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BUSINESS PERSPECTIVES ON REFORMING 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 ELEVENTH CONGRESS

SECOND SESSION

MARCH 9, 2010

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BUSINESS PERSPECTIVES ON REFORMING U.S. CHEMICAL SAFETY LAWS

TUESDAY, MARCH 9, 2010

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

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

Present: Senators Lautenberg, Vitter, Carper, and Whitehouse.

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

Senator LAUTENBERG. Good morning, and welcome to the third oversight hearing on the Toxic Substances Control Act in the Subcommittee on Superfund, Toxics and Environmental Health.

We began this push to reform the toxic substances law a few months ago after a review with EPA Administrator Lisa Jackson. Ms. Jackson reminded us that the current law does not provide her agency with the tools it needs to protect the public from hazardous chemicals.

We also heard from the experts at the Centers for Disease Control. They told us that most Americans are walking around with hundreds of industrial chemicals coursing through their bodies. We also learned that the Government Accountability Office has identified the Toxic Substances Control Act as a high risk area of the law. And I don't know whether we need any reminders, but this law was originally written in 1976. A long time has passed without a lot of action to support it.

Today as we cap off the hearings on this law, known as TSCA, we will hear—I am pleased to say—from the business community. What we hear might be a surprise. Executives at some of the world's leading chemical companies have determined that the status quo is not working for them, either. As a former CEO I know that executives have two major duties: to do what is right for your clients, your customers, while doing right for your company and your country. Reforming this broken law is an opportunity to do both.

The current law is not good for the environment, it is not good for our health, and it is ultimately not good for business. The reason is clear: the American people are more and more concerned about chemicals ending up in their bodies. Parents in particular

are dismayed that the Government is powerless to require testing of chemicals that are going into our children's bodies.

Many of the chemicals we use in our daily lives, perhaps even most—are safe. But our current law does not allow the EPA to draw a bright line between chemicals that are safe and chemicals that are toxic. So consumers are left confused and worried. This uncertainty hurts businesses all the way down the supply chain.

It hurts the chemical industry, which is critical to our economy. This industry is a major part of the American manufacturing base. It sustains jobs across the country, and it creates products that save lives.

In my home State of New Jersey the chemical industry employs more than 70,000 people. Nearly 1,500 New Jerseyeans work for DuPont, the company that is represented at the witness table today. The current law also harms major companies that use chemicals in their products, and they are joining the drum beat for reform also.

I want to insert a letter into the record from the trade association that represents companies like Procter and Gamble, S.C. Johnson and Honeywell. These companies "support the development and implementation of a gold standard in the United States for chemical management policy."

[The referenced letter follows:]

WRITTEN TESTIMONY
ON BEHALF OF THE
CONSUMER SPECIALTY PRODUCTS ASSOCIATION,
GROCERY MANUFACTURERS ASSOCIATION,
AND THE SOAP AND DETERGENT ASSOCIATION
BEFORE THE SENATE SUBCOMMITTEE ON SUPERFUND, TOXICS AND ENVIRONMENTAL HEALTH

The Consumer Specialty Products Association (CSPA), the Grocery Manufacturers Association (GMA), and the Soap and Detergent Association (SDA), appreciate the opportunity to submit written comments to the Senate Subcommittee on Superfund, Toxics and Environmental Health in connection with its March 9, 2010 hearing entitled *Business Perspectives on Reforming U.S. Chemical Safety Laws.* These three organizations primarily represent the processors and users of chemical substances, which they formulate into a broad array of consumer products.

Modernization of the Toxic Substances Control Act is a Widely Supported Public Policy Goal

CSPA, GMA and SDA, as well as their members companies, such as Honeywell International Inc., McLaughlin Gormley King Company, Reckitt Benckiser, S.C. Johnson & Son, Inc., and The Procter & Gamble Company support the development and implementation of a "gold standard" in the United States for chemical management policy and look forward to working on this very important issue with Senators Lautenberg, Inhofe, Boxer and all the other members of the Subcommittee.

The members of CSPA, GMA and SDA are committed to manufacturing and marketing safe and innovative products that provide essential benefits, including important public health benefits, to consumers while protecting human health and the environment. Product safety is at the very foundation of consumer trust. The consumer products industry devotes significant resources to achieving this goal. To that end, we support modernization of TSCA and continue to urge Congress to establish a stakeholder process to develop the most comprehensive chemicals management policy in the world. All stakeholders - Congress, regulators, downstream users, raw material suppliers, retailers, environmental, consumer, animal welfare, and labor groups - should work together to develop sound public policy on this complex issue. A stakeholder process would help ensure the development of public policy where EPA has the resources and the proper authority to boost public confidence in the federal government's chemical review and

management regime, and keep the U.S. in an enhanced position to lead the world in innovation.

Modernization Building Blocks Enhance Public Confidence, Innovation and Support Jobs

Among the issues we believe should be addressed by stakeholders in any effort to modernize TSCA include:

1) **Promote Innovation** – TSCA reform should boost confidence in government chemical management and promote even greater innovation by chemical manufacturers and users.
2) **Review Priority Chemicals** – EPA should establish a system to quickly identify and review "priority" chemicals based upon both hazard characteristics and exposures, including exposures to children.
3) **Provide Adequate Use, Exposure and Toxicity Information** – EPA should work with chemical manufacturers and users to ensure that EPA has timely and adequate information of chemical hazards, exposures and uses, including uses in children's products.
4) **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. Safety determinations should consider the effects of exposure to children and other sensitive populations.
5) **Clarify Risk Management Tools** – EPA should have clearer risk-based authorities to specify risk management measures that will ensure that chemicals of concern are reasonably expected to be safe for their intended uses.
6) **Leverage and Integrate Chemical Reviews** – Policymakers should take steps to leverage the chemical management programs undertaken by other nations and to integrate the patchwork quilt of laws governing chemical management.
7) **Meet Deadlines** – Policymakers should provide EPA with adequate resources and clear authorities to establish and meet deadlines to carry-out agency work under a revised TSCA program.
8) **Use the Best Available Science** – Policymakers should ensure that EPA relies upon the best available science regardless of its source.

The companies represented by CSPA, GMA and SDA devote substantial resources ensuring that the products they produce and market to consumers are safe for their intended uses. Safety is designed into products, beginning at the start of new product development when ingredients are carefully evaluated and selected. The focus on safety continues through evaluation in the labs just before products are marketed. It includes stringent specifications on raw materials and detailed attention to process control in product formulation. It even continues during post-market monitoring. Thus product safety is a key element through the entire product lifecycle. The decision about "safety" is made accounting for human and environmental effects including consideration of susceptible subpopulations. "Safe" means that under the conditions of intended use, the

product will not cause harm to human health or the environment. Consumers expect our products to be safe for their families and for the environment – and meeting that expectation is as important to us as the product's performance and cost.

Once a company assures the safety of a product internally, it must then ensure that those products meet the expectations for safety as defined by the various laws and regulations that govern consumer product safety. TSCA is designed to regulate chemicals in commerce, some of which become the ingredients that are formulated into the products that our companies manufacture and market. The underlying goal of TSCA is to evaluate the health and safety of these chemicals. The consumer products industry is extensively regulated by several statutes falling under the scope of various agencies including the Consumer Product Safety Commission, Department of Transportation, Environmental Protection Agency, Food & Drug Administration, Federal Trade Commission, and Occupational Safety & Health Administration. Together, these authorities regulate the product throughout its entire life cycle, including the manufacturing, transporting, labeling, packaging, advertising and disposal. While EPA has resources and authorities that cover much of the chemical supply chain, other agencies have significant expertise in the regulation of chemically formulated products developed for consumer use. This extensive infrastructure and network of agency and statutory authority in the U.S. system underscores this comprehensive approach to consumer product safety.

Our industry is also regulated by many individual state regulations; however, a uniform federal approach for chemical management is strongly preferred over what is currently a patchwork quilt of state laws and policies. A robust federal chemicals management law will provide state policymakers and consumers with a strengthened confidence in chemicals management. Provisions that directly regulate substances used in products wherever they are marketed must allow industry to operate efficiently and enable innovation. The burdens are real and substantial especially as companies are increasingly being required to meet differing, even sometimes conflicting, state law provisions. Policymakers should take steps to leverage information from the chemical management programs undertaken by other nations and to integrate the patchwork quilt of laws governing chemical management. If the pattern of individual state actions continues, in the future it may actually become easier to move products among the countries of Europe than among the U.S. states.

As Congress develops specific TSCA reforms, policymakers should take care to promote – and not stifle – innovation and new product development. A company's ability to innovate is essential in bringing continuous improvements to products in the marketplace and delivering benefits to the consumers. Innovation allows manufacturers to develop more sustainable and better performing products, to conserve resources and provide consumers with lower cost products that provide more benefits.

Modernization of the Toxic Substances Control Act Must Achieve Important Public and Global Leadership Goals

We have a unique opportunity to modernize chemical regulation the right way—protecting the public and the environment while retaining U.S. leadership in innovation. We look forward to working with Congress, the Administration and other stakeholders to reform TSCA: to identify "priority" chemicals which should be subject to greater review; to ensure that EPA has adequate information about chemical hazards and uses, as well as the resources to meet deadlines for priority chemical review; to leverage the chemical management programs undertaken by other nations; to integrate the patchwork quilt of laws governing product safety; to bring clarity to EPA's risk management tools; and to support more rapid innovation of safe and sustainable products. These improvements will work together to boost consumer confidence and strengthen America's competitiveness in the global economy.

CSPA, GMA and SDA and their member companies are committed to working with key stakeholders to develop the appropriate updates to TSCA that will restore consumer confidence and trust in the chemical industry. We appreciate this opportunity to submit written comments and look forward to working with you on this very important issue.

About CSPA
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 everyday. Through its product stewardship program Product Care®, 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.

About GMA
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.

About SDA
The Soap and Detergent Association, the Home of the U.S. Cleaning Products Industry®, represents the $30 billion U.S. cleaning products market. SDA 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. SDA and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. SDA's mission is to support the sustainability of the cleaning products industry through research, education, outreach and science-based advocacy. For more information visit www.cleaning101.com.

Senator LAUTENBERG. I look forward to hearing from our witnesses about why reforming our chemical laws is good for business.

Now I speak to my colleagues on the Committee. Throughout these hearings, I have noted the constructive comments of Republican friends. They have said that my bill to reform TSCA must set up a system that assesses chemicals based on risk, not just hazard, and it will. And you have said the bill must encourage innovation, and it will. And you have said that the bill must be based on good science, and it will.

And after taking into account the testimony we hear today I intend to introduce a bill that lays out a vision for strong, effective and pragmatic regulation of chemicals. But the introduced bill will be an invitation for all to play a part—friends on the Republican side, as well, obviously, as those on the Democrat side. I look forward to working with Senators on both sides of the aisle to refine the bill so it makes our environment cleaner, our children healthier and our economy stronger.

So now, before we hear from this important panel, I will turn to other members for any opening statements.

Senator Vitter.

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

Senator VITTER. Yes, thank you, Mr. Chairman. It is great to see you back, and thank you for this hearing.

As we move forward with this discussion, I want to stress a point you mentioned, which is the absolute critical importance of sound science. All being focused on sound science is important to, first, achieve maximum protection for U.S. citizens, achieving the overarching goals of ensuring human health and a safe environment, and also preserving competitiveness in the chemical industry in the global marketplace. We must work to ensure that our legislative efforts are paired with the appropriate resources also needed to update our chemical risk management framework and that scientists at EPA are getting those resources and getting the science right.

I am really glad the industry is interested in seeing TSCA reformed. Over the last several months numerous industry leaders have come into my office to discuss this need for reform, doing it in a way that protects health and competitiveness. It is important to note in that regard that more than half of the patents issued for chemical industry innovation over the last 5 years were authored by U.S. entities.

I want to quickly reiterate for the record what I have said before in this Committee about the five overarching principles that I think are important in this work. No. 1, I think EPA has to redo their inventory of chemicals in commerce. There aren't 80,000 chemicals in significant commerce, as we often hear. The number may be closer to one-quarter of that. And we need to know what it is and what they are, and then focus on them.

No. 2, a European registration evaluation authorization of chemical substances, a REACH-style program, I think would likely kill innovation in the U.S. and is a real recipe for ham stringing small and medium sized manufacturers in particular.

No. 3, assuming REACH is the wave of the future is entirely premature and could actually impair human safety by preventing critical products, helpful products in terms of safety from entering the marketplace.

No. 4, if the EPA decides to use any given study as a reason for limiting of terminating the use of a certain chemical, the results of that study need to be repeatable and proven in further supporting studies.

And No. 5, if the EPA is going to decide to utilize resources to re-review a chemical prior to the necessary mandated review period, that review sure as heck should be based on sound science and not just a New York Times article that uses politicized science from an environmental group. I am particularly talking about the atrazine episode. I think what I just said is a fair characterization of that, trying to scare the public.

So I look forward to this discussion. I will be keeping those principles in mind as we have the discussion and work on the bill, and thank you, Mr. Chairman.

Senator LAUTENBERG. Thank you, Senator Vitter.

Senator Whitehouse, welcome.

OPENING STATEMENT OF HON. SHELDON WHITEHOUSE, U.S. SENATOR FROM THE STATE OF RHODE ISLAND

Senator WHITEHOUSE. Thank you, Chairman.

First of all, let me thank you for holding this hearing and for your continuing and determined interest in protecting Americans from the onslaught of new chemicals that are turned out year after year after year after year, and whose use in our food supply and in our medications and in products that children and seniors and all Americans have access to is poorly enforced. We are way, way, way, way behind. We have a chemical safety deficit in this country, and we need to catch up. You are one of the most determined leaders in this, and I am delighted to join you at this hearing.

Senator LAUTENBERG. Thank you very much for being with us.

I now would like to start hearing from our witnesses. I will tell you in advance that votes are scheduled on the floor of the Senate. We are going to have to defer at some point. So we will try to move things along. If we do have to recess, I would ask your patience and your participation. It is not a scheme to keep us from being heard, I can tell you that.

So I would like to call first on Ms. Fisher. Ms. Fisher is Vice President for Safety, Health and Environment for DuPont; Mr. Williams, Vice President, Construction Specialties; Ms. Bosley, Managing Director of Boron Specialties, testifying on behalf of the Society of Chemical Manufacturers and Affiliates; Dr. Hawkins, Vice President for Environment, Health and Safety at Dow Chemical; Charles Drevna, President of the National Petrochemical and Refiners Association; and Ms. Kathy Gerwig, Vice President for Workplace Safety with the Kaiser Foundation Health Plan.

We ask you to present your testimony within 5 minutes. If it breaks the rule a little bit, we will be kind. Otherwise, the punishment is too difficult to discuss in public here. But please try to keep your remarks to 5 minutes.

Ms. Fisher, we invite you to speak first.

STATEMENT OF LINDA J. FISHER, CHIEF SUSTAINABILITY OFFICER, DUPONT

Ms. FISHER. Thank you, Senator Lautenberg.

My name is Linda Fisher, and I am currently Chief Sustainability Officer for DuPont. As you know, I spent many years at EPA, including managing the Office of Pesticides and Toxic Substances.

I have had the opportunity recently to be very involved with the American Chemistry Council's review of TSCA, and I fully support the recommendations that they have put forward.

DuPont is a diverse, 208-year-old company. We use a wide variety of chemicals to make products for markets that include agriculture, buildings, transportation, electronic goods and consumer products. We believe it is time to update TSCA.

Now, this is a shift in the position that industry has taken over the past several years, and there are a few reasons for that change. I bring these reasons to the Committee because they really have started to shape how industry feels about TSCA reform.

First of all, there is a growing awareness in the public, as you mentioned, Mr. Chairman, about the exposure to chemicals through products. That concern is being felt in the marketplace as consumers exercise their own buying decisions.

Second, chemical regulation is rapidly moving across the globe to countries including China and Canada and the European Union. Some of these regulatory schemes are imposing significant administrative burdens on companies. They will soon result in the generation of substantial amounts of data and risk management decisions that will have global impacts.

We should not cede to the European Union or China or any other country the responsibility to set global chemical policy. The U.S. should lead on sensible, risk based and cost effective environmental policymaking.

Third, in the absence of reforms to TSCA we are seeing evolving State programs and chemical-specific actions that are quite honestly creating a lot of uncertainty in our marketplace. As with every environmental legislation, I am sure we will have a big debate over preemption. But I think we all know that if there is a strong, Federal regulatory review of chemicals, the kind that will build confidence in the public, there will be much less incentive for the States to act in this important area.

In a reauthorized TSCA we need a regulatory program that provides greater public and market confidence in the safety of our chemicals with more timely, predictable and transparent decisions by EPA. Modernizing TSCA will be difficult and complex. It is important that we get it right with a deliberative stakeholder process.

And Mr. Chairman, I do want to compliment you and your staff for reaching out to those of us in industry and listening to our concerns.

Let me highlight some of the key elements of modernizing TSCA. Data gathering under TSCA is currently cumbersome and time consuming. A modernized TSCA should allow EPA to get the data they need when they need it. We hope that they would leverage the data that we have generated from industry and the data that will be generated through the REACH program. Then if there are data

gaps we would ask that EPA have the authority to collect that authority as quickly as they need to.

We also would like a statute and regulatory program that minimizes animal testing and again makes data available to the public.

EPA should be directed, under new language, to systematically assess existing chemicals on a prioritized basis to evaluate the safety of exposures associated with those uses and to make risk based decisions, integrating both hazard and exposure. But what should happen after EPA completes its safety assessment? Under TSCA section 6, it has proven quite difficult for the agency to address exposures to specific chemicals where it is warranted. EPA should have a range of risk management tools that would allow them to reduce exposures to appropriate levels in the most cost effective manner. That would include reducing exposures from plants, improve manufacturing controls as well as restrictions on particular chemical uses.

In doing so, EPA could reduce unacceptable levels of exposure by those actions that are most cost effective and that best preserve the beneficial uses of chemicals.

We hope that Congress will avoid presumptive bans and rigid, prescribed legislative phase-outs of chemicals. We think that that ignores risk and most importantly, ignores the realities of transitioning to new products to receiving needed consumer and regulatory approvals and modifying manufacturing facilities to bring new chemicals to the market. Such actions could lead to unnecessarily disrupting markets and reducing public access to important products in the marketplace.

The agency should focus on, again, the most effective ways to reduce exposures and to target areas of concern to the public. Along with changes to the PMN program and the CBI provisions of TSCA, which I talk about in my testimony, we think these measures would constitute a significant change in how EPA regulates chemicals and will build confidence in the public in the safety of the products that they use every day.

I thank you for the opportunity to speak with you this morning. Many in industry again recognize the need to reform TSCA. The time has come to bring our statutes in the U.S. more on par with what is going on in the rest of the world. It will be challenging. It is going to be difficult process for both industry and the Government. But we do look forward to working with you as you amend the statute and with EPA as they move to implement the program.

I thank you.

[The prepared statement of Ms. Fisher follows:]

STATEMENT OF LINDA J. FIISHER
CHIEF SUSTAINABILITY OFFICE, DUPONT
BEFORE THE SUBCOMMITTEE ON SUPERFUND, TOXICS AND ENVIRONMENTAL HEALTH
OF THE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE
MARCH 9, 2010
BUSINESS PERPECTIVES ON REFORMING U.S. CHEMICAL SAFETY LAWS

Chairman Lautenberg, Senator Crapo and members of the committee, I am happy to be here to talk about the important issue of modernizing US chemicals policies. My name is Linda Fisher and I am the Chief Sustainability Officer for DuPont. Some years ago, as the Assistant Administrator of the Office of Pollution Prevention and Toxic Substances and then Deputy Administrator of the Agency I had the privilege of working with the staff of EPA to implement TSCA. At DuPont I work with a group of equally dedicated professionals to assure that our products are safe. I am also actively involved in TSCA reform discussions at the American Chemistry Council and fully support ACC's reform principles.

DuPont is a broadly diverse 208 year old company. In addition to our agricultural seed and crop protection businesses, we use a wide variety of chemicals to make products for markets that include buildings, transportation, electronic goods and consumer products. We operate in 70 countries around the world under a variety of chemical management regimes. In the US alone we are regulated in some manner by EPA under both TSCA and FIFRA, USDA, FDA, and the Consumer Products Safety Commission. We also operate a global product stewardship process inside DuPont that assesses and manages the safe use of our products in commerce.

For years DuPont viewed the current TSCA as an appropriate tool for the regulation of industrial chemicals. However, as our own practices have evolved over time TSCA has not. And so our views of the need to update US chemical policies have evolved. Why? First there is growing public awareness of exposure to chemicals not only through environmental emissions but also through products. This has raised questions in the public's mind about the safety of those products, and that is having an effect on the market through consumer buying decisions. Secondly, chemical regulation is rapidly changing across the globe. Witness REACH, the new Canadian Chemicals Management Program and China's recent announcement of revisions to their chemicals program. For those of us who operate in the US or sell our products here it is important that our regulatory system keep pace and our government be a leader in global chemicals policy. And, of course, in the absence of reforms to TSCA we are seeing a plethora of State actions that are serving to create tremendous uncertainty in our markets. While there is a long standing tradition of both innovation and encouraging Federal action in State policies, we think a robust reformed TSCA would remove the motivation for state by state regulation of chemicals.

And so we believe that US chemical management practices, including TSCA, should be modernized, and intend to play a constructive role in seeking effective reforms. We have worked with a lot of different chemicals during our history and we have seen changes in public and marketplace expectations.

We have been responding to these changes for some time as well, using these trends to inform our innovation process. DuPont has become a leader in sustainability and green chemistry. We won the President's Green Chemistry Award for our biomaterial Bio-PDO™, a chemical produced from agricultural material instead of oil. Bio-PDO™ allows our customers Mohawk to market Smartstrand bio-based carpets and Killfrost to sell bio-based airplane de-icers. Our products are increasingly at the heart of solar photovoltaic cells, fuel cells, windmills and building and vehicle energy efficiency technologies.

The products of chemistry are some of the most actively traded materials in commerce. We operate globally under a variety of regulatory regimes, including the EU, where its modernized program REACH is coming into effect, and the Canadian Chemicals Management Program, where risk management decisions are currently being made for the highest priority chemicals. We are seeing chemical programs being updated in Australia, Turkey, Taiwan and China. Thus we face the challenge operating a global supply chain and market in the face of multiple regulatory regimes at different stages of development. We are also gaining experience with the significant administrative burdens of REACH, the large amount of data these programs will generate in the coming years, and the complexity of gathering all of the necessary data for chemical assessments from the wide variety of actors in the chemicals and materials value chain.

We do not believe it is wise to cede to the EU or China the responsibility to set the policies that will guide commerce in chemicals. We need to ensure the US chemicals management regime works with those frameworks and can take advantage of the data that will flow from them, while ensuring that the US continues to lead on sensible risk-based and cost effective environmental policy making. We also need a robust national framework for chemicals regulation that is predictable and manageable. State by state bans, restrictions, phaseouts and substitutions create a fractured and unpredictable market that makes it increasingly difficult to operate in the US. It is not often an industry asks to be regulated in a more comprehensive way, but that is precisely what we are asking for – regulations that provide greater public and market confidence in the safety of chemicals in commerce, greater predictability and greater transparency.

Modernizing TSCA is an important undertaking. It will also be a difficult and complex undertaking. The products of chemistry touch almost every corner of our economy, including buildings and their furnishings, electronics goods, advanced energy technologies, trains, planes and automobiles and consumer products. The economic breadth of chemicals policies are not unlike climate change legislation in their scope and complexity. It is important that we get this right, and that will mean a deliberate and thoughtful process that engages a wide variety of stakeholders. We have already begun that process ourselves, talking to NGOs, other companies, trade associations, EPA and

the Congress as we think through how best to reform TSCA. Getting it wrong could impede one of the US economy's engines of innovation and erode US competitiveness and employment.

Let me highlight some key elements that need to be on the table as we discuss modernizing TSCA. Broadly those fall into the categories of data and safety assessments, and what we do to ensure safety. I'll address each in turn.

TSCA does not currently require EPA to systematically assess existing chemicals. This has generated public concern about whether we know enough about the chemicals that we are exposed to every day. Moreover, current data gathering tools under TSCA are cumbersome and time consuming and the authorities it does have to identify and act on chemicals that pose concerns have proven difficult to implement. A modernized TSCA should include a streamlined approach for EPA to gather the data they need. We believe that chemical producers and our value chain partners need to provide adequate data to allow EPA to assess the safety of chemicals in use and to develop suitable risk management approaches. Today EPA's tools for data gathering are too cumbersome and slow, and if the new system is going to serve its purpose EPA needs the ability to promptly require industry to provide right data at the right time. EPA and companies should leverage existing data and data arising from other programs like REACH first, and then fill data gaps as necessary to make prioritization decisions and complete assessments. It is estimated that some five to nine thousand dossiers containing useful information will be submitted next year alone under REACH, with more submitted in 2013 and 2018. Where more information is required we should strive to minimize animal testing where there are tools to get adequate data with other means. We also believe that more data needs to be available to the public.

Revisions to TSCA should require EPA to work its way through the prioritized chemicals, assessing the safety of exposures associated with their uses. These assessments need to be risk-based and look at chemical hazard data of sound quality and the exposure data associated with the uses of the chemicals, integrating those into a picture of the safety of those exposures.

Perhaps the biggest question is what happens after the safety assessment. One of the most challenging parts of the current TSCA is the ability of the Agency to achieve timely risk reductions under Section 6 when faced with the need to reduce or eliminate exposures to a specific chemical. Although well intended by its drafters, the process under Section 6 has proven next to impossible for the Agency to successfully implement. This will be an area of significant debate and controversy as the Congress begins to reform TSCA. EPA should have a range of risk management tools at its disposal to reduce exposures to appropriate levels in a cost effective manner, including reducing plant emissions, improved manufacturing controls, and restrictions on chemical uses. In some cases even bans of specific uses of a chemical may be warranted to protect public health – after the proper risk-based assessment. It is important that the imposition of exposure controls be done so that safety is assured, but it is also important this be done in a cost-effective manner. Because exposure can occur through a variety of sources such

as plant emissions and waste management, not just products, EPA should seek exposure reductions where they are most cost-effective and best preserve beneficial uses of chemicals.

As it contemplates exposure reductions it is important that the agency be required to take into account the societal benefits from the use of chemicals and the time and complexity of bringing substitutes to market. We urge Congress to avoid presumptive bans or rigid phaseout schedules. Bans and deadlines for phaseouts or substitution fail to account for the realities of transitioning to new ingredients, receiving needed customer and regulatory approvals and modifying manufacturing facilities. Such actions could lead to unnecessarily disrupting markets, reduce public access to valued products and cede markets to global competitors.

Let me illustrate with two examples from DuPont's own experience. In the late 1980s, when we came to understand the chlorofluorcarbons, or CFCs, depleted atmospheric ozone, we committed to phasing out such ozone depleting substances. That effort took two successive large scale technology transformations and is still underway. It won't be substantially complete until 2020 – some thirty years after we started. And the Montreal Protocol under which we achieved this is widely viewed as one of the most successful environmental efforts of the last fifty years.

More recently we decided to cease use of a chemical that served as a manufacturing processing aid – it was not even an ingredient, and to change our chemistries that might create the chemical as an unintended byproduct. This was a voluntary action, global in scope, reflecting our business practices and market demands. It required millions of dollars to develop substitutes, and we are not done yet. It has required us to reformulate about 125 products. Another 30 or so products we simply dropped because of the cost to reformulate. We had over ten thousand individual customers to work with that spanned global markets including automobiles, aerospace, pharmaceuticals, textiles, paints and coatings and consumer products. We work with each customer to assure that the new product meets their specifications, a process that has taken six months to five years per customer depending on the application. We had to seek and receive over 70 product registrations from various regulatory agencies. Over 300 of our scientists, engineers and business people have been working on this for several years, and it has required $200 million in R&D investments and another $100 million in capital investment. It will take us at least eight years to complete. And this is for one processing aid that was never present in products above trace levels. While this new product development was underway, we achieved significant exposure reduction for this chemical by imposing process controls to dramatically reduced emissions from our plants.

I offer these examples to illustrate that removing existing chemicals from the marketplace is neither simple nor quick. Arbitrary timeframes for phaseouts simply will not work. Because exposure typically occurs from multiple sources, the Agency should focus on the most effective exposure reductions targeted to the risk at hand.

These steps will focus on existing chemicals, those were already in commerce when TSCA was enacted and were "grandfathered". But what about new chemicals? In order to facilitate innovation, increasingly bring green chemistry to market and allow substitution where warranted, we should preserve the ability of the pre-manufacturing notice, or PMN system, to provide a timely review of new chemicals. PMNs are often submitted at an early stage of development. EPA reviews the hazard and projected exposure information submitted as part of a PMN with a team of scientists, engineers and toxicologists, and applies a variety of evaluation tools. EPA has broad authority to reject or approve a new chemical with restrictions, such as imposition of use restrictions and/or production volume limits. The PMN program has been successful in allowing companies to explore the commercial viability of a new substance while allowing EPA to address any concerns through imposition of restrictions. This flexibility has helped to make the US a leader in chemistry innovation while providing EPA a strong role in the safety of new substances, and we need to preserve this ability. In particular, if we want to incent green chemistry, we need for it to be easy for producers to get new products into initial commercial application.

However, EPA should also have clear triggers that ensure that after receiving a PMN, if a new chemical enters the market and its production volume increase significantly, its uses expand, or at regular chemical inventory updates, it goes into the prioritization and assessment system for existing chemicals.

The issue of confidential business information, or CBI, has received a lot of attention. The ability to preserve legitimate CBI and prevent piracy of intellectual property is critical to competitiveness and innovation. There is active commercial and governmental industrial espionage seeking to steal trade secrets that needs to be recognized – if we simply give innovation away there is little reason to innovate. That said, I think everyone agrees that the CBI program is in need of review. At the time TSCA was written there were no relevant State agencies and other national or regulatory chemical regulatory programs did not exist. Sharing data with government peers wasn't an issue. Today, we believe there are some straightforward means to improve the CBI process.

Intergovernmental sharing of CBI data with proper protections, whether between state and federal governments or nation to nation, should be facilitated. Because CBI claims have not traditionally been systematically reviewed, it is certainly possible that some claims aren't as rigorous as they could or should be. Simple steps to require enhanced company certifications of claims, greater EPA review of claims, and the need to occasionally recertify claims would all drive more rigor that would help ensure only truly CBI info gets claimed for protection.

These measures would constitute a significant change in the US chemical regulatory regime. It would expand some authorities that are discretionary today, such as requiring a mandatory and systematic process for reviewing existing chemicals, and give EPA more tools to address chemical exposures where appropriate. It will require significant efforts on the part of companies and the government. It will produce significant amounts of information for the public to digest and for EPA to manage.

In closing, I thank you for this opportunity to share our views. Many of us in industry recognize that the time to modernize TSCA has come and that the United States needs to have the tools to be a leader in global chemicals policy. It will be a challenging undertaking, as the chemical industry is very complex. It is globally competitive with thousands of participants. We look forward to working with you on this effort. It is our sincere hope that we can continue a broad collaborative process amongst stakeholders to achieve legislation that brings TSCA into the 21st century.

I look forward to your questions.

Senator LAUTENBERG. Thank you.
Mr. Williams.

STATEMENT OF HOWARD WILLIAMS, VICE PRESIDENT, CONSTRUCTION SPECIALTIES, INC.

Mr. WILLIAMS. Thank you, Chairman Lautenberg, Senators, staff, Committee.

I am Howard Williams, Vice President and General Manager of Construction Specialties, Pennsylvania division. We are a small multi-national. We are about $300 million a year, 1,600 staff across the world, operate from 25 sites in 19 countries. So being able to compete from all of those sites is very important to us.

Equally important, too, is that we are in the construction market that is 14 percent of our gross domestic product. Within this marketplace, TSCA reform has an opportunity to inform and to enlarge the architectural building product market.

Elimination of persistent and bioaccumulative toxins is at the forefront of our built environment purchasing programs, building construction programs, for both private as well as what is going on within the Government sector. Federally mandated environmental preferable purchasing looks at PBTs, as do the LEED green building standards by which most of our Federal buildings, State and private buildings are constructed.

Broad based adoption of these green building standards has resulted in really very well documented and unprecedented benefits to the economy, to human health, as well as our environment. The same engine, this construction market engine that produced these results has an opportunity to greatly benefit human health as we go forward with a new chemical program.

A side note example is that in 2003 Kaiser Permanente, one of our very largest customers, came to us and said, if you would like to continue to sell product to us—and they are a major customer—then you need to develop a product that has no polyvinyl chloride in it, or risk losing our business. Within a year's time, we managed to do that. It is a product that the health care product as a whole embraced.

Now here we are 7 years later, we have been able to develop a PBT-free product that coincides with where the marketplace is at this time.

So awareness and materials chemistry within the construction market are rapidly expanding. For almost every building product with perhaps the exception of a two by four, chemistry is involved within that building product. The consumer awareness of what is going on with chemistry, they are making their decisions of what is going on, where they are buying off the shelf. But they really don't have a lot of opportunity to make the decision as to what is in the chemistry in their homes or in the hospital rooms or in their children's schools. That chemical effect, or that chemical question, is now embedded in a number of building standards, LEED green building products, Green Guide for Health Care, the Collaborative for High Performance Schools, and Practice Green Health.

The consensus based programs that answer these questions started off looking at off gassing and then made a rapid move to looking at, let's eliminate what is off gassing. They reject some of

the toxic effects. The best practices that they have developed are in harmony with executive orders. They are also in harmony with Federal purchasing standards. It is a time of people benefit environmentalism, and TSCA reform has an opportunity to weigh in very heavily on that.

Just within the green building product market, the green building product market is about a $10 billion per year marketplace. So we do need a clear identification of chemicals of high and low concern. We need—as manufacturers, we need reliability of that information. We need greater disclosure of chemicals of high concern so that we can make our product development questions, we can answer them and we can take that information to our specifiers.

I know that there are, certainly, within everyone's paths, some non-chemical hazards here. From a business standpoint, I think easing some of us into reform by giving us an opportunity to disclose things to perhaps a third party that we don't want to show to our competitors. This confidential business information I know is at the forefront of a question mark here. But I think the reality is, manufacturers need to have that opportunity to either disclose it or disclose it to a third party so they can product their information.

The NGOs that are involved—the NGOs are the voices of those of all of us, if we had the time to study and to personalize this information. The NGOs are saying the same things that we would be saying: it affects our lives, it affects our children.

The other part is, as a taxpayer, I would really prefer that, as a taxpayer, I not have to pay for this, that it be a part of—we in industry have the profit opportunity; we in industry should bear the expense and let the consumers make the decisions.

So reform, again, just making data available to us, identifying the chemicals of high concern and low concern, so that we all know what is safe and what is good. I would say that the buildings industry is really in a position today to partner with Federal Government and to help make this happen. Standards are being developed and emerging every day that work toward this, a high identification and a high level of change.

So I thank you for inviting me to testify today.

[The prepared statement of Mr. Williams follows:]

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

Re: Oral Testimony of Howard Williams, Construction Specialties, Inc.

Thank you Chairman Lautenberg, Senator Inhofe and Members of the Subcommittee for inviting me to give this business perspective.

I'm Howard Williams, V.P. & General Manager of the Pennsylvania division of Construction Specialties.

We're a privately owned US Company with worldwide revenues of $300MM and a staff of 1600.

Headquartered in Lebanon, NJ, we operate from 25 sites in 19 countries where we develop and manufacture architectural building products for nonresidential construction.

Construction accounts for over 14% of our GCP and TSCA reform has the potential to inform and support this powerful and profitable segment of our economy.

The elimination of PBTs from our built environment is at the forefront of materials purchasing and building standards for private and governmental programs.

Federal Environmentally Preferred Purchasing standards address PBTs as do the LEED, green building, standards by which our government buildings are constructed.

The broad-based adoption of LEED standards has resulted in unprecedented and well-documented benefits to our economy, our health, and our environment.

The same engine that produced these gains will deliver its share of occupant health benefits with the help of TSCA reform.

In 2003 Kaiser Permanente advised that we had one year to convert our PVC products to a non-PVC material or risk losing their business.

That led to a 2nd generation product that answered a growing demand from the healthcare sector.

We now have a 3rd generation product that is PBT-free.

Awareness of materials chemistry and the associated health affects is rapidly expanding within our market sector.

For most building products, aside from a simple 2 X 4, materials chemistry is inescapable.

Consumers are aware of the chemical affect in off-the-shelf products, and make their purchases accordingly, but few are in the position to choose the materials in their children's school, their hospital room, their workplace, or residence.

That chemical affect is now embedded into the building industry's best practices such as LEED, Green Guide for Health Care, Collaborative for High Performance Schools (CHPS), and Practice Green Health.

These consensus-based best practices have expanded beyond the early concerns about the off-gassing of chemicals, to further reducing exposure by eliminating PBTs.

They reject toxic additives that make plastics flexible or to meet fire codes, and disqualify concrete made with fly ash from a hazardous waste incinerator.

These best practices are in harmony with Executive Orders and Federal Purchasing standards.

In this time of people-benefit environmentalism, TSCA Reform will find the buildings industry ready to receive and broadly distribute its benefits.

We have a $10B per year green building product market.

We need a clear identification of chemicals of high and low concern to human and environmental health. Identify chemical constituents down to levels of 100 PPM so product manufacturers and end users can make informed decisions.

Reliability and clarity of information greatly affects speed to market for new products.

Greater disclosure of chemicals of high concern in products is essential. Specifiers and buyers are needlessly spending too much time trying to get answers about the stuff that's in the products they're buying.

Complying with our own Chemicals Policy, namely, **Know and Disclose,** in the PBT-free development of our 3rd generation product was challenging but essential because the seller's responsible, not the buyer.

There are non-chemical hazards in your path.

Ease some into the Reform; create a way for them to disclose to a credible 3rd party the confidential information that they don't want to reveal to their competitors.

Use 3rd party certifications from independent organizations meeting strict evaluation standards such as MBDC, Green Seal, TURI at UMass, and UL to legitimize the result and create private sector jobs.

Listen to the voices of the NGOs; they're not the enemy in this struggle. Their voices speak of what we'd all say if we took the time to research and personalize this matter.

Don't make the taxpayers pay for developing hazard, use and exposure data. Industry should pay; we have the profit opportunity and we should carry the cost.

Reform should include making the data available, identifying chemicals of concern, and promoting safer alternatives through Green Chemistry.

Reform in ways that reduce causation, improve life, and lower healthcare costs.

You, and the buildings industry through existing and emerging standards, have an opportunity to protect millions from building-related PBT exposure, while accelerating product innovation, job creation and economic growth.

Thank you.

Environment and Public Works Committee Hearing
March 12, 2010
Williams Response to Follow-Up Questions

Senator Barbara Boxer

1. Please describe whether federal policy that ensures chemical manufacturers provide the public and business with basic safety data on their chemicals would help Construction Specialties make better choices about purchasing appropriate products for its business.

Williams

1. Assuming the definition of "basic safety data" includes a complete inventory of the chemical content to 100 ppm, such would not only be helpful, but also a cost savings to us/others. Disclose once and it's useful to all; make everyone do independent research and unnecessary cost is added to the selection process. Costs to us that our European competitors may not incur under a more transparent EU policy. Help US companies compete globally.

Senator Barbara Boxer

2. Does Construction Specialties believe that reducing the use of toxic chemicals makes good business sense?

Williams

2a. Yes, reduction is essential. I think we're moving into a time of people/health-centered environmentalism and that bodes well for all of us. Toxic chemical reduction, whether resulting from legislative reform, consumerism, or businesses acting responsibly, will address causation and greatly contribute to an improved quality of life and reduced healthcare costs.

Environment and Public Works Committee Hearing
March 12, 2010
Williams Response to Follow-Up Questions

Senator James M. Inhofe

1. In your testimony, you make several references to circumstances where you consumers' preferences have driven the marketplace, I like that idea. Yet, you seem to base your support for TSCA reform on skepticism about the safety of certain chemicals found in products sold and used by your company.

   Is your concern about these products based on your own scientific expertise in chemicals and toxicology, or is based on news reports, information from activists' campaigns and/or consumer fears?

Williams
1a. My support for TSCA reform, as witnessed by my testimony and its accompanying documentation, was not intended to give cause to think I'm skeptical about the safety of certain chemicals found in products sold and used by our company.

1b. I'm a businessman and gave testimony on basis of my expertise as to the work done by our company and the markets we serve; I'm not a scientist, nor do I have expertise in chemicals or toxicology.

That aside, I know we both find the word, "toxic" fairly easy to understand, and not something we'd knowingly hand to our grandchildren.

But what does it mean relative to we non-scientists who manage companies and make things?

1c. My business interest and reading on this topic began in 2003. I've read white papers, opinions, news, talked to experts from the chemical & plastics industry, talked to activists, learned from each/all seeking to know how this affects building product design and use. When all of it is processed, I think our customers, the independent scientists, and the activists' arguments present credible reasons for the reduction even elimination, of toxic chemicals. Healthy products contribute to the health of people.

More specifically:

Some of the "activists" are our customers; as that term may describe Kaiser Permanente, Catholic Healthcare, Perkins-

Will Architects and hundreds of healthcare facilities, secondary schools, designers and architects as forceful activists for the reduction/elimination of PBTs.

Approximately 1000 Healthcare facilities from Coutersport, PA to Edmond & Ft. Sill, OK are members of Practice Greenhealth[1], an organization that some may call activistic, but I see as a group of highly informed customers to whom we should listen.

"Consumer fears" would say fear mongering is afoot, and if one reads/listens to only one side of an issue it would certainly affect their perspective. I would argue that consumer knowledge is the driving force within the markets we serve.

Senator James M. Inhofe

2. You suggest that EPA should identify all chemicals found in products at levels above 100 parts per million.

Please explain for me the scientific justification behind why you suggest 100 parts per million as a regulatory marker for all chemicals in the marketplace.

Williams
2a. Not being a scientist, to me, it's simple math. 100/1,000,000 tells us 99.9% of what's in the material/product and we can make critical decisions early in the product development process.

2b. Scientific justification: (my assumption = they know what they're doing)

- 100 ppm is a marker by which intentional toxins are identified and limited in packaging.[2]
- The Consumer Product Safety Improvement Act's lead level marker moves to 100 ppm on August 14, 2011.[3]
- McDonough Braungart Design Chemistry[4].

[1] Practicegreenhealth.org
[2] Toxicsinpackaging.org

[3] cpsc.gov
[4] mbdc.com

Senator James M. Inhofe

3. When you were developing your PVC-free product to align with your customers' demands, what steps did you take to ensure yourself, scientifically and legally, that the substitute chemical was in fact safer and did not pose a different set of equally unacceptable risks?

Williams
Insightful question. I share the concern that I think is behind your question. Always listen to the market, but do your homework and be certain the step you're taking is truly beneficial.

We approved the alternate product based on the following:
3a. Our scientific decision was based on the findings of an Assessment of the Health Risks specifically commissioned for our product and application. 2 Ph.D. scientists prepared it; one is a Board Certified Toxicologist. Consulting on the Report were industrial and environmental safety experts.

3b. We also commissioned McDonough Braungart Design Chemistry to assess the product without giving them the benefit of the above findings. They concluded the product safely met their requirements for Cradle-to-Cradle Silver Certification.

Senator Boxer, Senator Inhofe, thank you for giving me the opportunity to add further comment to this important question/legislation.

Respectfully submitted,

Howard Williams

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

Ms. Bosley, we will hear from you, please.

STATEMENT OF BETH D. BOSLEY, MANAGING DIRECTOR, BORON SPECIALTIES

Ms. BOSLEY. Good morning, Chairman Lautenberg and members of the Subcommittee. I am pleased to testify before you today on behalf of the Society of Chemical Manufacturers and Affiliates.

Since 1921 SOCMA has served the batch chemical industry with over 300 member companies. Those companies are usually small or medium sized businesses. We make a $60 billion impact to the U.S. economy, and we contribute to the chemical industry's position as one of the Nation's largest exporters.

First, I need to state that no one in the chemical industry wants a chemical that they manufacture or produce to cause harm to human health or the environment. Our families live in the communities near our plants, and we use the thousands of products that are made possible by modern chemistry.

Chemical innovations benefit many U.S. industries and enhance American competitiveness in global markets. Without U.S. based innovations, advantages such as lightweight transportation components, low emission paints and detergents that work in cold water would not be possible today. Our Nation's ability to reduce its carbon footprint will also depend heavily on the technology and innovation from a vibrant chemical industry.

The United States leads chemical innovation and is a leader in research and development, improved manufacturing techniques and process safety advances that are designed to reduce the impact of chemicals on human health and the environment. Our position as exporter and innovator is threatened by sharply increased competition from countries with lower resource costs, lower wage standards and lax regulations. This is more than an economic threat. Losing our manufacturing base to these developing countries does not make the American public safer. We need only read the headlines to find examples where foreign manufacturing has increased risk to U.S. individuals and decreased public confidence.

Modernized chemical regulation must take into account American industrial competitiveness not only to avoid losing jobs but also so that production is not pushed beyond the reach of U.S. law.

Many TSCA critics point to REACH legislation as a model for TSCA reform in the United States. But REACH is fundamentally flawed in that it does not prioritize by risk. Therefore, a low risk chemical will be screened with the same priority as a high risk chemical in the same volume threshold.

In contrast, Canada, through its use of a categorization and prioritization process, was able to demonstrate that over 80 percent of the chemicals in commerce in Canada did not present undue risk to human health or the environment. This approach allowed Canada to then systematically assign to the remaining chemical substances a priority for more in depth review.

Two principles are essential to a sustainable chemical management law that won't eliminate jobs or deter economic growth. TSCA priorities should be established based on risk, and emphasis should be placed on existing authority.

Basing priorities and regulatory criteria on scientific evaluation of hazard and exposure factors is critical. If a chemical is highly toxic but used only in strictly controlled industrial environments, then the risk to public health is readily manageable.

One mechanism needed first is an inventory reset, which was part of EPA's ChAMP program. Of the over 80,000 chemicals now listed on the inventory, EPA estimates that only about 20,000 of these are presently in commerce.

Another TSCA mechanism that has worked is EPA's New Chemicals program. They have successfully reviewed 35,000 chemicals without impeding innovation that is crucial to American competitiveness. Through this program, manufacturers submit pre-manufacture notices, and these chemicals undergo a risk based review by EPA. The fact that limited data is available during the PMN process can be expected given the early stage of development during which the PMN must be filed. This does not mean that the manufacturer has stopped testing, or it is selling products with inadequate health and safety data.

EPA has pioneered efforts using modeling and Structure Activity Relationships to help inform agency decisions. The scientists at EPA are extremely knowledgeable, and they make regulatory decisions based on conservative interpretation of their model data. Studies show that EPA's extensive modeling capabilities align closely with or are more conservative than measured test data.

It is important to emphasize that EPA is not limited to existing data and models when reviewing new chemicals. They have the authority to require companies submitting PMNs to generate and submit specific health data, and they have done so when they felt information was needed.

SOCMA members are proud of our track record in protecting our workers and communities. We favor a regulatory model that builds on the effective public-private relationship between EPA and industry to assess and manage chemical safety.

In summary, this model should involve risk based prioritization, proven regulatory mechanisms and existing authority. EPA should not be burdened with the determination that each chemical is safe for its intended use, and above all EPA needs adequate funding. The biggest weakness in the TSCA program today is lack of resources, not lack of authority.

I would like to thank you for the opportunity to discuss this pragmatic approach, and I look forward to your questions.

[The prepared statement of Ms. Bosley follows:]

Society of Chemical Manufacturers & Affiliates

Testimony
of
Beth D. Bosley

Managing Director
Boron Specialties

On behalf of the

Society of Chemical Manufacturers & Affiliates

Before the

U.S. Senate Environment and Public Works Committee
Subcommittee on Superfund, Toxics and Environmental Health

On

"Business Perspectives on Reforming U.S. Chemical Safety Laws"

March 9, 2010

1850 M Street, NW • Suite 700 • Washington, DC 20036
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Society of Chemical Manufacturers & Affiliates

Good morning, Chairman Lautenberg, Ranking Member Inhofe, and members of the Subcommittee. My name is Beth Bosley, and I am the Managing Director for my company, Boron Specialties in Pittsburgh, Pennsylvania. I am pleased to testify before you today on behalf of the Society of Chemical Manufacturers and Affiliates (SOCMA) regarding the Toxic Substances Control Act (TSCA).

Since 1921, SOCMA has served as the leading trade association representing the batch and custom chemical industry. SOCMA has roughly 300 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.

TSCA Should be Modernized in Ways that Do Not Seize Up the Engine of Innovation

As we testified before a House subcommittee twice last year, SOCMA supports EPA's – and Congress's – fundamental goal of protecting human health and the environment from harmful chemical exposure. SOCMA members are prepared to continue doing our part in that effort. We are pleased to have this opportunity to share with you our perspective on reforming US chemical safety laws.

First, let me state that no member of the chemical industry, from the CEO at a Fortune 100 company, to the scientists developing new technologies, to the operations personnel at a start-up company, want to have a chemical they produce cause harm to human health or the environment. Through their proprietary ChemStewards initiative, SOCMA members take great care to ensure that their products are appropriately manufactured, tested, packaged, shipped, and used responsibly. Our results of our commitment to product stewardship and process safety are evidenced by the decreasing trends in releases, process upsets, and transportation incidents.

SOCMA members agree that TSCA can be modernized, and that our chemicals policy goals can be accomplished in a way that doesn't devastate a strategic American industry that is already fighting recession and foreign competition. Chemical science innovation, as an enabling technology, benefits many US industries – aerospace, advanced materials, agriculture, pharmaceuticals, electronics, and telecommunications (among many others) – making these industries better able to compete in the increasingly global marketplace. Without such US-based innovations, advances such as lightweight transportation components (a major factor in increasing fuel economy), low-emission paint (resulting in a safer consumer environment), and detergents that work in cold water (resulting in lower energy usage) would not be available today. Our nation's ability to minimize its carbon footprint will also depend on technological innovation – premised on chemistry. Needless to say, all these advances of chemistry also contribute to Americans leading longer and healthier lives.

The US still leads chemical industry innovation; of the roughly 60,000 patents attributable to chemical sciences issued over the past 5 years, 35,000 of them are authored by US entities. US industry also leads the world in research and development of new chemical substances, better manufacturing techniques, and process safety advances designed to minimize the impact of chemicals on human health and the environment.

However, the US chemical industry's competitiveness has decreased substantially in recent years due to competition from countries with lower resource costs, lower wage standards, and a less burdensome regulatory environment. Shifting production to these developing countries does not make US citizens

safer – we need only read the headlines regarding lead in children's toys and sulfides in foreign manufactured drywall to find examples where offshore manufacturing has increased risk to US individuals and decreased public confidence. Of course we need protective chemical regulation, but it must be well-informed regulation, so that we maximize the improvement in our quality of life and minimize damage to US industry's competitiveness.

Canada's Model Is Worth Emulating; Europe's Is Not

Many TSCA critics point to the REACh legislation as a model for the United States. The REACh system is an overly burdensome regulation that, by most estimations, will cost jobs within the EU. REACh is fundamentally flawed in that there was no risk prioritization prior to commencing the initiative. Therefore, a low risk chemical (one that may exhibit some hazard, but very low probability of exposure, for instance) that is produced or imported at a volume of 25,000 lb/year will be screened with the same priority as a high risk chemical (one that is used in consumer products, for example) that is manufactured or imported at the same, or even a higher, volume threshold. According to the European Chemicals Agency, REACh testing costs for a product manufactured at 25,000 lb/year can be expected to reach $150,000. That cost could represent the entire profit margin for a chemical for 5 or even 10 years. Industry, already operating at reduced margins due to the economic downturn, cannot afford to continue to produce product at a loss for any sustained length of time. Eroding gross margins in the chemical industry contribute to the decline of R&D expenditures, the innovation that comes from robust industrial R&D, and the scientific and engineering jobs that drive R&D. Lower margins will also result in lower capital spending, and the job creation that comes with construction of new or upgrades to existing facilities. This REACh expenditure must be made without any certainty that risks will be reduced. Consequently, the manufacture and use of certain chemicals will move out of Europe, simply because the costs to stay in the European market are too high.

In contrast to the approach adopted by the EU under REACh, Canada, through its use of a "Categorization and Prioritization" process, was able to demonstrate that more than 80% of the chemicals in commerce in Canada did not present an unreasonable risk to human health and the environment. This approach allowed Canada to then systematically assign to the remaining chemical substances a priority for more in-depth review by Environment Canada and Health Canada. At present, Canada is much farther ahead of the EU with respect to evaluation of chemicals that may present a risk to human health and the environment.

TSCA Should Continue to Be Based on Risk Prioritization and Mechanisms that Work

Two principles are essential to a sustainable chemical management law that won't eliminate jobs, economic growth, or products. First, TSCA priorities should be established based on risk. Second, proven regulatory mechanisms should be the basis for modernization.

Prioritization based on risk must remain a fundamental principle of TSCA. Basing priorities and regulatory criteria on the scientific evaluation of toxicological dose/response and exposure factors is critical to a sustainable policy. For instance, if a chemical is highly toxic, but used only in strictly controlled industrial environments, or in small quantities, then the risk to public health is fairly small and readily manageable.

The second important principle for TSCA reform is leveraging regulatory mechanisms that work. We agree with EPA that the existing regulatory framework is better suited to American health, environmental, and economic interests than Europe's monolithic REACh regime. Applying an approach like REACh in the United States could devastate small and medium sized companies, including SOCMA members, and do so unnecessarily since a more practical alternative is available.

This is not to say that industry opposes the value of better regulation. We acknowledge the success of current environmental laws and programs. Moreover, as shown by the Canadian approach, these mechanisms show promise in being able to achieve new policy objectives without sacrificing hundreds of businesses and thousands of jobs.

Another mechanism supported by SOCMA was the "inventory reset", which was part of EPA's recently discontinued Chemical Assessment and Management Program (ChAMP). This would have provided an accurate measure of the chemicals now in commerce, which we believe is the only realistic starting point. Of the more than 80,000 chemicals now listed on the inventory, EPA estimates (based on its collection of data through the Inventory Update Rule) that only about 20,000 of these are presently in commerce. The program also identified categories of well-characterized chemicals, prioritized them, and systematically targeted them for further review. Even TSCA critics did not challenge the groupings identified by EPA and supported the notion of prioritization. The program then went into an evaluation of the risks associated with the exposures to these chemicals. We need to prioritize and categorize the universe of chemicals. While ChAMP may have been abandoned, it will have to be reinstituted under another name.

We should also embrace TSCA mechanisms that have worked well, like the New Chemicals Program, where EPA has successfully reviewed some 35,000 new chemicals since 1979 without impeding the innovation that is crucial to American competitiveness. Through this EPA program, known as the PMN process, over 1,000 chemicals undergo a review every year. This successful model could also be applied to existing chemicals. We should recognize the massive amount of data that was generated by EPA's High Production Volume Program and leverage that data in making initial determinations of risk. With reasonable amendments, TSCA could provide an easier mechanism to poll manufacturers and users for data on:

- volumes manufactured, processed, or used,
- health effects (all data should be collected, not simply adverse data), and,
- exposure characteristics, both environmental and human.

Section 71 of Canada's Environmental Protection Act effectively enables this sort of data collection.

A Safety Standard for a New TSCA

SOCMA members have a deep commitment to the safe use of chemicals, and we are proud of our collective track record in protecting our workers and communities. SOCMA favors a formulation whereby EPA would make a "safety" determination regarding chemicals. But let me make several observations about what this "safety" standard should involve:

- First, it should not overlook the basic principle of **risk**; that is evaluation of hazard and exposure.

- Second, because of the vast number of chemicals and applications, we do not think that EPA should be burdened with a determination that each chemical is safe for its intended use. This approach would almost certainly overwhelm EPA and disadvantage US industry. Specific chemicals and specific uses may be approached this way when dealing with a short list of chemicals with narrow uses, as pesticides are managed, for example, under FIFRA – or as drugs are managed under the Federal Food, Drug & Cosmetic Act. But, EPA probably could not implement such an approach across the universe of all chemicals without creating a bureaucratic nightmare. A requirement that all new uses of any chemical be specifically approved would seize up the engine of innovation that America depends on to revive our economy and transition to a lower-carbon future. Instead, under an improved TSCA, EPA should provide goals, prioritization, and oversight; implementation should be based on proven and practical regulatory mechanisms.

- Finally, and regardless of what approach Congress adopts, EPA will need to be adequately funded. The biggest shortcoming of the TSCA program today is lack of resources, not lack of authority. Companies submitting PMNs currently pay a fee, although that fee goes to the U.S. Treasury, not to EPA. SOCMA supports a reasonable new chemicals fee that would go to EPA. However, the benefits of innovation are shared by the public and submitters should not required to foot the bill for the entire new chemicals program.

The New Chemicals Program Works

The new chemicals program at EPA has come under fire lately, and I'd like to address some of the criticisms. EPA reviews over 1,000 new chemicals per year. Under TSCA Section 5, EPA has authority to compel Pre-manufacture Notice (PMN) submitters to provide additional data, either voluntarily or via administrative order. A PMN must be submitted very early in a product's life cycle (before the first commercial pound is manufactured). At that phase of product development, while the manufacturer hopes the product will be a commercial success, it has not produced material in commercial equipment, it doesn't have an established market, and the predicted total sales volume is only a rough estimate. Success of new products often relies upon the success of our customers' or even their customers' products.

Illustrating this fact, roughly 30% of PMNs submitted for new chemicals are never followed by a Notice of Commencement (NOC), indicating that 30% of the new substances reviewed do not commence commercial production. Industry must be ready for commercial manufacture, but there are a variety of reasons that a product may not make it to market.

The fact that limited data is available during the PMN process does not mean that the manufacturer has stopped testing or that it is selling products with inadequate health and safety data. The only mechanism that industry has to report health and safety findings to EPA is through TSCA section 8(e), where only adverse data is collected. If a manufacturer finds that a substance is less hazardous that it originally estimated, there is no mechanism by which to report this finding to EPA. However, if a substance is subsequently found to create a substantial risk, the manufacturer must report this data to EPA within 30-days of the finding.

EPA recognizes that, at the PMN stage, detailed information may not yet be available and has therefore pioneered efforts using modeling software and Structure Activity Relationships to help inform agency decisions. EPA's EPISuite™ software contains 17 individual models that estimate environmental fate,

aquatic toxicity, biodegradability, and other attributes that predict the effect of chemicals on human health and the environment. One of these tools is ECOSAR™, which is a tool utilizing structure-activity relationships (SARs) to predict the behavior of chemicals with limited test data based on chemicals with structural similarity for which detailed test data is available. The scientists and engineers at EPA are extremely knowledgeable and, in the absence of test data, make decisions on regulation of chemicals based on extremely conservative interpretation of the data from their models. Some of the analyses that commenters have argued that EPA should do for new chemicals, such as evaluating cumulative risks, are extremely complex, time-consuming and costly – and in many cases toxicologists are not in agreement on how such analyses should – or even can – be done.

It is important to emphasize, moreover, that EPA is not limited to existing data and models when reviewing new chemicals. EPA has the ability, directly and indirectly, to require companies submitting PMNs to generate and submit specific health data, and it has done so regularly where, in its judgment, such data were warranted. Finally, EPA has the ability, directly and indirectly, to limit the uses of new chemicals.

EPA has not systematically applied the knowledge developed through PMN's to the universe of related chemical substances that were grandfathered onto the inventory. Use of this sort of read-across data would help to inform EPA action on existing chemicals.

I thank you for this opportunity to describe a pragmatic approach to TSCA reauthorization, and I would be happy to answer your questions.

Environment and Public Works Committee Hearing
March 9, 2010
Follow-Up Questions for Written Submission

Responses from Bosley

Senator Barbara Boxer
1. Please provide me with a list of the Society of Chemical Manufacturers and Affiliates members, and a description of which members are subject to the European Union's Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals law.

Here is a link to the "Members List" page on SOCMA's website:

http://www.socma.com/MemberList/

Using this link will give access to a current and accurate list of SOCMA members.

SOCMA Members are subject to REACh to varying degrees: some not at all, some for a few products, and some for their entire product line. Exact statistics are not available, but we estimate that the split among our member companies is roughly 30% not subject to REACh, 40% partially subject to REACh, and 30% fully subject to REACh. It is important to recognize, however, that even those companies not directly subject to REACH through their activities or those of an affiliate company will still be impacted by as downstream users (i.e., because they are customers, directly and indirectly, of companies subject to REACh).

Senator Sheldon Whitehouse

1. There seems to be general concern from chemical manufacturers that imposing strict regulation on U.S. chemical companies could allow foreign companies that are subject to lower safety standards to outcompete them. I would prefer that we focus our efforts on strengthening the protection of American consumers at our borders, than that we forego domestic chemical safety precautions in order to participate in an international race to the bottom. I would appreciate thoughts and comments from you on ways to protect American consumers and American chemical companies from the import of unsafe chemicals and products.

First, I'd like to clarify that the U.S. chemical industry is already subject to strict regulation, and we would not advocate that U.S. statutes be made less stringent, or that we forego chemical safety regulations, for reasons of international competition. In the US alone, the following departments and agencies have authority to regulate the chemical industry:

> **EPA** (Clean Air Act, Clean Water Act, Toxic Substances Control Act, Resource Conservation and Recovery Act, Safe Drinking Water Act, Emergency Planning and Right to Know Act, and Comprehensive Environmental Response, Compensation, and Liability Act),
> **Consumer Product Safety Commission** (Federal Hazardous Substances Act, Poison Prevention Packaging Act),
> **Department of State** (International Traffic in Arms Regulations),
> **Department of Commerce** (Export Control Regulations, Chemical Weapons Convention),
> **DHS** (Chemical Facility Anti-Terrorism Standards),
> **DOT** (Hazardous Material Transportation Act),
> **FAA** (Dangerous Goods Regulations Administration and Enforcement),
> **OSHA** (Hazard Communication Standard, Process Safety Management Standard, Hazardous Waste Operations and Emergency Response Standard),
> and in some cases, the **DEA, NRC,** and **TTB.**

We do not advocate rolling back the protections provided by these laws. We do, however, urge Congress to take them fully into account – and to require their full implementation -- before imposing new requirements that may make it incrementally more difficult for U.S.-based manufacturers to compete in export markets.

The important and complex subject of safety in consumer products is managed at present by the Consumer Product Safety Commission, whose mandate is to protect the public from unreasonable risk of serious injury from consumer products. EPA performs ongoing risk assessments of chemicals, including those that might be used in consumer products. EPA's risk assessment process is quite robust and EPA has the authority under TSCA to require testing of existing and new chemicals if the chemicals may present an unreasonable risk to human health or the environment.

Because TSCA applies to "importers," chemicals that enter the United States from abroad are subject to the same risk-based review that domestically-manufactured chemicals are. In making judgments about possible risks, moreover, EPA is assisted by Section 8(e) of TSCA, which requires manufacturers, importers, processors and distributors of chemicals to report to EPA all adverse results for chemicals in commerce in the US. That includes adverse result information generated outside the U.S.[1]

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[1] I should point out that, while manufacturers, etc. are required by law to provide adverse testing results to EPA, the TSCA regulations do not currently provide an opportunity for the reporting of non-adverse results. This has led

When consumer products enter the US market, however, they are generally considered to be "articles," which are excluded from EPA review under TSCA. The consequence of such articles entering US commerce is not only the lost jobs associated with the manufacture of the chemical raw materials, plastic compounders, and final product fabricators; it is also that the materials used in formulation of the products are now beyond the reach of US law. Substances not used by responsible manufacturers in the US for the manufacture of children's toys, lead paint for example, may be (and have been) used in the plants of overseas manufacturers, causing real risks to US individuals.

Giving the CPSC additional inspection resources to would seem to be one way to combat undesirable products entering commerce. A more effective way to help ensure consumer safety may be to institute trade policies that help US manufacturers level the playing field and allow profitable manufacture of products in the US.

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to a biased data-set in the US EPA against synthetic chemicals. A more even-handed reporting requirement would yield a more representative and accurate database.

Senator James M. Inhofe
1. Some industry groups suggest that they could live with a "safe for intended use" standard of review, yet in your testimony you caution that this level of review would 'overwhelm' EPA. Please elaborate on why you believe Congress should not establish a "safe for intended use" standard? Do you believe the average consumer will appreciate qualifying safety by use, or will they just be more confused?

The "safe for intended use" standard is practicable where (i) the number of substances to be reviewed is more limited than those in the TSCA realm, (ii) the intended uses can be narrowly defined and specifically approved, and (iii) the extent of regulatory resources for such review is much greater than those at EPA's disposal. At FDA and under EPA's FIFRA regulations, this standard is workable. FDA uses a "safe and effective when used as directed" standard to approve approximately 20 New Molecular Entities per year as drugs for specific conditions. It regulates food additives in a similar way. EPA's Office of Pesticide Programs (OPP) approves a limited set of chemicals for use against specific pests in particular applications. In both cases, no one besides the applicant can use that chemical for that purpose, and no one can use it for any other medical or pesticidal purpose. By contrast, the New Chemicals Division at EPA approves (or approves with restrictions) roughly 1800 new substances each year. It does so, moreover, with about 1/3 the number of FTEs that OPP has. Increasing EPA's scope to include a "safe for intended use" determination for each substance would vastly increase the number of resources needed at the agency, or, more likely, dramatically increase the time required for each review. It would also hamper innovation, for two reasons. First, manufacturers would need to keep reapplying to EPA for approvals of additional uses as they were developed. Second, unless EPA's approvals were limited to only the applicant – an outcome we do not support – the business case for developing a new product, plus the voluminous information needed to support its approval, would be much harder to support, because others could free-ride on the submitter's work.

Since chemical manufacturers can't know in detail all the uses of their products (small businesses are not able to compel their larger customers to disclose uses, and large businesses don't want to disclose uses or markets to vendors, who may also be potential competitors), applicants will not be able to provide EPA with an exhaustive list of uses for each substance they propose to manufacture. Therefore, in order for EPA to make a "safe for intended use" determination, it will have to collect information from potential downstream users and perform a risk determination on each use.

The new chemical substances that undergo EPA review each year represent innovative and robust research and development in the chemical industry. That innovation in turn fuels the ability of the U.S. economy to improve our standard of living and produce cleaner and greener products. Stalling this process will result in fewer new substances and fewer advances in the many industries that rely on products produced by chemical manufacturers.

EPA currently has the authority to limit uses of any proposed new substance that may present an unreasonable risk to human health or the environment. Under this authority, EPA may issue a Significant New Use Rule, whereby the manufacturer or user would need approval from EPA prior to using a chemical substance in any new application. EPA may also issue a consent order on a proposed new substance, whereby they require the manufacturer to perform further testing prior to reaching a specific volume threshold. While SOCMA agrees that some aspects of TSCA warrant updating, the new chemicals provisions (Section 5) actually work quite effectively, protecting Americans while facilitating innovation.

I don't believe that the average consumer would encounter many "safe for intended use" determinations by EPA, since the actual consumer use of most substances is far removed from the manufacture of any one specific substance.

"Safe for intended use" is inherently a roadblock to innovation. Senator Lautenberg's "Safe Chemicals Act" (S. 3209) would require an evaluation process for new uses that does not provide a clear indication of requirements for success and would take too long. The bill would stifle innovative new uses for existing chemicals and would be a prohibitive impediment to the introduction of new chemicals. This can be readily seen by the experience of the EU. Originally, the EU established a 10kg low volume exemption (LVE) for new chemical substances, but the dataset for exceeding the 10-kg volume cost more than $100,000 and proved to be an impediment to new chemical substances being introduced to replace the grandfathered chemicals. The EU has replaced that exemption with a 1,000 kg LVE that also has a reduced dataset requirement. They recognized that, while the previous regulation was clearly protective of human health and the environment, it was an impediment to the introduction of new chemical substances designed to replace those grandfathered on to the EU's inventory. The new standard is still protective – indeed, it promotes safer chemicals in a way its predecessor did not.

A better standard to consider in any overhaul of TSCA is "safe for use" – i.e., safe in any foreseeable setting. If EPA had concerns about particular uses of a chemical, it could impose conditions on its approval of a chemical that would prohibit those uses or allow them only under certain conditions (e.g., use of personal protective equipment in manufacture, no use in products intended for children, etc.).

2. I share your concern about "seizing up the engine of innovation." And, if there is one overriding concern about reform TSCA, that is one of the most important to me. Can you please describe the types of provisions that, if passed into law, would stall the process of chemical review at EPA?

As described above, a standard by which EPA would approve specific uses of chemicals would substantially stall the new chemical review process.

Currently, manufacturers prepare and submit their pre-manufacture notices (PMNs) at least 3 months prior to making their first commercial pound of product. At this early stage of product development, it is not surprising that detailed studies have not yet been undertaken – the company is often far from a determination that it will commercialize the product. (Illustrative of this fact, only 1/2 of all PMN chemicals are ever marketed commercially – the rest are abandoned for economic or technical reasons.) EPA has always realized that data may not be available at the time of PMN submission, and so has developed Structure-Activity Relationship, read-across and other models that are predictive of toxicity and environmental fate. This risk assessment process uses extremely conservative interpretations of the data from those models. Importantly, EPA's analyses of their data show that their predictive models agree with, or are more conservative than, 90% of the test data that was accumulated subsequently.[2] Data that was collected through the HPV program can and should be used to update and inform EPA's models for assessing new chemicals. Such an effort would serve to make the models even more accurate.

EPA's use of modeling allows a chemical that presents low risk to move through the review process expeditiously. By contrast, if minimum data set requirements are implemented for all substances, without benefit of a prioritization based on risk, chemicals that have very little or no impact on human

[2] US EPA - Summary Report of Results for SAR/MPD Study, 1992

health and the environment – i.e., the vast majority of chemicals – will be overly burdened and may not be introduced into commerce in the US, pushing more high-paying chemical manufacturing jobs overseas and damaging our Nation's ability to adapt and prosper.

Such an overly burdensome regulatory scheme failed to promote innovation in the EU; the ELINCS program (European Listing of New Chemical Substances) rewarded the use of "old" chemicals because it was less expensive to enter the market under the grandfathered substances. While it is too soon to tell whether the burdensome REACh regulation will have a similar effect, it is a distinct possibility. Entering the market when multiple other companies have already performed the testing required may be more advantageous than entering the market as the sole notifier of a new chemical. For a single company to enter the market with a new chemical at a volume of 25,000-lb/yr, the cost of testing may represent an economic barrier that is too high to overcome. Therefore, the advantages presented by the new chemical substance may not be realized in the EU. The U.S. should not similarly hobble itself.

Senator David Vitter

1. Would you mind painting for us a broad picture of what has happened in the chemical industry over the last five years and what you predict of the next five? Where are new chemical manufacturing facilities being built? What countries do we see starting to take a lead in innovation?

The chemical industry directly employs approximately 850,000 people, with salaries averaging $70,000, much higher than other manufacturing industries. Since the chemical industry is an enabling industry, it directly affects about 4 million jobs in the US. We are also the nation's leading exporter.

However, chemical industry employment has fallen by about 10%, and the US share of world chemical production has fallen by 25% in the past five years. New chemical manufacturing facilities are being built in countries with lower wage standards and less burdensome regulatory environments – China, India, Vietnam, Eastern Europe, etc. The decline of the chemical industry in the US is expected to continue: eroding gross margins will make it impossible for businesses to spend on R&D and capital projects, pushing chemical industry innovation out of the United States.

Chemical industry advances enhance American health and prosperity, but if the current trend continues, our nation risks becoming overly dependent on foreign supply of products and services that represent strategic importance to our security, our telecommunications systems, our aerospace industry, and our way of life.

Major European and Asian chemical companies are not building new chemical plants in the US, nor are they spending as much capital to modernize and expand existing plants as in previous years. Instead their focus is to acquire, consolidate and close existing facilities. Not only does this lead to fewer high paying jobs for Americans, it leads to a greater reliance on imports. US-based companies in the chemical industry are following a similar path.

If we look back to the time of 1914-1920, we see that the US government found it unacceptable for our country to be burdened by total dependence upon imported chemicals. Various initiatives were begun at that time, with the encouragement of the government, that led to the development of a vigorous chemical industry in the US, one that provided high paying jobs to tens of thousands. Over the past 50 years, we have seen a serious reversal in this trend. We are likely, before we realize it, to be back where we were in 1914; in almost total dependence upon imported chemicals (natural and synthetic) for our economic survival. Congress should think long and hard about how to help reverse this trend, and certainly should not exacerbate it.

Senator LAUTENBERG. Thank you very much, Ms. Bosley.

Dr. Hawkins, we would like to hear from you now, please.

STATEMENT OF NEIL C. HAWKINS, SC.D., VICE PRESIDENT, EH&S AND SUSTAINABILITY, THE DOW CHEMICAL COMPANY

Mr. HAWKINS. Thank you. Chairman Lautenberg and members of the Subcommittee.

I am pleased to testify today on an issue that is critically important to the Dow Chemical Company and to me personally, product safety. I am responsible for Dow's product safety programs and compliance with chemical product safety laws in the U.S. and around the world.

Dow is a leading global manufacturer of advanced materials. We supply customers in over 160 countries. Our diverse chemistry can be found in applications that range from food ingredients to electronics to water purification, alternative energy including wind and solar, and personal care products.

As a global company, Dow goes well beyond compliance. Dow's 2015 sustainability goals include a progressive product safety leadership goal for which we publicly report our progress. We also have product stewardship management systems in place to ensure our products are safe for their intended uses.

Despite our collective efforts key stakeholders seem to lack confidence in the Federal regulatory system. For example, we continue to see an uptick in legislative proposals at the State and local level to ban specific chemical applications. Often these fixate on chemicals that have been in commerce for decades and are relatively well studied. It seems ineffective to take an ad hoc chemical by chemical approach to product safety under the assumption that data rich chemicals are risky and that alternatives must be safe.

Contrast that with the approach of other countries which in the last few years have required a comprehensive look at all chemicals in commerce to determine those uses that deserve special regulatory scrutiny.

We believe the U.S. law responsible for ensuring the safety of chemicals in commerce, TSCA, is in need of reform. We are not alone in our view. Dow has worked side by side with members of the American Chemistry Council, the value chain and with NGO stakeholders to call for modernization of the statute. ACC has developed comprehensive principles for TSCA reform, which we fully support.

First and foremost, we believe the Federal program ought to screen all chemicals in commerce to identify those chemicals and their uses that should be evaluated against a minimum safety standard. This type of screening process would help focus Government resources on priority chemicals and uses believed to pose the greatest risk.

An ideal chemical safety program would base safety decisions on the weight of scientific evidence. Research would be judged on the basis of scientific merit and quality without regard for funding source or where studies were conducted. At Dow, for example, we have hundreds of scientists with expert knowledge of the products we manufacture. Our analytical tools are considered the best in the

world, and our toxicology laboratory has been operating for more than 70 years, well before testing was required by any government.

Quality research must be used, and everyone, not just the industry, should be held to common quality standards.

Finally, reform should not only ensure that chemicals are safe for their intended uses, it should also provide incentives for sustainable chemistry—carrots, not just sticks. At Dow sustainable chemistry refers to a cradle to cradle approach—that drives all of us to use resources more efficiently and safely and minimize our total footprint. It builds on well established principles for green chemistry which are recognized by EPA.

As we consider changes to TSCA, we should explore incentives for sustainable chemistry, such as a collaborative Federal R&D program and development of tools to advance improvements in all aspects of a product's life cycle. The sustainable solutions for tomorrow are in our laboratories today. Let's find ways to bring them to market sooner through incentives.

We recognize that it is much easier to agree on general principles than specific legislative language, and the details are very important in this case. As Congress takes a hard look at TSCA, multistakeholder dialogue will speed us to meaningful reform. Collaboration is the quickest path to our common goal, a stronger and more effective chemicals regulatory program in the United States.

Thank you for the opportunity to testify today.

[The prepared statement of Mr. Hawkins follows:]

The Dow Chemical Company

STATEMENT FOR THE RECORD

SUBCOMMITTEE ON SUPERFUND, TOXICS,
AND ENVIRONMENTAL HEALTH
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

U.S. SENATE HEARING ON

Business Perspectives
on Reforming US Chemical Safety Laws

March 9, 2010

Submitted By:
Neil C. Hawkins, Sc.D.
Vice President, EH&S and Sustainability

Introduction

The Dow Chemical Company is pleased to offer our comments relating to the March 9, 2010 Subcommittee hearing, "Business Perspectives on Reforming US Chemical Safety Laws".

Dow was founded in Michigan in 1897 and is one of the world's leading manufacturers of chemicals and plastics. We supply products to customers in 160 countries around the world, connecting chemistry and innovation with the principles of sustainability to help provide everything from fresh water, food, and pharmaceuticals to paints, packaging, and personal care products.

Dow is committed to sustainability. Our ambitious 2015 sustainability goals underscore this commitment[1], along with our actions to ensure product safety (see Appendix).

As a global company, Dow complies with multiple regulatory programs across different countries and regions, has developed and adheres to its own high standards for product safety[2], develops and adheres to voluntary industry initiatives[3] including Responsible Care®, and leads in international efforts (e.g., the UNEP Strategic Approach to International Chemicals Management) to improve the safe management of chemicals. We have a management system in place to ensure that each of our products is safe for its intended use and meets or exceeds the requirements of our customers. Furthermore, we have adopted and published principles upon which product safety legislation or regulation should be based.[4] For many years now, these principles have guided our efforts and our advocacy. As a global company, Dow is working to ensure its principles are adopted around the world in ways that enhance chemical safety.

Reform TSCA

The United States needs a strong and effective federal program for ensuring that chemicals in commerce are safe for their intended uses. Such a federal program would be complementary to, and coordinated with, chemical management systems at all levels of government and also with voluntary programs designed to promote the safety of chemical products. Ideally, such a coordinated system would foster public confidence, create a level playing field among chemicals in commerce, and provide certainty for business investment, while maintaining the benefits for society associated with the use of chemical products.

Toward that end, Dow believes that Congress should reform the Toxic Substances Control Act (TSCA). We are not alone; there is an emerging consensus among

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[1] To learn more about Dow's commitment to sustainability, go to our website at http://www.dow.com
[2] To learn more, go to http://www.dowproductsafety.com
[3] For an example, go to http://www.icca-chem.org/en/Home/ICCA-initiatives/Global-product-strategy/
[4] To learn more, go to http://www.dow.com/commitments/goals/principles.htm

stakeholders that reform is necessary. The American Chemistry Council has developed principles for modernizing TSCA, and Dow has worked actively within ACC in development of these principles, and we fully support them.

As a company, we have learned the importance of undertaking a dialogue with stakeholder groups, especially in the context of public policy. Therefore, as Congress begins the process of taking a hard look at TSCA, we stand ready and willing to engage with other stakeholders centered around a discussion draft as we jointly work toward meaningful reform. Toward that end, we would like to offer our perspective on an ideal federal chemical safety program to serve as a model for TSCA. This perspective reflects Dow's commitment to sustainability, to our customers, and to our shareholders.

We urge the Subcommittee to create a federal chemical safety program that (1) creates a level playing field for all chemicals in commerce, (2) is objective in its evaluation of safety using the best available scientific information, (3) is both timely and effective, (4) provides incentives for innovation in sustainable chemistry, and (5) enhances the competitiveness of US companies.

Create a Level Playing Field

An ideal federal chemical safety program would screen all chemicals in commerce to determine further information needs in a tiered, risk-based fashion. An approach that focuses on initial screening for all chemicals based on existing information and a tiered approach to gather additional hazard and exposure information needs will allow the development of necessary and appropriate safety information in a way that informs regulatory action, conserves resources, and accelerates the evaluation process. Because a typical chemical has multiple uses/applications, each posing a unique safety profile, the focus should be on those chemical uses/applications where exposures could be expected to be higher.

There should be a systematic gathering of available valid hazard and exposure information to be used in chemical management decisions. This includes utilizing information gathered on similar chemicals though the use of validated non-animal test methods, computer modeling and/or quantitative structure-activity relationship (QSAR) activities.

Chemicals that have strict controls and have limited exposure and environmental release potential (e.g., intermediates in a chemical process) or limited potential to enter commerce are likely to require less information.

There should be a cooperative effort among producers, distributors, and users of chemicals (e.g., appropriate sharing/compensation systems) that ensures the information necessary in chemical safety assessment is developed, shared as appropriate, and applied.

Ensure a Scientifically Objective Evaluation of Safety

An ideal chemical safety program would base its decisions on a consistent scientific evaluation of both hazard and potential exposure (an evaluation of risk), using a weight-of-evidence approach. The Presidential/Congressional Commission on Risk Assessment and Risk Management, in a 1997 report required under the Clean Air Act, concluded that "a good risk management decision is based on a careful analysis of the *weight of scientific evidence* [italics added] that supports conclusions about a problem's potential risk to human health and the environment." The importance of a weight-of-evidence approach was further explained in the EPA's report on reference dose and reference concentration processes in 2002. "A weight of evidence approach ... requires critical evaluation of the entire body of available data for consistency and biological plausibility." The report further states that "If the mechanism or mode of action is well characterized, this information is used in the interpretation of observed effects in either human or animal studies." In other words, the cornerstone of a weight-of-evidence approach is to use all available scientific information.[5]

Studies conducted and funded by Dow are necessary and valuable contributions to the understanding of potential public health and environmental effects related to the manufacture and use of its products. Our scientists have expert knowledge of the chemicals we manufacture, especially as this relates to the development and interpretation of the science needed to comply with governmental requirements around the world. Research should be judged on the basis of scientific merit, without regard for funding source or where the studies are conducted (e.g. academia, government, or industry). A number of practices and procedures are in place by which policymakers and the public can be assured that studies performed by or funded by Dow and the rest of industry meet high scientific standards.

Allow EPA to Take Timely and Effective Action

An ideal chemical safety program would ensure a role for cost/benefit analysis in risk management decisions. If warranted, substitution should be considered only after a comparison of substances based on performance, health, environmental and socio-economic aspects in the relevant applications. Precautionary action to protect human health and the environment, as set out in Principle 15 of the Rio Declaration on Environment and Development, and as amended at Johannesburg and agreed at Dubai, should be proportional to the objective being pursued, provisional, and should employ the least burdensome option to provide adequate protection from the risk.

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[5] In a 2007 memorandum, the Office of Science and Technology and the Office of Management and Budget asked each federal agency to employ the best reasonably obtainable scientific information to assess risks to health, safety, and the environment. Pursuant to the 1996 amendments to the Safe Drinking Water Act, EPA is directed to use the best available, peer-reviewed science and supported studies conducted in accordance with sound and objective scientific practice.

To instill public confidence and provide regulatory certainty for business planning purposes, it is important that appropriate risk management actions be taken expeditiously.

Include Incentives for Sustainable Chemistry

An ideal chemical safety program would provide incentives for sustainable chemistry. Dow uses the term "sustainable chemistry" to describe our cradle-to-cradle concept that drives us to use resources more efficiently, to minimize our footprint, provide value to our customers and stakeholders, deliver solutions for customer needs and enhance the quality of life of current and future generations.[6]

We believe that chemical policy should provide incentives for investments in sustainable chemistry. Such incentives could include, but not be limited to, government support for research and development and for lifecycle assessment to promote sustainable chemistry, and government priority given to new products and processes that represent a significant improvement in sustainability over existing products and processes.

Enhance US Competitiveness

An ideal chemical safety program would ensure that chemicals are safe for their intended uses and would do so in a timely manner and with a minimum of additional resources. Such an ideal program would position the USA as a leader in chemical management and therefore would enhance the competitiveness of US companies.

Chemical policy impacts the competitiveness of businesses through the entire chain of commerce. Therefore, Congress should consider the views of all businesses that rely on chemical products to provide value to their customers. This hearing—with a range of business witnesses—represents a good start.

Under TSCA, EPA's new chemical program has been largely successful in fostering innovation while providing EPA with the tools it needs to ensure safety. Dow urges Congress to maintain these attributes of the new chemical program, which is largely acknowledged to be a success story in the US chemical management system.

It is important that legitimate confidential business information (CBI) be protected under any chemical safety program that relies on information provided by commercial interests. Details that implicate proprietary interests, such as certain information on the ingredients in a product, should be protected as confidential business information to ensure stimulus for innovation.

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[6] Sustainable chemistry builds on the strong foundation of green chemistry and engineering (as developed by Warner and Anastas and supported by the American Chemical Society and EPA) to include social dimensions which recognizes the value of chemical products to enhance our quality of life and protected the environment.

An ideal federal chemical safety program should develop and support means to share relevant safety information with other governments, while protecting legitimate business interests in proprietary information.

If the information that is used to make a determination of safety is of commercial value, provisions should be made for protecting the commercial interest while ensuring public access to the information.

Companies that invest in the conduct of chemical, physical property or health and environmental safety testing should receive fair compensation from other companies who choose not to participate in such studies, but wish to use the information generated for registration or compliance purposes. Health and safety information such as would appear on a material safety data sheet or otherwise be used solely for risk management (not for registration purposes) should always be made publicly available.

Conclusion

We urge the Subcommittee to reform TSCA so that it better reflects the ideal of a strong federal chemical safety program. We stand ready to assist Congress in its efforts to foster public confidence, create a level playing field among chemicals in commerce, and provide certainty for business investment, while maintaining the benefits for society associated with the use of chemical products.

Appendix: Dow Commitment to Product Safety

At Dow, chemical safety is a top priority, and it always has been. Dow first established a toxicology laboratory in 1934 to evaluate chemical hazards, and we continue to be a global leader in this field today. Dow was a pioneer when it established a formal product stewardship program in 1970. In the 1980s, Dow led in development of Responsible Care®, which represents the chemical industry's commitment to continuous improvement in environmental, health, and safety performance. Most recently, our 2015 Sustainability Goals emphasize our commitment to continually improve the safety of our products throughout their lifecycle. For example, we have committed to conducting safety assessments for all of our products and making the information publicly available. In developing these safety assessments, we will address relevant gaps in hazard and exposure information. See www.dow.com/productsafety/index.htm to better understand our processes by which we evaluate the safety of our products for their intended uses and to access these safety assessments. We are also committed to continuous improvement in our product safety assessment processes and to increased stakeholder scrutiny and dialogue on these topics.

Via our award-winning product stewardship program, we strive to develop, manufacture, transport and market our products in a safe and responsible manner. We work to ensure our products are handled safely and recycled or disposed of appropriately. Dow welcomes appropriate review by governments to maintain and enhance public acceptance of its operations and products.

If any party within the value chain identifies improper practices involving a product, it should work to improve those practices and, if, in the party's independent judgment, sufficient improvement is not evident, then the party should take further measures up to and including termination of product sale or use. Dow routinely refuses to sell products into applications where we don't believe the conditions for safe use can be met.

Dow believes there should be widespread support for the development of capabilities (competency) in nations that need to build their chemicals management framework to support the protection of human health and environment. We are actively working to assist small- and medium-sized companies and governments in developing countries to improve their capabilities to assess and manage chemicals safely.

Questions from the Senate Committee on Environment and Public Works
Response from Neil Hawkins, Vice President, The Dow Chemical Company

Senator Barbara Boxer

Q1. Does Dow believe that businesses have a responsibility to produce products that are safe for their intended uses?

A1. Dow believes that chemicals should be safe for their intended use. Dow routinely undertakes safety assessments for all of its products and proposed uses, and further, will not knowingly sell chemicals into uses which pose unacceptable risks to humans or the environment. Please visit www.dowproductsafety.com for a fuller explanation of product safety at Dow, including access to Product Safety Assessments for Dow products. In practice, chemical safety is a shared responsibility of all players in the value chain from chemical producers, to formulators, distributors, transporters, and end users. There is also a significant role for regulatory agencies, such as EPA, OSHA and others.

Industry should have the responsibility for providing sufficient hazard, use and exposure 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. Other agencies, such as FDA and CPSC, should continue to make safety decisions for products within their own jurisdictions.

Q2. Mr. Hawkins, is Dow subject to the European Union's Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals law (REACH)?

A2. Yes, Dow has major production facilities in the European Union and also exports large volumes of products to the European Union, thus we indeed are subject to the EU regulation known as Registration, Evaluation and Authorization of Chemicals (REACH).

Q3. If Dow is subject to REACH, is Dow complying with the law's current requirements?

A3. Yes, Dow is complying with requirements of REACH, and we are committed to be a leader in REACH implementation. It is Dow policy that each employee and officer is responsible to ensure that our products and operations meet applicable government and Dow standards, whichever is more stringent. Dow met the 2009 deadline for pre-registering all REACH relevant substances. At least four of our European facilities have been audited for REACH by EU member states and were found to be fully compliant with the pre-registration requirements. We are in the process of compiling REACH dossiers to register all relevant substances to meet the first REACH registration deadline later this year. Please visit http://reach.dow.com/ for a more detailed description of Dow's REACH implementation.

Senator Sheldon Whitehouse

Q1. There seems to be a general concern from chemical manufacturers that imposing strict regulation on U.S. chemical companies could allow foreign companies that are subject to lower safety standards to outcompete them. I would prefer to focus our efforts on strengthening the protection of American consumers at our borders, than that we forego domestic safety precautions in order to participate in an international race to the bottom. I would appreciate thoughts and comments from you on ways to protect American consumers and American chemical companies from the import of unsafe chemicals and products.

A1. Dow believes that the US chemicals management system should apply equally to chemicals whether they are produced domestically or imported into the U.S. This includes a safe use determination for all high priority chemicals and uses regardless of where they are produced.

To address concerns about deficiencies in the safety performance of chemical companies operating outside the U.S., Dow is co-leading an initiative of the global chemical industry to improve their performance under the auspices of the International Council of Chemical Associations (ICCA). This CEO-driven, voluntary initiative builds upon decades of industry-driven activities to improve product stewardship., including the Responsible Care program, the High Production Volume (HPV) chemical testing program, and the Long-Range Research Initiative (LRI) to strengthen the scientific basis for public policy. More recently, ICCA has taken the following actions:

- Defining and adopting a "base set of information" adequate to conduct chemical safety assessments.
- Developing a set of universal product stewardship guidelines for use by companies globally, to accelerate the implementation of their chemical management programs.
- Providing capacity building projects in a number of developing countries and countries with economies in transition, especially in Africa, Asia-Pacific, Eastern Europe and Latin America, to implement the best safety assessment practices and risk management procedures.
- Doubling the number of global company CEOs committed to the Responsible Care Global Charter and Global Product Strategy to more than 150.
- Extending the Responsible Care network to include Russia, and other countries in Eastern Europe; including establishing a pilot project with Chinese national companies; and helping to launch Responsible Care in the Middle East, an area of tremendous growth in petrochemical production.

To learn more about Dow's efforts to improve product safety in the global chemical industry please visit http://news.dow.com/feature/2009/06_10_09a/index.htm.

Senator James M. Inhofe

Q1. Please elaborate on your discussion of how to properly construct a provision that protects "confidential business information" – known as CBI – about a product or chemical while still providing the important health, safety, and ecological information needed to inform consumers, workers and health professionals.

What specific instruction would you like to provide the Committee on striking that balance between informing users and protecting business investment?

A1. Dow believes that health, safety and environmental information (*e.g.*, a robust summary) necessary to protect human health and the environment should always be publicly available. For example, Dow is making summaries of its product safety assessments publicly accessible at www.dowproductsafety.com. However, to avoid the undermining of the competitiveness of American industry, legitimate claims of Confidential Business Information (CBI) must be allowed. When a company has made significant research investment in the discovery of new chemistry, or to develop a new market for use of new or existing chemistry, or to generate health and safety data through product testing, there must be protections in place to avoid circumstances where competitors can market the chemistry without making similar investments. Other information submitted to EPA, including chemical identity, corporate identity, location, processes, etc. of the manufacturer/importer or any processors or users of the substance could also qualify for CBI protection under criteria for substantiating such claims.

Under the current version of TSCA, the barrier to claiming CBI is too low and EPA should have the authority to require industry to justify CBI claims against a set of established criteria. EPA should also be allowed to share CBI information with state, local and tribal governments as long as they also appropriately protect CBI.

We support EPA's mission to promote public understanding of the potential risks posed by chemicals in commerce, while protecting the critical information needed by businesses to innovate and succeed in a competitive marketplace. CBI is a critical provision of TSCA to protect the important R&D efforts of our member companies.

Q2. You said that safety must be evaluated objectively. That all studies should be judged on their scientific merit and the safety decision should be based on the weight of the entire body of evidence. Yet, some critics claim that industry cannot be objective and that their studies cannot be trusted.

Please elaborate on the policies and procedures that are in place to assure that the public can have confidence in industry studies performed and submitted to EPA.

A2. Studies conducted and funded by Dow and many other companies have long been and continue to be recognized as valid and credible by government agencies, non-governmental organizations, and the scientific community at large. Studies conducted and funded by Dow are necessary and valuable contributions to the

understanding of potential public health and environmental effects related to the manufacture and use of its products. Several procedures have been established that authorize independent review of scientific studies, in order to assure that the quality and credibility of studies conducted or funded by Dow meet the highest scientific standards:

- Typically, studies required by governments are conducted in accordance with Good Laboratory Practice (GLP) regulations which require full availability of the recorded, quality-assured data files[1,2] and which allow for unannounced audits by government authorities, such as the FDA or EPA. Dow also follows GLP requirements voluntarily for many other studies that it conducts.
- An internal Dow Quality Assurance Group reports independently of day to day laboratory management and audits all studies conducted to ensure compliance with GLP regulations. Employees also undergo training to understand the requirements of GLP regulations.
- Studies are conducted according to internationally agreed upon protocols and test guidelines.
- Scientists are encouraged to submit their results in the peer-reviewed scientific literature and to present them in scientific forums.
- All research involving human subjects is reviewed and conducted to comply with generally accepted ethical standards and requirements. This includes the Common Rule, the Nuremberg Code, the Declaration of Helsinki, and any other applicable local government requirements and guidelines which are at least equivalent to those provided by the Common Rule.
- All animal studies are conducted in full compliance with state and federal animal welfare regulations. In addition, Dow is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International, an achievement recognized as the highest attainable by the animal care profession.
- Studies that demonstrate adverse effects are made publicly available in a timely manner to comply with the U.S. laws of TSCA 8(e) and FIFRA 6(a)(2) or similar requirements in other countries.

Dow firmly supports and has full confidence in these processes. Research studies that adhere to GLPs deserve the very highest degree of confidence regarding (1) the specific and detailed experimental protocol design, (2) the measurements taken, and (3) the accuracy of the reported results, because all of these elements must meet GLP quality control and quality assurance requirements. Moreover,

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[1] [1]Furthermore, of the various types of data and information employed in risk assessment, GLP derived data will most readily meet the requirements of the Information Quality Act (USEPA 260/R-02-008, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, October, 2002). See http://www.epa.gov/QUALITY/informationguidelines/

[2] See also Becker RA, Janus ER, White RD, Kruszewski FH, Brackett RE 2009. Good Laboratory Practices and Safety Assessments. Environ Health Perspect 117:A482-A483. doi:10.1289/ehp.0900884

studies based on regulatory requirements often use standardized methods that have been scientifically validated and approved by regulatory bodies. Finally, GLP studies facilitate transparency and the ability of others to reproduce the test results.

Dow is strongly committed to the safe manufacture, use, and disposal of its products, especially as this relates to the development and interpretation of the science needed to comply with the laws and regulations of the chemical industry on a global basis. As members of professional associations, our scientists adhere to both personal and professional commitments to act in accordance with codes of ethics of their professions.[3] We believe research should be judged on the basis of scientific merit, without regard for funding source or where the studies are conducted (*e.g.*, academia, government, or industry).[4]

[3] http://www.toxicology.org/MemberServices/AboutSOT/ethics.html

[4] Conolly, R.B., Beck, B.D., and Goodman, J.I. (1999). Stimulating research to improve the scientific basis of risk assessment. Toxicological Sciences, 49, 1-4.

Senator LAUTENBERG. Thank you very much.

Mr. Drevna, we welcome your testimony.

STATEMENT OF CHARLIE DREVNA, PRESIDENT, NATIONAL PETROCHEMICAL AND REFINERS ASSOCIATION

Mr. DREVNA. Thank you and good morning, Chairman Lautenberg. It is really good to see you, sir. And Senators Whitehouse and Vitter, thank you for having us here today.

I am Charlie Drevna, President of NPRA, the National Petrochemical and Refiners Association. We are a national trade association representing virtually all U.S. refiners and the vast majority of domestic petrochemical manufacturers, who produce the chemicals that serve as the building blocks for everything from clothing and medicine to plastics and computers.

Again, I appreciate the opportunity to appear before you here today.

NPRA considers the current Federal chemical regulatory framework to be a solid foundation for protection of human health and the environment. NPRA also understands the Subcommittee's and others desires to example TSCA implementation and where needed consider the modifications to the statute. We support reasonable modernization of our Nation's chemical risk management policies.

However, we believe that a wholesale rewrite of TSCA is neither necessary nor desirable. In support of my views my written statement goes into great detail on a number of these things. Rather than simply summarize that information, I would like this morning to focus on several items that NPRA supports regarding the modernization of TSCA.

A strong legislative framework is critical to creating a successful chemicals management regulatory program and requires deliberate and careful consideration due to the complexity of the issues and their broad impacts on all parts of the American economy. To that end, NPRA supports an open and transparent process of updating our chemical risk management laws so that all stakeholders, including EPA and other relevant Federal officials, NGOs, the affected business community and Members of Congress and their staff can work together to update this statute. Only through such an open and inclusive dialogue can we be assured that steps toward modernization remain constructive. The end result will be a more effective chemicals policy management.

To ensure that kind of open and inclusive discussion needed to make TSCA modernization a success I strongly believe that any initial proposal should begin in the form of a discussion draft rather than a formally introduced bill. I fear that premature introduction of legislation may result in political lines being drawn in the sand which would ultimately impede meaningful discussion and potentially even negate progress. A discussion draft will enable a constructive dialogue among all stakeholders and allow the best ideas and principles to be brought forward.

NPRA also believes that all stakeholders should have a clear idea of what EPA has in terms of information and tools and what the agency needs. Although some claim that EPA is not able to effectively collect information on the risk of chemicals, the agency has in fact obtained a wealth of valuable chemical hazard and ex-

posure information over the years through its new chemicals program, consent agreements, voluntary programs like the HPV Challenge and data call-ins. The HPV Challenge alone resulted in the collection of hazard information for more than 2,100 high production volume chemicals, which represent 95 percent of all chemicals in commerce by volume.

Additionally, NPRA supports a TSCA dialogue focused on risks and not just the hazards a chemical may have. Hazards only speak to the intrinsic properties of a substance, while risk involves the likelihood of a substance to cause harm. As an everyday example of this, consider the automobile. By their very nature, cars are hazardous. They are large, heavy objects propelled by a highly flammable fuel. Yet when operated properly and in a safe manner the risk posed by automobiles is far outweighed by the benefits provided by modern transportation.

By the same token while many of the chemicals used to make products that enhance and improve our lives may have hazardous properties, the risks posed by those substances have been minimized by controls employed by the manufacturing community.

Finally, as we take steps to modernize our Nation's chemicals management policy care must be taken to ensure that TSCA continues to achieve its overarching goals of protecting human health and the environment while at the same time promoting innovation and economic growth of the United States. Here, Senator, in your opening remarks, we agree 100 percent. NPRA believes that these goals are complementary and not mutually exclusive.

There are also those who would like to see the United States adopt a program similar to that approach used in Europe under REACH. In reality, REACH is an unproven program that is already so much of a burden that the French government has set aside 600,000 Euros to help small businesses deal with it.

Mr. Chairman and members of the Subcommittee, we are a Nation of innovators. When it comes to crafting sound, effective, responsible chemical risk management policy, we as a Nation can do better than REACH.

Thank you for your time. I look forward to your questions.

[The prepared statement of Mr. Drevna follows:]

WRITTEN STATEMENT OF

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

"Business Perspectives on Reforming U.S. Chemical Safety Laws."

March 9, 2010

Good morning, Mr. Chairman and Ranking Member Inhofe. My name is Charlie Drevna, and I serve as President of NPRA, the National Petrochemical & Refiners Association. I appreciate the opportunity to testify at today's Subcommittee hearing on "Business Perspectives on Reforming U.S. Chemical Safety Laws." Our association represents more than 450 businesses, including virtually all U.S. refiners and petrochemical manufacturers, their suppliers, and vendors. NPRA members supply consumers with a wide variety of products used daily in their homes and businesses, including fuels, lubricants, and chemicals that serve as building blocks for everything from plastics to clothing, medicine, and computers. As you might imagine, NPRA members have a keen interest in the current legislative efforts to modernize the federal statute governing chemicals management – the Toxic Substances Control Act (TSCA). We appreciate this opportunity to submit our views on TSCA modernization.

I. Introduction

NPRA understands the Subcommittee's desire to examine the implementation of TSCA and, where necessary, consider modifications to the statute to ensure that its important goals and objectives are realized. NPRA supports this objective and looks forward to working with the Subcommittee during its review. We consider the current federal chemicals regulatory framework to be a solid foundation for protecting the health of consumers, our customers and the environment, while simultaneously allowing for the development of products to enhance health, safety and environmental quality. NPRA and our member companies support the responsible modernization of our chemicals risk management regulatory framework. However, NPRA does not believe that a wholesale rewrite of the statute is warranted.

By working together, sharing information, and appropriating the necessary resources, our collective task will be much less cumbersome and much more effective.

II. The U.S. Economy Depends on a Reliable Supply of Materials for Manufacturing

Petrochemicals and their first and second derivatives are the fundamental building blocks that have enabled the United States to maintain its position as a global economic power. Petrochemicals are used throughout the world of organic chemistry, from fundamental research in universities and government laboratories, to the commercial chemistries of specialty chemical producers. With few exceptions, the products of organic chemistry influence every finished good that is manufactured in the United States or imported into this country – whether as a raw material, processing agent or performance additive. From aspirin to asphalt, cosmetics to computers, seatbelts to soap, and umbrellas to zip-lock bags, these products would not be possible without petrochemical derivatives and performance additives made from petrochemical feedstocks. Without petrochemicals and their uses in other manufacturing sectors, our standard of living and the everyday conveniences we have come to expect in the modern world would simply not be possible. Our manufacturing and distribution infrastructure investments over the past decades have provided the entire U.S. manufacturing community with a consistent and abundant supply of raw materials.

III. The Science of Chemistry: Chemicals Are Fundamental

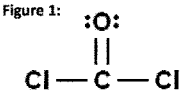
As previously stated, chemistry influences most, if not all, manufacturing in one form or another. Like all manufacturing processes, chemistry is bound by the laws of physics and nature. These physical laws place restrictions on what can and cannot be done when trying to make a chemical compound. For instance, a molecule (i.e., a chemical) is made up of atoms (e.g., sodium, carbon, chlorine, etc.) that are in specific locations or positions on the molecule. In organic chemistry the goal is to take the atoms from one molecule and move them to locations on another, different molecule for the target molecule to assume a specific function or behavior.

The laws of physics and thermodynamics dictate if, how and when those atoms can be moved. To achieve certain critical structural changes, reactive chemicals must be used, and many are by nature hazardous, e.g., toxic, flammable, explosive, etc. In light of these constraints, scientists seeking to achieve certain chemical changes are left with few alternatives. Where hazardous chemicals are used, they are regulated by the Environmental Protection Agency (EPA), the Consumer Product Safety Commission (CPSC), the Occupational Safety and Health Administration (OSHA), the Department of Transportation (DOT) and others, and appropriately managed by professional chemists in universities, government and industry.

Simply stated, scientists cannot produce the materials that make our standard of living possible without relying on specific chemicals. The production of medicine illustrates this point. Producing medicine often requires multiple steps. Each step in the process carefully moves atoms from one molecule to locations on another molecule. Eventually, the scientist will obtain the desired chemical that performs a precise medicinal function. The movement of these atoms, from one molecule to another, is a chemical reaction and can only take place using certain materials and conditions. The chlorine atom, for instance, when located on a specific part of a molecule, allows these steps (reactions) to take place. One common misconception, though, is that any chlorine atom will do. That is not the case. Chlorine atoms take on different behaviors, or physical properties, depending on the specific atoms to which they are attached.

For instance, common table salt consists of the sodium (Na) and chlorine (Cl) atoms, which make up the chemical sodium chloride (NaCl). The chlorine atom used to make medicine, however, often comes from phosgene (COCl2) or phosphorous trichloride (PCl3). Phosgene, for example, has one carbon atom bonded to one oxygen atom and two chlorine atoms (see Figure 1), giving the chlorine atoms in phosgene very

Figure 1:



specific characteristics that are quite different from the chlorine found in table salt. The very specific nature of the chlorine atom in phosgene is critical to its fundamental role in pharmaceutical manufacturing, and minimizes the formation of unwanted, potentially toxic by-products that would otherwise contaminate the medicine. The complex chemistry associated with making medicine has well-defined physical boundaries and requires the use of reactive and toxic chemicals.

IV. Chemical Risk Management Is an Essential Part of Doing Business

Recognizing that some chemicals can be reactive and toxic, vigorous protection of human health and the environment is imperative and requires appropriate chemical risk management. Even though most chemicals in commerce are used in industrial applications and never come in contact with the general public, there is a fundamental need for the federal government to ***appropriately*** manage the risks of all chemicals in commerce from production to disposal.

Like manufacturing, chemical risk management has also evolved over time. Shortly after the creation of the EPA in 1970, Congress realized the need to give the Agency broad authority to protect human health and the environment. Congress enacted specific statutes focused on specific environmental media (air, land and water), and crafted TSCA to focus on the production and distribution of chemicals introduced in commerce.

To assure compliance with the wide range of environmental and occupational safety laws and regulations, many chemical manufacturing companies, including NPRA members, have created and maintained environmental, health and safety (EH&S) departments to help fulfill their obligations under the law. EH&S departments of petrochemical manufacturers quickly concluded that, if approached in a well-organized, systematic manner, compliance with these statutory and regulatory requirements would be less difficult. The collective experience of

EH&S professionals world-wide has led to the current evolution in industrial chemical risk management. This approach has expanded beyond the petrochemical industry as the practice has been adopted by most other major manufacturing sectors, such as electronics, aerospace, automotive and consumer products.

V. Chemical Risk Management Must Be Appropriate for the Situation and Based on Sound Science

Effective chemical risk management strives for the balance between doing nothing – which is unacceptable – and zero risk tolerance – which is neither feasible, sustainable, nor desirable. Prior to the 1970s, society had little concern about industrial chemicals, primarily because it was assumed that the general public would never come into contact with these types of materials. Over time we have learned that certain industrial chemicals can be released during manufacture, use or disposal. Thus began a more comprehensive approach to chemical risk assessment and risk management.

When Congress enacted TSCA, its intent was to provide EPA with broad authority to regulate chemicals in commerce. While some believe TSCA does not provide EPA with the tools to effectively regulate chemicals on the market, it was the intent of Congress to provide a series of checks and balances so that regulatory decisions made under TSCA are scientifically and economically sound. TSCA charges EPA with the collection of existing health and hazard characterization information on all chemicals in commerce today; authorizes EPA to require chemical manufacturers to generate new information on these chemicals; requires manufacturers to report to EPA accounts of previously undetected hazards and risks; and requires both EPA and the manufacturers to manage known risks posed by certain chemicals. The statute also provides the Agency with an opportunity to review new chemicals prior to their introduction into commerce.

While TCSA imposes on EPA the duty to protect workers and consumers as well as the environment, there are provisions in the statute that reduce the likelihood of arbitrary or counter-productive decisions. For example, before EPA can require a company to conduct a costly and intensive toxicity test using laboratory animals, it must first have a sound basis for requiring the production of this information. The Agency must find that the substance in question is used in such a way that there may be a potential for substantial exposure to the chemical to workers or the public. Requiring these findings prior to issuing an order to conduct testing ensures that the information collected by EPA is necessary for the protection of the public and the environment. It also sets the framework for a scientifically and economically sound approach to chemicals management that is tiered, targeted and risk-based.

When EPA does find that a chemical presents, or will present, an unreasonable risk, TSCA provides the Agency with very broad authority to take action to reduce the risk. EPA can require a company to communicate the risk in a specific manner; place restrictions on how a chemical is used; ban certain uses of the substance; and even ban the chemical from the marketplace altogether. Some may argue that there are too many legal hurdles preventing EPA from taking quick and effective regulatory action. In reality, and because it gave the Agency such broad authority, Congress felt the need to ensure that the Executive Branch fully understood the potential consequences of its actions. TSCA requires that EPA fully explore various options to manage the risk, from scientific, economic and social perspectives, because restrictions and bans can cause far-reaching disruptions in the marketplace, including decreasing the availability of essential goods.

Congress took great care in writing TSCA to assure the protection of individuals and the environment, while simultaneously preventing the stifling of innovation and the vast benefits that come with economic prosperity.

VI. Regulatory Chemical Risk Management Has Evolved in the United States

To fully appreciate the evolution of regulatory chemical risk management in the United States, it is important to look at how the various sections of TSCA interact with each other in their entirety and resist isolating and focusing on individual sections. The first question that could be asked is: Why was a distinction made between existing and new chemicals? (This distinction was not made solely in the United States; in fact, it was made by all nations and regions that established chemical regulation laws in the 1970s.)

As enacted, Section 8 of TSCA required EPA to establish an inventory of chemicals that were already in commerce, and to promulgate regulations that required companies to update the health and safety information on those chemicals periodically. This was to provide a baseline of information that enabled the Agency to know what chemicals were in the marketplace and in what amounts. In reality, the approximately 62,000 chemicals originally reported to the TSCA Inventory were never reflective of the chemicals actually in commerce. EPA approached the creation of the Inventory by allowing industry to add whatever chemicals they were currently making – *or were going to make in the future*. This approach led to the addition of many chemicals that were never actually introduced into commerce, as well as the addition of some substances that are physically impossible to produce.

Requiring EPA to conduct risk assessments on all existing chemicals at the same time was simply not feasible or cost-effective because many of the chemicals on the TSCA Inventory were industrial intermediates used only to make other chemicals in closed systems and under tightly

controlled industrial environments (i.e., there was no risk of public exposure to those chemicals). Furthermore, some chemicals on the TSCA inventory have never even been produced; rather, they were simply added to the inventory in the event a company might decide to produce them in the future. Instead, Congress added provisions to Section 8 that required companies to keep records of alleged significant adverse reactions to any chemical and to report any known substantial risk immediately to the Agency. Congress provided EPA with additional authority under Section 8 to collect existing information related to hazards and exposures, even if the risks were not fully characterized.

If EPA determined that the existing hazard and exposure information was insufficient to adequately determine a chemical's risk, then Congress intended for the information collected under Section 8 actions to be used by the Agency to justify requiring companies to conduct additional testing and submit those studies to EPA under TSCA Section 4. Section 4 of TSCA gives EPA authority to require companies to conduct specific laboratory tests to augment the Agency's risk assessment and risk management activities. Once EPA had sufficient information, if it determined that the chemical posed an unreasonable risk, the Agency could take action under TSCA Section 6, which gives EPA very broad authority to take risk management actions. These actions include restricting the use of a substance, requiring specific protective measures, or even imposing an outright ban of a material. The caveat, however, is that EPA would have to fully consider the consequences of its proposed actions, such as a potential lack of available alternatives or a dramatic rise in the cost of goods due to potential disruption in the marketplace.

This approach to chemical risk management is straightforward and effective. However, the implementation phase has not always been so easy. Over the years, EPA has faced conflicting pressures – from activists on the one hand, who have wanted EPA to quickly determine the risks

of all chemicals in commerce and take immediate action on those that are found to present risks, and from the regulated community on the other, which has expressed concerns about the aggregate costs and cost-efficiency of an overzealous regulatory testing program. To find a balance between the two interests and maintain a workable and scientifically sound regulatory scheme, EPA has pursued a tiered, targeted and risk-based approach to chemicals management. Resources and testing are focused on those chemicals with the greatest potential to cause harm to the most people. The Agency first implemented this regulatory concept, in the late 1970s and early 1980s, in the area of new chemicals, which EPA is required to review before they enter into commerce.

TSCA responsibly addresses the issue of new hazard data for chemicals that companies wish to sell into commerce for good reason.[1] In the absence of measured data, EPA devised a more efficient and effective way to quickly review a chemical and decide whether or not the chemical could pose an unreasonable risk, or if the Agency needed more information to make a sound judgment. Due to the broad authority given to EPA, the Agency proposed that companies would submit processing and use-related information on a form, the pre-manufacture notification (PMN), which would allow agency technical staff to estimate the concentrations to which individuals could be exposed. If the estimates indicate a potential for significant exposures, EPA then has the authority to restrict certain processes and uses until more hazard information is developed to allow for a more adequate risk characterization. Over time and with the advent of computers, the Agency has been able to develop software models to assist in conservatively estimating concentrations of chemicals to which people could be exposed.

[1] The intent of Congress was to preserve the high degree of innovation in this country and not significantly raise barriers of entry into the marketplace, especially for small businesses. It can be readily observed that regions requiring overly burdensome or unnecessary testing before a chemical can be sold into commerce do not have nearly as many new chemicals introduced into their regional markets, including new and often safer chemicals that enhance human health and environmental protection, as do those regions that do not require testing.

In addition to new ways of obtaining potential exposure information, EPA determined that it was able to enter into enforceable consent agreements with companies, through which the manufacturer and the Agency would agree to an appropriate battery of tests to further characterize a chemical's hazards. This hazard information would provide greater clarity regarding the chemical's risk to the general public and the environment. EPA has been quite successful in securing the cooperation of companies for the submission of hazard information because it was not cost-effective for a company, under a threat of processing or use restrictions, to adjudicate the matter in court. In addition, companies that wanted to submit more new chemicals did not want to create a negative impression on the Agency that would be reviewing those new chemicals. Also, EPA chose the reasonable and workable approach to ask for testing in a tiered and targeted manner, which used exposure information to help determine which tests would be appropriate.

EPA has been successful in obtaining hazard and exposure information for new chemicals. Under the threat of regulatory action under Section 5, the Agency successfully entered into enforceable consent agreements with many companies, whereby companies submitted toxicity and other studies requested by EPA. Additionally, EPA collected extensive information related to use and exposure on the form used for pre-manufacture notices. These important and clarifying facts are often not mentioned in the TSCA reform debate.

During the nearly three decades of chemical reviews, Agency technical staff noticed that the hazard information under review revealed patterns that could be associated with certain chemicals' molecular structures. Scientists in the field of chemistry already knew that certain physical and chemical properties could be ascertained according to a chemical's molecular structure. Predicting the way that molecules behave is, in fact, the essence of the science of

chemistry. It was reasonable for Agency scientists to assume that structure-activity relationships (SAR) would hold true for chemical reactions taking place inside the human body. However, even today, the chemical reactions taking place inside the body are not nearly as well-understood as reactions taking place in a test tube, where most variables can be recognized and controlled.

EPA technical reviewers understood that predicting chemical reactions inside the body – the basis upon which the field of toxicology is based – was in its infancy (and still is when compared to other natural sciences). The question then became: To achieve protection of consumers and the environment, how accurate does EPA have to be when characterizing the hazards of chemicals? If the Agency took a conservative approach and overestimated potential impacts, it would limit the need for an extensive array of specific tests and still maintain protection of human health and the environment. Conservative approaches use default assumptions, which usually overestimate conditions and employ protective safety factors. This led EPA to begin estimating ranges of toxicity, rather than trying to characterize certain endpoints with exactitude.

Both a June 2005 and January 2009 GAO report to Congress on TSCA questioned the accuracy of the long-standing models used by EPA to review new chemicals. The reports failed to note, however, that the conservative nature and protectiveness of the models is sufficient to achieve their risk assessment and risk management objectives. With an ever-increasing amount of data from testing programs and consent agreements under both the new and existing chemicals programs, EPA has more than sufficient data to refine its models.[2] Patience is needed, however, because this is not and cannot be an overnight process.

The field of toxicology is still evolving, and the discipline should be afforded the same time needed by other natural sciences to develop. The constant demand by some that EPA be

[2] Data collected under consent agreements and the voluntary HPV Challenge are typically not included in discussions concerning the effectiveness of TSCA Section 4. Including these sources of information, EPA has data on several thousand chemicals.

required to do everything at an unreasonably rapid pace, as is the case under the new European chemicals policy, is ill-advised and may inhibit the natural evolution of toxicology as a science, and ultimately lead to errant decision-making.

VII. EPA Has Faced Challenges When Implementing TSCA, but Has Met Those Challenges

While proponents of a dramatic overhaul to domestic chemicals policy have argued that TSCA prevents EPA from carrying out its duties, NPRA believes that the challenges with TSCA implementation are more due to grossly inadequate funding, outside pressure that results in hasty regulation, and the sequence in which the TSCA tools have been implemented. A thorough and careful review of the Federal Register and associated dockets reveals that in some early risk management actions, EPA did not, or was not able to, do as thorough a job as was necessary. A review of opinions from related court cases over the years readily affirms this.

That is not to say NPRA believes that EPA has not been doing its job well. On the contrary, when TSCA was passed, chemical risk management was in its infancy, as were certain aspects of the fields of toxicology, exposure assessment, and chemical risk assessment. EPA has been able to successfully develop ways to achieve the objectives and goals of TSCA, while allowing innovation to foster in the marketplace. The main factors contributing to EPA's difficulties in implementing TSCA are due more to its choices in the timing and sequence of Section 4 test rules, and over-reaching bans of uses in Section 6 risk management actions, versus challenges posed by the statute.

Many proponents of TSCA reform point to one specific case (*Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991)), where EPA attempted to ban asbestos using its authority under Section 6, as proof that TSCA does not provide EPA sufficient authority to manage risks. EPA was challenged in court because there was a critical need for asbestos in this particular use

(brake linings), no suitable alternatives for asbestos existed in this application, and the Agency did not explore other ways to manage the risk. The clearly written opinion of the Court of Appeals for the Fifth Circuit demonstrates that EPA could have maximized its chances for success in regulating only certain uses of asbestos. If EPA had taken the appropriate approach towards the risk management of asbestos – concentrating resources first on those uses that could result in the highest concentrations of airborne particles and where alternatives could be used – the Agency would have been in a significantly better position to prevail in the case. Instead, the Agency tried to ban a critical use of the substance for which there were no readily available substitutes. Further, EPA did not evaluate other risk management approaches short of a ban. NPRA believes that this, and not some inherent TSCA shortcoming, is the primary reason the rule was successfully challenged in court. After EPA lost this case, the Agency basically stopped trying to issue Section 6 actions. An agency that has rarely used its authority cannot simply blame the statute that grants it that authority for lack of action. Attempts to ban most uses of a substance with readily demonstrable benefits, especially public health or life-saving benefits, must meet a very high burden of proof.

The Agency's difficulties in promulgating test rules have been due less to TSCA statutory problems than to decisions made by EPA on timing and sequence. In most cases, if the Agency had chosen to collect use and exposure information under Section 8 first, and then reviewed the available information, especially pertaining to uses and potential exposures, the Agency would not have faced the challenges that it had faced early on when attempting to promulgate Section 4 test rules. Because EPA will now be collecting use and exposure information as part of the Inventory updates from industry, in addition to its use of information collections under other

parts of Section 8, issues surrounding the promulgation of Section 4 test rules should begin to diminish.

After these early experiences in court, EPA has been reluctant to attempt Section 6 and Section 4 actions. The Agency has stated that the findings for actions under these particular sections are difficult to make. EPA has recently used its Section 8 authority, however, to successfully collect the necessary use and exposure information to justify more Section 4 test rules on the remainder of the high production volume chemicals that have not been voluntarily tested by industry. The first Section 4 test rule was successfully promulgated several years ago, and the Agency plans to finalize another test rule within the next several months.[3] Additionally, EPA has stated that it will continue issuing test rules until all HPV chemicals are either volunteered or covered under a rule.

Regarding Section 6, EPA has used collaborative partnerships and stewardship programs to provide manufacturers along the supply chain with opportunities to voluntarily discontinue certain products. All cases where the Agency has taken a collaborative approach have resulted in demonstrable success (e.g., withdrawal of the substance from commerce or establishment of a specific timeframe for withdrawal). In addition, EPA typically follows up with a Section 5 Significant New Use Rule, which authorizes the Agency to require companies to submit notifications (similar to PMNs) when a company wants to reintroduce the existing chemical back into the marketplace. During public meetings of the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), EPA and other stakeholders repeatedly expressed that Section 5 was an effective risk management tool for new uses of existing chemicals as well as new chemicals. NPRA is puzzled and somewhat perplexed that EPA and others appear to have

[3] The first HPV test rule was not challenged in court by any chemical company, primarily because EPA worked together with industry and collected sufficient information to make the appropriate exposure findings.

recently altered their views about the effectiveness of Section 5 and, in general, the new chemicals program within OPPT.

In addition to the authorities provided under TSCA, EPA collaboration with multiple stakeholders is probably the most workable and efficient use of its resources when assessing and managing the risks of chemicals. The collaborative approach was put to the test in a dramatic manner in the late 1990s, when the High Production Volume Chemical Challenge (HPV Challenge) was created. EPA asked chemical companies to voluntarily provide a base set of hazard and environmental fate information for all chemicals manufactured or imported at greater than 1 million pounds per year in aggregate. The chemical industry willingly complied and sponsored over 2,150 chemicals, either in the U.S. HPV Challenge program or the Organization for Economic Cooperation and Development (OECD) HPV Programme. The HPV Challenge has resulted in more publicly available hazard data, generated in a timelier manner, than any other program in the world, regulatory or otherwise.

Building upon the success of the HPV Challenge and coordinating with its counterpart in Canada, in 2008 EPA committed to conducting hazard and risk characterizations on all HPVs and moderate volume chemicals (MPVs) in commerce as part of the U.S. government commitment to the Security & Prosperity Partnership of North America.[4] The name for this initiative was the Chemical Assessment and Management Program (ChAMP). Under ChAMP, EPA would have been able to prioritize risk assessment and risk management activities for chemicals in a more transparent and expeditious manner than ever before. Unfortunately, those commitments and plans have been abandoned. The decision to abandon that ground-breaking

[4] MPVs are described as chemicals manufactured or imported at quantities between 25,000 pounds and 1,000,000 pounds per year in aggregate. Most chemicals below the 25,000 pound-per-year threshold are primarily either research and development chemicals or certain fine chemicals, both of which are typically used in tightly controlled industrial environments.

program had nothing whatsoever to do with the TSCA statute. In fact, EPA stated that it abandoned ChAMP in favor of using more of its authorities under TSCA, which seems contradictory to its calls for TSCA reform.

There have been calls from some groups to completely overhaul domestic chemicals policy and follow the European approach to chemicals management. The European Union has just started to implement new legislation – Registration, Evaluation and Authorization of Chemicals (REACH) – which dramatically overhauls its chemicals policy. It calls for extensive animal and other testing of chemicals, based primarily on the quantities at which they are manufactured or imported. There are many misconceptions about REACH that must be examined and resolved, such as:

- Assertion: REACH relieves the government of the burden of chemical safety and places it on industry.

  Reality: REACH only increases the burden on industry. It does not reduce the burden on government. No government authority is going to receive a chemical dossier from industry and take it at face value. Rather, the government authority will conduct its own risk assessment, based on available information, and render its own decisions, risk-based or not. This will be just at least as time-consuming and resource-intensive under REACH as it is under TSCA. In fact, it will likely be more time-consuming because EU authorities will have to sift through a plethora of data that it collected, whether that data was needed or not. A careful reading of the REACH statute shows that the authorities must fully evaluate socio-economic considerations before proposing a restriction or ban, much like what EPA is required to do under Section 6 of TSCA. Furthermore, REACH places so much burden on industry that small- and medium-sized chemical manufacturers are facing significant difficulties complying with the program. For example, the French government recently announced a plan to provide over €600,000 in assistance to help French companies meet the November 2010 REACH registration deadline[5]. It is mostly in the risk management decision-making criteria that the two approaches diverge. Decisions in the U.S. must be based on sound science and weight of the evidence, while decisions in the EU can be based on partial science (i.e., only hazard) and current political disposition.

- Assertion: REACH will spur innovation in safer chemicals.

[5] Chemical Watch. "French Government and Industry Join Forces to Meet REACH Deadline. 16 Feb 2010.

Reality: Innovation is a function of spending on research and development and ease of entry into the marketplace. Little more than a decade ago, the EU decided to require companies to conduct overly burdensome toxicity and environmental fate testing, disregarding whether or not there were any actual exposures to the substances, before a particular chemical could enter the marketplace. This approach has inhibited the development of products in Europe that could enhance health and the environment. This fact can be verified through the number of new, and usually safer, chemicals introduced into the European marketplace (around 2,000 over the past ten years), versus the number of new chemicals that companies have at least attempted to introduce in the U.S. (between 1,200 and 1,500 *per year*). Another compounding factor is that in business, toxicity and other laboratory testing is considered part of research and development and typically comes out of R&D budgets. That leaves much less money for new, and often safer, product development.

- Assertion: REACH fully considers animal welfare.

  Reality: No matter what the statutory language reads, REACH will have a devastating impact on animals. It is disingenuous for the European Commission to require testing for thousands of chemicals, based solely on volume, and claim that it has fully considered animal welfare.

- Assertion: REACH is the wave of the future for chemicals policy.

  Reality: REACH is a regulatory concept that has never been attempted anywhere in the world, at any time. It is entirely premature to draw any conclusions about REACH and it is equally untimely to attempt any comparison between REACH and regulatory programs that have been in effect for decades. In fact, authorities in Europe have already been inundated with so much information that they simply cannot keep up.

Pursuit of a program like REACH, taken on with the best of intentions for human health and safety, could very well impair health and safety by denying critical products entry into the marketplace. Such a program will place unnecessary burdens on industry that will result a significantly higher cost of doing business, inhibiting the development of products to enhance our way of life. The United States should resist adopting or moving towards this type of program as it explores modernizing TSCA.

VIII. Due to Current Economic Uncertainty, Care Must Be Taken When Reforming Chemicals Policy

This Subcommittee will examine TSCA's implementation and, where necessary, make the appropriate modifications to the statute to ensure that its goals and objectives are realized. In the same vein, however, we live in an era where global competition and rapid technological change – now unfortunately coupled with a debilitating financial crisis – are calling into question the economic constructs on which our prosperity has rested for decades. Care must be taken to ensure that the overarching goals of TSCA – protecting human health and the environment – are achieved while at the same time promoting innovation, economic growth and U.S. competitiveness in the global marketplace.

NPRA is confident that these goals are complementary, not mutually exclusive, and NPRA pledges to work with Congress and all stakeholders to ensure the desired outcome.

IX. Conclusion

Chemical risk management has evolved and is continuing to evolve in the United States. EPA is recognized as a world leader in chemicals policy, and the Agency's opinion is highly valued in the international community. A thorough study of the TSCA statute clearly reflects that Congress has given EPA broad authority to regulate chemicals in commerce. The intent of Congress – protection of human health and the environment while maintaining an appropriate system of checks and balances – is also clear in both the statute and the Record.

Our nation's current chemicals policy has allowed American businesses to survive in an increasingly competitive marketplace. Reform of domestic chemicals policy will necessarily take time and careful deliberation. NPRA therefore urges Congress to consider an inclusive, transparent process when crafting language to modernize the Toxic Substances Control Act.

Answers to Follow-Up Questions
Senate Environment and Public Works Committee Hearing on March 9, 2010

Submitted by Charles T. Drevna, President
National Petrochemical & Refiners Association

Question from Chairman Barbara Boxer

1. **Please provide me with a list of the National Petrochemical and Refiners Association members, and a description of which members are subject to the European Union's Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals law.**

Answer:
NPRA's website – www.npra.org – has a list of our regular members that refine crude oil into useful products or manufacture petrochemicals through similar engineering processes. The main product exported from U.S. refineries to Europe is diesel fuel, which is subject to certain REACH requirements. NPRA does not track which companies are specifically selling into European markets.

Petrochemicals are traded worldwide, but trading may be done through a series of intermediaries. It can be difficult to discern which petrochemicals make it into which specific markets. Many NPRA members are international companies and have operations or do business in Europe. We do not have an exact count, but companies with European operations are likely subject to REACH.

Question from Ranking Member James Inhofe

1. **Do you have any scientific or legal concerns with inserting a safety standard in TSCA?**

Answer:
If safety were approached in a manner that included consideration of hazard and exposure, similar to how EPA currently approaches its assessment of industrial chemicals, NPRA could be supportive of a safety standard. However, NPRA is concerned that such a safety standard would be approached in a similar manner as EPA's pesticide programs. Laws governing the risk management of pesticides are by necessity different than laws governing industrial chemicals. Pesticides have a higher likelihood of coming into contact with the public because of their use on crops and in living and working spaces and, therefore, are subject to enhanced testing and other requirements to ensure their safety. Industrial chemicals are not pesticides and should not be treated as such.

EPA has a history under its pesticide programs of requiring extremely extensive testing before it is confident in saying that a substance is "safe." This is one of the chief concerns for NPRA. For example, in the case of a certain family of pesticides, EPA asked for so much information that the manufacturer decided to discontinue its $300 million per year product line. When a company discontinues a product, jobs are lost and consumers are deprived of choices, including choices of potentially safer chemicals. The producer discontinued manufacture is because it would have taken years to recover the costs of testing, even at the higher profit margins of pesticide formulations. For industrial chemicals the profit margins are very slim and it would take even longer to recover the costs of testing. A chemical management system should not

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force products out of the market unless the results of a risk assessment warrant that kind of action. If EPA takes an approach to safety for industrial chemicals like it do for pesticides, NPRA would not support such an initiative.

2. **In your testimony, you discuss the now defunct Chemical Assessment and Management Program (ChAMP). Under ChAMP, EPA would have prioritized risk assessment and management of chemicals. As you noted, 'the decision to abandon that program had nothing to do with the statute ... EPA stated that it abandoned ChAMP in favor of using more of its authorities under TSCA, which seems contradictory to EPA calls for TSCA reform. '**

   I agree with you, and wonder whether you would find some of the elements of ChAMP appropriate to incorporate into modernizing the statute?

Answer:
In August 2007, the United States, Canada and Mexico entered into an agreement (the Montebello Agreement) to coordinate chemical risk management in North America. From that agreement, the Chemical Assessment & Management Program (ChAMP) was launched by EPA, which set forth a plan to assess and prioritize all chemicals in commerce produced or imported in commercial quantities. EPA committed to continue its close work with Canada and look to the Canadian Chemical Management Plan as a viable model for chemical prioritization. The U.S. government should honor its obligations under the Security and Prosperity Partnership of North America.

There are elements of ChAMP that are appropriate for TSCA modernization. EPA should be required to prioritize chemicals in commerce using existing data and its predictive models and given the appropriate resources to do so. EPA should also follow a tiered, targeted and risk-based approach to risk assessment and risk management.

The batch process employed by Canada allows authorities to use conservative methods to estimate hazards and exposures, post the results on a public web site and invite industry to prove the government's findings otherwise. It places the burden on companies to prove that their chemicals are safe. Canada's approach to prioritization and subsequent testing has been efficient and effective, and is more suited to the North American business model than the European approach to chemicals management. EPA should follow a similar path.

Answers to Follow-Up Questions
Senate Environment and Public Works Committee Hearing on March 9, 2010

Submitted by Charles T. Drevna, President
National Petrochemical & Refiners Association

Question from Senator David Vitter

1. **Do you have any scientific or legal concerns with some of the safety standards being discussed for TSCA reform?**

Answer:
If safety were approached in a manner that included consideration of hazard and exposure, similar to how EPA currently approaches its assessment of industrial chemicals, NPRA could be supportive of a safety standard. However, NPRA is concerned that such a safety standard would be approached in a similar manner as EPA's pesticide programs. Laws governing the risk management of pesticides are by necessity different than laws governing industrial chemicals. Pesticides have a higher likelihood of coming into contact with the public because of their use on crops and in living and working spaces and, therefore, are subject to enhanced testing and other requirements to ensure their safety. Industrial chemicals are not pesticides and should not be treated as such.

EPA has a history under its pesticide programs of requiring extremely extensive testing before it is confident in saying that a substance is "safe." This is one of the chief concerns for NPRA. For example, in the case of a certain family of pesticides, EPA asked for so much information that the manufacturer decided to discontinue its $300 million per year product line. When a company discontinues a product, jobs are lost and consumers are deprived of choices, including choices of potentially safer chemicals. The producer discontinued manufacture is because it would have taken years to recover the costs of testing, even at the higher profit margins of pesticide formulations. For industrial chemicals the profit margins are very slim and it would take even longer to recover the costs of testing. A chemical management system should not force products out of the market unless the results of a risk assessment warrant that kind of action. If EPA takes an approach to safety for industrial chemicals like it do for pesticides, NPRA would not support such an initiative.

2. **Can you discuss some of the problems with EPA's chemical inventory? My understanding is that they list 80,000 chemicals as being in commerce and the number is probably 1/4 that.**

Answer:
The TSCA Inventory is outdated and does not accurately reflect the chemicals in commerce. In fact, some of the chemicals originally registered on the TSCA inventory did not and do not exist. They were registered in anticipation of being created, but they were never developed. Many other chemicals on the list are no longer in commerce.

The current TSCA statutory language directs EPA to "compile, keep current, and publish a list" of chemicals in commerce. As part of the Chemical Assessment & Management Program (ChAMP), EPA planned to work with stakeholders and resolve issues with the TSCA Inventory and make it reflective of the substances that are actually in commerce. EPA has since abandoned

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the ChAMP initiative. EPA still retains the authority to update the TSCA Inventory; however, NPRA is not aware how the Agency will go about it.

3. **In your testimony, you discuss the now defunct Chemical Assessment and Management Program - known as ChAMP. Under ChAMP, EPA would have prioritized risk assessment and management of chemicals. As you noted, "the decision to abandon that program had nothing to do with statute ...EPA stated that it abandoned ChAMP in favor of using more of its authorities under TSCA, which seems contradictory to EPA calls for TSCA reform." I wonder whether you would find some of the elements of ChAMP appropriate to incorporate into modernizing the statute?**

Answer:
In August 2007, the United States, Canada and Mexico entered into an agreement (the Montebello Agreement) to coordinate chemical risk management in North America. From that agreement, the Chemical Assessment & Management Program (ChAMP) was launched by EPA, which set forth a plan to assess and prioritize all chemicals in commerce produced or imported in commercial quantities. EPA committed to continue its close work with Canada and look to the Canadian Chemical Management Plan as a viable model for chemical prioritization. The U.S. government should honor its obligations under the Security and Prosperity Partnership of North America.

There are elements of ChAMP that are appropriate for TSCA modernization. EPA should be required to prioritize chemicals in commerce using existing data and its predictive models and given the appropriate resources to do so. EPA should also follow a tiered, targeted and risk-based approach to risk assessment and risk management.

The batch process employed by Canada allows authorities to use conservative methods to estimate hazards and exposures, post the results on a public web site and invite industry to prove the government's findings otherwise. It places the burden on companies to prove that their chemicals are safe. Canada's approach to prioritization and subsequent testing has been efficient and effective, and is more suited to the North American business model than the European approach to chemicals management. EPA should follow a similar path.

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

Ms. Gerwig, we look forward to hearing from you.

STATEMENT OF KATHY GERWIG, VICE PRESIDENT, WORKPLACE SAFETY AND ENVIRONMENTAL STEWARDSHIP OFFICER, KAISER PERMANENTE

Ms. GERWIG. I would very much like to thank Chairman Lautenberg and members of the Subcommittee for inviting me to testify before you today.

My name is Kathy Gerwig. I am Vice President of Workplace Safety and the Environmental Stewardship Officer for Kaiser Permanente, the Nation's largest integrated health care delivery system. Our mission is to provide high quality, affordable health care services and to improve the health of members that we serve. Our commitment to the issues the Subcommittee is exploring today is an important and integral part of this mission.

At Kaiser Permanente we understand that healthy communities and a healthy environment are critical to the health and wellness of every person. We are dedicated to environmental sustainability because it has direct, positive effects on individual and community health. Since the organization was founded in 1945, we have worked to curb our overall impact on the environment by using safer chemicals, building greener hospitals, reducing waste, purchasing locally grown food and using sustainable energy. We believe that through our practices we can promote the creation and adoption of safer chemicals and sustainable materials in a way that supports a healthy economy, healthy environment and healthy people.

Kaiser Permanente spends $14 billion annually on products and services. Despite this leverage we have experienced limitations in achieving our goal of using products and materials that are environmentally sustainable. To address the lack of chemical safety information our procurement and supply staff developed a supplier disclosure process that is used for major medical product purchases across our entire system. This disclosure is unique because we require information on a product specific basis. The information to be disclosed includes whether the product contains heavy metals, halogenated flame retardants, polyvinyl chloride, or PVC, diethylhexyl phthalate or DEHP, or ingredients contained on California's Proposition 65 list of chemicals that cause cancer or reproductive harm.

We also ask for information on the supplier's safer alternatives. The process requires comprehensive vendor education and aggressive demands for safety and ingredient information. Another challenge we face is that many products that are labeled green are made from chemicals without adequate or any safety testing. A truly green product is one that is environmentally and biologically benign throughout its life cycle.

Kaiser Permanente was the first health system in the U.S. to contract for patient controlled analgesia sets that are totally free of PVC and DEHP. This is significant because we purchase the equivalent of 18 miles of tubing annually. While the cost of this change reflected a savings over our prior contract, it would have been even less expensive to buy tubing that was made from PVC

and DEHP. Balancing pricing with environmental and public health considerations is always a challenge.

To address chemicals found in fabrics, we created a sustainable fabric alliance program to embed environmental considerations into choosing fabric and fabric vendors. The considerable time and resources committed to this work was justified because there was no other way for us to ensure that our fabrics were free of chemicals of concern.

We also support safer chemicals through research. Our division of research conducted the first study to look at the effect of high levels of workplace exposure to bisphenol-A, or BPA, on the male reproductive system in humans. This recent study adds to the body of evidence questioning the safety of BPA, a chemical used in the production of polycarbonate plastics and epoxy resins found in baby bottles, plastic containers, the lining of cans used for food and beverages, and in dental sealants. Kaiser Permanente purchases baby bottles that are free of BPA, and we continue to push for safer alternatives to products that contain BPA.

As we strive to advance an economy where the production and use of chemicals are not harmful for humans and the environment Kaiser Permanente invests significant time and resources. That degree of investment is simply not feasible for most products and materials we buy, nor is it possible for most organizations that don't have the resources and skills that we have developed over the decades. Mechanisms are needed to support downstream users in procuring the safest products and materials for our needs.

Mr. Chairman and distinguished members of the Committee, thank you for the invitation to testify here today. I look forward to answering any questions you may have.

[The prepared statement of Ms. Gerwig follows:]

KAISER PERMANENTE®

Testimony of Kathy Gerwig, Kaiser Permanente

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

March 9, 2010

I would very much like to thank Chairman Lautenberg, Ranking Member Inhofe and Members of the Subcommittee for inviting me to testify before you today. My name is Kathy Gerwig. I am Vice President for Workplace Safety and Environmental Stewardship Officer for Kaiser Permanente, the nation's largest integrated health care delivery system. Our mission is to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve. Our commitment to the issues the Subcommittee is exploring today is an important and integral part of this overall mission.

At Kaiser Permanente, we understand that healthy communities and a healthy environment are critical to the health and wellness of every person. We are dedicated to environmental sustainability because it has direct, positive effects on individual and community health. Since the organization was founded in 1945 we have worked to curb our overall impact on the environment by using safer chemicals, building greener hospitals, reducing waste, purchasing locally grown food, and using sustainable energy. Our aim is to provide health care in such a way that the production and use of chemicals are not harmful for humans or the environment.

We've taken a cautious approach to materials, meaning that where there is credible evidence that a material we're using may result in environmental or public health harm, we strive to replace it with safer alternatives. We believe that through our practices, we can help promote the creation and adoption of safer chemicals and sustainable materials in a way that supports a healthy economy, healthy environment, and healthy people.

Kaiser Permanente spends $14 billion annually on products and services. We lease or own more than 65 million square feet of real estate. During 2009 we opened three hospitals, one new hospital tower and 17 medical office buildings. Despite this leverage, we have experienced limitations in achieving our goal of using products and materials that are environmentally sustainable.

To address the lack of chemical safety information, our procurement and supply staff developed a supplier disclosure process that is used for major medical product purchases across our entire system. The disclosure is unique because we require information on a product-specific basis. The information to be disclosed includes whether the product contains heavy metals, halogenated flame retardants, polyvinyl chloride (PVC), diethylhexyl phthalate (DEHP), or ingredients contained on California's Proposition 65 list of chemicals that cause cancer or reproductive harm. We also ask for information on the suppliers' safer alternatives. The process requires comprehensive vendor education and aggressive demands for safety and ingredient information.

Many of the ingredients on the disclosure document are not present on the Occupational Safety and Health Administration's (OSHA's) required Material Safety Data Sheets due to trade secret caveats and the exemption of small concentrations from reporting even though the chemicals may cause harm in low doses.

Another challenge we face is that many products are labeled "green "or "environmentally friendly" for reasons that include reduced energy use, recycled content or reduced waste production. Some of these so-called "green" products are made from materials that are toxic or made from chemicals without adequate or any safety testing. A truly "green" product is one that is environmentally and biologically benign throughout its life cycle.

Exam gloves proved to be one of our successes. In the desire to move away from powdered latex and vinyl exam and surgical gloves, a decision was made to purchase gloves made of nitrile. Latex gloves present a problem for patients and staff with allergic reactions, and vinyl gloves create the byproduct of dioxin pollution in both manufacturing and disposal processes. Kaiser Permanente's decision to buy an alternative to vinyl gloves affected the entire medical glove industry because we use more than 50 million gloves each year. The change increased the national supply of nitrile gloves and eventually lowered the cost of nitrile gloves for all glove purchasers.

Kaiser Permanente was the first health system in the United States to contract for patient-controlled analgesia (PCA) sets that are totally free of polyvinyl chloride (PVC) and DEHP. This is significant because we purchase the equivalent of 18 miles of tubing annually. While the cost of this change reflected a savings over our prior contract, it would have been even less expensive to buy tubing that was made from PVC and DEHP. Balancing pricing with environmental and public health considerations is always a challenge.

To address chemicals found in fabrics, Kaiser Permanente created a Sustainable Fabric Alliance Program to embed environmental considerations into choosing fabric and fabric vendors. With a reduction of vendors in the Alliance program, the vendors obtain increased sales volumes, allowing KP to use sustainable fabrics at a savings. The considerable time and resources committed to this work was justified because there was no other way for us to ensure that our fabrics were free of chemicals of concern.

We also support safer chemicals through research. Our Division of Research conducted the first study to look at the effect of high levels of workplace exposure to Bisphenol-A, or BPA, on the male reproductive system in humans. This recent study, which appeared in the journal *Human Reproduction*, adds to the body of evidence questioning the safety of BPA, a chemical used in the production of polycarbonate plastics and epoxy resins found in baby bottles, plastic containers, the lining of cans used for food and beverages, and in dental sealants. Kaiser Permanente purchases baby bottles that are free of BPA, and we continue to push for safer alternatives to other products that contain BPA.

As we strive to advance an economy where the production and use of chemicals are not harmful for humans or the environment, Kaiser Permanente invests significant time and resources. That degree of investment is simply not feasible for most products and materials we buy, nor is it possible for most organizations that do not have the resources and skills that we have developed over decades. Mechanisms are needed to support downstream users in procuring the safest products and materials for our needs.

Mr. Chairman and distinguished members of the Committee, thank you again for the invitation to testify here today. I look forward to answering any questions you may have.

KAISER PERMANENTE®

April 19, 2010

The Honorable Barbara Boxer, Chairman
The Honorable James M. Inhofe, Ranking Member
Committee on Environment and Public Works
410 Dirksen Senate Office Building
United States Senate
Washington, DC 20510

Dear Chairman Boxer and Ranking Member Inhofe,

Thank you for the opportunity to provide additional information to the testimony presented at the March 9, 2010 hearing of the Subcommittee on Superfund, Toxics and Environmental Health titled "Business Perspectives on Reforming U.S. Chemical Safety Laws."

Questions from Senator Boxer:
1. Would a federal policy that ensures chemical manufacturers provide the public with basic safety data on their chemicals help Kaiser make better choices about purchasing appropriate products for its business?

Response: We make use of available information to inform our purchasing decisions, and having additional data on product safety would improve our ability to evaluate the options. We have found that data on the Occupational Safety and Health Administration's (OSHA's) required Material Safety Data Sheets is not adequate due to trade secret caveats and small concentrations that exempt manufacturers from reporting although the chemicals may cause harm in low doses.

2. Please describe whether the current federal law regulating the use of chemicals in the United States provide public health protections for vulnerable individuals, such as infants and children, who come to Kaiser for medical care?

Response: Infants and children are at a disadvantage when exposed to harmful chemicals. Per pound of body weight, children take in more air, water and food than adults, which means greater exposure to environmental toxicants. And because their systems aren't yet fully developed to detoxify industrial chemicals, they absorb more toxins. Regulation that reduces toxins in the environment would benefit public health.

Question from Senator Inhofe:
In your testimony you said that Kaiser is 'challenged' by the fact "that many products are labeled 'green' or 'environmentally friendly'" for reasons not related to toxicity or safety. And, that, "A truly 'green' product is one that is environmentally and biologically benign throughout its life cycle." Are you suggesting that TSCA be reformed to review chemicals for 'green-ness'? What is your scientific definition of 'environmentally and biologically benign throughout' a chemical's life cycle? Do you believe that it's a standard that all chemicals and compounds should have to meet? And, if so, wouldn't water have a hard time meeting that test?

Response: My comment was to share a challenge we face when trying to purchase environmentally sustainable products, which is that manufacturers sometimes claim that a product is "green" when it has one such attribute (e.g., conserves energy) when in fact it may contain toxic materials or be made from chemicals without adequate or any safety testing. If TSCA is reformed to ensure adequate safety testing, we will benefit from that information as we make product choices.

In referring to environmentally and biologically benign products, I mean those that are made of chemicals that have low to no toxicity and degrade into innocuous substances in the environment.

Thank you very much for your interest in this topic.

Sincerely,

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Senator LAUTENBERG. Thank you very much, Ms. Gerwig.

I want to say that your testimony, the testimony from each one of you was worth hearing. I assure you, we listened carefully.

I also want to say if I was to play the role of the school teacher, the class was excellent; timing was wonderful. You did a great job in meeting the rigid standards of our time requirements.

Ms. Fisher, in our oversight hearings, two main problems have arisen over and over. First, that EPA cannot get all of the data it needs on chemical safety, and second, EPA cannot adequately regulate risks from chemicals. Are you in agreement that EPA should be able to acquire more safety data on chemicals and restrict the use of high risk chemicals?

Ms. FISHER. Thank you, Mr. Chairman. I think the way TSCA is currently drafted it requires a lot of process and rulemaking for EPA to gather the data it might need to assess chemicals. Similarly, when the agency moves to take risk management decisions the tools are there but the way they are currently drafted, they become very time consuming. I think that has led to the frustration that the public feels and sometimes, quite honestly, industry feels, in getting them to make a decision.

Senator LAUTENBERG. Under current law, EPA bears the burden of proving that a chemical is unreasonably dangerous before the agency can restrict it to protect public health. Even EPA's effort to ban asbestos failed to meet this heavy burden. Should the chemical companies have the responsibility to prove that their products are safe before us, Ms. Fisher?

Ms. FISHER. Absolutely. I think the industry should have the burden to show that the products they are bringing to the market are safe.

Senator LAUTENBERG. Dr. Hawkins, how do you feel about that?

Mr. HAWKINS. I think the burden of proof should rest with the private sector, with industry. So that I definitely agree with.

But I do also believe that EPA needs to have the authority and power when there is a use of a chemical that they believe creates risk that needs to be regulated and stopped that they have the authority to act. And so it is really two-pronged. We have the responsibility to provide the information and the substantiation of the safety. But we do need decisions on the tail end as well.

Senator LAUTENBERG. The one thing that I gleaned from the testimony overall is to be careful about the way a TSCA reform should be developed. I assure you that casual carelessness is not the place we want to be. Sound science, we want that to be the top indicator as to what it is we should proceed with.

So the cautionary notes that we get, I hear those as well. But I assure you that we don't want to produce a product that is just a product. We want to produce a product that has value. We want to produce a product that will prevent lots of diseases that children seem to be acquiring, whether it is cancer, neuro-behavioral, asthma, et cetera. We know that there is a significant influence on materials in human development. We want to make sure we do whatever we can to protect our children, including my 10 grandchildren and everybody else's grandchildren across this country.

Ms. Gerwig, because the Government is not adequately reviewing the safety of chemicals your company has spent an enormous

amount of money trying to ensure that you are not exposing patients to dangerous chemicals. I note that the material in gloves was changed. I wasn't aware of that. It sounds simple when you have done the right thing, I must say.

Would requiring chemicals to be reviewed by EPA scientists reduce costs and do you think improve profitability for companies like yours?

Ms. GERWIG. Shifting the burden away from downstream users, such as us, and pushing it toward the EPA and toward chemical manufacturers would certainly allow us to allocate our resources to providing health care as opposed to looking at the substances that are in the products that we use.

Senator LAUTENBERG. Ms. Fisher, I am not picking on you, but we do want to hear from you further. Chemicals that we call PBTs buildup in our bodies, fail to break down over time and are known to be toxic. Other governments have taken action to restrict most uses of these PBTs without putting these chemicals through a traditional risk assessment process. Should we provide a way to reduce the use of PBTs quickly, without waiting for the risk assessment process to run the course? Are they so dangerous?

Ms. FISHER. First of all, Mr. Chairman, EPA has done a lot to regulate many of the PBTs that have historically been in commerce under a number of different statutes. I think that we have to be careful how we construct TSCA. You want EPA to make prompt decisions based on good science. But to make the proper risk management decisions they are going to have to understand where the exposures are coming from.

We really do want them to comment on where people are being most exposed. So they need to have enough information to make those calls.

Senator LAUTENBERG. Thank you.

Senator Whitehouse, you have acquired 7 minutes' worth of time to balance our discussion here.

Senator WHITEHOUSE. Thank you.

I thank all the witnesses for their testimony. I was particularly struck by the testimony of the representatives from DuPont and Dow, the great chemical companies of our country, who both said, Ms. Fisher from DuPont, the time to modernize TSCA has come, and Dr. Hawkins for Dow, Congress should reform TSCA; there is an emerging consensus that reform is necessary. So I think that puts us in a good position to move forward.

I have a number of questions. The first has to do with protections from foreign competition. Whenever heightened environmental and safety standards are proposed for American companies, we very often hear back that, well, we really shouldn't do that because it puts us at a competitive disadvantage with other countries.

I would rather solve that problem with protections at the border to make sure that harmful products are not imported to our country than I would by continuing to allow American industry to make unsafe products in a sort of international race to the bottom of product safety. I would love to have your advice, and I would be delighted to take this as a question for the record, if you wanted to have a moment to think about it, and to write down what your specific recommendations would be, what we should be doing to as-

sure that our products that are imported meet our safety standards.

In that context, I would also like to ask each of you—each of your organizations, anyway—to take a look at the Foreign Manufacturers Legal Accountability Act, which is a bipartisan piece of legislation proposed by me and Senator Sessions of Alabama, that would require foreign competitors of American companies that import their products into our country to do something as simple as to file an agent for service of process so that as one of the witnesses mentioned—I think it was you, Ms. Bosley—when the sulfide contaminated wall board or the lead painted toys come into our country, and somebody is injured as a result, they can find relief and a remedy from the importing company.

We had an Alabama contractor here reporting that to protect his own reputation he had to make good on the sulfide damage that was caused by the Chinese defective sulfide contaminated wall board. But there was no way he could find anybody to get any compensation from. In many cases there are very arcane laws; you have to translate the complaint into the foreign nation's language. We should require a simple agent for service of process here. We do it for American corporations; we should require it for foreign corporations.

If there are other steps you think we should take, I would be very interested in those. I think it really is important that we not allow international competition to degrade into a race to the bottom of safety.

Ms. Gerwig, thank you for what Kaiser is doing. I hope that we can use the Kaiser process as a benchmark for where TSCA could and should go. Clearly, a great number of the chemicals that you require notification of through your supplier disclosure process are ones that are not presently restricted through EPA's chemical analysis review, correct?

Ms. GERWIG. Correct.

Senator WHITEHOUSE. So you are ahead of them. And you have based your decisions, presumably, on sound science, correct?

Ms. GERWIG. Sound science, credible evidence that is available to us that shows their connections between those chemicals and disease.

Senator WHITEHOUSE. And in particular, thank you for your work on latex gloves. You mentioned that in your testimony. As somebody who has seen a child standing outside of an emergency room bleeding in the rain because they had not yet cleared a latex-safe pathway for that child through the emergency room, I think for families who have latex sensitivity around the country, that was a wonderful thing for you to help lead on.

Ms. Bosley, you said in your testimony something that I was interested to read. I just want to highlight it. Let me know if it is in fact what you meant. "Because of the vast number of chemicals and applications we do not think that EPA should be burdened with a determination that each chemical is safe for its intended use." Did you really mean to say that?

Ms. BOSLEY. I do. I believe that industry should be responsible for knowing the uses. EPA should certainly provide the regulatory authority and the guidance and the oversight. But it is industry

who should determine whether a chemical is safe for its intended use.

Senator WHITEHOUSE. We should rely on the manufacturer to determine the safety of the product? How well did that work out with tobacco? How well did that work out with lead?

Ms. BOSLEY. There are certainly chemicals that are due for more scrutiny than are industrial chemicals. I think that is where the risk prioritization comes into play. If you have a chemical that has a very high risk potential EPA can take more time and do much more due diligence on the safety of that chemical for its intended use.

But for the vast majority of industrial chemicals that are used in a strict industrial environment, that level of authority would not be necessary. I think it would just seize up EPA, frankly.

Senator WHITEHOUSE. I am a little bit surprised. I assumed that there was, I don't know, some mistake here. Because there are so many chemicals, we don't think EPA should be responsible for determining whether a chemical is safe for—isn't that the purpose of environmental regulation, is to assure that a chemical is safe for its intended use?

Ms. BOSLEY. That is the purpose of things like FDA, certainly for food, and for food contact items and for drugs. It is the position of EPA through its program for pesticides. That universe of chemicals is much smaller. And once again the risk is much higher. These are chemicals that are meant to be ingested, that are meant to be injected and the risk for human exposure is much higher.

If you consider a chemical that is used to manufacture, perhaps a certain industrial polymer that will never be used in a consumer product, that type of use is where the vast majority of industrial chemicals are.

Senator WHITEHOUSE. So to put a limiter on that sentence, we do not think that EPA should be burdened with the determination that each chemical is safe for its intended use, where its use is not intended to expose that chemical to the public, is really what you mean to say?

Ms. BOSLEY. That is right. It is all about that risk prioritization and risk determination. That is—looking at the hazard of the chemical in association with its exposure potential.

Senator WHITEHOUSE. In terms of a reasonable new chemicals fee that would go to EPA to support this, do you have a proposal in mind on that or any vehicle that would actually assure that those funds ended up at EPA?

Ms. BOSLEY. At this point, I think the PMN fee, the pre-manufacture notice fee is $2,500. It goes to the Treasury, not EPA. That is, I think, a fundamental flaw in the situation. There are certainly other fees that EPA could assess. I know confidential business information is a difficult premise for EPA to maintain. It is very burdensome for EPA to maintain confidential business information. Perhaps they would like to charge for that service.

Senator WHITEHOUSE. My time has expired, Chairman.

Senator LAUTENBERG. If you have another question, we have time. I have a couple.

Senator WHITEHOUSE. Let me just ask one more about the question of the confidential business information. There has been a lot

of static about that. I am told that 16,000 chemicals in the TSCA inventory are classified as confidential business information, which has the effect of restricting information on the toxicity of those chemicals even with State and local public health officials, which really doesn't seem to make a lot of sense. Clearly, if somebody wished to stall and create additional cost and bureaucratic burden on the regulator there is a strong incentive to upgrade the confidential business information claim and make that a point of dispute.

Is anybody comfortable with the confidential business information standard as it presently exists, and what suggestion do you have for repairing it so that it more prudently reflects chemical risks and the access for particularly State and local public health officials to that information?

Ms. BOSLEY. The public face of any chemical is really its material safety data sheet. Those are public documents that are available on most manufacturers' Web sites; if not on their Web sites then certainly from a call to the manufacturer. That toxicity data is not confidential with respect to OSHA. It is on every material safety data sheet. The entire study is certainly not there; it would be too cumbersome to put it there. But the results of that study are there; all available toxicity data is required by OSHA to be public information. That information is available to anybody who would like it.

Senator WHITEHOUSE. So it is your position that no further disclosure of confidential business information, no change in that process at EPA is justified at this stage?

Ms. BOSLEY. No. As I said, I think it is extraordinarily burdensome for EPA to maintain confidential business information. I think it is important that they do where it is necessary. But I think, for instance, that there may be a sunsetting of confidential business information that would be appropriate.

Senator WHITEHOUSE. So you don't think the where it is necessary the line is being drawn correctly at the moment, that needs to be adjusted?

Ms. BOSLEY. That is correct.

Senator WHITEHOUSE. You had your hand up? Same answer. Very good.

Senator LAUTENBERG. Thanks very much, Senator Whitehouse.

I just have a couple of things here. Dr. Hawkins, new techniques for testing chemicals are being developed so that scientists can obtain faster and more accurate results without relying on animal testing. These techniques will also be far less expensive than existing animal testing. How will these techniques affect the volume and the quality of safety data that you can provide to EPA?

Mr. HAWKINS. Actually, we are very excited and test and prototype many of these advanced approaches you are describing as well as other approaches like structure activity relationships and looking at mechanisms of how chemicals work. But it is very important that you brought that up because this whole issue of animal welfare is very important. We work with many stakeholders from the animal welfare community relative to our tox lab.

So as TSCA is reformed we need to be careful that we are only calling for tests with animals that uniquely need to be done with animals. At the same time we need to make sure that the non-ani-

mal testing yields valuable information and are validated. We work on that with suppliers and are aggressively pursuing those.

Senator LAUTENBERG. You mentioned also, Dr. Hawkins, in your testimony that American companies should not be disadvantaged by competition from outside the country. Is there a disadvantage now to American companies as a result of our lack of testing or verification of the quality and safety of the products?

Mr. HAWKINS. I think we are heading into a period here with REACH being implemented. That is still an experiment. It is a big experiment. But it is ongoing. As to how that might change the global chemical marketplace, American chemical industry and related industries are big exporters. So as you get into these elaborate regulatory systems in a place like Europe or Canada or elsewhere I think there is a potential for us being disadvantaged if our system is not cognizant of the receiving end. We are big exporters, all of us. So we need to be cognizant of that.

Senator LAUTENBERG. Mr. Williams, current law allows chemical makers to hide health and safety data from the public and companies like yours by making broad claims of confidential business information. How would limiting these claims to legitimate business secrets help companies like yours?

Mr. WILLIAMS. It is a great question, because I have a good example. We use McDonough Braungart Design Chemistry, cradle to cradle certifications. We have particular material, an adhesive, that is used in our products. We approached the adhesives manufacturer and said, we want to know what is in there. And they absolutely refused. We offered a non-disclosure agreement, no, we are not going to give it.

They did sign a non-disclosure agreement with McDonough Braungart Design Chemistry, because they were willing to reveal to someone that wasn't about to—they thought we were going to copy their material, they thought we were going to give their information to someone else and create a competitor against them. So I think the need for businesses to be able to disclose, in perhaps a safe environment, is highly important.

But we need to know that information. We absolutely must have that information in order to make the environmental and health claims that we make. We have gone through businesses that have required us to sign non-disclosure agreements before we get in the door, and they have all said, what we do here is confidential; no one else does it; it is proprietary. Well, we have walked through 43 other businesses that are doing the very same thing.

Some of our proprietary claims in business are as much in our own thinking and our own pride in authorship, and then there are the real ones that are relative to simply not wanting to tell our competitors what we are doing. So I believe reform needs to take that into consideration because various manufacturers think they are going to need to be eased across that threshold and understand that doing this is very important. It is essential. And yet doing it in a safe way of protecting that competitive information, there has to be a means of doing that.

Senator LAUTENBERG. Thank you. Thank you all, each of you, for your testimony.

What we are discussing here today is essential to at least warrant to the public that we are trying to do whatever we can to protect them. The anxiety that now accompanies pregnancy is quite a different condition than some time ago when we counted fingers and toes and things of that nature and said, OK, there is a healthy baby. And we must do whatever we can to assure those who would bear children, to assure those children's development, that we have done everything possible. We know there is a presence of materials in almost everybody across our Nation. We must do whatever can to protect that development of that child, to protect the health and well-being of people across our country.

There is no secret that things like diabetes and asthma have shown growth. And I am not suggesting here that it is a chemical product. But nor can we say that no, and I think Senator Whitehouse's commentary about the things that have been left over the years to industry, and I salute the industry, I think it is a wholesome, necessary industry in our society, the chemical industry. But when we talk about things like asbestos and the kinds of fights that we had to establish the fact that asbestos is so lethal. And we saw it in the State of New Jersey, where we have a huge industrial presence.

So my thanks to each one of you. This hearing is concluded. It is of great value to us in trying to develop a process, a way to get things done without enough of a benefit to add some more burden to the business of doing business. Thank you all.

[Whereupon, at 11:13 a.m., the Subcommittee was adjourned.]

[An additional statement submitted for the record follows:]

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

Chairman Lautenberg, I am very pleased to see you here today and am glad to know you are feeling well.

As we consider legislation aimed at modernizing the Toxic Substances Control Act (TSCA), Congress must avoid creating new burdens that hurt consumers and the economy. This principle is especially important today as the economy continues to struggle and unemployment remains near 10 percent. So, thank you for having this hearing, Mr. Chairman. It is critical that we listen to private sector concerns and consider ideas from the business community. I'd like to request that the written statement of the American Chemical Council be entered into the record.

TSCA regulates thousands of basic chemicals and compounds—chemicals that are the foundation of our way of life and on which our economy, health and welfare depend. I believe that TSCA is a fundamentally sound statute. But it is 30 years old, and the science of chemical risk assessment has evolved. As you've heard me say before, I am open to the idea of modernizing the Act.

The chemical industry has set out principles for reform. And in previous hearings I also laid out principles. Let me say this again: in order for me to accept changes to TSCA, the revisions must be based on risk assessment using the best available science, must include cost-benefit considerations, must protect proprietary information, and must prioritize reviews for existing chemicals.

I have high expectations that the perspectives we hear today will focus on sound science, risk based decisionmaking and prioritization of review. Let it be known, however, that I do not want to hear suggestions that create artificial advantages favoring one sector over another—in other words, please do not give us ideas that create an uneven playing field among companies or products or cause economic harm to consumers.

I look forward to hearing from the witnesses on their productive and constructive ideas for reforming TSCA. Welcome to the Committee.

[The referenced statement follows:]

March 8, 2010

The Honorable Frank R. Lautenberg
Chairman, Subcommittee on Superfund, Toxics and Environmental Health
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

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

Dear Chairman Lautenberg and Ranking Member Inhofe:

The Senate Committee on Environment and Public Works' Subcommittee on Superfund, Toxics and Environmental Health is scheduled to hear testimony from several witnesses on March 9, 2010 concerning industry's perspectives on modernizing the Toxic Substances Control Act (TSCA). The American Chemistry Council (ACC) requests that this letter reflecting ACC's perspectives on this topic be entered into the record of the subcommittee's hearing.

As you know, ACC and its members welcome Congress' review of the Toxic Substances Control Act (TSCA) and the measures that might be taken to modernize the statute. In our view, Congress should have several broad objectives in modernizing TSCA:

- Ensure the protection of public health, including children's health.
- Enhance confidence in the federal chemical regulatory system and ensure the continued, safe, beneficial use of chemicals.
- Reflect the scientific and technological advances that have been made since TSCA was enacted.
- Assure continued innovation from the U.S. chemical industry so that we can keep and grow jobs making the products that save lives, make our economy more energy efficient, and reduce greenhouse gas emissions.

In August 2009, ACC released a set of ten principles (attached) that we think provide a sound basis for modernizing TSCA. We were gratified to see that the Environmental Protection Agency's (EPA) six principles for TSCA modifications released in September 2009 reflect substantial

agreement with industry's principles and those released by other stakeholders. These principles go to the heart of the federal government's efforts to assess and address potential risks to human health and the environment from chemical exposures.[1] I strongly believe that the national interest in a robust federal chemical management system would be well-served if those areas of agreement become the focal points for dialogue among all stakeholders.

In our Dec. 1, 2009 statement to this Committee ACC emphasized the need for a systematic screening and prioritization process in a modernized TSCA to identify those chemicals and exposures that should be subject to safety assessments by EPA. We also discussed the importance of a science-based integrated testing and assessment framework, one that relies on existing data and information in the first instance, including data from other programs such as REACH. We discussed avoiding, as appropriate, further animal testing if other scientifically sound and validated test methods are available to provide needed data/information. In our February 4, 2010 statement to this Committee we discussed the value, role and limitations of biomonitoring data in understanding chemical exposures. These two statements focused in large measure on how to better manage existing chemicals in commerce today.

In this statement we would like to offer some thoughts on the new chemicals program of TSCA. TSCA plays an extremely important – although largely unrecognized – role in assuring continued American innovation in the development of essential new products and technologies. For example, the U.S. chemical industry is developing the technologies and making the products that are vital to the U.S. effort to use energy more efficiently and to reduce U.S. greenhouse gas emissions. Notable among such products are highly efficient insulation materials, compact florescent and lithium-diode lighting, catalytic converters, low rolling resistant tires, solar panels, wind turbines, and products essential to technologies for capturing and storing carbon. In TSCA, Congress designed a regulatory system that provided EPA different tools to protect against unreasonable risk of injury to health or the environment from chemical substances, while promoting innovation in chemistry – innovation that in turn can reduce chemical risks and provide significant societal and economic benefits.

TSCA's new chemical program is the best reflection of this balance of policies. It has been recognized as a success in both regulation (e.g., over a thousand chemicals have been "banned or restricted" under TSCA's new chemicals provisions) and in reducing barriers to innovation (e.g. the U.S. leads the world 6 to 1 in numbers of new chemicals patented). The U.S. leadership in chemical patents is attributable to American ingenuity, but also to TSCA's new chemicals program. Three times more new chemical pre-manufacturing applications are filed in the United States than in any other country or region – an indication that the chemical regulatory structure can promote an early dialogue with regulators in a way that does not create barriers to innovation.

[1] It is worth noting that ACC's principles also reflect a broad consensus in the international community. In 2008, the 21 member economies of the Asia Pacific Economic Cooperation (APEC) Forum adopted a set of Principles for Best Practice Chemical Regulation that includes among other recommendations a risk-based, science justified approach to chemical regulation, consultation with stakeholders and public transparency. See APEC, 2008/SOM2/CD/002rev1 (May 22, 2008).

Under the new chemicals program today, companies provide EPA hazard, use and exposure information for EPA's review of a new chemical before manufacturing can begin. In addition, EPA relies upon modeling data, category approaches and read across capability that leverages available information to assess the risk posed by the new chemical for its intended use. This is appropriate because new chemicals typically are produced at lower volumes for targeted uses that create fewer opportunities for exposures that increase risks to health and the environment. If during EPA's review, however, the Agency determines the need for more data or information, it can and does request that information from the manufacturer. If the information is determined to be insufficient, EPA may propose an order to limit or prohibit manufacture. We propose that new chemicals, once in commerce, would also enter the same systematic prioritization process we've discussed in our earlier statements on modernizing TSCA.

The chemical industry is a dynamic, forward-looking, innovative industry. It is a keystone of the "new economy" and a leader in protecting the environment. It's also an enabling and transforming business. Almost every industry purchases some products and services of chemistry and, therefore, directly depends on the business of chemistry. Indeed, most manufactured goods are directly touched by chemistry. Given the complexity of TSCA, its impact on our industry, its ramifications for other downstream industries and businesses that rely on our products and services, and its role in a healthy U.S. economy, it's extremely important to get TSCA modernization right. Therefore, I urge you to release your legislation first as a discussion draft for a productive multi-stakeholder dialog.

The business of chemistry has a major stake in this debate and has given considerable thought to practical ways in which TSCA can be improved to protect health and the environment, promote innovation and create jobs. ACC and its members look forward to working with you and the entire Committee as active discussions around modifications to TSCA get underway. If we can provide any additional information on ACC's position on TSCA modernization, please contact me.

Sincerely,

Cal Dooley

Cal Dooley
President and CEO

cc: Committee on Environment and Public Works

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Attachment

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.

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- 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.

[Additional material submitted for the record follows:]

Written Testimony of Bob Moore,

Chairman and Chief Executive Officer of iGPS Company,

before the

Subcommittee on Superfund, Toxics, and Environmental Health

Committee on Environment and Public Works

United States Senate

March 9, 2010

Chairman Lautenberg, Ranking Member Inhofe, and other members of the subcommittee, on behalf of iGPS Company LLC (iGPS), I appreciate the opportunity to submit this testimony. I am Bob Moore, the Chairman and Chief Executive Officer of iGPS, operator of the world's first pallet rental service offering all-plastic shipping pallets with embedded radio frequency identification technology. iGPS supports your efforts, and those of your colleagues, in striving to modernize our nation's chemical-regulatory programs, and to update for the first time in more than thirty years the core provisions of the Toxic Substances Control Act (TSCA). As an end user of chemical substances that are subject to TSCA, iGPS encourages you to consider revisions to the Act that will ensure that risk-management determinations that will be made by the U.S. Environmental Protection Agency will be based on sound science and with appropriate consideration given to the unintended consequences that Agency actions might have as a result of the imposition of restrictions upon critical uses of chemical substances for which no viable substitutes currently exist.

iGPS was formed in 2006 with the goal of reengineering the basic shipping pallet in order to produce a new generation of pallets that are more durable, cost-effective, safer and more environmentally friendly than the pallets of the past. The company's plastic pallets provide

important strategic advantages over common wood pallets with respect to supply chain security, food and drug safety, and conservation of precious resources, as well as enhanced economic efficiency. iGPS pallets are constructed of sturdy, high density polyethylene (HDPE), a material that allows the pallets to be used for up to twenty years and is 100% recyclable. Plastic pallets offer environmental benefits: they have a far longer life span than wood pallets, are 30% lighter than wood, and do not require depletion of forests. Due to the nonporous nature of plastic pallets, iGPS pallets present less potential for harboring contaminants and organic matter (*e.g.*, bacteria and other pathogens) as well as migration of these organisms from pallet surfaces. Moreover, plastic pallets are washable and less likely than wood to splinter or otherwise degrade over time, thereby affording greater protection both to the products loaded on them and to the workers who handle them.

In addition to these safety advantages, iGPS pallets are equipped with the latest Radio Frequency Identification (RFID) technology, which allows for tracking and traceability at points along the supply chain. This technology provides iGPS' customers with unprecedented asset visibility and reporting, thereby improving supply chain management and security by allowing shippers to rapidly locate and, if necessary, divert products in the event of a problem, such as the outbreak of foodborne illness.

As an innovator in the field, iGPS provides millions of durable and long-lasting plastic shipping pallets to a variety of industries, from food suppliers to shippers of consumer products, including many of the this country's largest and most respected manufacturers and retailers. In all of these applications, iGPS pallets are the safest, most cost-effective, durable, and environmentally sustainable pallet available.

With respect to the purpose of today's hearing -- business perspectives on the reform to TSCA -- I present the views of iGPS as an end user of a chemical regulated under that law. The polymer matrix material used to create iGPS pallets incorporates small quantities of a proven flame retardant, decabromodiphenyl ether (Deca). Deca is one of the most widely used fire retardants in the world and is found in both commercial applications and consumer goods, including airplanes and automobiles, building materials, consumer electronics, and fabrics. Through the use of this flame retardant, iGPS pallets have received certification under UL 2335 (file no. R25482) and FM Approvals 4996, establishing a proven fire safety factor equal, or superior, to wood. Through the addition of small amounts of Deca to the polymer that is used to form its pallets, iGPS has been able to provide its customers with a high level of protection against the risk of injury and property loss in fires.

Let me reiterate: iGPS supports your efforts to modernize our nation's chemical management system. The time is right for TSCA to be brought into the 21st Century to keep pace with recent advances in science and technology. In updating TSCA, we believe that it is important for Congress to ensure that, when EPA is assessing the impact of any regulatory effort, the Agency consider fully the potential impacts of proposed regulatory actions on critical uses of a substance for which there may be no substitutes, as well as the benefits and costs of undertaking such actions on society and the environment.

For example, there have been several recent efforts taken by state legislators attempting to prohibit the use of Deca, both in commercial products generally, and, in one state, in the iGPS pallet in particular. These efforts, for the most part, have ignored the fact that there is no other fire retardant currently available that enables a plastic pallet to meet the performance standards necessary for use in our nation's supply chain. While proponents may believe that the complete elimination of Deca would be a good thing, they have failed to consider that, absent a viable substitute for Deca in

the iGPS plastic pallet, the alternative will be greater reliance on wood shipping pallets. This will lead to increased deforestation and associated build up of greenhouse gases in our atmosphere, more fuel consumption due to wood pallets' heavier weight, more opportunities for the spread of invasive pests which can infest wood pallets and attack our forests and crops, and more opportunities for the spread of foodborne illnesses due to the capacity of wood surfaces to be penetrated by harmful bacteria and other microorganisms.

We therefore recommend that any amendments to TSCA should require that the Administrator provide assurance that, when the Agency is considering taking action under TSCA to severely limit or prohibit the use of a chemical substance, due consideration will be given to both the intended and possible unintended consequences of the potential regulatory action. A modernized TSCA should provide the Agency with all of the data it needs to fully assess a chemical substance, while ensuring that the Administrator will consider carefully whether the particular chemical substance being considered for regulation might be essential for some or all of its current and intended uses. In so doing, the Administrator should be expected to determine whether there are substitutes that are not only commercially available, but also viable in each of the specific applications for which the targeted chemical substance currently is used. Viability of substitutes should be assessed by taking into consideration the functional performance *and* cost effectiveness in particular applications, including in mixtures and articles that contain the chemical substance under review. In addition, the Administrator should consider the overall environmental impacts of a potential regulation by assessing foreseeable unintended consequences across all environmental media such as adverse impacts of the action on energy consumption; the generation of pollutants during new processes made necessary by the transition to substitute substances, mixtures and articles that contain the substitute substances; the adverse impact of substitution of other products for those using the regulated substance; and these

impacts on our nation's efforts at conservation and preservation of our forests, wildlife, land, soil, air and climate.

* * *

I appreciate the opportunity to present this testimony today, and thank you for allowing me to provide this perspective.

March 8, 2010

The Honorable Barbara Boxer
United States Senate
112 Hart Senate Office Building
Washington, DC 20510

The Honorable James Inhofe
United States Senate
453 Russell Senate Office Building
Washington, DC 20510

The Honorable Frank Lautenberg
United States Senate
324 Hart Senate Office Building
Washington, DC 20510

The Honorable Henry Waxman
United States House of Representatives
2204 Rayburn House Office Building
Washington, DC 20515

The Honorable Joe Barton
United States House of Representatives
2109 Rayburn House Office Building
Washington, DC 20515

The Honorable Bobby Rush
United States House of Representatives
2416 Rayburn House Office Building
Washington, DC 20515

The Honorable Ed Whitfield
United States House of Representatives
2411 Rayburn House Office Building
Washington, DC 20515

Dear Chairmen and Ranking Members,

The organizations listed below remain committed to a robust dialogue on the modernization of the Toxic Substances Control Act (TSCA). A strong legislative framework is critical to creating a successful chemicals management regulatory program and requires deliberate and careful consideration due to the complexities of the issues and their broad impact on all parts of the American economy. To that end, our organizations, which represent virtually all suppliers of materials for manufacturing in the United States and firms throughout the chemistry value chain, urge Congress to establish a transparent and robust multi-stakeholder dialogue to modernize TSCA and provide for continued safety, while ensuring that we retain American innovation and jobs.

Paramount to the success of a comprehensive legislative proposal is the ability to discuss ideas and concepts in a transparent fashion and allow for meaningful discussion by all key stakeholder groups. To achieve this goal of a transparent and meaningful dialogue, we urge the release of a discussion draft bill as opposed to formal bill introduction.

With a discussion draft, ample opportunity would exist to follow through with Chairman Bobby Rush's idea of holding an open, deliberative stakeholder dialogue. At last year's hearing on *Revisiting the Toxic Substances Control Act of 1976* before the House Subcommittee on Commerce, Trade & Consumer Protection, Chairman Rush received unanimous support for such a process from the witnesses who testified. Since then, there has been a series of hearings focused on certain aspects of TSCA, but Chairman Rush's idea of a stakeholder dialogue has not been pursued.

To be clear, our organizations remain committed to the modernization of TSCA. We put forward our proposal for an open and transparent process after release of a discussion draft bill as a means to help achieve this objective.

Sincerely,

Adhesive and Sealant Council, Inc.
American Chemistry Council
American Coatings Association
American Petroleum Institute
Consumer Specialty Products Association
ETAD North America
Fragrance Materials Association
Grocery Manufacturers Association
National Association of Chemical Distributors
National Petrochemical and Refiners Association
North American Metals Council
Silicones Environmental, Health and Safety Council of North America
Specialty Graphic Imaging Association
SPI: The Plastics Industry Trade Association
Soap and Detergent Association
Synthetic Organic Chemical Manufacturers Association
The Fertilizer Institute
Vinyl Institute

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