicals to prevent the movement of harmful substances from air to water to waste. Second, TSCA does not reward the development of newer safer alternatives. Newer chemicals are reviewed more carefully than existing ones and the lack of regulation of hazardous existing chemicals does not create an incentive to remove them from the market. Congress needs to examine ways to create incentives for greener chemicals and chemical use patterns. TSCA should support and reward companies for research and development and for creating safer substitutes through tools such as exemptions and more rapid approvals for market. TSCA should be a tool to break down the "silos" at EPA to assure that chemicals are managed properly from cradle to grave and not inappropriately shifted from one medium to another (for example, from water to air).

International Management of Chemicals

Increasingly it is recognized that a number of very persistent and/or very hazardous chemicals need to be managed globally. In 1992 the Rio Conference adopted Agenda 21, which contained a number of goals for international management of toxic substances. Since that time we have seen the development of many new institutions including: the Intergovernmental Forum on Chemical Safety, a global treaty on prior informed consent for the import of highly toxic chemicals (the Rotterdam convention or PIC) and the global treaty on Persistent Organic Pollutants (POPs). Yet the US has been

slow to join these issues and in fact has not ratified the POPs and PIC conventions. Ratification is needed so that the US can fully participate in these important efforts to protect the health of the global community. Only a very limited TSCA change is made to allow ratification.

Priority Setting

Because there are so many chemicals on the market that have yet to be evaluated, what is needed is for Congress to set a clear agenda for priorities in evaluation and management of chemicals, as well as clear expectations for action. Some factors that might be considered include:

- Children's exposure pathways and uses that are likely to expose children
- Biomonitoring and environmental data; which chemicals are in peoples bodies
- Cancer, developmental, reproductive and ecological effects and chemicals classes associated with such effects
- Higher production volumes
- Bioaccumulative or environmental persistence properties
- Use patterns; chemicals uses more likely to result in exposures to humans and the environment

Along these lines, there are numerous chemicals that we already know have potential risks. TSCA needs to provide the EPA with the tools to address the risks as they are identified. It would be a mistake to hamstring the agency with requirements to do comprehensive assessments and reassessments of all chemicals before any action is taken.

Practical Advice

Last year I, in collaboration with three other former EPA officials who have served under both democrats and republicans, wrote a paper for the American Bar Association that I have submitted for the record ("Practical Advice for TSCA Reform: An Insider Perspective"). The paper provides "practical advice" for TSCA reform, is included as an appendix to my testimony.

1. There is much to be recommended in the approach in the Food Quality Protection Act (FQPA), especially the safety standard, which is clear and public health-based. However, for regulating the thousands of toxic chemicals on the market EPA will need a more flexible and prioritized system.
2. Second EPA's Toxics program has limited organizational capacity. Any new legislation will need to address this problem. It will be important to have a reasonable phase-in period, provision for fee-supports and clear and reasonable schedules.
3. Third, all chemicals are not created equally. Congress needs to assure that the EPA first focuses on the several hundred chemicals that are in most need of control. We guesstimate this to be about 5-10% of 6,200 non-polymeric chemicals with significant (>2,500 lbs/yr) annual production.
4. Fourth, there are areas within the current chemical regulatory system that need to be continued. The chemical inventory, the new chemicals review process, the use

of the Significant New Use Rule (SNUR), and EPA's current efforts to focus on the riskiest chemicals are all examples of efforts that have been successful and should be sustained and enhanced.

5. Fifth, chemicals are increasingly managed internationally. The data that are being produced by industry under the EU REACH program should be made available to the EPA and will be a valuable resource for a reformed TSCA. TSCA needs provisions that allow the US to fully participate in international chemical management schemes, including the Stockholm and Rotterdam conventions (mentioned above), as well as other efforts like the Globally Harmonized System for classification and labeling of chemicals and the Strategic Approach to International Chemicals Management. New TSCA amendments should affirmatively recognize and embrace these growing global realities.
6. Finally, we caution against efforts to prescribe how the regulatory science is conducted or evaluated under TSCA. No matter how well driven by current scientific approaches, any specific approaches are likely to soon be outmoded. Rather, EPA needs to evolve its approaches over time, in recognition of the inevitable changing science behind chemical evaluation and assessment as well as the regulatory options that might be available in the future.

Conclusion

In summary, overhaul of TSCA is long overdue. EPA needs clear requirements and regulatory authority that requires placing a high priority on protecting health (especially for vulnerable populations) and the environment. .Minus congressional action on TSCA we will continue to see the erosion of federal management of chemicals on many levels. We will see more states taking action to manage chemicals, thereby creating confusion in the markets and unequal levels of protection state by state. We also will continue to see the dwindling down of activities on the federal level with a commensurate increase in the risk that "bad actors" will get through the net. And we will increasingly see the European Union and others move into the lead in this area, thus putting us at a competitive disadvantage. This is a complicated area but at the end of the day there is one simple principle that should be kept foremost, which is assuring the American public that the products on the market, the air they breathe, the food and the water, are safe. Fortunately, at this time there is a major opportunity for reform. Not only EPA but also a number of stakeholder groups, including industry, have put forward principles for reform. The need for change is clear. It now is time to bring the parties together to craft a reasonable, science-based and health protective overhaul of TSCA.

The American Bar Association
Section of Environment, Energy, and Resources
Special Committee on TSCA Reform

Practical Advice for TSCA Reform: An Insider Perspective

By

James V. Aidala, Jr., Charles M. Auer,
Lynn R. Goldman, M.D., and James B. Gulliford

An Introduction and Overview As to Why SEER Formed a Special Committee on TSCA Reform and What the White Paper Contributes to the TSCA Debate

June 30, 2010

The Toxic Substances Control Act (TSCA) was enacted in 1976, and remains largely unchanged with regard to the management of industrial chemicals. Whether this fact evidences a durable federal law that has withstood the test of time or proof that our domestic chemical management law is out of date and in need of modernization has been the subject of vigorous debate for years. What is less open to debate is that Congress, the U.S. Environmental Protection Agency (EPA), the business community, and environmental and public health advocates of all varieties seem more committed now than ever to tackling the difficult task of amending TSCA.

Several signs point in this direction.

First, the 111th Congress has scheduled more hearings on various aspects of TSCA than any predecessor. Since February 2009, there have been an unprecedented seven hearings on topics ranging from the current science on public exposure to toxic chemicals to obtaining business perspectives on reforms.[1]

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[1] *See* House Committee on Energy and Commerce Subcommittee on Commerce, Trade, and Consumer Protection hearing on "Revisiting the Toxic Substances Control Act of 1976" (Feb. 26, 2009); House Committee on Energy and Commerce Subcommittee on Commerce, Trade, and Consumer Protection hearing on "Prioritizing Chemicals for Safety Determination" (Nov. 17, 2009); Senate Committee on Environment and Public Works and Subcommittee on Superfund, Toxics and Environmental Health joint hearing on "Oversight Hearing on the Federal Toxic Control Substances Act" (Dec. 2, 2009); Senate Committee on Environment and Public Works Subcommittee on Superfund, Toxics and Environmental Health hearing on "Current Science on Public Exposures to Toxic Chemicals" (Feb. 4, 2010); House Committee on Energy and Commerce Subcommittee on Commerce, Trade, and Consumer Protection hearing on "TSCA and Persistent, Bioaccumulative, and Toxic Chemicals: Examining Domestic and International Actions" (Mar. 4, 2010); Senate Committee on Environment and Public Works Subcommittee on Superfund, Toxics, and Environmental Health hearing on "Business Perspectives on Reforming U.S. Chemical Safety Laws" (Mar. 9, 2010); Senate Committee on Environment and Public Works hearing on "Hearing on the Government Accountability Office's Investigation of EPA's Efforts to Protect Children's Health" (Mar. 17, 2010).

Second, on April 15, 2010, Senator Lautenberg introduced sweeping legislation amending TSCA. The proposed legislation amends virtually every core TSCA provision in ways that reflect considerable thought and commitment.

Also on April 15, Representatives Waxman and Rush circulated a "discussion draft" of companion House legislation amending TSCA. Over the next several months, the House convened invite-only stakeholder meetings to discuss key aspects of the discussion draft.

Finally, a diverse group of stakeholders, including EPA, have each prepared and circulated detailed "TSCA reform principles" according to which TSCA reform legislation should be measured and on which such principles TSCA legislation should be based.

In light of these momentous events, and in anticipation of the initiation of TSCA reform legislation being pursued in earnest, American Bar Association (ABA) Section of Environment, Energy and Resources (SEER) Chair John C. Cruden last year formed a Special Committee on TSCA Reform. The sole purpose of the Special Committee was to reach out to former EPA Assistant Administrators (AA) of the Office of Prevention, Pesticides, and Toxic Substances (OPPTS) (renamed on April 22, 2010, the Office of Chemical Safety and Pollution Prevention (OCSPP)) and other senior EPA officials with hands-on experience in implementing TSCA and managing EPA's program offices tasked with implementing TSCA's many technical and challenging provisions. The expectation was that from the perspective of a group that has "been there, done that" with regard to managing TSCA's implementation, the Special Committee could add invaluable insights on the formidable task that lies ahead, and assist Congress and other stakeholders in framing TSCA reform issues through a lens shaped by significant experience and EPA program office implementation expertise.

The Special Committee members represent a bi-partisan group of former senior EPA officials with deep and broad TSCA experience. The group included:

- James V. Aidala, who is now Senior Government Consultant, Bergeson & Campbell, P.C., Washington, D.C. Aidala served as AA for OPPTS (now OCSPP) under the Clinton Administration from 2000 until the end of the Administration in 2001. Prior to serving as AA, he was an Associate AA for OPPTS from 1993 until 2000.

- Charles M. Auer, who was the former Director of EPA's Office of Pollution Prevention and Toxics (OPPT) and currently is President of Charles Auer & Associates, LLC.

- Lynn R. Goldman, M.D., M.P.H., who is a Professor at the Johns Hopkins University Bloomberg School of Public Health Department of Environmental Health Sciences where her areas of focus are children's environmental health, public health practice, and chemical regulatory policy. In August 2010, Dr. Goldman will be joining the George Washington University as Dean of the School of Public Health and Health Services. Dr. Goldman served as AA for OPPTS from 1993 until 1999.

- James B. Gulliford, who is the Executive Director of the Soil and Water Conservation Society. Gulliford served as AA for OPPTS from 2006 until 2009.

After many months of work and deliberation, the White Paper the Special Committee on TSCA Reform prepared offers comment on various elements of the legislative debate regarding how to move TSCA reform forward. Rather than offer an independent set of "principles" similar to those offered by other constituencies, the Special Committee decided instead to "provide observations and cautions about select elements of the debate heard thus far." The Special Committee reviewed several broad categories of issues pertinent to TSCA reform, including consideration of using the Food Quality Protection Act as a template for TSCA reform, EPA's organizational capacity for undertaking and completing chemical assessments, what TSCA has accomplished over the years, the role of related global initiatives, and the need to keep the law flexible to accommodate evolving science. The views of the Special Committee are unique, tempered by the Committee members' significant collective experience working within EPA administering the TSCA program and managing on a real-time basis the many challenges and opportunities TSCA implementation has inspired over the years.

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The American Bar Association
Section of Environment, Energy, and Resources
Special Committee on TSCA Reform

Practical Advice for TSCA Reform: An Insider Perspective

By
James V. Aidala, Jr., Charles M. Auer,
Lynn R. Goldman, M.D., and James B. Gulliford

Introduction

The American Bar Association (ABA) Section of Environment, Energy, and Resources (SEER) Special Committee on TSCA Reform assembled a group of former U.S. Environmental Protection Agency (EPA) senior officials, both career staff and political appointees, of past Administrations, both Democrat and Republican, to offer their thoughts on Toxic Substances Control Act (TSCA) reform.[1] With the perspective of a group which has "been there" in terms of being responsible for managing large federal chemical management programs, the Special Committee offers the following comments on various elements of the expected legislative debate about how to move TSCA forward and more effectively assess and control possible health and environmental risks from industrial chemicals.

Very purposefully we do not seek to offer an independent set of "principles" similar to those offered by other constituencies relevant to the TSCA debate. Other groups have done so, including the Obama Administration, and broadly speaking, they converge in a number

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[1] The group included:

- James V. Aidala, who is now Senior Government Consultant, Bergeson & Campbell, P.C., Washington, D.C. Aidala served as AA for OPPTS (now OCSPP) under the Clinton Administration from 2000 until the end of the Administration in 2001. Prior to serving as AA, he was an Associate AA for OPPTS from 1993 until 2000.
- Charles M. Auer, who was the former Director of EPA's Office of Pollution Prevention and Toxics (OPPT) and currently is President of Charles Auer & Associates, LLC.
- Lynn R. Goldman, M.D., M.P.H., who is a Professor at the Johns Hopkins University Bloomberg School of Public Health Department of Environmental Health Sciences where her areas of focus are children's environmental health, public health practice, and chemical regulatory policy. In August 2010, Dr. Goldman will be joining the George Washington University as Dean of the School of Public Health and Health Services. Dr. Goldman served as AA for OPPTS from 1993 until 1999.
- James B. Gulliford, who is the Executive Director of the Soil and Water Conservation Society. Gulliford served as AA for OPPTS from 2006 until 2009.

of areas, as agreement on broad principles is easier to attain than agreement on particulars. We instead provide observations and cautions about select elements of the debate heard thus far. Hearings in both the House and Senate, as well as release of "principles" documents and public statements, provide an ample basis to identify not only what the key issues are likely to be, but also where there is likely disagreement over particular details of any proposals. We hope to provide useful lessons and observations relevant to the eventual legislative debate based on our experience as former senior EPA decision-makers.

Almost all of the text that follows was written before the introduction of Senate legislation and the release of a House discussion draft with specific proposals for changes to TSCA. As we do not endorse any specific set of changes, we hope these comments are useful to those who now face the daunting task of attempting to forge anything resembling a consensus as the legislative process unfolds.

1. FQPA As a Template for TSCA Reform

There is discussion concerning a number of significant risk assessment criteria and the safety standard that could be taken from the Food Quality Protection Act (FQPA) and that might be appropriate for TSCA. Of particular note is the FQPA requirement for a special focus on exposure to children, that to ensure more protection for children that there be an additional safety factor ("extra" 10x factor for children's exposure), that aggregate exposure to all sources of possible exposure to the same chemical be evaluated (aggregate risk), that exposure to chemically (really toxicologically) similar compounds be evaluated together (cumulative risk), and that all exposures meet a standard of "reasonable certainty of no harm." This scheme has served the pesticide evaluation process well, and EPA was able timely to meet its ambitious schedule of evaluating approximately 450 pesticides and their 10,000 associated uses within a ten year time-frame.

Our observation in this regard would be to suggest that FQPA should be seen more appropriate as a guide than a specific template for parallel assessment and control of industrial chemical exposures. We expect that ultimately the FQPA standard will be a reference point for any new TSCA safety standard in that some variant of examining exposure to a chemical's aggregate exposure, and exposure to toxicologically-related substances, will be offered. Our contribution to this aspect of the debate is to note that there are critical similarities and differences that should be considered when evaluating how closely any new TSCA language should mimic the parallel FQPA language. The similarities are obvious. In applying the FQPA standard, there is the need to use science-based approaches toward consideration of cumulative and aggregate risk, and to assure the protection of those who are most vulnerable.

On the other hand, there are notable differences. Like pharmaceuticals, pesticides are more "data rich" than most industrial chemicals, and always will be. As a condition of registration, pesticide registrants must submit health and ecological effects data to demonstrate the pesticide does not pose an unreasonable adverse effect to human health or the environment. Pesticide exposure pathways are less complex and therefore easier to characterize in standardized fashions (food intake surveys, pesticide data program (PDP) monitoring results, and Food and Drug Administration (FDA) market basket food surveys). Unlike pesticides, TSCA chemicals are not designed to be biologically active, and relatively few are intended for intentional release to the environment and/or use in food production. Unlike industrial chemicals, pesticides are registered for a limited number of specific uses with specified use practices. Finally, there are

approximately 1,100 active ingredients registered as pesticides. There are over 86,000 chemicals listed on the TSCA Inventory with many potential new chemicals that could be developed in the future.

To overcome some of the differences between the two universes of pesticides and industrial chemicals, we would recommend an approach that includes a tight focus and application of more urgent deadlines in those settings with direct human exposures, especially those involving vulnerable populations and/or more direct exposures (*e.g.*, products intended for children; consumer product exposures; products used in the home; and products with worker exposure) and chemical uses involving ecological scenarios that threaten ecosystems (*e.g.*, potential greenhouse gases, aquatic or terrestrial bioaccumulators). Less urgent deadlines could be applied to other uses and exposures, such as those involved in industrial or commercial settings with low probability of worker exposures. Such an approach would focus data generation, risk evaluation, and stricter exposure mitigation requirements on selected areas where they are most needed. Otherwise, we are concerned that the process can become overwhelmed by data development and analytic demands and that consequent delay could result in failure to apply protections where protections are needed. In other words, in the case of chemicals, uniform sets of deadlines and requirements for all chemicals and all chemical uses regardless of their potential for exposure and risk would be self-defeating.

As data become available that indicate potential threats from a particular chemical or family of compounds, more ambitious evaluation goals could be imposed. This might suggest a basis for prioritizing or staging the approach to the evaluation process for the same compound (*e.g.*, exposures related to household chemicals would be assessed as a priority; risk triage for individual chemicals before imposing deadlines for cumulative risk analysis). Some avenues of exposure, such as occupational exposure, are already regulated by other entities such as the Occupational Safety and Health Administration (OSHA) and the Consumer Products Safety Commission (CPSC), and enhancement of data development needed by such entities as well as clarification to better sort out such dual authority situations may be needed.

The risk standard of "reasonable certainty of no harm" is a cornerstone of FQPA for evaluating exposures to pesticide residues in food. Taken on its face, it seems a reasonable starting point for a chemical regulatory standard. At the same time, many exposures to industrial chemicals are incidental or unintended, and best managed through mechanisms other than registration and licensing activities, such as control of the transport, storage, and handling of chemicals as well as control of waste disposal. Such technology-based standards will continue to be appropriate in the context of industrial chemicals, as efforts to make risk-based determinations will be fraught with very little data on potential exposure and levels of uncertainty such that the confidence bands are so wide as to render many initial assessments almost meaningless. This is not advice to abandon the use of risk assessment in favor of technology-based standards but rather to recommend application of technology-based standards as a more rapid way to achieve risk reduction during a time when chemicals hazards and exposures are not well understood.

Also, in relationship to the paucity of data for many chemicals, Congress needs to establish mechanisms to allow EPA to do screening risk assessments. For example, in our experience with pesticide re-evaluation, in the earliest rounds of screening assessments for certain pesticides, where data were especially lacking on actual exposures and were replaced by "default" exposure values, some calculated exposures ranged as high as 700,000% of the allowable exposure limit. In many cases, when more realistic exposure data were made

available, it was found that actual risk was well within a regulatory standard of a "reasonable certainty of no harm." By its nature, risk assessment is an iterative process. In the case of chemicals, if an initial screening assessment using protective defaults showed a chemical use not to present a potential concern, we would not advocate to push the analytic process further. Given that defaults by design overestimate exposures, however, the converse should not be a cause for an immediate public alarm or making conclusionary characterizations of the product in question. EPA needs to be given the space to work these issues through to conclusion, and needs the resources and the impetus to do it quickly and in a way that does not erode the public's confidence in EPA assessment procedures and conclusions. Our comment about misleading characterization of products is driven only in part by a general sense of fairness, as avoiding unwarranted controversies over exposure to a chemical, but also our sense that there could be very high transaction costs for the regulators, consuming significant resources that could otherwise be applied for the assessment and management of chemical risks.

If, as is likely, there is a requirement for aggregate assessment to a chemical, some exposure avenues may be found to contribute only incidentally to a product's risk profile. It should be possible for EPA to exclude from analysis exceedingly small exposures that otherwise will take a disproportionate amount of programmatic time and resources to evaluate and control, unless there is a subpopulation for whom this is a significant exposure.

2. EPA Organizational Capacity

It seems certain that any new law will have deadlines imposed for completing assessments over unknown time periods (X number of chemicals in Y number of years, or X per year, and so forth). EPA's experience with deadlines has been less than stellar overall (with FQPA being a notable exception). One unseen advantage of missing a deadline and having a court order for EPA to meet certain milestones comes in the internal budget battles within EPA. At the same time, overly ambitious deadlines both frustrate public expectations and can adversely impact program morale. In this subject area, we would offer the following advice.

First, any testing and evaluation plan will need a phase-in period. One oversight in drafting FQPA was the absence of a transition time between requirements for meeting the old and the new standards. Simply understanding the new requirements organizationally, as well as developing interpretations and policy in line with new legislative mandates, takes time. A transition period of 6-18 months is a minimum amount of time needed to begin to devise new policies and procedures and to engage stakeholders and the scientific community around these efforts. If elements of the new requirements are to be completed through some element of rulemaking, the rule development process takes at least two years minimum and typically longer.

There is also likely to be some kind of fee system imposed on the regulated community. We would note that devising any such scheme will also take time, which means some delay in the generation of resources to enable the hiring and training of appropriate personnel to implement any new or revised programs. Determining the appropriate way to impose, collect, and share any fee schemes will not be an easy task, and more difficult than was the case of FQPA which had an existing fee scheme imposed by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Congress should carefully craft this provision to enable EPA to move to implementation as quickly as possible.

Even more of a rate-limiting step in the initial phase will be the practical issues of recruitment and hiring. Many observers have stated that it took 18 months for the pesticide program to evaluate new requirements, devise new policies and procedures, and hire new personnel before outside constituencies believed that EPA had "digested" the new law and was acting with some semblance of order and predictability. Calling for a delay of one or two years when Congress and the White House announce with fanfare new and needed reforms finally becoming law is an unlikely scenario. At the same time, reasonable expectations in this regard could include some tiering or phasing-in of certain requirements, or explicit statutory provisions designed to bypass some of the otherwise inevitable sources of delay (*e.g.*, certain rulemaking procedural requirements, or provisions regarding the hiring of new staff or awarding certain support contracts), at least in the earliest stages of implementing any new legislation. Also, new requirements could similarly be phased-in -- for example, one-half the rate of chemical evaluations could be expected to be completed in the first years of implementation as compared to some later periods.

3. Numbers

The TSCA debate has regularly centered on what might be described as a "numbers game." That is, numbers are variously thrown about in the political debate to support the need for reform, usually starting with the general statement that with over 86,000 industrial chemicals listed on the TSCA Inventory, how many have been regulated under TSCA Section 6 (less than ten), how many have been required to be tested (a few hundred), and how many are "bad actors" (no one knows). The debate about numbers is a serious one not only as it provides needed energy and political interest in pursuing amendments (Congress has been woefully inattentive to TSCA since its inception), but also it impacts how legislatively to structure a revitalized regulatory program. A program designed to impose testing requirements and evaluate 86,000 chemicals has different needs and programmatic implications from one which is designed to handle an expected 6,200 chemicals (this being the number of non-polymeric chemicals produced in volumes greater than 25,000 pounds/year at a site in the 2006 Inventory Update Reporting (IUR) cycle).[2] The Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), the European Union (EU) system of modern chemical control, is already strained by the scale of the demands imposed on industry and regulators and its cumbersome registration requirements, and it remains to be seen whether it can lead to a focus and actions on important risks and issues.

Similarly, if one has in mind that ultimately hundreds to a few thousand chemicals might require significant regulatory scrutiny as opposed to tens of thousands of chemicals, designing deadlines for Agency actions will be considered in a different light. The number is dependent on information yet to be had (the classic criticism of the current law), but the point here is to illustrate that reasonable estimates, or best guesses, can at least begin to inform how to structure any revitalized program. One simple element, for example, in determining any industry fee scheme must encompass an expectation of how big any enhanced program will need to be. Should the number of current staff of approximately 350 be tripled or quintupled? The pesticide program, evaluating a universe of about 500-600 chemicals has a staff of approximately 900.

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2 *See* http://www.epa.gov/iur/pubs/2006_data_summary.pdf.

The evaluation of each pesticide is more intense. Arguably, the task under TSCA is far more challenging because of the greater array of chemical types and exposure scenarios.

To help inform estimates in this regard, we note that in the history of the premanufacture notification (PMN) review program, approximately 8% of submissions have resulted in some further testing requirements or the imposition of some kind of regulatory controls while an additional approximately 5% of cases were voluntarily withdrawn by the submitters (often this occurred in the face of possible action).[3] Further, if one assumes that approximately 50% of current TSCA Inventory-listed chemicals are no longer in production, 5% to 10% of 43,000 leaves one with the crude estimate of up to approximately 2,100-4,300 chemicals that may require some type of control action. Then again, if this analysis focuses on the approximately 6,200 nonpolymeric chemicals produced above 25,000 pounds per year at a site, it yields an estimate that ranges between 310 and 620 chemicals (5% to 10% of the 6,200). It is our collective guess that the likely number of chemicals that will require some type of control falls between these ranges.

Reasonable expectations about such numbers are more important given that some statutory deadlines are likely to be embedded in any new legislation, so evaluating 200 chemicals a year for ten years leads to a different design scheme than 8,600 or so a year for ten years. All chemicals among the 86,000 that are still in commerce will be subject to any new requirements and, given the numbers, there will be a need for an early triage element to establish the precise universe at issue. Our comments here are to avoid having the early triage phase as meeting simple numerical quota deadlines for the first years of any new program. In the absence of clear definition of goals efforts targeting chemicals most likely to be harming human health or the environment, EPA could "review" thousands of chemicals a year in the first years of a new program without making any meaningful risk reduction.

4. What TSCA Has Accomplished

The situation with TSCA's accomplishments is not as bleak as some observers have suggested. At the same time, there are important areas where the law did not -- or could not -- function effectively. The most important accomplishments under TSCA include:

- The creation of the Inventory in the late 1970s. When TSCA was passed in 1976, it was not known how many and what chemicals were in commerce in the U.S. and in what quantities. The TSCA Inventory was the first national Inventory created and contained some 60,000 chemicals manufactured or imported into the U.S. Since 1979, over 26,000 new chemicals have been reviewed and added to the Inventory and, starting in 1986, EPA has periodically updated the Inventory to obtain basic information about chemicals that are being manufactured, or imported. While largely invisible to the general public, the Inventory has resulted in

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[3] EPA Inspector General, EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities, Report No. 10-P-0066 (Feb. 17, 2010), available at http://www.epa.gov/oig/reports/2010/20100217-10-P-0066.pdf.

massive benefits to public health and needs to be sustained and strengthened.

- The PMN Review Process. TSCA Section 5 requires advance notification from manufacturers and importers of new chemicals to allow EPA to review the new chemicals and consider the need for control actions or testing. The question of upfront testing on new chemicals received a lot of attention during the Congressional debate on TSCA and, in the end, test data were not required to be included in the notification. Because of this, the PMN program at the outset was seen by many as likely to fail. To deal with the fact that about 70% of PMNs included no test data and 85% included no health data, EPA developed and has relied on Structure-Activity Relationship (SAR) analyses to predict physical-chemical properties, environmental fate, and human and environmental effects. EPA is now recognized as the world leader in the use of SAR analysis and used the techniques to assess and regulate new chemicals and to implement ground-breaking efforts such as that on new chemicals that are Persistent, Bioaccumulative, and Toxic (PBT). While it is clear that EPA's decisions could have been strengthened by availability of additional data in many cases, at the same time EPA has used SAR tools to regulate approximately 8% of the over 40,000 new chemicals submitted while an additional 5% were withdrawn by their submitters often in the face of regulation. Many observers consider the new chemicals program to have been successful in its efforts to assess and manage new chemicals while encouraging continued innovation. Progress can be made in the future to improve SAR methods using newer insights about toxicology mechanisms and new high throughput technologies for biological assays, as well as providing EPA with additional authority to obtain information when required. Moreover, Congress should consider whether it is appropriate for EPA to put the same level of effort into all new chemicals that are notified, when only about 50% will ever be manufactured and, of these, only a subset will be commercially successful.

- Other important successes include creative use of the Significant New Use Rule (SNUR) authority to regulate several thousand new and existing chemicals (it was particularly effective in dealing with the PFOS chemicals, a class of perfluorinated substances that the TSCA program was first to recognize as presenting significant risk concerns) and voluntary efforts such as the High Production Volume (HPV) Challenge Program (which, despite its limitations, considerably increased the available test data on HPV chemicals) and the PFOA 2010/2015 Stewardship Program (which appears likely to lead to significant reductions in the presence of PFOA and related perfluorinated chemicals in products and environmental releases). While not perfect, the SNUR process can be sustained and improved via Congressional authorization and oversight.

- Finally, some of the concepts found in the Chemical Assessment and Management Program (ChAMP), specifically the need to assess and

prioritize existing chemicals for further action and to reset periodically the TSCA Inventory to keep the chemical listing reflective of what is actually in commerce, should be considered in developing a new legislative approach.

At the same time, TSCA Sections 4 and 6 proved inadequate to deal, respectively, with testing and risk management of existing chemicals, with testing regulations taken on only a few hundred chemicals and five chemicals regulated under TSCA Section 6. The 1991 decision that overturned much of EPA's Section 6 regulation on asbestos-containing products is a clear indication of TSCA's limitations.[4]

5. Recognize and Incorporate Related Global Activities

Any TSCA revision in 2010 or later needs to incorporate the changed world in which we live compared to circumstances in 1976. The REACH program is not only a driver behind some groups' desire to support TSCA modernization, but as an independent force REACH will generate substantial amounts of data and its authorization and restriction actions will occur over time. Also, the deadlines and expected schedules behind the REACH program will be relevant to what is reasonable to expect out of a revitalized EPA program. By the same token, the chemical assessment and management work that is underway in Canada, as well as that which has been or will be done in Japan, Australia, and other countries, also represent important contributions that could be relevant to the U.S. situation. Any new TSCA elements will have to incorporate the realities of REACH's data development requirements while recognizing and, as appropriate, incorporating the assessments and actions that are taken not only by the EU but also by Canada and other countries.

There is also a need for any legislative deliberation about TSCA to include the provisions necessary to implement U.S. international commitments made as part of the Stockholm and Long Range Transboundary Air Pollution (LRTAP) treaties on persistent organic pollutants as well as the Rotterdam Convention on prior informed consent. The U.S. has been hampered in international forums because, as a signatory not having ratified these conventions, our ability to influence the debate has considerably waned. It is time for the U.S. to step-up and regain a leadership role in this arena.

Lastly, there are other international activities that will continue to impact how chemicals are produced and regulated in the U.S. Scientific guidelines for hazard evaluation and risk assessment are constantly evolving and being discussed in these forums. There will be an ever increasing need for coordinating regulatory approaches in a global economy. An example here is the agreed upon Global Harmonized System (GHS) for classification and labeling. Technical assistance to help establish modern regulatory regimes in the developing world will continue to be a U.S. obligation, especially in the context of the Strategic Approach to International Chemicals Management. New TSCA amendments should affirmatively recognize and embrace these growing global realities.

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

6. Keep It Flexible

Our last exhortation to those interested in modernizing the TSCA program is to ensure that we do not freeze in time or structure those elements that might seem eminently sensible today, but which over time might have quite unforeseen impacts. That in large part is the root of some current TSCA frustrations. In 1976, the idea of insisting that any TSCA Section 6 requirements be "least burdensome" seemed reasonable. The legislative record indicates there was little discussion of how the procedural steps needed to impose testing requirements might bog down into a 36-year delay (most concern centered on whether to require all new chemicals to have some required base set of testing).

Polychlorinated biphenyls (PCB) in the Hudson River were a major driver of the TSCA debate then, and what seems like a straightforward Congressional mandate in TSCA Section 6(e) has bedeviled the program to this day. EPA's most recent "discovery" of PCBs in window caulk comes to mind. Today, there is controversy about any number of specific chemicals (dioxin, arsenic, formaldehyde) and emerging technologies, such as the products of nanotechnology and biotechnology, and such concerns legitimately become both a rallying cry and flash point for many in the political debate about what is needed to modernize the law.

The science underpinning any hazard assessment framework, including the endpoints of concern (yesterday: cancer; today: endocrine effects; tomorrow: who knows) also continues to evolve. Currently, the gold standard of testing and evaluation involves years of work, thousands of sacrificed animals, and a large resource investment. These might be replaced or supplanted by advances in "21st Century Toxicology" and other discoveries as yet unknown. Likewise, risk assessment methods have been evolving away from one-size-fits-all assumption-laden models and crude assumptions of exposure to more sophisticated modeling techniques that incorporate information about modes of action and pharmacokinetics. It is tempting to try to enshrine these newer scientific approaches into a statute. Requirements which are overly specific about how the regulatory science is conducted or evaluated, however, might be seen as outmoded, inefficient, or inappropriate in relatively short order if the Congressional appetite for TSCA legislative amendments appears only twice as often as Haley's Comet.

Our point here is to recommend that any set of new requirements, even if driven by an intense focus on any of today's problematic chemical exposures (real or perceived), or today's latest approaches to regulatory toxicology, be allowed to evolve with changes in both the inevitable changing science behind chemical evaluation and assessment as well as the regulatory options available to any then-incumbent decision-makers. The heated passions of political debate lead more to blunt and categorical pronouncements sometimes captured in legislation, which often later lead to unintended consequences years later as the regulators are constrained in available scientific tools and regulatory options.

Recent Developments

In mid-April, both the House and Senate saw draft legislation circulated that would fundamentally change the current EPA toxics program. In the Senate, S. 3209 has been introduced by Senator Lautenberg (D-NJ). In the House, Representatives Bobby Rush (D-IL), Chairman of the Subcommittee on Commerce, Trade, and Consumer Protection, and Henry Waxman (D-CA), Chairman of the House Energy and Commerce Committee, released a "discussion draft" of detailed legislative amendments to the current law. Rep. Waxman has also

initiated a series of discussions among the many parties which have expressed an interest in toxics legislation, and hopes to have some agreements on a proposal during the summer of 2010. All observers believe that no final legislative action will be possible this year, given the complexities of the sweeping nature of the proposals and the fundamental limitations of the Congressional calendar (*e.g.*, an earlier adjournment and an already cluttered legislative agenda given the off-year elections of November).

As this current document was intentionally written without endorsing a separate set of "principles" or offering specific legislative recommendations, we hope the advice offered is of utility to those who will now attempt to negotiate the particulars of how to meet the broadly agreed upon goals. The new drafts of the language in circulation are full of particulars as they are each over 100 pages long, and now the long process of negotiation has begun. It would appear that some of the circulated language is intentionally broad if not vague (*e.g.*, how to allocate data development costs among affected parties), while other text appears to be finely crafted by the authors and now subject to the artful process of negotiation (*e.g.*, the list of specific priority chemicals to be most immediately reviewed by EPA under the House discussion draft language, with no parallel specificity in S. 3209).

As the discussion evolves, the language of the current drafts will likely change significantly. As the process unfolds, and the fruits of those labors are made publicly available, it may be useful for the authors of this current document to opine on the state of affairs at that future time. For now, however, we will not offer comment on the particulars of either draft.

June 30, 2010

Senator LAUTENBERG. Thank you, Dr. Goldman. I thank each one of your for your testimony. In my view, I characterize it as excellent in highlighting the issues that we face as we try to reform TSCA.

I welcome two colleagues who are here for their new membership to the committee, to the subcommittee. One of the things that I would like to establish before I enter my questions, and that is, as much as possible, I hope that we can enlist the support and not, I am not asking for a vote, positive vote, but I am asking my newer colleagues here on the committee to see if we can establish a dialog that has us engaged in serious discussion, not only when we are here in front of the public, but when we have a chance to discuss this privately.

Anybody here who didn't hear me? If you didn't hear me, please let me know.

Anyway, so I start, Dr. Goldman, with a question for you. You served as Assistant Administrator at EPA when a Republican Congress passed the Food Quality Protection Act to regulate pesticides. It was a Democrat President who signed it. Based on that experience, what do you think of the prospects for reforming TSCA in this divided Congress? You have had the experience of working with two sides of the aisle. We invite your comment.

Dr. GOLDMAN. I think it is very possible, and I think what happened during that period is instructive, in that the way that legislation was crafted is that while everybody had their principles that they brought to the table, that there needed to be a lot of discussion, a lot of give and take in the actual drafting of the legislation. We had legislation in the Food Quality Protection Act that passed unanimously through both houses of Congress. That only happened because of a lot of very hard work, which has happened, actually, in the case of chemicals reform. A lot of groundwork has been done, the fact that people have been giving it a lot of thought over many months. So I think there is reason to be hopeful for that.

I think the other point that needs to be made is, I don't think there has been a time in history where enactment of environmental legislation has been done without considerable amount of bipartisan support. Environmental protection has always been a bipartisan issue, because hazards in the environment affect all of us. This is not actually a partisan issue at all, but more of an issue for the American people, for our industry, and for being able to both promote industrial development and all of the good things that we want to see with chemicals, while at the same time regulating that industry so that the public's health is protected.

Senator LAUTENBERG. But how do you really feel about this?

[Laughter.]

Senator LAUTENBERG. Ms. Semrau, in the absence of a strong Federal framework, SC Johnson faces a patchwork, you indicated that, of sometimes inconsistent regulations from State and foreign governments. Fair to say that modernizing TSCA can set a strong kind of unified standard, Federal standard for safety that might not only be good for the people who buy your products, and apparently there are numerous of those, but also for the business opportunities that SC Johnson faces?

Ms. SEMRAU. Mr. Chairman, consumer confidence is vital in the safety of chemicals that go into everyday products. Also, as you mentioned, the proliferation of a patchwork quilt of State regulations of chemical management programs, that causes unpredictability.

So you are right in that, if we can boost consumer confidence, if we can get a modernized TSCA that clearly boosts the States' confidence, so that we don't have the proliferation. But as my colleagues have said today, we want to make sure it is risk-based, we make sure that innovation and green chemistry are heavily supported. We would also need true CBI, but we are very willing, as I have put in my written testimony, to move on CBI.

Then the industry would need time to adapt to this new regulation.

But clearly, Senator, those things really do affect the bottom line. So you are right in that, if we have more confidence, it does help the bottom line for companies like ours.

Senator LAUTENBERG. We also can substantially, an observation I will make here, I come out of the corporate world, reduce costs for individuals and families and Government and treatment and disruption in life that comes with conditions that result from exposure to dangerous materials.

Mr. Goldberg, like many large chemical manufacturers, BASF must comply with European and Canadian chemical laws that mandate much greater testing than is required under TSCA. Yet BASF earned record profits last year. That is a good accomplishment. We like to see that, because that also implies jobs, job availability in our Country.

Do you think that TSCA can be modernized in a way that guarantees safety but allows companies like yours to continue to thrive and grow?

Mr. GOLDBERG. Mr. Chairman, absolutely. I think that we would not be supporting TSCA modernization if we did not think BASF could thrive as a sustainable enterprise under a modernized TSCA. You are quite correct that we do comply with a variety of regulatory regimes around the world, with very different standards from time to time. BASF takes a global approach to the products we make and sell.

Many of those regulatory schemes have pluses, but a lot of minuses, bureaucratic aspects and the like. I think we can learn from this and Congress can learn from this in developing a system that has the advantages, that is informed by much of the data that is being created, for example, under REACH, but at the same time provides the chance for innovation while protecting health and the environment.

Senator LAUTENBERG. Mr. Dooley, the American Chemistry Council represents the largest chemical manufacturers in the Country. Under their leadership, ACC has issued 10 principles for modernizing TSCA, and supported reform in general. Are you prepared to share with us your specific ideas as needed for a workable chemicals management system? You outlined the steps that should be taken. How about information sharing to achieve that goal? Do you think your group is ready to impart the knowledge that they

gain as they either have had experience in the past or are developing in the future?

Mr. DOOLEY. Yes, Mr. Chairman, what we are absolutely committed to is being a constructive part of a bipartisan process in both the House and the Senate to effectively modernize TSCA. We are certainly prepared to offer our ideas and thinkings and learnings from our engagement, not only with TSCA, but with the Canadian plan as well as the REACH program that is in development.

Senator LAUTENBERG. Thank you, very much, all of you. Some have suggested that the elections and the outcome diminished chances of fixing TSCA in this Congress. Can I ask for a very short statement for the record that, are you and your organization still committed, presently committed to working to modernize TSCA? Your testimony says it. Did I interpret it clearly?

Ms. SEMRAU. Mr. Chairman, absolutely. From SC Johnson's point of view, there isn't a better time for the bipartisan effort to modernize TSCA.

Senator LAUTENBERG. Mr. Goldberg.

Mr. GOLDBERG. I would 100 percent agree with Ms. Semrau. I think this is an opportunity in this Congress, given the fact that it would have to be bipartisan to achieve effective modernization of TSCA that satisfies both the needs to strengthen the statute and preserve innovation.

Senator LAUTENBERG. Ms. Beinecke, I am going to make it easy for you. Is protecting health, children's growth, reducing costs and the agony that comes with disease, is that a worthwhile mission, enough to be bipartisan? Or is that strictly the province of one party?

Ms. BEINECKE. I think it is clearly bipartisan, and we have examples all over the Country in many different States where there has been bipartisan, coming together to pass State laws. We certainly look forward to having that happen here in Congress as well, and look forward to working on it with you and other members of the committee.

Senator LAUTENBERG. Thank you.

Mr. Dooley.

Mr. DOOLEY. As I stated in my written testimony and my oral testimony, we are committed to being a part of a bipartisan process to achieve modernization of TSCA.

Senator LAUTENBERG. Dr. Goldman.

Dr. GOLDMAN. It can be done.

Senator LAUTENBERG. I asked the question, liking the music I am hearing, and it was so good that I wanted it repeated.

[Laughter.]

Senator LAUTENBERG. Senator Johanns, take all the time you need for your questions.

Senator JOHANNS. Thank you, Mr. Chairman.

Dr. Goldman, maybe I will start on that side of the table and we can work our way down. We have certainly heard the criticism toward TSCA, kind of from all elements. I always look for a starting point. If we are going to redo TSCA, we should start with the notion that maybe there is something in TSCA that has worked, that

was a step in the right direction, and that should not be thrown out.

So where would you start there? What about TSCA has been a success story that we should consider incorporating, whatever the rewrite would turn out to be?

Dr. GOLDMAN. Thank you, Senator. I can name a few things that I think have actually worked fairly well. One certainly is the chemical inventory. Even though it hasn't been perhaps updated as frequently as many of us would like to, maybe it could have more information in it. That was a real step forward, establishing it. Everybody in the world wants one now, and that needs to be continued and sustained, probably improved.

A second is EPA's new chemical review process. Even though it can be strengthened, it has been a good process. One of the great things that EPA has pioneered through that process is the use of structure activity modeling, which I happen to believe should be upgraded through the use of newer computational methods. But nonetheless, has been a really wonderful process.

Something that EPA itself innovated was not in TSCA, but it has been able to do under, and ought to be really looked at carefully by Congress is the significant new use rule, which has been a wonderful way of managing the new uses of newer chemicals as they have come on the market, making sure that those uses are limited to the areas where those chemicals are going to be safe. Actually, as Mr. Dooley said, real looks carefully at the intended use for the chemical, not just the hazard of the chemical, but also the intended use of that chemical. It has worked very well.

Senator JOHANNS. Before I go to Mr. Dooley, let me ask you also, when I hear 62,000 chemicals were grandfathered, I just go, my goodness. If you did a study on 62,000 chemicals, we would be here into the next century. Am I missing the point here? Give me your perspective on that. I can't imagine that we could empower EPA to review 62,000 chemicals in any kind of reasonable period of time.

Dr. GOLDMAN. I think when I talked about a need to have priority setting, and also tiering of evaluations, it was really to address that. Because it is not just the original 62,000, but then it is the 24,000 that have come on the market since that time. So it is really a lot of chemicals.

However, all of those are not being manufactured at all in this Country. Of those that are being manufactured, most of them are not being manufactured in significant quantities. There are really 6,200 where the quantities are fairly significant. Even that is the list where I think that EPA could prioritize the evaluation of those in order to go after the worst first.

I don't think one would ever say that there would be chemicals that would be, if they are in active use, that would be on put on a shelf and EPA would never look at them. But I think it is very clear that there are some that are more deserving of immediate attention than others, and that Congress needs to point EPA in that direction to make sure it would happen that way.

Senator JOHANNS. Mr. Dooley, I would like your observations. What in TSCA would the industry say was absolutely a step in the right direction?

Mr. DOOLEY. I would associate myself with the remarks of Dr. Goldman, where she identified the new chemicals provisions of TSCA, Section 5. We think that has served consumers, it has served the industry and served the U.S. economy well. Clearly, when we look at the challenges of trying to maintain the U.S. competitiveness on the development of new innovations and technologies, we think we have a strong foundation in that new chemicals provisions of TSCA that really result in a collaborative effort between the private sector and Government and EPA, where we submit the data and respond to additional requests by EPA to ensure that they can make an appropriate determination on the assessment of the safety of those chemicals.

So we think that is an integral component of any modernized TSCA, is that you don't want to throw the entire statute out. You want to keep those provisions that are working well, and certainly the new chemicals provision is what we think is working quite well.

Senator JOHANNS. Ms. Beinecke, if you could give me your thoughts too on what has worked well in this. Then I would also like to have your sense of Dr. Goldman's testimony on the 62,000 chemicals that you have mentioned. Is it 62,000 that you want me to worry about, or is it 6,200, or is it 620?

Ms. BEINECKE. Senator, first, having an inventory I think is very important. I think it has been important for the public to know what the range of chemicals are out there. The fact that they don't know that much about any of them or that the information has not been that readily available is a problem, and we hope that reform of TSCA will correct that. But knowing sort of the scale of the problem is important.

To your question of 62,000 chemicals, no, we don't expect EPA to go one by one through the chemicals. I think there are classes of chemicals that there are concerns about, persistent chemicals, bioaccumulating chemicals, toxic chemicals, chemicals that are thought to be carcinogens or to cause reproductive health problems. I think that what you would do is create a set of criteria for what are the highest areas of concern and then what are the chemicals in those classes that need to be thoroughly assessed by EPA.

Particularly one of the things we are asking for is that the industry really have the responsibility to demonstrate safety and provide the information and for EPA to evaluate that. Because I think we all fully understand that EPA will not have the capacity to do the kind of analysis in great detail on the number of chemicals that are in the marketplace. But because industry is putting them into the marketplace, it is really their responsibility, we would advocate it is their responsibility to provide that safety data for EPA to assess.

Thank you.

Senator LAUTENBERG. Thank you, Senator.

Senator Whitehouse, welcome. You have your 5 minutes for questions, and we invite you to do that.

Senator WHITEHOUSE. Thank you, Mr. Chairman. Let me just begin by saying again how much I appreciate your leadership on this issue. It is a model for a new Senator like me of persistence, determination and the aggregation of expertise. It has been very

important and I want you to know that for what it is worth, I do appreciate it very, very much.

I would love to ask Ms. Beinecke, the environment that these changes will take place in is one in which a great majority, I would expect, of the chemical companies involved are either international companies already or are companies that have international markets. So they are not only obliged to meet American standards, they are also obliged to meet European and Canadian standards. European and Canadian governments appear to have run well ahead of us in modernizing their laws.

At the same time, we have State regulatory authority as well, and in some cases the multiplicity of conflicting regulations creates an undue burden for the industry and situations that are very hard to reconcile. In other cases, a very pioneering and knowledgeable State can exercise real leadership that we don't want to discourage out of Washington. What thoughts do you have for us about how we can best be most effective in the context of those two concerns, the frontier of regulation moving ahead in Europe and Canada that is going forward without us, that we need to catch up with, and the preservation of room for our sovereign States to take reasonable steps to protect their constituents without creating a morass of overlapping and conflicting regulations?

Ms. BEINECKE. Senator, I think you have posed a challenging question, because clearly, I think one of the great challenges to the industry, and it would be worth asking them directly, is the multiplicity of regulations that they are under. There has been some discussion about that, Dr. Goldman particularly called out the need to put TSCA reform in the context of the globalized market and the changes that are happening more at the international level.

At the same time, the fact is that 18 States have acted on toxic laws, 30 States are considering them while they wait for Congress to act. I think as far as protecting the American public goes, that is very, very important to assure the public that there will be action. I think that it will be a challenge for this committee to figure out, as you go forward, how to ensure that innovation can happen at the State level, that States particularly who have particular problems that they are concerned about within their own boundaries can take action early. Because one of the things that we have discovered with 35 years of TSCA is that these chemicals haven't been evaluated, it takes a long time. Even with TSCA reform, things will take time to develop.

So I think you cannot put States in a position of not acting to protect the people within their boundaries. But figuring out how to incentivize and how to provide some uniformity at the Federal level is certainly something that we are all looking forward to. I think that is why on this panel there is so much agreement that reforming TSCA is absolutely critical at this point because first of all, the public is very concerned, and there is a lack of consumer confidence in what their exposures are, but also because they are faced with multiple jurisdictions.

Senator WHITEHOUSE. In my remaining 40 seconds, would anybody else care to chime in?

Senator LAUTENBERG. You can have more than that.

Senator WHITEHOUSE. Mr. Dooley.

Mr. DOOLEY. Clearly, I would just like to address one issue, and Mr. Goldberg might want to comment on this. I think that what we are committed to is really developing the gold standard on chemicals management here in the United States. We hear a lot of talk about REACH, and in some ways, I think it is almost a myth here that REACH is a gold standard here. REACH is just in its infancy. Nobody knows how well it is going to work yet. It has had one data call-in that occurred in December. But industry nor the NGO community has any knowledge to date in terms of what is going to be the practical implications of its regulation of chemicals in commerce.

So before we succumb to this idea that somehow we are falling behind on a regulatory construct because the EU has adopted REACH, we ought to step back and do a thorough evaluation of just what it has brought to the industry as well as the NGO community. I think that story remains to be told.

But clearly I think that when we look at moving forward, we understand that we have to have a modernized system that is science-based, that is risk-based, that restores the public confidence in EPA's assessment of the safety of chemicals. If we do that, we will mitigate the need and the interest of State governments and local governments from promulgating their own approaches to chemical management. That is in the interest of the consumers, and that is clearly in the interest of industry.

Senator WHITEHOUSE. Thank you very much. Thank you, Mr. Chairman.

Senator LAUTENBERG. At this point, I would ask you each to respond to any inquiries that you get. Dr. Goldman, I have the report from the committee, ABA, and their evaluation. They lead with the statement that what is open to debate, Congress, U.S. environment, EPA, business community environment, public health advocates of all varieties seem more committed now than ever to tackling the difficult task of amending TSCA. I hope that is right.

I thank each one of you for your testimony and my colleagues here who joined in the hearing today. Thank you. This hearing is adjourned.

[Whereupon, at 11:33 a.m., the committee was adjourned.]

Additional material submitted for the record follows.]

STATEMENT OF HON. JAMES M. INHOFE, U.S. SENATOR FROM THE STATE OF OKLAHOMA

I would like to thank Senator Lautenberg for scheduling this important hearing to examine the effectiveness of the Toxic Substances Control Act, or TSCA. I want to thank him, and his staff, for continuing an important dialog with my staff on how to modernize TSCA. I will continue to work with him, and I hope that as we further define our principles, we can reach an agreement to develop a workable bill, one based on the best available science, one that protects human health, and one that balances the need to protect jobs and economic growth.

Another important consideration is that we craft a bill that can pass both the House and Senate. This is an important test, because if we can't get the votes we need for a comprehensive solution, then we may have to consider alternative legislative options to address specific issues that might have broader bipartisan support. I hope today's hearing will help us identify some of those issues as we continue our dialog to modernize TSCA.

We have an impressive witness list today, with experts from various backgrounds who can offer unique perspectives on TSCA and its implementation. An important issue for me, which I hope the witnesses will address, is TSCA's broad reach over chemical manufacturing, and its potential, and real, impacts on the economy. TSCA

regulates the manufacturing, distribution, use, and disposal of chemicals—authority that covers thousands of transactions and decisions by thousands of people every day.

Given this fact, we need to ensure that EPA is regulating properly. When we think about modernizing TSCA, several questions come to mind: Will reform allow EPA to foster, rather than stifle, innovation? Will reform inspire public confidence in EPA's decisions as well as the products industry produces? Will reform rely on the best available science? Will reform ensure EPA is protecting human health and the environment?

These are fairly basic questions, but they must be answered, as we are dealing with a statute that is 35 years old, one passed before the myriad of innovations that have dramatically changed the chemical industry. It is time to bring TSCA into the 21st Century.

That would certainly require legislation of some kind. As I have stated many times, modernization of TSCA should:

- be based on the best available science;
- use a risk-based standard for chemical reviews;
- include more rigorous cost-benefit requirements;
- protect proprietary information;
- reduce the likelihood of litigation;
- avoid compelling product substitution; and
- prioritize reviews for existing chemicals.

I also look forward to working with EPA as we conduct oversight of the TSCA program. I want to thank Steve Owens for his testimony today, and his willingness to make his staff accessible to the committee as we seek greater understanding of EPA's path forward on TSCA implementation. There are certainly policy and legal issues on which we disagree, but the fact that we are working together inspires great confidence.

I am glad to hear that in the House, Representative Shimkus, chairman of the Subcommittee on the Environment and Economy, has made TSCA oversight one of his top priorities. Representative Shimkus and I will no doubt work together to ensure the TSCA program is working effectively within the confines of the law.

Again, I appreciate Senator Lautenberg's work on this issue and I look forward to hearing from the witnesses today on their constructive ideas for updating, improving, and modernizing our chemical safety laws.

WRITTEN STATEMENT OF THE

NATIONAL PETROCHEMICAL & REFINERS ASSOCIATION (NPRA)

AS SUBMITTED TO THE

SUBCOMMITTEE ON SUPERFUND, TOXICS AND ENVIRONMENTAL HEALTH

Committee on Environment and Public Works
United States Senate

on

Assessing the Effectiveness of U.S. Chemical Safety Laws

February 3, 2011

NPRA, the National Petrochemical and Refiners Association, appreciates the opportunity to submit this statement on the effectiveness of United States chemical safety laws.

NPRA is a trade association representing high-tech American manufacturers of virtually the entire U.S. supply of gasoline, diesel, jet fuel, other fuels and home heating oil, as well as the petrochemicals used as building blocks for thousands of vital products in your daily life. NPRA members make modern life possible, meet the needs of our nation and local communities, strengthen economic and national security, and provide jobs directly and indirectly for more than 2 million Americans.

We appreciate the commitment the Environment and Public Works Committee has placed on ensuring the effectiveness of our nation's chemical safety laws. There is nothing more important to NPRA's members than the safety of the products they produce. Our industry supports the reasonable modernization of our chemical safety laws, such as the Toxic Substances Control Act (TSCA), but we also believe that any modernization must be tiered, targeted, and risk-based. Furthermore, chemical regulation modernization must take into consideration domestic innovation, the ease of entry into the marketplace, American competitiveness, and information protection.

NPRA strongly believes that chemical safety laws cannot take a one-size-fits-all approach, and instead must utilize a risk-based standard of regulation. The greater the likelihood of societal exposure to particular substances, the higher priority they should be given in terms of testing, information collection, and – for those substances that present significant hazards – potential risk management actions. These regulations must allow the EPA and industry to proportionally focus finite time and resources on assessing the potential hazards of chemicals with which consumers most often come into contact. This is the most efficient and effective way to ensure the safety of consumers who use these products every day.

Chemical safety laws must not stifle domestic innovation and cannot raise overly burdensome barriers to, or the cost of, entry into the marketplace. There is a direct correlation between ease of entry into the marketplace and domestic innovation. Some recently proposed chemical regulation legislation would place an undue burden on market entrants to submit, collect, and manage an overabundance of test data with no regard to what information is useful, needed, or legitimate for risk management purposes. Furthermore, raising barriers of entry into commerce would have a negative impact on green chemistry, innovation, and the development of new and safer chemicals.

For generations, the United States has been one of most economically productive countries in the world. America has long been a world leader in innovation and technology, and our laws should foster this innovation rather than impeding it by giving advantages to our foreign competitors. It is pivotal that any chemical regulation program protect human health and the environment while at the same time promoting innovation, economic growth, and American competitiveness in the global marketplace.

A critical element of such an approach is ensuring the protection of confidential business information (CBI). Some past legislative proposals call for making detailed information about American chemical products publicly available. NPRA strongly cautions against this approach, as it would greatly impair American innovation by enabling overseas competitors to easily discover the formulations and chemical compounds of American products through government databases. Overseas firms would then be able to manufacture these products, possibly at a lower price, and export them to the United States, placing American companies at a competitive disadvantage.

NPRA supports the sound, science-based modernization of our nation's chemical safety laws. However, we urge Congress to be mindful of the need to preserve those areas of regulation that work well while striving to improve the areas that are lacking. We hope that the 112th Congress proceeds with addressing chemical safety legislation in a bipartisan manner and through a process that includes all stakeholders. NPRA stands ready and willing to work with the Committee towards the responsible modernization of our nation's chemical safety laws.

February 2, 2011

The Honorable Frank Lautenberg
Chair, Senate Subcommittee on Superfund, Toxics and Environmental Health
324 Hart Senate Office Building
Washington, DC 20510-6175

The Honorable James Inhofe
Ranking Member, Senate Subcommittee on Superfund, Toxics and Environmental Health
205 Russell Senate Office Building
Washington, DC 20510-6175

Re: Subcommittee Hearing on "Assessing the Effectiveness of U.S. Chemical Safety Laws"

Dear Chairman Lautenberg and Ranking Member Inhofe:

On behalf of the members of the Society of Chemical Manufacturers and Affiliates (SOCMA), I would like to share with you our perspective on the subject of your hearing this week, with an emphasis on evaluating the effectiveness of Toxic Substances Control Act (TSCA). Since 1921, SOCMA has served as the leading trade association representing the batch, custom and specialty chemical industry. SOCMA has roughly 250 member companies, which are typically small to medium-sized businesses, each with up to $100 million in annual sales. Our members make a $60 billion annual impact on the U.S. economy and contribute to the chemical industry's position as one of the nation's largest exporters.

SOCMA appreciates the Subcommittee's continued efforts to pursue improvements to the status quo of chemicals management. Unfortunately, in the realm of TSCA modernization, legislative efforts thus far have overreached by proposing an unachievable model for industrial chemicals. SOCMA understands that TSCA modernization is a complex issue that deserves close scrutiny. But so is assessing the effectiveness of the current TSCA program over the past 34 years. Many relevant factors should be considered, most of which, we believe, fall outside the statute itself. A fair-minded and in-depth look would demonstrate that only certain parts of TSCA require a re-write. It is for these reasons that SOCMA has consistently advocated carefully tailored updates that are not done in haste.

SOCMA believes that many of the most widely-cited chemical statistics paint an incomplete picture of TSCA's effectiveness:

- Many critics of TSCA have routinely pointed to the relatively small number of regulated chemicals, failing to acknowledge that chemicals already undergo a great deal of testing.

Just because the EPA does not issue a large number of test rules does not mean that testing is not required. Additionally, most chemicals can, in fact, be used safely, and hence do not require regulation. While there are some procedural hurdles for EPA worth examining, the effectiveness of an entire statute should not rest on the one metric of how many regulations are promulgated.

- While there is certainly a heightened awareness of chemical exposures, particularly among consumers and the general population, there has been a failure to recognize the many other chemical laws that create federal jurisdiction over different universes of chemicals. It is our hope this hearing sheds some light into this fact given that the subject is on "chemical laws" and not just TSCA. We could probably learn some lessons from the Consumer Product Safety Improvement Act of 2008.
- More chemicals are being detected in humans via biomonitoring; however, advances in science, such as the field of analytical chemistry where detections levels are possible at much lower levels than have ever been available previously, should be acknowledged before blaming TSCA for what might appear to be an increase in exposures. Additionally, the Centers for Disease Control and Prevention (CDC) have regularly noted that detection of a chemical does not equate to harm.

SOCMA asks that the subcommittee consider a variety of metrics and seek to understand them fully prior to introduction of new legislation. We would encourage the Subcommittee to explore, for example:

- The number of new chemicals reviewed by EPA staff under Section 5 since TSCA's inception.
- The number of PMNs that were withdrawn as a result of those reviews.
- The number of PMNs whose review periods were voluntarily suspended while the submitter conducted tests or gathered other data.
- The number of Significant New Use Rules (SNURs) issued by EPA.
- The number of Section 5 orders that have ever been successfully challenged.
- The number of new drug applications and pesticide registrations or reregistrations processed during the same time period, and the average time for each process.
- The number of FTEs employed in the TSCA and FIFRA programs and in the FDA's Center for Drug Evaluation and Research.
- The number of new chemicals that were commercialized in the U.S. since TSCA's inception, vs. the number commercialized elsewhere in the world.
- The number of patents for new chemicals granted in the U.S. versus the number granted elsewhere in the world.
- The number of existing chemicals actually in commerce in the U.S.

- The change in life expectancy among Americans since TSCA was enacted.
- Properly adjusted rates of incidence of cancer among Americans since TSCA was enacted.

The subcommittee should understand that many factors are in play when looking at the effectiveness of governing chemicals management laws. Ultimately, success will not depend solely or primarily on how many chemicals are restricted, but on the net health, environmental and economic effects of implementing these laws. More on SOCMA's position can be found at www.safeforuse.net.

Sincerely,

Lawrence Sloan
President and CEO, SOCMA

cc. Senate Committee on Environment and Public Works

TESTIMONY OF

PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE

AND

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

BEFORE THE

SUPERFUND, TOXICS, AND ENVIRONMENTAL HEALTH SUBCOMMITTEE

OF THE

SENATE ENVIRONMENT AND PUBLIC WORKS COMMITTEE

ON

ASSESSING THE EFFECTIVENESS OF U.S. CHEMICAL SAFETY LAWS

February 3, 2011

SUBMITTED February 11, 2011

Kristie Sullivan, MPH
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I. Summary of Recommendations

The large number of chemicals in commerce requires a smarter approach; despite decades of toxicity testing using surrogate animal "models" of human physiology, we have been able to comprehensively test only a fraction of the substances produced and used. Even substances that have been tested extensively (such as Bisphenol-A, which has been tested in more than nine hundred experiments to date) are the subject of fierce debates regarding interpretation and application of results to human health.

As the NRC and EPA[1] both state, advances in computational and cellular technologies will allow more predictive and protective toxicological assessments of chemicals. While this vision is being progressively realized, existing methods and approaches can be used in addition to exposure variables, physical-chemical information, and existing knowledge to prioritize chemicals for regulation or further study.

21st-Century chemical regulation needs 21st-Century toxicity testing. As the committee embarks upon efforts to modernize the current TSCA, we urge you to consider reform of toxicity testing methods an integral part of chemical regulation reform, and to follow the principles we propose here, in order to better protect human health, the environment, and animals in laboratories.

Common-sense guidelines for chemical prioritization

1. Update TSCA inventory.
2. Tabulate and review all existing data, including data accessible only through agreements with other regulatory bodies.
3. Make regulatory determinations now where possible.
4. Group chemicals according to common modes of action or structural class.
5. Apply QSAR and high-throughput biological methods to prioritize chemicals and design integrated strategies for further testing.
6. Determine and fulfill information needs according to exposure.
7. Prevent duplicative testing by providing incentives for data sharing.
8. Allow waivers for tests that are impractical, inhumane, or clearly redundant.

[1] See The U.S. Environmental Protection Agency's Strategic Plan for Evaluating the Toxicity of Chemicals, located at: http://www.epa.gov/spc/toxicitytesting/index.htm.

Ensure implementation of new technology

1. The principle of animal testing as a "last resort" should be a foundation of US policy.
2. Computational, cell and tissue-based methods can be used now to prioritize chemicals or groups of chemicals that are of primary concern.
3. New legislation should not prescribe a minimum data set/check-list of toxicity tests to which all substances must be subject.
4. New legislation should provide EPA with significant funding and organizational support, guidelines for an efficient and flexible peer review process, and clear benchmarks of success, to ensure rapid implementation of better testing methods.
5. New legislation should offer strong incentives for companies to fund, develop, and use new methods and testing strategies
6. As non-animal/alternative methods become available, legislation should require the use of such methods in place of animal tests.
7. A mix of public, private, and government advisors is essential to ensure implementation of new testing methods.

II. Background

While estimates of the number of chemicals in commerce differ, there could be environmental exposure to anywhere between 10,000 and 100,000 chemicals. Understanding the potential health and environmental risks posed by chemicals currently in the environment, while ensuring new chemicals are safe for use, presents a monumental challenge. For ethical, scientific, and practical reasons, this challenge cannot be met using toxicity test methods that use animals.

In order to effectively assess both existing and new industrial chemicals, we must reform the way in which toxicity testing is conducted, including the science used to evaluate chemicals. If carried out thoughtfully, reform of the Toxic Substances Control Act (TSCA) represents an unprecedented opportunity to implement an effective program of chemical assessment and management that is consistent with the National Academy of Sciences' recent landmark report presenting a vision and strategy for toxicity testing in the 21st Century (NRC, 2007). Without the committee's careful consideration of all stakeholders' concerns and subsequent careful drafting, TSCA reform could result in more ineffective chemical testing programs that waste time, money, and hundreds of thousands of animals while leaving human health and the environment unprotected. Incorporation of the approach outlined in the NRC report is essential to creating a feasible and effective program, and increasing the efficiency with which EPA can identify and manage hazardous substances. While some of the elements outlined in the report will require research and development before they can be implemented, a number of existing methods and approaches can be used now for prioritization.

The current TSCA Inventory contains approximately 80,000 chemicals; in order to review this number of chemicals over 10 years, the EPA would have to review approximately 6,000 – 8,000 chemicals each year (approximately 20 each day), at heavy expense to the taxpayer. Currently, the EPA's Office of Pollution, Prevention, and Toxics—the office that would be charged with implementing this legislation—reviews about 1000 pre-manufacture notices[2] each year – review of existing chemicals would be in addition to these PMN reviews.

Evaluation of this tremendous backlog of existing chemicals, as well as the generation of robust information regarding new chemicals, is simply not feasible under the current toxicity testing paradigm used by the EPA and other regulatory agencies. This paradigm is largely based on experiments on animals, particularly rodents, rabbits, and dogs, and uses methods that were developed as long ago as the 1930s and 40s - tests that are time-consuming, expensive, and in some cases use thousands of animals apiece. For example, a single two-generation reproductive toxicity study requires a minimum of two years, $380,000, and 2,600 animals. There are simply not enough laboratories in the world to conduct all the testing required in a reasonable time-frame. In addition, the current testing paradigm has a poor record of predicting effects in humans (Seidle and Stephens, 2009; Knight and Bailey 2006a, 2006b; Ennever and Lave 2003) and an even poorer record of leading to actual regulation of hazardous chemicals (Seidle 2006).

In light of these concerns, the Environmental Protection Agency (EPA) realized that the current toxicity testing paradigm is in urgent need of overhaul and requested the National Academy of Sciences' National Research Council (NRC) assess the current paradigm and recommend actions to improve it. The NRC Committee on Toxicity Testing and Assessment of Environmental Agents (NRC Committee)[3] set out to create a vision for the future of toxicity testing and a strategy that, once implemented, would improve the depth and breadth of toxicology and its usefulness as a predictive—and protective—science (Edwards and Preston 2008). *Toxicity Testing in the 21st Century: A Vision and Strategy* outlines such a vision, together with an initial roadmap for its implementation (NRC 2007). The NRC Committee envisions an iterative process of chemical characterization, toxicity testing, and dose-response and extrapolation modeling informed by population-based data and human exposure information. The report calls for the development of a suite of human-based *in vitro*[4] cell and tissue assays instead of whole-animal tests for hazard assessment and regulatory decision-making.

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[2] http://www.epa.gov/oppt/ar/2007-2008/reviewnewchem/index.htm

[3] The Committee on Toxicity Testing and Assessment of Environmental Agents is an ad-hoc committee convened by the National Academies' National Research Council to create a vision and strategy for 21st-century toxicity testing at the request of the Environmental Protection Agency.

[4] *In vitro* refers to assays that take place in a culture dish or test tube.

Not only would use of these new technologies increase the depth and breadth of information available about each chemical, they would dramatically decrease the time required to evaluate each substance. The result is that a vastly larger number of chemicals could be evaluated within a shorter period of time. This approach could also address currently intractable problems such as the toxic effects of chemical mixtures and nanoparticles, synergistic effects of chemicals, susceptibility of sensitive sub-populations, sensitivity at different life stages, gene-environment interactions, the need to test the effects of chemicals over wider dose ranges, and the effects of chemicals at very low, environmentally relevant doses (Gibb 2008).

The conclusion of the report is that the reduced reliance on whole-animal testing leads to a more human-relevant and efficient toxicity testing paradigm, resulting in increased protections for people and the environment.

Since the publication of this report, numerous organizations and entities have released statements supporting this vision or conducted other activities either to help realize, or adapt their own activities to, this vision, including:

Environmental Protection Agency
Food and Drug Administration
National Institutes of Health
American Chemistry Council
International Life Sciences Institute
District of Columbia Bar Association
California Environmental Protection Agency
European Commission
Society of Toxicology
American Society for Cellular and Computational Toxicology
National Academy of Sciences
Environmental Law Institute
Society for Risk Analysis
Health Canada
The Hamner Institute for Health Sciences
Johns Hopkins University School of Public Health
The American Chemical Society
European Chemical Industry Council

III. Short-Term Solutions: Smarter Testing

While the 2007 NRC report outlines a way forward that will take time to fully achieve, available methods and technologies can be applied to the prioritization of chemicals today (Andersen 2009). For example, *in vitro* or *in silico* models can be relied upon as a first "tier" in order to characterize the potential mechanisms of action of test chemicals. In another example, data from the EPA Office of Research and Development's ToxCast

Program[5] has been used to create a prioritization scheme for detecting chemicals with the potential to disrupt the endocrine system.[6] Shaw et al. (2008) showed the feasibility of a similar process for prioritizing 50 different nanomaterials based on likely biological reactivity according to differences in material characteristics. Last year, scientists at the NIH Chemical Genomics Center (NCGC) published results of a mechanism-of-action study that used 26 assays in 13 different cell types to cluster 1,408 compounds given at 14 different concentrations according to mechanism of action. The results compared favorably with current information about the chemicals' toxic profiles, and provide support for such approaches (Huang et al. 2008).

Recent changes in chemical legislation in Europe, i.e. the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation, has presented a similar challenge of scale (EC 2006). In an attempt to ensure that REACH is successful, European, American, and multi-national bodies such as the Organization for Economic Cooperation and Development (OECD), are working to further develop strategies to streamline toxicity testing and risk assessment. The REACH legislation also requires that animal tests be used only as a last resort, after all avenues to obtain the required information without animals (i.e. existing data, read-across from similar chemicals) have been exhausted.

In addition to the mandatory use of suitable non-animal testing methods, REACH includes:

- An emphasis on the acquisition and use of existing information
- Use of chemical categories with similar properties
- Use of weight-of-evidence approaches
- Incorporation of non-guideline test results in weight-of-evidence approaches
- Criteria for identifying situations where testing is not feasible
- Exemption of chemicals with no exposure potential

In addition to these sensible strategies, an OECD-sponsored international collaboration including the US EPA is developing and standardizing computer algorithm-based models, known as Quantitative Structure Activity Relationship models (QSARs) for use in chemical assessment. These models can group and classify chemicals based on similar structure or activity profiles, help extend information about similar chemicals to substances with little data (known as bridging), and provide data for classification or risk assessment. Scientists and regulators influential to the REACH legislation are currently demonstrating how these models can—and must—be used in order to quickly assess

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[5] High-throughput systems capable of running hundreds of chemicals at many different doses through suites of different cell-based and biochemical assays are being used to generate information predictive of the modes of action of test chemicals, to create clusters of chemicals with similar mechanisms of action, and to prioritize chemicals for immediate investigation or regulation.

[6] Kavlock, Robert. Nov. 11, 2009. Presentation given at Johns Hopkins University School of Public Health, Center for Alternatives to Animal Testing, Chemical Information Day.

chemical hazards in the scientific literature (Schaafsma et al. 2009; vanLeeuwen et al. 2009).

Incorporating these strategies into TSCA reform will allow the U.S. to take advantage of the experiences of other regions in regulating industrial chemicals and create the best and most protective policies.

IV. Detailed Recommendations

Common-sense guidelines for chemical prioritization

A first step in implementing updated TSCA regulations will be setting priorities for assessment and regulatory action. We suggest the following guidelines when determining how to set priorities:

1. Review of TSCA inventory: It is important to get a true picture of the chemicals currently manufactured within or imported into the U.S., and the current and near future use and exposure patterns, in order to evaluate and prioritize information needs.

2. Tabulate and review all existing data: Companies should submit to the EPA all unpublished studies for manufactured or imported chemicals relating to physical-chemical properties, environmental dispersal, toxicity, and human and environmental exposure. The EPA should also gather information from other governmental bodies, such as Health and Environment Canada and the European Chemicals Agency, and solicit any additional information from public sources.

3. Make regulatory determinations now where possible: Using available data, make determinations of safe use or put necessary risk management controls in place where possible and warranted. Here, special emphasis should be placed on chemicals with known high exposure profiles or those with high potential to remain in the environment after an accidental release.

4. Group chemicals according to common modes of action or structural class: Assessing chemicals as members of scientifically-supported categories has several advantages, the strongest of which is that in some cases hazard information from one or more chemicals can be extrapolated to other members of the category lacking information. Methods mentioned in (5) can support the formation of categories, as can regulator or scientist expertise.

5. Apply QSAR and high-throughput biological methods to prioritize chemicals and design integrated strategies for further testing, if warranted. For some chemicals, cellular and computation methods can be used to fill information needs; in other

cases these methods can be used to detect priority chemicals and endpoints that require further study.

6. Determine and fulfill information needs according to exposure: Prioritization should be based on potential risk, including potential exposure. For example, chemicals that are produced within a verified closed system may not need extensive hazard information. In addition, a data "gap" is not necessarily a data "need," and the EPA should be given the flexibility to determine the information needed to make a regulatory decision without requiring a fixed list of data requirements that would apply comprehensively to all chemicals. Testing should be tailored to the chemical based on its toxicity profile and expected exposure. Testing beyond such a determination would waste time, money, and animal lives.

7. Prevent duplicative testing by providing incentives for data sharing. Companies should be required to form consortia and share data where appropriate, in order to prevent duplicative testing on the same chemical or category of chemicals.

8. Where appropriate, allow waivers for tests that are not practical to conduct or clearly redundant, such as inhalation testing of solid materials or aquatic testing for insoluble substances (Sandusky et al 2006).

Ensure Implementation of New Technology

The next decade will see extensive development of new high-throughput and high-content cell, tissue, and computer-based toxicity testing methods. Any effective modernization of TSCA must allow for and encourage adoption of this evolving technology. By providing legislative support to this effort as it modernizes TSCA, Congress will also send a strong message: that more effective chemical regulation is dependent on more effective and humane testing methods. To do this, we urge the Congress to be mindful of the following considerations:

1. The principle of animal testing as a "last resort" should be a foundation of US policy.

2. Computational, cell and tissue-based methods can be used now to prioritize chemicals or groups of chemicals that are of primary concern. These methods can also be used to satisfy information needs for some chemicals. Further development and application of these methods for use in risk assessment should be encouraged in the new legislation.

3. New legislation should be flexible enough to allow the inclusion of new testing methods and Integrated Testing Strategies as they are developed, and should not prescribe a minimum data set/check-list of toxicity tests to which all

substances must be subject.

4. New legislation should provide EPA with significant funding and organizational support, guidelines for an efficient and flexible peer review process, and clear benchmarks of success, to ensure rapid implementation of better testing methods.

5. New legislation should offer strong incentives for companies to fund, develop, and use new methods and testing strategies; and, as non-animal/alternative methods become available, require the use of such methods in place of animal tests.

6. A mix of public, private, and government advisors is essential to ensure implementation of new testing methods. It is inappropriate to expect that a small committee of government agency representatives--like the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM), which has a documented inability to work effectively--will be able to advise the EPA on the wide range of computational, in vitro, high-throughput, and other non-animal technologies that are being developed and implemented, based on past and current performance and priorities.

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February 15, 2011

The Honorable Frank Lautenberg, Chairman
Subcommittee on Superfund, Toxics, and Environmental Health
of the Senate Environment and Public Works Committee
Suite 410
Dirksen Senate Office Building
Washington, DC 20510

Dear Mr. Chairman and Members of the Subcommittee:

The Society of Toxicology is a broad-based, multidisciplinary organization whose members share the common goal of *"Creating a Safer and Healthier World by Advancing the Science of Toxicology."* The Society includes more than 6,800 members from more than 60 different countries. Members are drawn from academic institutions, industry, government agencies and other organizations.

A priority and one element of the Society's strategic plan is to advocate the value of toxicology through (1) increasing the reliance of decision-makers on the science of toxicology and (2) increasing the Society's role in proactively defining issues and bringing forth toxicological knowledge for policymakers and the public.

The Toxic Substances Control Act (TSCA), the primary mechanism and statute by which chemicals in commerce are regulated in the United States has been the focus of former and current Congressional efforts relative to reform, motivated primarily by the question of how well the existing statute reflects current scientific knowledge and societal needs.

Because of its commitment to "Creating a Safer and Healthier World" and owing to the depth of knowledge amongst its membership relative to chemicals, toxicology, and the assessment of human health risk, the Society has created a TSCA Task Force that is committed to providing the U.S. Congress with science-based assistance regarding future TSCA reform. Specifically, the TSCA Task Force is committed to providing

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1) education and discussion on scientific topics that are directly related or tangential to legislation and 2) insight on how transformations in toxicology and risk assessment may influence future chemical regulation such that legislative expectations and implementation are scientifically feasible. Consistent with this objective and the expertise of the Society's members, the following guidelines have been established regarding engagement on TSCA reform with Congressional representatives.

- We are willing to explain and clarify the science of toxicology and methodologies for assessing hazard and risk to anyone representing Congress, regarding TSCA reform. Our engagement may take the form of personal visits, training sessions or briefings, non-confidential and transparent written responses to questions, or expert testimony.

- We will facilitate engagement between Congressional representatives and members of the Society who have specific expertise that may be needed. To the extent that there may be a range of views on any particular topic, we will seek to represent the full range of scientifically-credible views.

- We will avoid any attempts to advocate for specific positions, interpretations, or application of the science when scientific consensus is lacking. As warranted, consensus may be tested *via* a subset of members representing the range of views within the Society.

- We will avoid engagement on issues that are not scientific in nature; e.g. issues involving legal principles, costs, administration, and specific drafting of legislative language.

The Society of Toxicology appreciates the opportunity to advance science and protection of public health through the application and incorporation of toxicological principles in legislation and decision-making. Please feel free to contact Dr. Holsapple at (202) 659-3306 or Dr. Juberg at (317) 337-3787 for more information.

Sincerely,

Michael P. Holsapple
SOT President

Daland Juberg
Chairman, SOT TSCA Task Force

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February 3, 2011

The Honorable Frank Lautenberg
Chairman
Subcommittee on Superfund, Toxics and Environmental Health
U.S. Senate Committee on the Environment and Public Works
Washington, D.C. 20510

The Honorable James Inhofe
Ranking Member
Subcommittee on Superfund, Toxics and Environmental Health
U.S. Senate Committee on the Environment and Public Works
Washington, D.C. 20510

Dear Chairman Lautenberg and Ranking Member Inhofe:

Our organizations are the leading trade associations representing the downstream users of chemical substances. We appreciate this opportunity to provide input for today's hearing before the Senate Subcommittee on Superfund, Toxics and Environmental Health. Our members are committed to manufacturing and marketing safe, innovative and sustainable products that provide essential benefits to consumers while protecting human health and the environment.

Ensuring the safety of our products is the single most important goal of the consumer products industry. Product safety is the foundation of consumer trust, and our industry devotes substantial resources toward achieving this goal.

Consumer products companies recognize that it is time to update the Toxic Substances Control Act (TSCA) of 1976. A modernized TSCA will help improve confidence in the safety of chemicals used to manufacture consumer products and packaging and promote even greater innovation and U.S. competitiveness in the global economy.

Improvements to TSCA should recognize changes in science and technology, establish deadlines for review of priority chemicals, ensure that the U.S. Environmental Protection Agency (EPA) has timely and adequate information on use and exposure, leverage ingredient and chemical management programs undertaken by other nations, promote innovation, and integrate the patchwork quilt of laws governing product safety. In particular, we look forward to working with you to address the following policy challenges:

- **Setting Priorities** - Congress should consider ways to identify "priority" substances that should be reviewed, including chemicals that may pose health risks to sensitive

populations. In particular, Congress should examine how industry studies that meet EPA standards for protocols and procedures should be used to support government efforts.

- **Use and Exposure Information** - Congress should work with the consumer products industry and others to ensure that EPA has adequate and timely information on chemical use and exposure to assess "priority" chemicals and to have sufficient information to establish science-based limits on the use of certain substances, if appropriate.

- **Deadlines** - Congress should consider how to establish clear but achievable deadlines for the review of priority chemicals, and should ensure that EPA has adequate resources to meet these deadlines. Congress also should explore ways to leverage reviews by Canada, the European Union and other nations with modern product safety systems to avoid duplicative and wasteful testing.

- **Risk Management** - Congress should revisit and clarify EPA and other federal agency authority to manage and mitigate the use of chemicals that present risk concerns to public health or the environment, and should ensure that the regulatory system continues to assess the costs and benefits of new restrictions and potential alternatives.

- **Innovation** - Congress should ensure that improvements to TSCA promote – and not stifle -- innovation and new product development. Maintaining the global competitiveness of the producers and users of chemicals is critical to our economy. Protecting confidential business information, clarifying the roles of the states, and promoting a level global playing field will foster greater innovation.

As the Subcommittee moves forward to consider enhancements to TSCA, we urge you to continue to engage stakeholders in a process that will reflect the impact of the broad application of this law across our economy, and the critical role played by the consumer products industry. We hope this input is helpful as you work to modernize TSCA to meet shared goals of fostering innovation, enhancing consumer confidence and protecting human health and the environment.

Sincerely,

D. Christopher Cathcart	Pamela G. Bailey	Ernie Rosenberg
President & CEO	President & CEO	President & CEO
CSPA	GMA	ACI

The Consumer Specialty Products Association (CSPA) is the premier trade association representing the interests of approximately 240 companies engaged in the manufacture, formulation, distribution and sale of approximately $80 billion annually in the U.S. of hundreds of familiar consumer products that help household, institutional and industrial customers create cleaner and healthier environments. Our products include disinfectants that kill germs in homes, hospitals and restaurants; candles, fragrances and air fresheners that eliminate odors; pest management products for home, garden and pets; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used every day. Through its product stewardship program Product Care®, and scientific and business-to-business endeavors, CSPA provides its members a platform to effectively address issues regarding the health, safety, sustainability and environmental impacts of their products. For more information, please visit www.cspa.org.

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The Association promotes sound public policy, champions initiatives that increase productivity and growth and helps ensure the safety and security of consumer packaged goods through scientific excellence. The GMA board of directors is comprised of chief executive officers from the Association's member companies. The $2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers, and contributes over $1 trillion in added value to the nation's economy. For more information, visit the GMA Web site at www.gmaonline.org

The American Cleaning Institute® (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. ACI's mission is to support the sustainability of the cleaning products industry through research, education, outreach and science-based advocacy. For more information, please visit the ACI website at www.cleaninginstitute.org.

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PRESIDENT
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e-mail: Doug_Clark@mudnebr.com

January 28, 2011

U.S. Senator James M. Inhofe
205 Russell Senate Office Building
Washington, D.C. 20510-3603

RE: Water Quality

Dear Senator Inhofe:

The Metropolitan Utilities District of Omaha serves drinking water to over 200,000 customers in the Omaha area. We meet and exceed all Safe Drinking Water Standards and are dedicated to providing safe drinking water on a continuous basis to all of our customers. Our city was included in the recent report **Chromium-6 in U.S. Tap Water** by the Environmental Working Group. According to a test they performed on our water, we had 1.07 parts per billion (ppb) of Chromium-6 in our tap water.

The current maximum contaminant level for total chromium (including chromium-6) is 100 ppb. Our water easily meets the current standard. We are required to test quarterly for total chromium, but have tested monthly for nearly ten years. In response to EPA's recent guidance, prompted by the EWG report, we have also voluntarily begun quarterly testing for chromium-6 at our water treatment plants and in our distribution system. Omaha is going (and has gone in the past) above and beyond required chromium testing.

We feel very strongly that EPA must proceed with the chromium issue by following principles of the Safe Drinking Water Act (SDWA). Toxicology information must be peer reviewed. The Unregulated Contaminant Monitoring Rule (UCMR) process needs to be followed. Laboratory results should reflect performance standards for laboratories using defensible, comparable analytical methods. Regulatory action, if anticipated, **must** follow EPA's process for reviewing existing standards. That process must include proper data collection, proper assessment of health benefits, and costs. EPA should keep everyone informed of its timeframe for moving forward with any regulatory change.

Thank you for this opportunity to comment on this very important issue. Please contact us any time if you have comments or questions.

Sincerely,

Douglas R. Clark
President

DRC/sms

cc: U.S. Senator Ben Nelson
U.S. Senor Mike Johanns

February 3, 2011

Dear Senator Lautenberg:

As people of faith we are taught that all humankind is made in the image of God and receives nourishment from the bounty of God's Creation (Genesis 1:26). Therefore, caring for our own bodies is an essential aspect of our call to honor God's Creation (1 Corinthians 6:19; Genesis 2:15). We are also taught to care for and seek justice for vulnerable populations such as children, women, and those living in poverty.

These values are challenged by the fact that toxic chemicals enter and harm our bodies through air and water pollution, and chemicals in household products including cleaners, electronics, textiles, and children's toys. Some contaminants can cause health problems ranging from asthma to cancer, especially in children. Of particular concern is the fact that some populations are more vulnerable to health concerns related to toxic chemicals—children, newborns, women, the elderly, and communities of color.

Yet, these chemicals are poorly understood and inadequately regulated. The U.S. Government Accountability Office found that only 200 of the more than 83,000 registered industrial chemicals have been tested. The Environmental Protection Agency (EPA) cannot do this alone. Chemical companies should practice good moral stewardship by providing critical data necessary to determine chemical safety. The current system does not effectively ensure chemical safety.

As people of faith from diverse traditions, we affirm that reforming current chemical policies is vital to protecting people and life on God's Earth. We urge Congress to take immediate action to update our nation's chemical policy that will ensure the safety of both existing and new toxic chemicals so that we can protect vulnerable populations such as children, women, the elderly, and communities of color from the negative health impacts of toxic chemicals.

Sincerely,

Episcopal Church USA
Evangelical Lutheran Church in America
National Council of Churches USA
Presbyterian Church USA
Union for Reform Judaism
United Church of Christ
The United Methodist Church - General Board of Church and Society

UNION FOR REFORM JUDAISM
SERVING REFORM CONGREGATIONS IN NORTH AMERICA

GreenFaith

Interfaith Statement for Chemical Policy Reform

The Problem: Toxic Chemicals Threaten Life on Earth

Toxic chemicals enter and harm our bodies, plants and animals, and natural systems through air and water pollution, and chemicals in household products including cleaners, personal care products, plastic food and drink containers, textiles, and children's toys. Yet these chemicals are poorly understood and inadequately regulated. The U.S. Government Accountability Office found that only 200 of the more than 80,000 registered industrial chemicals have been tested[1]. Existing chemical policies fail to protect the web of Creation, including the human community.

While all people are at risk, some are more vulnerable. Communities of color and low-income communities suffer disproportionately from pollution caused by current and past industrial activity, waste disposal[2], heavily-traveled transportation routes, and consumer products containing toxic chemicals. Researchers also warn that toxic chemicals negatively impact children, expectant mothers, and workers.[3] Chemical workers suffer from chemical exposures because of the lack of public data on chemicals they use, unsafe workplaces, and lax enforcement of regulations.

As religious leaders and people of faith and conscience from diverse traditions, we affirm that reforming current chemical policies is vital to protecting people and life on God's Earth.

Our Shared Call: Four Religious Values

The world's faith traditions share values which serve as a foundation for ethical decision-making regarding toxic chemicals. Four core values shared by the world's great traditions are as follows:

- All life is to be respected.
- People of faith must ensure that air, water, and land – which belong to the Divine - sustain life on Earth.
- Society owes justice and care to its most vulnerable people and communities, and to future generations
- Our faith traditions call us to protect and promote the health of the human body.

The conclusion of this statement contains reference to religious teachings that reflect these shared values. Sadly, existing chemical policies fail to respect these values.

The Principles: Strong Toxic Policies to Sustain All Life

Government policy on chemicals can and should protect people and all life on Earth. Chemical legislation should:

Protect People and All Life on Earth

- Remove the most dangerous chemicals, such as chemicals that persist, bioaccumulate, or are acutely toxic (PBTs), from use except when no safe alternative is available.
- Hold companies accountable for demonstrating that chemicals are safe.

Protect Vulnerable Populations

- Reduce the disproportionate burden of chemical exposure placed on workers, low-income people, people of color, indigenous communities, pregnant women, and children, and other vulnerable groups.
- Expand government biomonitoring, particularly in at-risk communities, to measure people's toxic exposure.

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[1] Government Accountability Office. Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program. 2005. 22.

[2] United Church of Christ. *Toxic Waste and Race*. 1987.

[3] For examples see President's Cancer Panel. Reducing Environmental Cancer Risk: What We Know and What We Can Do. Letfall, LD and Kripke, M. May 2010, ;Environmental Working Group. Body Burden: A Benchmark Investigation of Industrial Chemicals, Pollutants, and Pesticides in Human Umbilical Cord Blood., 2004; Christiansen S, M Scholze, M Dalgaard, AM Vinggaard, M. Axelstad, A. Kortenkamp and U. Hass. Synergistic disruption of external male sex organ development by a mixture of four antiandrogens. Environmental Health Perspectives doi:10.1289/ehp.0900689. September 2009; California Environmental Protection Agency Department of Toxic Substances Control. PBDE Levels in Falcon Egg Studies Highest Ever., May 2008.

- Invest in research to understand and protect children's health from chemical harm.
- Provide chemical health and safety information to workers and the public.

Promote a Sustainable, Healthy Economy

- Fund "green" chemistry and engineering research to create safer chemicals and industrial processes.
- Promote a "green" economy that will allow all life to flourish and bring green jobs to low-income communities and communities of color.

Religious Teachings that Affirm Strong Protections from Toxic Chemicals

These teachings represent humanity's shared moral and spiritual heritage, and affirm the importance of protecting society and all life on Earth from the threats posed by toxic chemicals.

Judaism affirms that human beings are created *b'tselem Elohim,* in the divine image (Genesis 1:26), and that God recognized all Creation as "very good" (Genesis 1:31), implying the importance of respect and care for the human body and all Creation. Judaism emphasizes God's command to treat vulnerable communities with compassion and justice, take precautions to prevent possible harm, and forbid people from knowingly harming themselves or others (Leviticus 19:28, Deuteronomy 15:7). Classical Jewish sources mandate proper waste disposal and that potentially dangerous production processes be sited at a safe distance from our homes and communities. (e.g. Deuteronomy 23:13-15, *Mishnah* Baba Batra 2:9). Jewish tradition recognizes the inherent value of children and future generations (Shabbat 119b).

Christianity echoes Jewish teachings about Creation's goodness, and the New Testament teaches that Christ's salvation encompasses not only humankind but "all things" or "the entire world" (Colossians 1:15-20; John 3:16) -, demonstrating the importance of the whole of Creation. Jesus teaches that those who receive gifts from the Creator are required to use these responsibly (Matthew 25:14-30, Luke 19:12-28), and that Christians are called to seek justice for society's most vulnerable (Matthew 25:31-40). Paul writes that our bodies are a "temple of the holy spirit" (1 Cor. 6:19-20), and Jesus healed numerous people suffering from illnesses, showing God's care for human health and the body.

Islam teaches that the natural world is a "sign" ("aya") that points to the existence of Allah and that all of Creation glorifies Allah (Qur'an 27:88, 24:41). Human beings are God's "viceregents" and stewards (Qur'an 2:30, 6:165, 33:72) and are divinely ordained to maintain Creation's balance and harmony (Qur'an 55:1-13). Allah forbids self-harm – an implicit caution in regards to use of toxic substances (Qur'an 2:195, 4:29). Justice for the vulnerable is central to Islam – whether through care for those who suffer or through the prevention of suffering. For example, Prophet Muhammad declared, "Help your brother whether he is an oppressor or he is an oppressed one." People asked, "O Messenger of God,... how can we help the oppressor?" Prophet Muhammad replied, "By preventing the oppressor from committing acts of injustice" (Sahih Bukhari 45:4).

Hinduism affirms veneration of nature in its Vedas, Upanishads, Puranas, Sutras, and other sacred texts. Millions of Hindus recite Sanskrit mantras which recognize the divine in sacred rivers, mountains, trees, and animals. Hinduism's yogic traditions affirm the importance of human health, while Hindu theologies note that Earth is to be revered as a manifestation of the goddess (Devi). Mahatma Gandhi taught that simple living is the foundation of sustainable economies, and that "dharma" – often translated "duty" - can be interpreted to support respect for Earth. Gandhi emphasized the Hindu teaching of "ahimsa," or nonviolence towards the web of life. The ancient Indic tradition of **Jainism** declares non-violence as its supreme virtue and endorses vegetarianism to benefit human health and prevent animal suffering.

Buddhist teachings such as "dependent co-arising" ("paticca samupadda") and the Jewel Net of Indra affirm that all life is interconnected, and by extension recognize that toxic chemicals damage this web of life. Buddhism also affirms "ahimsa," or non-violence, recognizing that we must reduce avoidable suffering, and teaches the importance of restraint and self-mastery as methods to achieve individual and collective harmony, criticizing the self-indulgence and greed that characterizes the reckless use of toxics. Buddhism affirms our duty to show compassion to society's most vulnerable members. For example, Bodhisattvas are great spiritual leaders who draw near to enlightenment and then, instead of entering nirvana, choose to help the less fortunate achieve enlightenment and well-being.

Current national and state-based signatories: American Baptist Churches of Connecticut, Center for the Celebration of Creation (PA), Earth Ministry (WA and national), Ecumenical Ministries of Oregon Interfaith Network for Earth Concerns), The Episcopal Church, Evangelical Lutheran Church in America, GreenFaith (NJ and national), Interfaith Center for Corporate Responsibility, Interreligious Eco-Justice Network (CT), Maine Council of Churches, Massachusetts Council of Churches, Minnesota Council of Churches, National Council of Churches, Northwest Center for Corporate Responsibility, Oblates of Mary Immaculate Justice, Peace/Integrity of Creation Office, Pennsylvania Council of Churches, Presbyterian Church (U.S.A.) Office of Public Witness, Texas Impact, Union for Reform Judaism, Unitarian Universalist Association, United Church of Christ Justice and Witness Ministries, Voices for Earth Justice (MI).